TIMOTHY RAY BROWN
HE’S NOT JUST
‘THE BERLIN PATIENT’

FAR FROM HOME
SOME HOMELESS YOUTH
CHOOSE TO HIT THE ROAD

THE SECOND ANNUAL
HEPATITIS C
DRUG GUIDE

New guidelines, new treatments.
POSITIVELY AWARE teams up with Project Inform
for a look at the standard of care for HCV in 2014

COMMEMORATING 25 YEARS

POSITIVELY AWARE
JULY-AUGUST 2014
What is STRIBILD?

STRIBILD is a prescription medicine used to treat HIV-1 in adults who have never taken HIV-1 medicines before. It combines 4 medicines into 1 pill to be taken once a day with food. STRIBILD is a complete single-tablet regimen and should not be used with other HIV-1 medicines.

STRIBILD does not cure HIV-1 infection or AIDS. To control HIV-1 infection and decrease HIV-related illnesses you must keep taking STRIBILD. Ask your healthcare provider if you have questions about how to reduce the risk of passing HIV-1 to others. Always practice safer sex and use condoms to lower the chance of sexual contact with body fluids. Never reuse or share needles or other items that have body fluids on them.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about STRIBILD?

STRIBILD can cause serious side effects:

• Build-up of an acid in your blood (lactic acidosis), which is a serious medical emergency. Symptoms of lactic acidosis include feeling very weak or tired, unusual (not normal) muscle pain, trouble breathing, stomach pain with nausea or vomiting, feeling cold especially in your arms and legs, feeling dizzy or lightheaded, and/or a fast or irregular heartbeat.

• Serious liver problems. The liver may become large (hepatomegaly) and fatty (steatosis). Symptoms of liver problems include your skin or the white part of your eyes turns yellow (jaundice), dark “tea-colored” urine, light-colored bowel movements (stools), loss of appetite for several days or longer, nausea, and/or stomach pain.

• You may be more likely to get lactic acidosis or serious liver problems if you are female, very overweight (obese), or have been taking STRIBILD for a long time. In some cases, these serious conditions have led to death. Call your healthcare provider right away if you have any symptoms of these conditions.

• Worsening of hepatitis B (HBV) infection. If you also have HBV and stop taking STRIBILD, your hepatitis may suddenly get worse. Do not stop taking STRIBILD without first talking to your healthcare provider, as they will need to monitor your health. STRIBILD is not approved for the treatment of HBV.

Who should not take STRIBILD?

Do not take STRIBILD if you:

• Take a medicine that contains: alfuzosin, dihydroergotamine, ergotamine, methylergonovine, cisapride, lovastatin, simvastatin, pimozide, sildenafil when used for lung problems (Revatio®), triazolam, oral midazolam, rifampin or the herb St. John’s wort.

• For a list of brand names for these medicines, please see the Brief Summary on the following pages.

• Take any other medicines to treat HIV-1 infection, or the medicine adefovir (Hepsera®).

What are the other possible side effects of STRIBILD?

Serious side effects of STRIBILD may also include:

• New or worse kidney problems, including kidney failure. Your healthcare provider should do regular blood and urine tests to check your kidneys before and during treatment with STRIBILD. If you develop kidney problems, your healthcare provider may tell you to stop taking STRIBILD.

• Bone problems, including bone pain or bones getting soft or thin, which may lead to fractures. Your healthcare provider may do tests to check your bones.

• Changes in body fat can happen in people taking HIV-1 medicines.

• Changes in your immune system. Your immune system may get stronger and begin to fight infections. Tell your healthcare provider if you have any new symptoms after you start taking STRIBILD.

The most common side effects of STRIBILD include nausea and diarrhea. Tell your healthcare provider if you have any side effects that bother you or don’t go away.

What should I tell my healthcare provider before taking STRIBILD?

• All your health problems. Be sure to tell your healthcare provider if you have or had any kidney, bone, or liver problems, including hepatitis virus infection.

• All the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. STRIBILD may affect the way other medicines work, and other medicines may affect how STRIBILD works. Keep a list of all your medicines and show it to your healthcare provider and pharmacist. Do not start any new medicines while taking STRIBILD without first talking with your healthcare provider.

• If you take hormone-based birth control (pills, patches, rings, shots, etc).

• If you take antacids. Take antacids at least 2 hours before or after you take STRIBILD.

• If you are pregnant or plan to become pregnant. It is not known if STRIBILD can harm your unborn baby. Tell your healthcare provider if you become pregnant while taking STRIBILD.

• If you are breastfeeding (nursing) or plan to breastfeed. Do not breastfeed. HIV-1 can be passed to the baby in breast milk. Also, some medicines in STRIBILD can pass into breast milk, and it is not known if this can harm the baby.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see Brief Summary of full Prescribing Information with important warnings on the following pages.
STRIBILD is a prescription medicine used as a complete single-tablet regimen to treat HIV-1 in adults who have never taken HIV-1 medicines before. STRIBILD does not cure HIV-1 or AIDS.

I started my personal revolution

Talk to your healthcare provider about starting treatment.

STRIBILD is a complete HIV-1 treatment in 1 pill, once a day.

Ask if it’s right for you.

STRIBILD®
elvitegravir 150mg/ cobicistat 150mg/ emtricitabine 200mg/ tenofovir disoproxil fumarate 300mg tablets
Patient Information

STRIBILD® (STRY-bild)
(elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/
tenofvir disoproxil fumarate 300 mg) tablets

Brief summary of full Prescribing Information. For more information, please see the full Prescribing Information, including Patient Information.

What is STRIBILD?

- STRIBILD is a prescription medicine used to treat HIV-1 in adults who have never taken HIV-1 medicines before. STRIBILD is a complete regimen and should not be used with other HIV-1 medicines.
- STRIBILD does not cure HIV-1 or AIDS. You must stay on continuous HIV-1 therapy to control HIV-1 infection and decrease HIV-related illnesses.
- Ask your healthcare provider about how to prevent passing HIV-1 to others. Do not share or reuse needles, injection equipment, or personal items that can have blood or body fluids on them. Do not have sex without protection. Always practice safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

What is the most important information I should know about STRIBILD?

STRIBILD can cause serious side effects, including:

1. **Build-up of lactic acid in your blood (lactic acidosis).** Lactic acidosis can happen in some people who take STRIBILD or similar (nucleoside analogs) medicines. Lactic acidosis is a serious medical emergency that can lead to death. Lactic acidosis can be hard to identify early, because the symptoms could seem like symptoms of other health problems. **Call your healthcare provider right away if you get any of the following symptoms which could be signs of lactic acidosis:**
   - feel very weak or tired
   - have unusual (not normal) muscle pain
   - have trouble breathing
   - have stomach pain with nausea or vomiting
   - feel cold, especially in your arms and legs
   - feel dizzy or lightheaded
   - have a fast or irregular heartbeat

2. **Severe liver problems.** Severe liver problems can happen in people who take STRIBILD. In some cases, these liver problems can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis). **Call your healthcare provider right away if you get any of the following symptoms of liver problems:**
   - your skin or the white part of your eyes turns yellow (jaundice)
   - dark “tea-colored” urine
   - light-colored bowel movements (stools)
   - loss of appetite for several days or longer
   - nausea
   - stomach pain

   You may be more likely to get lactic acidosis or severe liver problems if you are female, very overweight (obese), or have been taking STRIBILD for a long time.

3. **Worsening of Hepatitis B infection.** If you have hepatitis B virus (HBV) infection and take STRIBILD, your HBV may get worse (flare-up) if you stop taking STRIBILD. A “flare-up” is when your HBV infection suddenly returns in a worse way than before.

   Do not run out of STRIBILD. Refill your prescription or talk to your healthcare provider before your STRIBILD is all gone.

   Do not stop taking STRIBILD without first talking to your healthcare provider.

   If you stop taking STRIBILD, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your HBV infection. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking STRIBILD

Who should not take STRIBILD?

Do not take STRIBILD if you also take a medicine that contains:

- adeefovir (Hepsera®)
- alfuzosin hydrochloride (Uroxatral®)
- ciaspride (Propulsid®, Propulsid Quicksol®)
- ergot-containing medicines, including: dihydroergotamine mesylate (D.H.E. 45®), ergotamine tartrate (Cafergot®, Migrergot®, Ergostat®, Medihaler Ergotamine®, Wigraine®, Wigrettes®), and methylergonovine maleate (Ergotrate®, Methergine®)
- lovastatin (Advicor®, Altoprev®, Mevacor®)
- oral midazolam
- pimozide (Orap®)
- rifampin (Rifadin®, Rifamate®, Rifater®, Rimactane®)
- sildenafil (Revatio®), when used for treating lung problems
- simvastatin (Simcor®, Vytorin®, Zocor®)
- triazolam (Halcion®)
- the herb St. John’s wort

Do not take STRIBILD if you also take any other HIV-1 medicines, including:

- Other medicines that contain tenofovir (Atripla®, Complera®, Truvada®)
- Other medicines that contain emtricitabine, lamivudine, or ritonavir (Atripla®, Combivir®, Complera®, Emtriva®, Epivir® or Epivir-HBV®, Epzicom®, Kaletra®, Norvir®, Trizivir®, Truvada®)

STRIBILD is not for use in people who are less than 18 years old.

What are the possible side effects of STRIBILD?

STRIBILD may cause the following serious side effects:

- See “What is the most important information I should know about STRIBILD?”
- **New or worse kidney problems, including kidney failure.** Your healthcare provider should do blood and urine tests to check your kidneys before you start and while you are taking STRIBILD. Your healthcare provider may tell you to stop taking STRIBILD if you develop new or worse kidney problems.
- **Bone problems** can happen in some people who take STRIBILD. Bone problems include bone pain, softening or thinning (which may lead to fractures). Your healthcare provider may need to do tests to check your bones.
- **Changes in body fat** can happen in people who take HIV-1 medicine. These changes may include increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the middle of your body (trunk). Loss of fat from the legs, arms and face may also happen. The exact cause and long-term health effects of these conditions are not known.
- **Changes in your immune system** (Immune Reconstitution Syndrome) can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you start having any new symptoms after starting your HIV-1 medicine.
The most common side effects of STRIBILD include:

- Nausea
- Diarrhea

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

- These are not all the possible side effects of STRIBILD. For more information, ask your healthcare provider.
- Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What should I tell my healthcare provider before taking STRIBILD?

Tell your healthcare provider about all your medical conditions, including:

- If you have or had any kidney, bone, or liver problems, including hepatitis B infection
- If you are pregnant or plan to become pregnant. It is not known if STRIBILD can harm your unborn baby. Tell your healthcare provider if you become pregnant while taking STRIBILD.
  - There is a pregnancy registry for women who take antiviral medications during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk with your healthcare provider about how you can take part in this registry.
- If you are breastfeeding (nursing) or plan to breastfeed. Do not breastfeed if you take STRIBILD.
  - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
  - Two of the medicines in STRIBILD can pass to your baby in your breast milk. It is not known if the other medicines in STRIBILD can pass into your breast milk.
  - Talk with your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements:

- STRIBILD may affect the way other medicines work, and other medicines may affect how STRIBILD works.
- Be sure to tell your healthcare provider if you take any of the following medicines:
  - Hormone-based birth control (pills, patches, rings, shots, etc)
  - Antacid medicines that contain aluminum, magnesium hydroxide, or calcium carbonate. Take antacids at least 2 hours before or after you take STRIBILD
  - Medicines to treat depression, organ transplant rejection, or high blood pressure
  - amiodarone (Cordarone®, Pacerone®)
  - atorvastatin (Lipitor®, Caduet®)
  - bepridil hydrochloride (Vascor®, Bepadin®)
  - bosentan (Tracleer®)
  - buspirone
  - carbamazepine (Carbatrol®, Epitol®, Equetro®, Tegretol®)
  - clarithromycin (Biaxin®, Prevaco®)
  - clonazepam (Klonopin®)
  - clorazepate (Gen-xene®, Tranxene®)
  - colchicine (Colcrys®)
  - medicines that contain dexamethasone
  - diazepam (Valium®)
  - digoxin (Lanoxin®)
  - disopyramide (Norpace®)
  - estazolam
  - ethosuximide (Zarontin®)
  - flecainide (Tambocor®)
  - flurazepam
  - fluticasone (Flovent®, Flonase®, Flovent® Diskus®, Flovent® HFA, Veramyst®)
  - itraconazole (Sporanox®)
  - ketoconazole (Nizoral®)
  - lidocaine (Xylocaine®)
  - mexiletine
  - oxcarbazepine (Trileptal®)
  - perphenazine
  - phenobarbital (Luminal®)
  - phenytoin (Dilantin®, Phenytek®)
  - propafenone (Rythmol®)
  - quinidine (Neudexta®)
  - rifabutin (Mycobutin®)
  - rifapentine (Priftin®)
  - risperidone (Risperdal®, Risperdal Consta®)
  - salmeterol (Serevent®) or salmeterol when taken in combination with fluticasone (Advair Diskus®, Advair HFA®)
  - sildenafil (Viagra®, Cialis®) or vardenafil (Levitra®, Staxyn®), for the treatment of erectile dysfunction (ED). If you get dizzy or faint (low blood pressure), have vision changes or have an erection that last longer than 4 hours, call your healthcare provider or get medical help right away.
  - tadalafil (Adcirca®), for the treatment of pulmonary arterial hypertension
  - telithromycin (Ketek®)
  - thioridazine
  - voriconazole (Vfend®)
  - warfarin (Coumadin®, Jantoven®)
  - zolpidem (Ambien®, Edular®, Intermezzo®, Zolpidem®)

Know the medicines you take. Keep a list of all your medicines and show it to your healthcare provider and pharmacist when you get a new medicine. Do not start any new medicines while you are taking STRIBILD without first talking with your healthcare provider.

Keep STRIBILD and all medicines out of reach of children.

This Brief Summary summarizes the most important information about STRIBILD. If you would like more information, talk with your healthcare provider. You can also ask your healthcare provider or pharmacist for information about STRIBILD that is written for health professionals, or call 1-800-445-3235 or go to www.STRIBILD.com.

Issued: October 2013
Whether you’re positive or negative, we are all affected by HIV. Take your best shot against HIV by taking part in A Day with HIV, POSITIVELY AWARE’s awareness and anti-stigma campaign. On September 9, use your smartphone or digital camera and take a snapshot of an everyday moment of your life, then upload it along with a caption to adaywithhiv.com or email them to photo@adaywithhiv.com. Select photos will appear in a special section of the November-December issue of POSITIVELY AWARE.
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ONLY ON POSITIVELYAWARE.COM

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BY ENID VÁZQUEZ

‘ADAM’ chose homelessness as an escape from a difficult situation and a search for something better.
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PHOTO: CHRIS KNIGHT

JULY + AUGUST 2014 VOLUME 26 NUMBER 5

POSITIVELY AWARE COMMEMORATING 25 YEARS
THE SECOND ANNUAL HEPATITIS C DRUG GUIDE IS A COLLABORATION OF POSITIVELY AWARE AND PROJECT INFORM.
HEART AND SOUL

I thought I should write to request another year of P.A. The 50+ Issue is, no pun intended, fabulous. I am also looking forward to the 2014 HIV Drug Guide [March+April]. The Guide is the heart of P.A. The other issues are the body and soul, and all of you are the brains. I would be in the dark without you. Thank you.

—ANTHONY DIGIOVANNI
RIVERS CORRECTIONAL INSTITUTION,
WINTON, NC

TWEETING THANKS

T/Y for your 18th annual #HIV #drug guide. Helping us poz folks stay healthy & informed.

—ROBERT TOTH
@ROBND216

—BLACK AIDS INSTITUTE
@BLACKAIDS

LET’S CONNECT. All communications (letters, email, online posts, etc.) are treated as letters to the editor unless otherwise instructed. We reserve the right to edit for length, style, or clarity. Let us know if you prefer we not use your name and city. You can also write: POSITIVELY AWARE 5050 N. Broadway St., Suite 300, Chicago, IL 60640-3016.

SOUTHERN EXPOSURE

IN THE MAY+JUNE ISSUE, WE ASKED

Have you experienced any problems with ACA exchange insurance plans?

60%
YES

40%
NO

IN BOX

25 years of stories.
Share yours with us.

As POSITIVELY AWARE commemorates 25 years of HIV reporting, we want to hear from you about how the magazine has affected your life. We’ll share your stories as part of PA’s celebration.

surveymoniker.com/s/PVPCY33

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READERS POLL

YOUR COMMENTS

“Who do I blame? I used to have insurance—until the insurance company canceled my policy because of the ACA. Now, I’m going to have to buy a new policy which is going to cost me more money than what I had before Obamacare.”

“Thanks to Obamacare, I finally have health insurance.”

THIS ISSUE’S QUESTION

Have you ever been tested for hepatitis C?

VOTE AT POSITIVELYAWARE.COM
OR ON FACEBOOK:
https://a.pgtb.me/ffPCjX
Not everyone who has HCV and undergoes treatment is cured, but with new treatments on the horizon there is hope for even these individuals.

FOLLOW JEFF @PAEDITOR

"I’m cured!"

This was the news I just received from a friend of mine who underwent a somewhat grueling therapy for hepatitis C over the past year. Two simple words, in the form of a text message, filled with hope and excitement for a life free from HCV.

I’m thrilled to hear the news for my friend, as well as for another who underwent a much simpler, all-oral therapy as part of a study last year, and is now considered HCV-free. Sustained virologic response (SVR) is the correct term, which basically means that during the six months after you complete treatment, there is no detectable hepatitis C virus in your blood.

I look forward to one day when we’ll be able to communicate those two simple words to each other about HIV. Until that day, there have been some amazing advances in HCV treatment, with many more on the way.

This is our second annual POSITIVELY AWARE HCV Drug Guide, and this year it’s a collaboration between Project Inform and Test Positive Aware Network. Here you’ll read about all the FDA-approved drugs used to treat HCV and those expected to be approved in the coming year, plus dosing information, potential side effects, drug interactions, and guidelines for testing and treatment. Special thanks to Andrew Reynolds of Project Inform, who researched and compiled the information contained in this guide.

As I was reading the issue and reviewing the guidelines for testing, I was reminded of the fact that since I am on the tail end of the “baby boomer” generation it’s recommended that I be tested for HCV at least once in my lifetime. Not to mention that I’m a sexually active gay man, and HIV-positive (it’s also recommended for those populations as well, boomer or not).

Even though I was aware of the guidelines I had never gotten tested, so I arranged to have a test performed here at the office. I was immediately impressed by the knowledge and skill of my counselor, Antoine, whose demeanor instantly put me at ease while he explained the test to me and talked about risk behavior.

He had to step out for a moment, and I was suddenly transported back to when I took my HIV test in 1989. Here I was sitting alone again in a room, staring at a flyer taped to the wall but not really registering what I was reading. I wondered what I would do if the test came back positive. How would my life change? Would I have to undergo treatment? Should I have gone to my doctor and taken the test in a more private setting? What would people think?

The stigma of HCV may feel different to some, but it’s no less real and impactful for those who experience it. Life is forever altered when you test positive for HIV, and while finding out you have HCV is still cause for concern, there is treatment available that can lead to a cure. For reasons that are not understood, around 15–25% of people will clear HCV on their own without treatment, but they still show antibodies to the virus. False positives are also possible using the rapid test, so you always need to follow up with a confirmatory test that checks for the actual virus in your blood.

My test came back negative for HCV antibodies. There’s a small chance that it could be a false negative, so if I have elevated ALT (a blood liver enzyme) unexplained liver disease, other risk factors for HCV, or a CD4 cell count less than 200, it’s recommended that I take the confirmatory HCV RNA test.

I should point out that not everyone who has HCV and undergoes treatment is cured, but with new treatments on the horizon there is hope for even these individuals. High cure rates, even 100% in some small studies, and all-oral regimens with little to no side effects are just around the corner.

One of the biggest obstacles to overcoming HCV is access to testing, treatment, and care. Lately there’s been a lot of attention being given in mainstream media and advocates who are furious about the high cost of these drugs, and there are serious questions as to whether private insurers and public health care systems, which bear the burden of these costs, will ever be able to sustain them as more people get tested and treated. We need to ensure that those who are in greatest need of treatment are not denied due to cost or because they lack adequate access to testing and care.

So if you’re reading this right now, you may want to consider getting an HCV test. It’s quick, it’s (relatively) painless, and it’s easy. And there is hope if you test positive, just as there is with HIV. But at what cost?

Take care of yourself, and each other.
Briefly

ENID VÁZQUEZ  @ENIDVAZQUEZPA

DHHS updates HIV treatment guidelines

People on HIV therapy for at least two years who have 300 to 500 T-cells can wait another year to have their T-cells measured, while those with more than 500 may stop measuring them altogether, according to treatment guidelines updated in May by the Department of Health and Human Services (DHHS). “The [guidelines] Panel recommends resumption of more frequent CD4 count monitoring in patients who experience virologic [viral load] rebound; who develop new HIV-associated clinical symptoms; or who develop conditions or initiate therapy that may lead to reduction of CD4 cell count,” the update stated.

The panel also shifted away from listing drug combinations for first-time therapy as “preferred” to simply “recommended,” citing the many combinations available for treatment-naïve people. “Recommended” regimens in turn are divided into two categories: those for individuals regardless of baseline viral load or T-cell count and those only for people with less than 100,000 viral load.

Among the slew of updates: There is now a formal discussion of the cost of therapy and its effect on adherence; key principles to use when switching patients and a new table of drug options for switching in the face of adverse effects. Go to aidsinfo.nih.gov.

CDC issues PrEP guidelines

The U.S. Public Health Service (USPHS) of the Centers for Disease Control and Prevention (CDC) issued guidelines in May for the use of Truvada as pre-exposure prophylaxis (PrEP). Guidance from the USPHS makes it easier to get insurance coverage for PrEP. The document notes “substantial risk” for HIV as having:

- an HIV-positive sex partner;
- a recent STI;
- a high number of sex partners;
- a history of inconsistent or no condom use; and
- participation in commercial sex work.

In addition, for heterosexuals, risk is also attributed to being in a high-prevalence area or sexual network (although this has been shown to be true of gay men as well, especially black men).

For people who are injection drug users, substantial risk is defined as having an HIV-positive injecting partner, sharing injection equipment, and recent drug treatment followed by continued injecting.

Lists and charts of additional risk behaviors for various populations are included in the guidelines.

The 64-page document for clinicians covers such questions as how long it takes for the drug to reach protective levels in the body (unknown, but seems to be about a week for rectal tissue and three weeks for the female genital tract) to financial matters (varies, but the manufacturer can often provide assistance to cover the cost). The guidelines were published in the May 14 Morbidity and Mortality Weekly Report. Go to cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf. A more reader-friendly version of the CDC’s factsheet on the strategy is at http://1.usa.gov/SokItJ.

Hep C combo drug

Janssen has filed for FDA approval of a hepatitis C medication that combines Olysio (simeprevir) with Sovaldi (sofosbuvir). The drug would be for the treatment of genotype 1 chronic Hep C in treatment-naïve (first time on therapy) adults with advanced liver fibrosis, and also null responders (whose therapy has failed) with all stages of liver fibrosis. The company called the filing a move in the direction of providing an all-oral hepatitis C treatment.

Hepatitis C among African Americans

The National Black Leadership Commission on AIDS, Inc. (NBLCA) has a new campaign to raise awareness about the effects of hepatitis C among black people. “Blacks are twice as likely to have ever been infected with the hepatitis C virus,” NBLCA reported in a press release. “Death related to the hepatitis C virus is almost double the rate for black Americans compared with non-Hispanic white Americans.” Last year, NBLCA, in conjunction with the Harm Reduction Coalition and the Coalition on Positive Health Empowerment (C.O.P.E.), created the National African American Hepatitis C Action Day, July 25, to promote education, testing, and treatment. Go to nblda.org.
Complera and rifabutin

In June, the Food and Drug Administration approved a change to the drug label of the fixed dose HIV medication Complera. The label now says to add an additional 25 mg tablet of Edurant (which is one of the medications in Complera) when also using rifabutin. This drug interaction with the tuberculosis medication was already known, but with the approval, rifabutin can be taken off Complera’s contraindication list.

Reyataz now for younger kids

Also in June, the FDA approved a powder formulation of Reyataz for use in children ages three months and older who are between 22 and 55 pounds. The powder must be mixed with food or beverage and taken with Norvir. Previously, the drug was only approved for children ages six and up. Reyataz is one of two protease inhibitor medications (along with Prezista) recommended for first-time antiviral therapy under U.S. HIV treatment guidelines.

Memoir of an HIV doctor

Who knew that Dr. Michael Saag could write so well outside of a medical journal? The HIV specialist, who has treated patients with HIV/AIDS from the beginning of the epidemic, recently published a memoir, Positive: One Doctor’s Personal Encounters with Death, Life, and the U.S. Healthcare System. Dr. Saag, co-founder of the University of Alabama’s famed 1917 Clinic, tells the stories of his patients, as well as his constant struggle for funding to take care of them. It’s a book that should be read by anyone who is interested in the history of HIV and the struggle to make insurers and other funding sources accountable for the health and well-being of patients.

HIV is Not a Crime conference

The first-ever “HIV is Not a Crime” national conference was held in June. The conference’s aim was to help advocates work for criminalization reform in their home states. Later in June, the Iowa Supreme Court threw out a 2009 conviction of “criminal transmission of HIV” in a case where transmission did not occur. Go to HIVisNotaCrime.com. Read early reports from the conference at TheBody.com.

When dogs heal

Pet photographer Jesse Freidin is taking photos of HIV-positive people whose dog provides them with much-needed support. The San Francisco-based photographer recently teamed up with FredSays.org in Chicago (raising money for HIV-positive adolescents) to take photos in the Windy City. Freidin already has two books to his credit. Go to JesseFreidin.org.

Venezuelans with HIV desperately seeking meds

HIV treatment activist Nelson Vergel is urging people to send leftover medications to the non-profit AID for AIDS in New York City, which distributes unexpired drugs to Latin American countries.

“As some of you probably know, I am originally from Venezuela, an oil producing country that used to have one of the best standards of living in Latin America. That has all changed since Hugo Chavez and his Castro-backed regime took office 15 years ago,” Vergel wrote in an article posted at TheBody.com. “He died in March 2013 and left his protégé Nicolas Maduro in charge after a dubious election.”

Due to the political instability, the country’s HIV patients are quickly running out of medications. Read Vergel’s plea at thebody.com/content/74516/nelson-vergels-asks-for-your-help-to-save-hiv-vene.html. Go to aidforaids.org/recycling-drive.
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I was always a pretty private person,” he said of his life before he was cured of HIV in 2007, “but at some point I decided that I had to tell my story. My heart was with the HIV community, as it is now, and I want there to be a cure for everyone.”

And people want to hear his story, even doctors.

Richard D’Aquila, MD, of Northwestern University, beamed when he introduced Brown, who he brought to Chicago in April to speak at a national cure forum at the school. “He’s the reason we have renewed research around the world looking for a cure for HIV, because he proved it could be possible,” said D’Aquila. “Five or 10 years ago, we couldn’t say ‘cure’ without getting laughed out of the room.”

Deborah Persaud, MD, of “Mississippi Baby” fame, said she was “thrilled” to be in the same room with Brown, and “thrilled” is not a word researchers normally use. Timothy Henrich, MD, the Boston doctor who, along with his colleagues, attempted a cure for a few patients following the example of Brown’s case, said at the Northwestern forum, “You were an inspiration to a lot of us in research, showing it could be done. You energized us.”

Speaking at a public forum in the Chicago Cultural Center in April, D’Aquila said doctors in the U.S. would have called the attempt to replace Brown’s cells with HIV-immune cells “crazy.” Brown clarified that his doctor in Germany was told that the idea was crazy. But it worked.

Timothy Ray Brown’s cure, ironically, came as a result of being diagnosed with terminal cancer. The story of his cure is complex, but in the end, the point is that modifying cells to resist HIV, as is seen in “elite controllers,” or people who are naturally immune to the virus, has the potential to help control, and even cure, infection.

While in Chicago, Brown spoke at Test Positive Aware Network (TPAN), publisher of POSITIVELY AWARE, addressing the staff and other HIV service providers invited from around the city, many of whom have HIV themselves.

He had just been in Washington, D.C., where he visited Congress members, including Florida Democrat Debbie Wasserman Schultz. It turned out that
her office was directly across from that of Tea Party Republican Michele Bachmann, known for making outrageous comments (for example, she expressed concern that *The Lion King* could promote homosexuality because Elton John wrote the soundtrack). Brown went to see her but she wasn’t in.

“I wanted her to ask me how I got HIV, so I could say, ‘From a toilet seat.’” He laughed.

**CANCER AND HIV**

Timothy Ray Brown was born and raised in Seattle. At 21, he traveled throughout Europe, where eventually he fell in love with a German, Michael (pronounced “mee-shall”), and moved to Berlin to live with him.

Brown tested positive for HIV in 1995. A year later, protease inhibitors (PIs) came on the market, and he went on a PI combination. The beginning of his cure began 10 years later.

“I was studying political science and doing well on meds,” he told his TPAN audience. “After leaving university, I did translation work. In 2006, I went to a commitment ceremony in New York, a gay wedding. I was extremely tired, but I thought it was jet lag. It didn’t help that the person I was staying with was going online all night looking for sex (not that I’m against that!) and his desk was right next to my bed, so I couldn’t sleep. I heard the tapping on the keyboard all night long. The entire wedding was a blur.”

It wasn’t until the extreme fatigue continued after he returned to Germany that he realized he needed immediate medical attention.

At first, he was diagnosed with anemia. “They kept giving me transfusions. My red blood cells would go up and the next day they would drop down again,” he said.

“That continued for several days, then the doctor said, ‘I think I need to send you to an oncologist.’”

He was diagnosed with acute myeloid leukemia (AML) and told to check into a hospital. Brown was in shock. He walked out to the car where his partner was waiting and gave him the news. “He just cried and cried,” Brown said.

“I told the doctor I wanted a hospital where they didn’t have stigma against people with HIV, because my partner had gone to a hospital in another city where a nurse told someone, ‘Watch out, he’s got AIDS,’ in a loud voice so everyone could hear. The doctor suggested the university system hospital, the Charité. He called the oncology unit there and got Dr. Gero Hutter on the phone. Gero said ‘send him in,’ so I went the next day and started chemotherapy.”

He was surprised to learn that his chemotherapy would not last for just a few days, but consisted of four rounds, several weeks apart. “After the second round, I developed bacterial pneumonia. After the third round, I developed a sepsis infection, which meant that I had severe problems with bacteria in my blood. I was put into an induced coma. When I woke up, I saw the doctor looking down at me and talking to me, and he looked like the Grim Reaper. I was scared. I thought, ‘Oh, my God—I’m dead!’”

Dr. Hutter suggested Brown stop chemotherapy and take a break. He spent three weeks in Italy with his mother, whose co-workers at the sheriff’s department in Seattle donated their vacation time so that she could be with him.

**THE TRANSPLANT IDEA**

It was previous to this, during his second round of chemo, that Dr. Hutter had made a suggestion.

“He had read something in med school about people who were highly resistant to HIV,” said Brown. “People who have a CCR5 delta 32 deletion [a genetic trait found in about 1 to 3% of Northern Europeans] were highly resistant, if not immune, to HIV, and that’s what gave him an idea.

“Two deletions [in a person’s CCR5 genetic profile] mean that the doorway that HIV uses to enters the CD4 cell is missing. So people with this mutation, which is a natural mutation—a good mutation!—are basically immune to HIV,” said Brown. “There is another doorway that the virus can use to enter the cells, X4, but the HIV that most people in the United States and Europe have is R5. X4 is very rare in the United States and Europe.”

The Red Cross in Germany maintains a database of potential stem cell transplant donors, sometimes used in severe cases of cancer. Dr. Hutter had submitted a sample of Brown’s blood “just in case” he needed a transplant.

Most people who need a donor have about four matches. “I had 267 potential donors.”
donors—that’s huge. I was quite lucky,” says Brown. “Basically, because I had so many possible donors, Dr. Hutter decided he was going to find out if one of these donors had the deletion, making them basically immune to HIV and if I got their stem cells, he speculated that I would also be immune to HIV. Maybe it would cure both my leukemia and my HIV.”

At this point, August of 2006, Brown was still doing well on HIV medications and his leukemia was in remission. The transplant had a 50% chance of death. Brown initially said no—he didn’t want to be a guinea pig.

Despite Brown’s lack of enthusiasm, Dr. Hutter began the long and expensive effort to find a donor match with a CCR5 delta 32 deletion. However, he needed special permission to search for a match.

After Dr. Hutter obtained that permission, he began to test the donor blood samples, going through sample after sample until he found the right donor, on the 61st try. He told Brown he had found a “hit”—a match—and he suggested that Brown get the transplant.

Brown talked with friends and family, including his grandmother, to whom he was very close. He asked what they would do. “It’s not that important to me to be cured of HIV,” he told them. “I can live a normal lifespan with medication.” He also sought a second opinion from a professor in another German city, who agreed that it wasn’t worth risking his life, and Brown decided against the transplant.

“I started working again and going to the gym, getting back into shape, but in December, the leukemia came back and it was clear I had to get the transplant.” Without it, he would die. This time, he said yes to Dr. Hutter’s suggestion of a transplant using the donor cells with the CCR5 deletion.

Before the transplant, however, he required chemotherapy again, followed by full body radiation, to destroy his immune system in order to prepare his body for receiving the donor’s cells. Under the guidelines for the operation, Brown was supposed to continue his HIV medications. His partner, however, had done some research on the Internet and determined that his HIV meds should not be continued in the face of a transplant, because the medications would not allow the new immune cells to reproduce and the transplant would not work.

So on the morning of the transplant, Brown announced that he would not continue his HIV meds and walked out when the transplant team insisted that he continue them, because it was in the protocol (the established procedure) for the operation.

The next day, Dr. Hutter told him the protocol had been changed and the transplant could continue. It was February 2007.

Three months later, no trace of HIV could be found in Brown’s body. The cost of the transplant, including the search for a donor: approximately two million dollars.

Though the entire process was beyond the realm of normal medical care, Brown benefitted from Germany’s approach to health care. “Germany has nationalized health care,” said Brown, “although there is competition between the public providers and the private providers. I had a public provider who gave the most benefits. The whole time I was in Germany I never paid one dime, for medications or anything. I was living in Germany and it was assumed I deserved treatment. In fact, I had hollow cheeks from wasting syndrome caused by HIV and I actually got fat injections into my face. They paid for it 100%.”

CURED

“I stopped taking HIV medication the day of my transplant and I haven’t taken any since,” Brown told his audience at TPAN. “It’s pretty amazing. So I am cured and I want everybody else to be cured as well.”

Asked how he feels to be HIV-negative, he said, “It’s a very wonderful feeling. It’s nice not to have to take medication every day and not have to think about it every day except for my promotion of the cure. I am very lucky.” In 2012, he created the Timothy Ray Brown Foundation to advocate for research and awareness of an HIV cure.

Asked how he identifies now, he said, “I basically say I’m negative, but I have very strong ties to the HIV community. Most of my friends have HIV and my [new] boyfriend has had HIV for 20 years. I feel very connected to people who are HIV-positive.”

While HIV could not be found in his body, the leukemia came back a year later and Brown needed another transplant. “The question was, will the donor agree to give cells for a second time? Fortunately, he did,” said Brown.

“A stem cell transplant is like a bone marrow transplant, but it’s easier,” Brown pointed out. “It doesn’t involve opening you up and grafting bone marrow on to your bones. It involves taking a bunch of blood from the donor and filtering out the stem cells. They give the donor medication that kicks the stem cells out of the blood.”

The second transplant, in February 2008, did not go as well and he had a difficult recovery, which included having to learn how to walk again after being paralyzed. He had been sent home, but he suffered from severe delirium and other problems, and his partner persuaded the doctors to put him in a hospital, arguing that he would otherwise die. Brown was placed in a center for patients with severe brain injury, where he was able to recover under constant, expert care.

“Without the kindness and loving care of my partner through all this, I don’t think I would be here,” Brown said.

One of his closest friends traveled from Seattle to be with him during this time, thinking she would be with him when he died, but instead she saw him go from a wheelchair to a walker to walking again. “She was the first person I came out to [about being gay],” said Brown. “We consider ourselves surrogate siblings. She’s ecstatic that I survived.”

RESEARCH AND HOPE

“Right now many institutions, universities, private companies, and even big pharmaceuticals like Gilead and Merck are doing research on finding the cure,” Brown said. “The NIH [National Institutes of Health] has started a program and invested millions of dollars into it. There are three collaborators that are looking for the cure. One thing is that there’s something called zinc finger nucleases, which is basically when they take millions of CD4 cells from the patient and they can pull out the R5 from the CD4 cells. Then they give the cells back to the patients and there are several patients who have done very well on this. In fact, I know one of them. He said he had never had a CD4 cell level above 400 before and now his CD4 level is around 800. So he’s doing very well. That’s not really a cure, but it’s a step in the right direction.”

Brown said he wants a cure for everyone.
with HIV around the world, as well as in the U.S., including underserved communities.

“I believe wholeheartedly that there’s going to be a cure in my lifetime. I don’t think there’s going to be one cure. With all these institutions, I think there will be several kinds of cure.”

Brown has lingering physical problems from his ordeal. While standing up after one talk, Brown was wobbly. “I still have trouble with my balance,” he said, smiling. He can’t walk or run the way he used to, but uses a treadmill instead of running on pavement (which he usually finds too uneven, given his balance). He goes to the gym three or four times a week to stay fit.

Brown has moved back to the United States, to San Francisco, where he has a new partner.

He also has a new doctor—prominent HIV specialist and researcher Stephen G. Deeks, of the University of California at San Francisco, who told him, “I’ve never had a patient who had HIV before. I don’t know what to do with you.”

Deeks understood clearly one thing he needs to do: ship Brown’s blood and tissue to research labs around the country. There are many layers of investigations still being done on his cure. Lingering questions remain as to whether it was one or both of the transplants with the CCR5 deletion, the aggressive immunosuppressive therapy that accompanied them, the chemotherapy for the leukemia, or some combination thereof that contributed to Brown’s cure. This year Brown was officially declared cured because there has been no sign of replication-competent HIV in those samples for more than seven years.

Speaking at the Northwestern forum, he joked with researchers that, “I feel like I know many of you intimately … because probably you have my tissue in your lab.”

He had a message for patients: Join the cure studies. But, “If you participate in a study, it won’t mean you’re cured. You would do it to help other people.”

He said he had hundreds of people to thank for his life, including Hutter. He told the researchers, “I was the first person in the world to be cured. I know in my heart I will not be the last. So on behalf of an AIDS-free world, I thank you from the bottom of my heart.” PA

FOR A LIST of ongoing HIV cure studies, go to treatmentactiongroup.org/cure/trials. See the online version of this page for a photograph of the author with Timothy Ray Brown.
For Adam, homelessness was an escape. Although he lived in a typical suburb in the Midwest, he felt he had to get away from a difficult situation at home. Running away seemed to be the only option.

“I had some wanderlust, but for me, it was because I lived in a very rigid household,” says Adam (to protect his privacy, his real name has been changed). “I couldn’t dress or act any different from what my father thought I should be. I lived a double life for a while: I’d be the perfect ideal son at home, and then outside of the house, I was escorting, doing drugs, and drinking. It got to the point where I was intoxicated all the time. I got so depressed and fed up that I hated everything. I decided I didn’t want to stay at home anymore, but I didn’t know where else to go.”

Turning to the Internet for information, Adam discovered a very loosely knit community of “traveling” youth, young people who had chosen to hit the road to escape their problems. “I don’t like the word escape,” Adam
says. “I was changing my circumstances. I wasn’t running away because I was trying to escape the world I had created, I was running away because I wanted to find a better one for myself.”

According to the National Alliance to End Homelessness, a national non-profit advocacy organization, there are approximately 550,000 single youth and young adults up to age 24 in the U.S. each year who have experienced homelessness for at least a week. Of those, about 380,000 are under 18.

Ebony Barney is a client services associate at Test Positive Aware Network, a non-profit AIDS service organization (and publisher of POSITIVELY AWARE), and a case manager at a homeless shelter in Chicago. Many of Barney’s clients are youth who face a number of issues, including homelessness. Asked if she had ever encountered any traveling youth, Barney realized she might have been trying to offer the help she thought they needed, but that some of her clients weren’t looking for.

“If you don’t have a home to live in, and you’re homeless, then my job is to help you figure out how to not be homeless,” Barney says. “I never even considered there would be a difference among people who are categorized as homeless.”

What’s the difference between youth who are homeless and those who are travelers? “Homeless youth are typically those who are forced out on to the streets by circumstances beyond their control,” Adam says. “Most of them are trying to become a more functional member of society—they’re trying to get social services, medical help, get into schools, find work. Traveler youth, however, instead of trying to work with the system and survive that way, it’s more about learning how to survive outside of the box, without society’s help.”

As he read more about them, Adam found the travelers’ extreme sense of self-reliance and rejection of society appealing. “Knowing how their lifestyle works, the thought of being free from the stigma I had been dealing with and being free from any obligations was very enticing,” says Adam.

“Some travelers have had a rough time growing up and have thus developed a loathing for structure and rules,” Adam says. “There’s also a large influx of suburban kids who had great parents and great lives, but they’ve decided that they’re bored with it and are out on the road because they have nothing better to do. Then there are people who simply have a distrust of the system. That distrust is probably what traveling youth have [most] in common.”

Adam was 19 when he decided to leave home and “travel.” He placed his cell phone on top of a note written to his parents, leaving both on his bed, and disappeared. Adam set out for South Carolina, where he had friends who were also traveling. Once he was on the road, his family was no longer on his mind. Adam felt a sense of freedom despite being homeless. “I was very nervous, scared, kinda depressed—a whole whirlwind of emotions—but mainly, I felt excitement,” he says. “I could go anywhere, be anyone, say anything, and not face any repercussions. That’s why a lot of people travel. They have the ability to go out and become whatever person they want and not have to suffer the consequences of some of their actions.”

However, this newfound freedom wasn’t without its downsides. “You don’t know where you’re going to sleep, what you’re going to eat,” Adam concedes. “Is someone gonna beat the shit out of you just for the hell of it? There are a lot of crazy people out there. You have to always be on guard against people, other travelers, normal people. It puts you on edge and you develop a mentality of you against the world—and not in a romantic sense, in a survival sense.”

GENTLEMEN OF THE ROAD

His survival skills and code of conduct as a traveler are patterned after the traveling hobos who were common during the Great Depression of the 1920s and ’30s, who were euphemistically referred to as “gentlemen of the road.”

“I always kept moving,” Adam says. “Whenever I stayed in one place, I avoided becoming stagnant. I’d always try to find a job and put a roof over my head. I would travel somewhere, and then I would settle

GENTLEMEN OF THE ROAD
I got into traveling because I wanted to be somewhere else and be someone else.

don't want to do anything unless they themselves want to do it," says Adam.

Some will visit drop-in centers for health information and aid. "A lot of travelers rely
on drop-in centers to get treatment for a lot of things—staph infections, scabies, hep C," Adam said. "Most drop-in centers and youth clinics will give you information and help you; however, not every traveler necessarily wants to get treated. Most of the time, the kid won't really care [about getting treatment]."

There are some who get out of traveling to take care of themselves and get treatment," Adam says, "but others don't and they die. It's their choice. It's not that they can't get help, it's that they have made the choice not to get help. It's something they have control over, rather than someone making the choice for them."

Addressing travelers on their own terms is a new realization for TPAN case manager Barney, but it’s an idea she says she will be more mindful of. "It’s not my place to convince someone who is using to stop what they’re doing," she says. "But it is my job to connect with my client and let them know that we will be here, when they are ready, with what they need."

COMING IN FROM THE COLD

Now in his early 20s, Adam has once more settled down. He's found a job he enjoys and has a new circle of friends. While things have improved with his mother, Adam’s father still refuses to talk with him. He’s not ruled out that his wanderlust might return and that he’d rejoin his fellow travelers.

“Part of me is envious of them," Adam admits. "When you’re traveling, you don’t have the same day-to-day concerns other people have. When you’re traveling, you have real stressors—finding someplace dry to sleep, getting food. When you have such basic concerns, you don’t really care about anything else.”

Whatever their reasons, like most people, travelers are looking for a purpose, Adam says. "They get out of the traveling game when they finally find whatever it is they were looking for. If they never find it, they stay out there."
COMPLERA is a complete HIV-1 treatment in 1 pill a day. It is for adults who have never taken HIV-1 medicines before and who have no more than 100,000 copies/mL of virus in their blood. COMPLERA can also replace current HIV-1 medicines for some adults who have an undetectable viral load (less than 50 copies/mL) and whose healthcare provider determines that they meet certain other requirements. COMPLERA does not cure HIV-1 or AIDS.

Just the one for me

COMPLERA is a complete HIV-1 treatment in only 1 pill a day.

Ask your healthcare provider if COMPLERA may be the one for you.
**What is COMPLERA?**

COMPLERA (emtricitabine 200 mg, rilpivirine 25 mg, tenofovir disoproxil fumarate 300 mg) is a prescription medicine used as a complete HIV-1 treatment in one pill a day. COMPLERA is for adults who have never taken HIV-1 medicines before and who have no more than 100,000 copies/mL of virus in their blood (this is called ‘viral load’). COMPLERA can also replace current HIV-1 medicines for some adults who have an undetectable viral load (less than 50 copies/mL) and whose healthcare provider determines that they meet certain other requirements.

COMPLERA combines 3 medicines into 1 pill to be taken once a day with food. COMPLERA is a complete single tablet regimen and should not be used with other HIV-1 medicines. It is not known if COMPLERA is safe and effective in children under the age of 18 years.

**COMPLERA does not cure HIV-1 infection or AIDS.** To control HIV-1 infection and decrease HIV-related illnesses you must keep taking COMPLERA. Ask your healthcare provider if you have questions about how to reduce the risk of passing HIV-1 to others. Always practice safer sex and use condoms to lower the chance of sexual contact with body fluids. Never reuse or share needles or other items that have body fluids on them.

**IMPORTANT SAFETY INFORMATION**

**What is the most important information I should know about COMPLERA?**

COMPLERA can cause serious side effects:

- **Build-up of an acid in your blood (lactic acidosis),** which is a serious medical emergency. Symptoms of lactic acidosis include feeling very weak or tired, unusual (not normal) muscle pain, trouble breathing, stomach pain with nausea or vomiting, feeling cold especially in your arms and legs, feeling dizzy or lightheaded, and/or a fast or irregular heartbeat.

- **Serious liver problems.** The liver may become large (hepatomegaly) and fatty (steatosis). Symptoms of liver problems include your skin or the white part of your eyes turns yellow (jaundice), dark “tea-colored” urine, light-colored bowel movements (stools), loss of appetite for several days or longer, nausea, and/or stomach pain.

- **You may be more likely to get lactic acidosis or serious liver problems** if you are female, very overweight (obese), or have been taking COMPLERA for a long time. In some cases, these serious conditions have led to death. Call your healthcare provider right away if you have any symptoms of these conditions.

- **Worsening of hepatitis B (HBV) infection.** If you also have HBV and stop taking COMPLERA, your hepatitis may suddenly get worse. Do not stop taking COMPLERA without first talking to your healthcare provider, as they will need to monitor your health. COMPLERA is not approved for the treatment of HBV.

**Who should not take COMPLERA?**

Do not take COMPLERA if you:

- **Take a medicine that contains:** carbamazepine (Carbatrol, Equetro, Tegretol, Tegretol-XR, Tegretol), oxcarbazepine (Trileptal), phenobarbital (Luminal), phenytoin (Dilantin, Dilantin-125, Phenytek), rifabutin (Mycobutin), rifampin (Rifater, Rifamate, Rimactane, Rifadin), rifapentine (Priftin), dexamethasone (Dexilant), esomeprazole (Nexium, Vimovo), lanosoprazole (Prevacid), omeprazole (Prilosec), pantoprazole sodium (Protonix), rabeprazole (Aciphex), naproxen sodium, or abacavir (Ziagen, Epzicom, or Atripla).

- **Take other medicines that interact with COMPLERA** and cause kidney problems, or a medicine that may cause kidney problems, your healthcare provider may also check your kidneys before starting treatment with COMPLERA. If you have had kidney problems, or take other medicines that may cause kidney problems, your healthcare provider may also check your kidneys before starting treatment with COMPLERA.

- **Depression or mood changes.** Tell your healthcare provider right away if you have any of the following symptoms: feeling sad or hopeless, feeling anxious or restless, have thoughts of hurting yourself (suicide) or have tried to hurt yourself.

- **Changes in liver enzymes.** People who have had hepatitis B or C, or who have had changes in their liver function tests in the past may have an increased risk for liver problems while taking COMPLERA. Some people without prior liver disease may also be at risk. Your healthcare provider may do tests to check your liver enzymes before and during treatment with COMPLERA.

- **Bone problems,** including bone pain or bones getting soft or thin, which may lead to fractures. Your healthcare provider may do tests to check your bones.

- **Changes in body fat** can happen in people taking HIV-1 medicines.

- **Changes in your immune system.** Your immune system may get stronger and begin to fight infections. Tell your healthcare provider if you have any new symptoms after you start taking COMPLERA.

**The most common side effects** of COMPLERA include trouble sleeping (insomnia), abnormal dreams, headache, dizziness, diarrhea, nausea, rash, tiredness, and depression. Other common side effects include vomiting, stomach pain or discomfort, skin discoloration (small spots or freckles), and pain. Tell your healthcare provider if you have any side effects that bother you or do not go away.

**What should I tell my healthcare provider before taking COMPLERA?**

- **All your health problems.** Be sure to tell your healthcare provider if you have or had any kidney, mental health, bone, or liver problems, including hepatitis virus infection.

- **All the medicines you take,** including prescription and nonprescription medicines, vitamins, and herbal supplements. COMPLERA may affect the way other medicines work, and other medicines may affect how COMPLERA works. Keep a list of all your medicines and show it to your healthcare provider and pharmacist. Do not start any new medicines while taking COMPLERA without first talking with your healthcare provider.

- **If you take antacids.** Take antacids at least 2 hours before or at least 4 hours after you take COMPLERA.

- **If you take stomach acid blockers.** Take acid blockers at least 12 hours before or at least 4 hours after you take COMPLERA. Ask your healthcare provider if your acid blocker is okay to take, as some acid blockers should never be taken with COMPLERA.

- **If you are pregnant** or plan to become pregnant. It is not known if COMPLERA can harm your unborn baby. Tell your healthcare provider if you become pregnant while taking COMPLERA.

- **If you are breastfeeding** (nursing) or plan to breastfeed. Do not breastfeed. HIV-1 can be passed to the baby in breast milk. Also, some medicines in COMPLERA can pass into breast milk, and it is not known if this can harm the baby.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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emtricitabine 200mg/rilpivirine 25mg/tenofovir disoproxil fumarate 300mg tablets

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Brief Summary of full Prescribing Information

COMPLERA® (emtricitabine 200 mg, rilpivirine 25 mg, tenofovir disoproxil fumarate 300 mg) tablets

Brief summary of full Prescribing Information. For more information, please see the full Prescribing Information, including Patient Information.

What is COMPLERA?

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- COMPLERA is a complete regimen and should not be used with other HIV-1 medicines. HIV-1 is the virus that causes AIDS. When used properly, COMPLERA may reduce the amount of HIV-1 virus in your blood and increase the amount of CD4 T-cells, which may help improve your immune system. This may reduce your risk of death or getting infections that can happen when your immune system is weak.
- COMPLERA does not cure HIV-1 or AIDS. You must stay on continuous HIV-1 therapy to control HIV-1 infection and decrease HIV-related illnesses.
- Ask your healthcare provider about how to prevent passing HIV-1 to others. Do not share or reuse needles, injection equipment, or personal items that can have blood or body fluids on them. Do not have sex without protection. Always practice safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

What is the most important information I should know about COMPLERA?

COMPLERA can cause serious side effects, including:

- Build-up of an acid in your blood (lactic acidosis). Lactic acidosis can happen in some people who take COMPLERA or similar (nucleoside analogs) medicines. Lactic acidosis is a serious medical emergency that can lead to death. Lactic acidosis can be hard to identify early, because the symptoms could seem like symptoms of other health problems. Call your healthcare provider right away if you get any of the following symptoms which could be signs of lactic acidosis:
  - feel very weak or tired
  - have unusual (not normal) muscle pain
  - have trouble breathing
  - having stomach pain with nausea or vomiting
  - feel cold, especially in your arms and legs
  - feel dizzy or lightheaded
  - have a fast or irregular heartbeat

- Severe liver problems. Severe liver problems can happen in people who take COMPLERA. In some cases, these liver problems can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis). Call your healthcare provider right away if you get any of the following symptoms of liver problems:
  - your skin or the white part of your eyes turns yellow (jaundice)
  - dark “tea-colored” urine
  - light-colored bowel movements (stools)
  - loss of appetite for several days or longer
  - nausea
  - stomach pain

- You may be more likely to get lactic acidosis or severe liver problems if you are female, very overweight (obese), or have been taking COMPLERA for a long time.

Worsening of Hepatitis B infection. If you have hepatitis B virus (HBV) infection and take COMPLERA, your HBV may get worse (flare-up) if you stop taking COMPLERA. A “flare-up” is when your HBV infection suddenly returns in a worse way than before. COMPLERA is not approved for the treatment of HBV, so you must discuss your HBV with your healthcare provider.

- Do not run out of COMPLERA. Refill your prescription or talk to your healthcare provider before your COMPLERA is all gone.
- Do not stop taking COMPLERA without first talking to your healthcare provider.
- If you stop taking COMPLERA, your healthcare provider will need to check your health often and do blood tests regularly to check your HBV infection. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking COMPLERA.

Who should not take COMPLERA?

Do not take COMPLERA if you also take any of the following medicines:

- Medicines used for seizures: carbamazepine (Carbatrol, Equetro, Teretogol, Teretogol-XR, Teril, Epitol); oxcarbazepine (Trelpile); phenobarbital (Luminal); phenytoin (Dilantin, Dilantin-125, Phenytex)
- Medicines used for tuberculosis: rifabutin (Mycobutin); rifampin (Rifater, Rifamate, Rimactane, Rifadin); rifapentine (Priffin)
- Certain medicines used to block stomach acid called proton pump inhibitors (PPIs): dexlansoprazole (Dexilant); esomeprazole (Nexium, Vimove); lansoprazole (Prevacid); omeprazole (Prilosec, Zegerid); pantoprazole sodium (Protonix); rabeprazole (Aciphex)
- Certain steroid medicines: More than 1 dose of dexamethasone or dexamethasone sodium phosphate
- Certain herbal supplements: St. John’s wort
- Certain hepatitis medicines: adefovir (Hepsera), lamivudine (Epivir-HBV)

Do not take COMPLERA if you also take any other HIV-1 medicines, including:

- Other medicines that contain tenofovir (ATRIPILA, STRIBILD, TRUVADA, VIREAD)
- Other medicines that contain emtricitabine or lamivudine (ATRIPILA, Combivir, EMTRIVA, Epivir, Epzicom, STRIBILD, Trizivir, TRUVADA)
- rilpivirine (Edurant)

COMPLERA is not for use in people who are less than 18 years old.

What are the possible side effects of COMPLERA?

COMPLERA may cause the following serious side effects:

- See “What is the most important information I should know about COMPLERA?”

New or worse kidney problems, including kidney failure. Your healthcare provider should do blood and urine tests to check your kidneys before you start and while you are taking COMPLERA. If you have had kidney problems in the past or need to take another medicine that can cause kidney problems, your healthcare provider may need to do blood tests to check your kidneys during your treatment with COMPLERA.

Depression or mood changes. Tell your healthcare provider right away if you have any of the following symptoms:

- feeling sad or hopeless
- feeling anxious or restless
- have thoughts of hurting yourself (suicide) or have tried to hurt yourself

Change in liver enzymes. People with a history of hepatitis B or C
virus infection or who have certain liver enzyme changes may have an increased risk of developing new or worsening liver problems during treatment with COMPLERA. Liver problems can also happen during treatment with COMPLERA in people without a history of liver disease. Your healthcare provider may need to do tests to check your liver enzymes before and during treatment with COMPLERA.

• Bone problems can happen in some people who take COMPLERA. Bone problems include bone pain, softening or thinning (which may lead to fractures). Your healthcare provider may need to do tests to check your bones.

• Changes in body fat can happen in people taking HIV-1 medicine. These changes may include increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the main part of your body (trunk). Loss of fat from the legs, arms and face may also happen. The cause and long term health effect of these conditions are not known.

• Changes in your immune system (Immune Reconstitution Syndrome) can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider if you start having any new symptoms after starting your HIV-1 medicine. The most common side effects of COMPLERA include:

  • Trouble sleeping (insomnia), abnormal dreams, headache, dizziness, diarrhea, nausea, rash, tiredness, depression

Additional common side effects include:

  • Vomiting, stomach pain or discomfort, skin discoloration (small spots or freckles), pain

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

• These are not all the possible side effects of COMPLERA. For more information, ask your healthcare provider.

• Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What should I tell my healthcare provider before taking COMPLERA?

Tell your healthcare provider about all your medical conditions, including:

• If you have or had any kidney, mental health, bone, or liver problems, including hepatitis B or C infection.

• If you are pregnant or plan to become pregnant. It is not known if COMPLERA can harm your unborn child.
  – There is a pregnancy registry for women who take antiviral medicines during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.

• If you are breastfeeding (nursing) or plan to breastfeed. Do not breastfeed if you take COMPLERA.
  – You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
  – Two of the medicines in COMPLERA can pass to your baby in your breast milk. It is not known if this could harm your baby.
  – Talk to your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements:

• COMPLERA may affect the way other medicines work, and other medicines may affect how COMPLERA works.

• If you take certain medicines with COMPLERA, the amount of COMPLERA in your body may be too low and it may not work to help control your HIV-1 infection. The HIV-1 virus in your body may become resistant to COMPLERA or other HIV-1 medicines that are like it.

• Be sure to tell your healthcare provider if you take any of the following medicines:
  – Antacid medicines that contain aluminum, magnesium hydroxide, or calcium carbonate. Take antacids at least 2 hours before or at least 4 hours after you take COMPLERA.
  – Certain medicines to block the acid in your stomach, including cinemetine (Tagamet), famotidine (Pepcid), nizatidine (Axid), or ranitidine hydrochloride (Zantac). Take the acid blocker at least 12 hours before or at least 4 hours after you take COMPLERA. Some acid blocking medicines should never be taken with COMPLERA (see “Who should not take COMPLERA?” for a list of these medicines).
  – Medicines that can affect how your kidneys work, including acyclovir (Zovirax), cidofovir (Vistide), ganciclovir (Cytovene IV, Virtase), valacyclovir (Valtrex), and valganciclovir (Valcyte).
  – clarithromycin (Biaxin)
  – erythromycin (E-Mycin, Eryc, Ery-Tab, PCE, Pedialzole, Ilosone)
  – fluconazole (Diflucan)
  – itraconazole (Sporanox)
  – ketoconazole (Nizoral)
  – methadone (Dolophine)
  – posaconazole (Noxafil)
  – telithromycin (Ketek)
  – voriconazole (Vfend)

Know the medicines you take. Keep a list of all your medicines and show it to your healthcare provider and pharmacist when you get a new medicine. Do not start any new medicines while you are taking COMPLERA without first talking with your healthcare provider.

How should I take COMPLERA?

• Stay under the care of your healthcare provider during treatment with COMPLERA.

• Take COMPLERA exactly as your healthcare provider tells you to take it.

• Always take COMPLERA with food. Taking COMPLERA with food is important to help get the right amount of medicine in your body. A protein drink is not a substitute for food. If your healthcare provider decides to stop COMPLERA and you are switched to new medicines to treat HIV-1 that includes rilpivirine tablets, the rilpivirine tablets should be taken only with a meal.

Keep COMPLERA and all medicines out of reach of children.

This Brief Summary summarizes the most important information about COMPLERA. If you would like more information, talk with your healthcare provider. You can also ask your healthcare provider or pharmacist for information about COMPLERA that is written for health professionals, or call 1-800-445-3235 or go to www.COMPLERA.com.

Issued: December 2013

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DAWN OF A NEW ERA

New guidelines, new treatments: Project Inform’s Andrew Reynolds takes a look at the standard of care for HCV in 2014

Welcome to the 2014 POSITIVELY AWARE HCV (hepatitis C virus) Drug Guide. Not long ago this guide would have consisted of only two drugs: interferon and ribavirin. In 2011, two new HCV protease inhibitors came on the scene: Incivek and Victrelis. These first generation HCV protease inhibitors marked a significant step forward in the HCV treatment landscape, but they required up to 48 weeks of therapy with several debilitating side effects.

Many patients and providers chose to wait for newer, less toxic, and potentially interferon-free regimens. At the end of 2013 two more drugs, Sovaldi and Olysio, were approved by the FDA, marking the beginning of what is called the “Direct Acting Antiviral” (DAA) era. There are several others that have been submitted to the FDA and are anticipated to be approved and available by the end of 2014, with even more expected to be approved in 2015. With these new medications, we now have a clear goal in HCV treatment: Cure!

NEW GUIDELINES

With new advances in HCV, we also have new recommendations to guide decisions for its testing, management, and treatment. The American Association for the Study of Liver Diseases (AASLD) and Infectious Diseases Society of America (IDSA) released the “Recommendations for Testing, Managing, and Treating Hepatitis C” to keep medical providers up to date with the rapidly changing treatment landscape. It is a very comprehensive document that provides guidance for doctors, physician’s assistants, and nurse practitioners (hereafter referred to as medical providers) who may not be as experienced with HCV as are liver specialists like hepatologists or gastroenterologists. Many HIV providers and infectious disease specialists can already manage HCV treatments, and as these regimens get simpler and easier to manage and the need for specialists decreases, primary care providers will become very important players in the treatment of HCV. And finally, although these guidelines are written for medical providers, it is a fairly accessible document for patients to use to inform themselves and be better advocates for their own personal health: The more informed you are, the better your care will be. Read the AASLD’s complete guidelines at hcvguidelines.org.

HCV SCREENING: WHO SHOULD BE TESTED?

To be perfectly candid, we have not done a very

Who should get tested for HCV?
What to consider when deciding if you should get tested

Anyone born between 1945 and 1965 should be tested for HCV at least once in their lifetime.

Anyone with risk factors for HCV should be tested at least once, or on an on-going basis at intervals to be determined.

The following risk behaviors or exposures call for HCV testing:

- Injection drug use, even if it was just once
- Intranasal drug use (from straws)
- Any incarceration
- Long-term hemodialysis
- Getting a tattoo in an unregulated setting
- Children born to an HCV-infected mother
good job of testing people for HCV, with estimates of 50–75% of people living with HCV who are unaware they have the virus. The reasons for this are many, but include lack of funding, stigma (especially for people who inject or have injected drugs), and lack of access to health care. In addition, poor HCV treatment options with limited effectiveness were a common rationale for not testing: Why test someone to tell them they have a disease for which there is poor treatment? With new advances in HCV therapy and improved access to health care under the Affordable Care Act (ACA), many of the old barriers are disappearing. The U.S. Centers for Disease Control and Prevention (CDC) and United States Preventative Services Task Force (USPSTF) have recommended HCV screening in two distinct groups: (1) People born between 1945 and 1965, the so-called “baby-boomer” guidelines, and (2) people with risk factors for HCV (see box below and at right). The USPSTF recommendations are particularly important, as they have positive consequences for public and private health insurance coverage of screening.

SEXUAL TRANSMISSION OF HCV: CONSIDERATIONS FOR HIV-POSITIVE INDIVIDUALS

Overall, the risk of sexual transmission of HCV is quite low: Studies have shown very low rates of HCV in non-injecting, HIV-negative individuals, regardless of gender or sexual orientation. Although sexual transmission of HCV is not a universally accepted risk factor, there is a consensus that HIV-positive people, especially gay men, are at increased risk of infection through sex. HIV-positive gay men have higher rates of sexually transmitted HCV, and as such, they should be screened routinely. It is standard practice to screen for HCV upon entry to HIV primary care, but while there are no clear guidelines for routine screening, an annual HCV test for sexually active gay men should be considered.

WHAT TO TAKE, AND WHEN?

In addition to pegylated interferon (PEG) and ribavirin (RBV), there are four FDA approved DAAs available: Incivek, Victrelis, Olysio, and Sovaldi. While the ultimate goal of HCV treatment is to use non-interferon-based regimens for 12 weeks or less, we are not fully there yet. We do have some non-interferon-based treatments, but it won’t be until the end of 2014 that we will start to see a wide array of FDA-approved ones.

Incivek and Victrelis are no longer recommended for the treatment of HCV. It’s not that these drugs don’t work, but rather they just don’t match up in effectiveness, side effect profile, or length of treatment when compared to the newer DAAs. With these new drugs, HCV can be treated with a variety of different regimens depending upon variables like treatment experience, presence of other co-morbidities (such as HIV or renal disease), and genotype (GT). Genotype is especially important: There are several different types of HCV, numbered from 1–6, and there

- Blood exposures on the job, including needle sticks or blood splashes to mucous membranes
- Received clotting factors before 1987
- An organ transplant or transfusion as follows:
  - Received a blood transfusion before July 1992
  - Received an organ transplant before July 1992
  - Any notification of having received blood from a donor who later tested positive for HCV
- Received a blood transfusion before July 1992
- Received an organ transplant before July 1992
- Any notification of having received blood from a donor who later tested positive for HCV
- Received clotting factors before 1987
- An organ transplant or transfusion as follows:
  - Received a blood transfusion before July 1992
  - Received an organ transplant before July 1992
  - Any notification of having received blood from a donor who later tested positive for HCV

Other medical conditions:
- HIV infection
- Unexplained chronic liver disease, hepatitis, and/or elevated liver enzymes

SOURCE: RECOMMENDATIONS FOR TESTING, MANAGING, AND TREATING HEPATITIS C, P. 8
are even subtypes that are designated by letters (1a, 1b, etc.). Different GTs respond to medications differently, and some require more drugs and/or a longer length of time for treatment. For people who are treatment naïve, Sovaldi (sofosbuvir) is the recommended DAA for GT 1 through 6, along with ribavirin. Pegylated interferon is still recommended for GT 1, 4, 5, and 6, but GT 2 and 3 are FDA approved to be treated without it. As new HCV drugs get approved by the FDA, the AASLD/IDSA guidelines will be updated to include new recommended and alternative treatment regimens for people to consider.

For those who cannot tolerate interferon, there are alternative interferon-free regimens. One worth noting is the off-label (non-FDA-approved, but scientifically validated) use of Sovaldi and Olysio (simeprevir) with or without ribavirin for the treatment of GT 1: This is the first DAA combination that has been used in this manner to treat HCV and serves as a harbinger of what’s to come.

The new AASLD/IDSA guidelines do not yet offer guidance on when to start HCV therapy (that will come in a later version), so deciding on treatment is a decision left to you and your medical provider (and in some cases, your insurance carrier, see below). Some people are choosing to treat now, even with interferon-based regimens, while others are still waiting for the easier to take, all-oral regimens at the end of this year and beyond. That said, people with fibrosis scores—a measure of the amount of scarring of the liver using a range of 0 (no scarring) to 4 (cirrhosis)—of F2 or F3 might not want to wait to start treatment. Similarly, HIV/HCV co-infected persons should be considered for treatment due to the risk of more rapidly advancing liver disease. There may be other factors in deciding to start treatment now, and HCV-infected people should start having that discussion with their medical provider and making a treatment plan.

A chart listing the recommended and alternative HCV treatments for treatment naïve, treatment experienced and HIV/HCV co-infected people can be found on page 36.

**HIV/HCV TREATMENT OPTIONS**

**HIV/HCV co-infection** is a very serious issue. In addition to the increased risk of sexual transmission discussed earlier, HIV often leads to a faster progression of HCV-related liver disease. Good HIV care and a healthy immune system may slow down HCV disease progression, but it is not a cure. Until recently, the only FDA-approved HCV treatments for HIV-positive people were pegylated interferon and ribavirin. The first generation PIs could be used off-label, but the drug-to-drug interactions and side effects of these medications made them very challenging for co-infected people to take. Sovaldi was approved for use in co-infected people, and has shown very promising cure results in this population.

The AASLD/IDSA guidelines include recommendations for treatment of co-infection with both interferon-based and non-interferon-based treatments. The future of treatment for this population is also bright: Several of the new DAAs are either expected to be approved for treatment in HIV/HCV co-infection, or are under study. Many of these clinical trials have shown very promising results.

**A NOTE ON COST AND ACCESS TO HCV MEDICATIONS**

For all the excitement over the effectiveness of the most recent HCV drugs, as well as those soon to be approved, there is significant concern about the cost of these treatments. Sovaldi is listed at $1,000 per pill, or $84,000 for a 12-week course of treatment and $168,000 for a 24-week one. Olysio is less expensive, at $790 per pill, but that is still over $66,000 for 12 weeks, plus the cost of the additional weeks of pegylated interferon and ribavirin. The cost of these medications are putting significant pressure on both public and private insurers, and many of them are scrambling to see how they can afford to cover the cost of HCV treatment without bankrupting the system.

These are challenging issues that health economists, policy makers, and medical ethicists need to wrestle with, but for you the patient, the only thing that matters is achieving a cure. Do not let the high cost of these drugs prevent you from seeking treatment. There are programs that can help you cover some or all of the costs of the medications. We have a list of patient assistance programs, co-pay assistance programs, and other resources in this issue, found on page 37.

**A BRAVE NEW WORLD**

It is a very exciting time in the world of hepatitis C. Along with new HCV treatments, we have HCV screening guidelines to identify new infections, the ACA to improve access to medical care for those infected, and the AASLD/IDSA testing, management, and treatment guidelines to guide care and treatment. This HCV Drug Guide is designed to further educate and empower you in your care and treatment, and we hope you find it useful.
HOW TO USE THIS GUIDE

Here’s where you’ll find definitions and descriptions of things you’ll need to know about in order to make an informed decision about your HCV care and treatment.

The HCV Drug Guide will include medications that are FDA approved, expected to be approved this year, or are likely to be approved through June of 2015. The information provided on FDA-approved drugs comes from the package labels, as well as other data sources such as conference presentations and medical journal articles. For the non-FDA-approved drugs, the information comes from conference presentations and medical journals.

All current HCV drugs must be taken in combination with other drugs. Pegylated interferon is an injectable medication, but all other HCV medications are taken as pills. Although there are currently no fixed dose combination (FDC) pills for HCV like there are for HIV (Atripla, Combivir, etc.), there are several on the horizon that are likely to be approved by Fall 2014.

Each drug page will include:

**DRUG NAMES**
Drug names can be very confusing. We include the brand name, the generic name and often an abbreviation. For example, Sovaldi is the brand name of sofosbuvir. Sovaldi can be abbreviated as SOV, and sofosbuvir is abbreviated as SOF. Drugs that have been FDA-approved will have a brand name, while those that have not yet reached that stage will have a generic name. In some cases, it might not even have a name, but rather a series of letters and numbers (for example, ABT-450). For those drugs which have been FDA-approved, the brand name will appear first, at the top of the page, followed by the common name(s); for all other drugs the common or generic name will appear first.

**FDA STATUS**
We will indicate if a drug is approved, and any drug that has been submitted for FDA approval will have an estimate of its approval date. Drugs or drug combinations are listed in order of approval, or expected approval date.

**DRUG CLASS**
Just as HIV medications are divided into several different drug classes, the “DAA” (direct acting antiviral) era of HCV treatment has seen the development of several different classes as well. Currently, there are four classes of HCV drugs:

- Pegylated interferon alfa
- Nucleoside analogs
- NS3/4A protease inhibitors
- Nucleoside and nucleotide NS5B polymerase inhibitors

In the years to come, we will see more drugs from some of these classes, as well as two new classes:

- NSSA inhibitors
- Non-nucleoside NS5B polymerase inhibitors

Toward the end of 2014, we will begin to see FDCs of two drugs from different classes, with several more in the development pipeline.

**GENOTYPE**
Genotype (GT) refers to the strains or variations of HCV. Worldwide, there are probably 11 distinct...
genotypes, but for this guide we will only refer to GT 1–6. In the United States, GT 1–4 are most prevalent, with GT 1 the most common overall. Within each genotype, there are several subtypes that are indicated by numbers and letters (GT 1a and GT 1b and so on). The different genotypes do not have a role in disease progression or severity, but they do respond differently to different HCV drugs so they impact treatment choices. Some genotypes can be treated for a shorter amount of time and without interferon. We will list the genotype(s) that the specific HCV medication works against. In the long run, the goal of treatment will be to create a “pan-genotypic” treatment regimen that works across all genotypes with equal effectiveness.

APPROVED FOR HIV/HCV CO-INFECTION
To date we have not had many options for treating HCV in HIV-positive people. Indeed, prior to Sovaldi, the only treatment that was FDA approved for HIV/HCV co-infected people was the dual therapy of pegylated interferon and ribavirin. It remains to be seen which of the forthcoming HCV medications will be approved for co-infection.

MANUFACTURER
This section includes the name of the company that makes the drug.

AVERAGE WHOLESALE PRICE (AWP)
The AWP is the measure used by insurance companies—both private and public—to determine the average cost of prescription drugs. HCV drugs are very expensive, and there is much concern over the burden these high costs are going to place on programs like Medicaid and Medicare, as well as the Veterans Administration and private insurance carriers. Patients should never have to pay for medications at this price, but it’s still important to know these costs when shopping for health insurance coverage. Each of the pharmaceutical companies has a Patient Assistance Program (PAP) to help uninsured and underinsured people cover all or part of the costs. There are also pharmaceutical co-pay programs and non-profit organizations that can help with some additional support for co-pays. We provide a list of HCV drug patient assistance and co-pay programs on page 37.

DOSAGE
HCV drugs are taken in a variety of ways, at different times, and with differing food restrictions. Sometimes, the same drug is taken differently depending upon a variety of factors like genotype or liver health. This section will describe the dosage requirements for the drug, as well as provide details about restrictions and other relevant information.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS
This section offers information about side effects (including adverse events) associated with the HCV drugs. It’s not an exhaustive list, but rather a selection of the most commonly reported side effects. The information comes from the package insert and study data for the FDA-approved drugs, and clinical trial and study data for the ones that have yet to receive FDA approval. Since HCV medications are never taken alone, we’ll cover potential side effects that are associated with the entire regimen, as opposed to a single drug. It would be hard to separate one cause of a side effect from another, and in the end, it doesn’t really matter what the cause is but only that you are experiencing it. Everyone experiences side effects differently: Just because it’s listed doesn’t mean you will automatically have it. Talk to your medical provider about side effects before starting treatment, communicate with him or her about any you may have during treatment, and get blood tests as directed to look for side effects such as anemia (low red blood cell count) or neutropenia (low white blood cell count).

POTENTIAL DRUG INTERACTIONS
This section provides information about the variety of known and potential drug interactions. Like the side effects section, it’s not an exhaustive list of interactions, but rather the most important ones for drugs that are commonly used by people living with HCV. You can find a complete list in the package insert, but you should also talk to your medical provider and/or pharmacist about any medications you are taking so you can minimize drug interactions. The information comes from the package insert and study data for the FDA-approved drugs, and clinical trial and study data for the ones that have yet to receive FDA approval.

MORE INFORMATION
This section contains information that does not fit in any of the above sections, but is still important for you to know.
## HCV medications by class

<table>
<thead>
<tr>
<th>CLASS</th>
<th>BRAND NAME</th>
<th>GENERIC/COMMON NAME</th>
<th>STATUS</th>
<th>GENOTYPE (FDA AND OFF-LABEL)</th>
<th>IFN-FREE?</th>
<th>APPROVED FOR HIV/HCV CO-INFECTION?</th>
<th>MANUFACTURER</th>
<th>FIND IT ON PAGE</th>
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<tr>
<td>Pegylated interferon</td>
<td>PegIntron</td>
<td>Peginterferon alfa-2b PEG; IFN</td>
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<td>Peginterferon alfa-2a PEG; IFN</td>
<td>Approved</td>
<td>1,2,3,4,5,6</td>
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<td>Yes</td>
<td>Genentech</td>
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<td>Ribosphere</td>
<td>ribavirin RBV</td>
<td>Approved</td>
<td>1,2,3,4,5,6</td>
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<td>Yes</td>
<td>Kadmon</td>
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<tr>
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<td>Copegus</td>
<td>ribavirin RBV</td>
<td>Approved</td>
<td>1,2,3,4,5,6</td>
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<td>ribavirin RBV</td>
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<td>boceprevir BOC</td>
<td>Approved</td>
<td>1</td>
<td>No</td>
<td>No</td>
<td>Merck</td>
<td>40</td>
</tr>
<tr>
<td>NS3/4A protease inhibitor</td>
<td>Olysio</td>
<td>simeprevir, SMV</td>
<td>Approved</td>
<td>1</td>
<td>No</td>
<td>No</td>
<td>Janssen</td>
<td>46</td>
</tr>
<tr>
<td>NS3/4A protease inhibitor</td>
<td>N/A</td>
<td>asunaprevir ASV</td>
<td>Submitted for approval</td>
<td>1b</td>
<td>Yes</td>
<td>TBD</td>
<td>Bristol-Myers Squibb</td>
<td>49</td>
</tr>
<tr>
<td>NS3/4A protease inhibitor</td>
<td>N/A</td>
<td>ABT-450/r</td>
<td>Submitted for approval</td>
<td>1</td>
<td>Yes</td>
<td>TBD</td>
<td>AbbVie</td>
<td>50</td>
</tr>
<tr>
<td>Nucleoside and Nucleotide NS5B polymerase inhibitor</td>
<td>Sovaldi</td>
<td>sofosbuvir SOF, SOV</td>
<td>Approved</td>
<td>1,2,3,4,5,6</td>
<td>Yes, for GT 2 and 3; in limited cases for GT 1</td>
<td>Yes</td>
<td>Gilead Sciences</td>
<td>47</td>
</tr>
<tr>
<td>NSSA inhibitor</td>
<td>N/A</td>
<td>ledipasvir LDV</td>
<td>Submitted for approval</td>
<td>1 (possibly 3)</td>
<td>Yes</td>
<td>TBD</td>
<td>Gilead Sciences</td>
<td>48</td>
</tr>
<tr>
<td>NSSA inhibitor</td>
<td>N/A</td>
<td>daclatasvir DCV</td>
<td>Submitted for approval</td>
<td>1,2,3,4</td>
<td>Yes</td>
<td>TBD</td>
<td>Bristol-Myers Squibb</td>
<td>49</td>
</tr>
<tr>
<td>NSSA inhibitor</td>
<td>N/A</td>
<td>ombitasvir (ABT-267)</td>
<td>Submitted for approval</td>
<td>1</td>
<td>Yes</td>
<td>TBD</td>
<td>AbbVie</td>
<td>50</td>
</tr>
<tr>
<td>Non-nucleoside NS5B polymerase inhibitors</td>
<td>N/A</td>
<td>dasabuvir (ABT-333)</td>
<td>Submitted for approval</td>
<td>1</td>
<td>Yes</td>
<td>TBD</td>
<td>AbbVie</td>
<td>50</td>
</tr>
<tr>
<td>Non-nucleoside NS5B polymerase inhibitor</td>
<td>N/A</td>
<td>BMS-791325</td>
<td>Phase III clinical trials</td>
<td>1</td>
<td>Yes</td>
<td>TBD</td>
<td>Bristol-Myers Squibb</td>
<td>49</td>
</tr>
</tbody>
</table>
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This page intentionally left blank.
In early 2014, the American Association for the Study of Liver Disease/Infectious Diseases Society of America (AASLD/IDSA) “Recommendations for Testing, Managing, and Treating Hepatitis C” were released. The following charts summarize the various recommendations for treating HCV in patients who’ve never had treatment (treatment-naïve), those who were treated but had the virus bounce back afterwards (viral relapse), those for whom treatment failed (prior non-responders), and in HIV/HCV co-infected persons. The recommendations come from the FDA-approved package labels, as well as “off-label” (not FDA approved, but accepted and scientifically studied use of drugs and drug combinations), and other evidence-based research and studies. There are also “Not recommended” and “Allowable HIV” regimens listed at the website.

The charts on this page are not exhaustive. There are also recommendations for people with varying degrees of cirrhosis, post-transplant patients, and people with renal (kidney) disease. For details, as well as for the various regimens listed in these charts at right, check out the full guidelines at hcvguidelines.org.

### AASLD/IDSA recommendations

#### RECOMMENDATIONS FOR TREATMENT-NAÏVE PATIENTS OR THOSE WHO HAD A VIRAL RELAPSE AFTER PRIOR PEGYLATED INTERFERON/RIBAVIRIN THERAPY

<table>
<thead>
<tr>
<th>HEPATITIS C GENOTYPE</th>
<th>RECOMMENDED REGIMENS</th>
<th>ALTERNATIVE REGIMENS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GT 1</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IFN eligible:</td>
<td>SOF + PEG + RBV for 12 weeks</td>
<td>(1) IFN eligible: SMV for 12 weeks + PEG + RBV for 24 weeks</td>
</tr>
<tr>
<td>(1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IFN ineligible:</td>
<td>SOF + SMV + RBV for 12 weeks</td>
<td>(2) IFN ineligible: SOF + RBV for 24 weeks</td>
</tr>
<tr>
<td>(2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>GT 2</strong></td>
<td>SOF + RBV for 12 weeks</td>
<td>None</td>
</tr>
<tr>
<td><strong>GT 3</strong></td>
<td>SOF + RBV for 24 weeks</td>
<td>SOF + PEG + RBV for 12 weeks</td>
</tr>
<tr>
<td><strong>GT 4</strong></td>
<td>(1) SOF + PEG + RBV for 12 weeks</td>
<td>SMV for 12 weeks + PEG + RBV for 24-48 weeks</td>
</tr>
<tr>
<td>(1)</td>
<td>(2) SOF + RBV for 24 weeks</td>
<td></td>
</tr>
<tr>
<td><strong>GT 5</strong></td>
<td>SOF + PEG + RBV for 12 weeks</td>
<td>Peg + RBV for 48 weeks</td>
</tr>
<tr>
<td><strong>GT 6</strong></td>
<td>SOF + PEG + RBV for 12 weeks</td>
<td>Peg + RBV for 48 weeks</td>
</tr>
</tbody>
</table>

#### RECOMMENDATIONS FOR PATIENTS IN WHOM PREVIOUS PEG/RBV TREATMENT HAS FAILED

<table>
<thead>
<tr>
<th>HEPATITIS C GENOTYPE</th>
<th>RECOMMENDED REGIMENS</th>
<th>ALTERNATIVE REGIMENS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GT 1</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SOF + PEG + RBV for 12 weeks</td>
<td>SOF + PEG + RBV for 12 weeks</td>
<td></td>
</tr>
<tr>
<td>SMV for 12 weeks and PEG + RBV for 24 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>GT 2</strong></td>
<td>SOF + RBV for 12 weeks</td>
<td>SOF + PEG + RBV for 12 weeks</td>
</tr>
<tr>
<td><strong>GT 3</strong></td>
<td>SOF + RBV for 24 weeks</td>
<td>SOF + PEG + RBV for 12 weeks</td>
</tr>
<tr>
<td><strong>GT 4</strong></td>
<td>SOF + PEG + RBV for 12 weeks</td>
<td>SMV for 12 weeks + PEG + RBV for 24-48 weeks</td>
</tr>
<tr>
<td>(1) IFN ineligible:</td>
<td>SOF + RBV for 24 weeks</td>
<td></td>
</tr>
<tr>
<td>(2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>GT 5</strong></td>
<td>SOF + PEG + RBV for 12 weeks</td>
<td>SOF + RBV for 24 weeks</td>
</tr>
<tr>
<td><strong>GT 6</strong></td>
<td>SOF + PEG + RBV for 12 weeks</td>
<td>SOF + RBV for 24 weeks</td>
</tr>
</tbody>
</table>

#### RECOMMENDATIONS FOR HCV TREATMENT IN PATIENTS WHO ARE CO-INFECTED WITH HIV/HCV

<table>
<thead>
<tr>
<th>HEPATITIS C GENOTYPE</th>
<th>RECOMMENDED REGIMENS</th>
<th>ALTERNATIVE REGIMENS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GT 1, treatment-naïve and those with viral relapse after prior PEG/RBV treatment</strong></td>
<td>(1) IFN eligible: SOF + PEG + RBV for 12 weeks</td>
<td>SMV + PEG + RBV for 12 weeks, followed by PEG + RBV for additional 24 weeks</td>
</tr>
<tr>
<td>(1)</td>
<td>(2) IFN ineligible: SOF + RBV for 24 weeks</td>
<td>IFN ineligible: None</td>
</tr>
<tr>
<td>(2)</td>
<td>SOF + SMV + RBV for 12 weeks</td>
<td></td>
</tr>
<tr>
<td><strong>GT 1, treatment-experienced</strong></td>
<td>SOF + SMV + RBV for 12 weeks</td>
<td>(1) IFN eligible: SOF + PEG + RBV for 12 weeks</td>
</tr>
<tr>
<td>(1)</td>
<td>(2) IFN ineligible: SOF + RBV for 24 weeks</td>
<td>(2) IFN ineligible: SOF + RBV for 24 weeks</td>
</tr>
<tr>
<td><strong>GT 2, regardless of treatment history</strong></td>
<td>SOF + RBV for 12 weeks</td>
<td>SOF + PEG + RBV for 12 weeks</td>
</tr>
<tr>
<td><strong>GT 3, regardless of treatment history</strong></td>
<td>SOF + RBV for 24 weeks</td>
<td>SOF + PEG + RBV for 12 weeks</td>
</tr>
<tr>
<td><strong>GT 4, regardless of treatment history</strong></td>
<td>(1) IFN eligible: SOF + PEG + RBV for 12 weeks</td>
<td>None</td>
</tr>
<tr>
<td>(2) IFN ineligible: SOF + RBV for 24 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>GT 5 or GT 6</strong></td>
<td>SOF + PEG + RBV for 12 weeks</td>
<td>None</td>
</tr>
</tbody>
</table>

(SEE PAGE 31 FOR DRUG ABBREVIATIONS)
Hepatitis C Co-Pay and Patient Assistance Programs (PAPs)

Like HIV, treatment for HCV is expensive, but the good news is that help is out there. Many of the pharmaceutical companies have a patient assistance program (PAP) to help uninsured and underinsured people cover all or part of the costs of their drug. There are also pharmaceutical co-pay programs and non-profit organizations that can help with some additional support for co-pays. Check with each program for details.

<table>
<thead>
<tr>
<th>DRUG</th>
<th>COMPANY</th>
<th>CONTACT INFO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Copegus</td>
<td>Genentech</td>
<td>(888) 941-3331; pegaysaccesssolutions.com</td>
</tr>
<tr>
<td>Incivek</td>
<td>Vertex Pharmaceuticals</td>
<td>(855) 837-8394; incivek.com</td>
</tr>
<tr>
<td>Olysio</td>
<td>Janssen Pharmaceuticals</td>
<td>(855) 565-9746; janssenprescriptionassistance.com/olysio-cost-assistance; olysio.com</td>
</tr>
<tr>
<td>Pegasys</td>
<td>Genentech</td>
<td>(888) 941-3331; pegaysaccesssolutions.com; pegasys.com</td>
</tr>
<tr>
<td>PegIntron</td>
<td>Merck</td>
<td>(866) 939-4372; merckhelps.com; pegintron.com</td>
</tr>
<tr>
<td>Sovaldi</td>
<td>Gilead</td>
<td>(855) 769-7284; mysupportpath.com; sovaldi.com</td>
</tr>
<tr>
<td>Virectis</td>
<td>Merck</td>
<td>(866) 939-4372; merckhelps.com; virectis.com</td>
</tr>
</tbody>
</table>

ADDITIONAL PROGRAMS

**Harbor Path**
haborpath.org
Provides a single site for all patient assistance program applications for both HIV and HCV medications.

**Needy Meds**
needymeds.com
Provides a one-stop site for patient assistance programs and other discount opportunities for a variety of pharmaceuticals; also has a very useful database to find free and low-cost medical clinics.

**Patient Access Network Foundation**
(866) 316-7263
panfoundation.org
Has an HCV-specific program, and can offer up to $7,000 in financial assistance for eligible individuals.

**Patient Advocate Foundation**
www.copays.org/diseases/hepatitis-c
Has an HCV-specific program, and can offer up to $7,500 in co-pay assistance for eligible individuals.
PegIntron; Pegasys

COMMON NAMES: PEG; IFN; pegylated interferon; interferon

Potential side effects and adverse events
Interferon has a large number of side effects associated with it: fatigue, headaches, nausea, chills, insomnia, anemia, pyrexia (fever), injection site reactions, loss of appetite, rash, myalgia (muscle pain), neutropenia, irritability, depression, alopecia (hair loss), dyspnea (shortness of breath), arthralgia (joint pain), pruritis (itching), flu-like feelings, dizziness, diarrhea, cough, weight loss, vomiting, unspecified pain, dry skin, anxiety, abdominal pain, leukopenia and thrombocytopenia. In the case of the psychiatric/emotional side effects: interferon has been associated with depression, anxiety and in rare cases, suicidal thoughts. If you have a history of any of these conditions, talk to your provider before starting HCV treatment (it does not mean you can’t take HCV treatment, you just want to watch for signs and be able to take preventative actions ahead of time). As an injectable, injection site reactions (redness, swelling, and/or itching) and inflammation are common. If you have autoimmune hepatitis, or are allergic to any of the ingredients in interferon, you should not take it.

Potential drug interactions
There are few drug interactions with interferon: Be sure to tell you medical provider or pharmacist about all the medications and herbs you take, whether prescribed, over the counter, or illicit, before starting this drug. Caution is advised when taken with warfarin, phenytoin, or methadone. Methadone levels may increase due to interferon, so methadone levels and signs and symptoms of a stronger narcotic effect should be monitored.

More information
Interferon is the oldest HCV drug we have, and quite frankly it’s the one most people can’t wait to get rid of. Most of the severe side effects that people experience while on HCV treatment are caused by interferon, and the fact that it is an injectable drug makes it even less desirable to people. The DAA era will likely make this drug obsolete, but there may still be a role for select patients. In the meantime, interferon is still used and recommended in many treatment regimens for GT 1 and 4.

FDA STATUS: Approved
CLASS: Interferon (interferon alfa-2a, interferon alfa-2b)
GENOTYPE: 1, 2, 3, 4, 5, 6
Approved for HIV/HCV co-infection.

DOSAGE:
Administer one injection once a week with or without food; must be taken in combination with ribavirin and other HCV drugs (see below for more details). Interferon should never be taken by itself. Take your missed dose as soon as possible on the same day or the next day and then continue on your regular dosing schedule; if multiple days are missed, check with your medical provider about what to do; never double dose or take doses too close together.

MANUFACTURER:
PegIntron: Merck;
Pegasys: Genentech (Roche)

AWP:
$800 per week for four 180 mcg syringes
Copegus, Rebetol, Ribasphere

COMMON NAMES: ribavirin, RBV

Generic available

FDA STATUS: Approved

CLASS: Nucleoside analog

GENOTYPE: 1, 2, 3, 4, 5, 6

Approved for HIV/HCV co-infection.

DOSAGE:
Ribavirin dosage depends upon the brand, and is given in either fixed doses or in doses related to weight (“weight-based”). The dose range is 800 mg to 1,400 mg per day taken in two divided doses. Must be taken with food. Ribavirin should never be taken by itself. Take your missed dose as soon as possible, unless it’s too close to your next dose. Never double dose.

MANUFACTURER:
Genentech (Copegus);
Merck (Rebetol);
Kadmon (Ribasphere)

AWP:
$325 per week, based on 1,200 mg/day

Potential side effects and adverse events
There are two very serious potential side effects associated with ribavirin: Anemia, and birth defects or fetal death. The anemia can be very severe and can happen very quickly, usually within the first 1–2 weeks of starting treatment. The anemia can cause severe fatigue, dizziness, headaches, and shortness of breath; routine blood testing to look for anemia, neutropenia, and other blood conditions is recommended. The anemia may also cause or worsen cardiac conditions. The other major side effect is birth defects or fetal death in pregnant women. Pregnant women or women who are trying to become pregnant cannot take ribavirin; women of childbearing age and their male sexual partners must use two forms of birth control throughout treatment and for six months post-treatment. It is unknown if ribavirin passes through breast milk or the impact it could have on breastfeeding babies. Other side effects that have been reported with ribavirin include rash and itching, and there is a small risk of pancreatitis. If you experience any symptoms related to pancreatitis (severe stomach pain that radiates to your back, nausea, vomiting, and/or diarrhea) you should call your advice nurse (when applicable) or go to an emergency department for evaluation.

Potential drug interactions
Ribavirin cannot be used with didanosine (Videx-EC, Videx, ddI) as this combination can lead to potentially fatal levels of ddI; similarly, azathioprine (an immunosuppressive) cannot be used; ribavirin is okay to take with other HIV antivirals, but check closely for anemia.

More information
It’s not entirely understood how ribavirin works against HCV, but along with interferon, it’s been a major part of HCV treatment for years, and will continue to play an important role in the future. The side effects can be challenging, even without interferon. Consequently, just as interferon-free treatment is the goal of the new standard of care, there is a move for ribavirin-free ones as well.

Important labs for monitoring your hematological levels
Ribavirin (and some other HCV medications), can affect your body’s production of red blood cells, white blood cells and platelets. Follow your medical provider’s directions for regular screening to check for these conditions. Be sure to keep copies of your lab results and track them over time. NOTE: Whenever a lab test is out of range, there is usually an indication (such as a star or other way to highlight it).

<table>
<thead>
<tr>
<th>CONDITION</th>
<th>LAB TEST</th>
<th>NORMAL RANGE</th>
<th>SYMPTOMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anemia</td>
<td>Hemoglobin</td>
<td>Male: 13.5-17.5 Female: 12.0-16.0</td>
<td>Fatigue, shortness of breath, chills, rapid heart rate, depression</td>
</tr>
<tr>
<td></td>
<td>Hematocrit</td>
<td>Male: 42–54 Female: 37–47</td>
<td></td>
</tr>
<tr>
<td>Neutropenia</td>
<td>Neutrophils</td>
<td>45–75% of white blood cells (WBC)</td>
<td>None</td>
</tr>
<tr>
<td>Leukopenia</td>
<td>Leukocytes</td>
<td>4.5-11.0 (x10³/mm³)</td>
<td>Usually none, but regular or unusual infections may indicate this condition</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>Platelets</td>
<td>150–399 (x10³/mm³)</td>
<td>Easy or excessive bleeding, spontaneous nosebleeds or bleeding gums, unusually heavy menstrual flows, and/or blood in urine or stools</td>
</tr>
</tbody>
</table>
VICTRELIS

COMMON NAMES: boceprevir, BOC

FDA STATUS: Approved

CLASS: NS3/4A protease inhibitor

GENOTYPE: 1

Not approved for HIV/HCV co-infection. (Off-label treatment is possible, but there are many drug interactions to monitor.)

DOSSAGE: Take four 200 mg capsules three times daily—every 7–9 hours—with food; must be taken in combination with pegylated interferon and ribavirin. Victrelis should never be taken by itself. Take your missed dose as soon as possible, unless it is closer to the time of your next dose. Never double your dose. A four-week lead-in period of pegylated interferon and ribavirin is necessary, followed by the introduction of Victrelis (continuing with PEG/RBV) for a length of time that is determined by treatment response. The chart at the bottom of this page summarizes the various treatment durations.

MANUFACTURER: Merck

AWP: $1,750 per week

Potential side effects and adverse events
The most commonly reported side effects are fatigue, anemia, nausea, taste changes, chills, insomnia, diarrhea, decreased appetite, and neutropenia (low white blood cell count). Victrelis is taken with pegylated interferon and ribavirin, and the most common side effects reported by people taking this regimen related to those two medications are: fatigue, headaches, nausea, fever, chills, and joint pain. For more information see their respective drug pages. Pegylated interferon has been associated with depression, anxiety, and in rare cases, suicidal thoughts. If you have a history of any of these conditions, talk to your provider before starting HCV treatment (it does not mean you can’t take HCV treatment, you just want to watch for signs and take preventative actions). When Victrelis is used with ribavirin, pregnant women or women who are trying to become pregnant cannot take it; women of child-bearing age and their male sexual partners must use two forms of birth control throughout treatment and for six months after treatment. Changes in hematological (blood) values are common, and routine blood testing to look for anemia (low red blood cell count), neutropenia, and other blood conditions is recommended.

Potential drug interactions
Before starting treatment, talk with your medical provider or pharmacist about any medications, supplements, or herbs you are taking, including prescribed, over-the-counter, or illicit substances. Victrelis interacts with many other drugs; for a complete listing refer to the package insert. Do not take with St. John’s wort. Do not take with Sustiva (efavirenz) and avoid Kaletra (lopinavir/ritonivir), Prezista (darunavir), and Reyataz (atazanavir). Can be taken with nucleoside reverse transcriptase inhibitors (including Truvada), Isentress (raltegravir), Tivicay (dolutegravir), Edurant (rilpivirine); dose adjustments needed if taken with Selzentry (maraviroc). Victrelis increases the levels of erectile dysfunction drugs (Viagra, Cialis, and Levitra), so these doses should not exceed 10 mg Cialis or 2.5 mg of Levitra per 72 hours, or 25 mg of Viagra per 48 hours. Do not take with rifampin, lovastatin, simvastatin, nor with sedatives/hypnotics such as midazolam or triazolam; can be taken with methadone and buprenorphine, but monitoring of methadone levels and patient discomfort is recommended as some may need a dose increase due to reduced concentrations of methadone.

More information
Victrelis is not likely to be used any longer due to its limited effectiveness, high pill burden, and long length of treatment duration. The AASLD/IDSA no longer recommend its use. High levels of drug resistance in people who don’t achieve an SVR is another problem with this drug. Merck is developing other HCV drugs that look more promising than Victrelis, including some excellent early results for treating HIV/HCV co-infected people, likely to be submitted for approval in late 2015.

Approved treatment durations for Victrelis

<table>
<thead>
<tr>
<th>Patient’s Treatment History</th>
<th>HCV RNA Levels at Week 8</th>
<th>HCV RNA Levels at Week 24</th>
<th>Treatment Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment-naive</td>
<td>Undetectable</td>
<td>Undetectable</td>
<td>Continue 3-drug regimen through week 28</td>
</tr>
<tr>
<td>Treatment-naive</td>
<td>Detectable</td>
<td>Undetectable</td>
<td>Continue 3-drug regimen through week 36 and then take PEG/RBV through week 48</td>
</tr>
<tr>
<td>Partial responders or viral relapers</td>
<td>Undetectable</td>
<td>Undetectable</td>
<td>Continue 3-drug regimen through week 36</td>
</tr>
<tr>
<td>Partial responders or viral relapers</td>
<td>Detectable</td>
<td>Undetectable</td>
<td>Continue 3-drug regimen through week 36 and then take PEG/RBV through week 48</td>
</tr>
</tbody>
</table>

OTHER CONSIDERATIONS FOR TREATMENT CONTINUATION:
- If a patient has a detectable viral load of above 100 IU/mL at week 12, discontinue treatment.
- If a patient has a detectable viral load of any level at week 24, discontinue treatment.
Potential side effects and adverse events
The most serious side effect of Incivek is a severe rash that may require treatment in a hospital, and in extreme cases can possibly be fatal. Any rash, blisters, or skin lesions, mouth sores, red or inflamed eyes, swelling and/or fever should be reported to your medical provider; you may not have to stop treatment, but only a medical provider can make that call. Other side effects include fatigue, pruritis (itching), anal pruritis and discomfort (burning sensation), nausea, diarrhea, vomiting, and hemorrhoids. Incivek increases anemia severity. Incivek is taken with pegylated interferon and ribavirin; the most common side effects related to those two medications are: fatigue, headaches, nausea, fever, chills, and arthralgia (joint pain). For more information, see individual drug pages. Pegylated interferon has been associated with depression, anxiety, and in rare cases, suicidal thoughts. If you have a history of any of these conditions, talk to your provider before starting HCV treatment (it does not mean you can’t do HCV treatment, you just want to watch for signs and take preventative actions). When Incivek is used with ribavirin, pregnant women or women who are trying to become pregnant cannot take it; women of childbearing age and their male sexual partners must use two forms of birth control throughout treatment and for six months after treatment.

Potential drug interactions
Before starting treatment, talk with your medical provider or pharmacist about any medications, supplements, and herbs you are taking, including prescribed, over-the-counter, or illicit substances. Incivek interacts with many other drugs; for a complete listing refer to the package insert. Do not take Incivek with St. John’s wort. Avoid Kaletra (lopinavir/ritonavir), Lexiva (fosamprenavir), and Prezista (darunavir); can be taken with Norvir-boosted Reyataz (atazanavir), as well as the nucleoside reverse transcriptase inhibitors (NRTIs or nukes), including Truvada; non-nukes (NNRTIs) Edurant (rilpivirine) and Intelenze (etravirine); INSTIs Isentress (raltegravir) and Tivicay (dolutegravir). Dose adjustments needed if taken with Sustiva (efavirenz) or Selzentry (maraviroc). Incivek increases the levels of erectile dysfunction drugs (Viagra, Cialis, and Levitra), doses should not exceed 10 mg Cialis or 2.5 mg of Levitra per 72 hours, or 25 mg of Viagra per 48 hours. Do not take with carbamazepine, phenobarbital, phenytoin, rifampin, lovastatin, simvastatin, nor with sedatives/hypnotics such as midazolam or triazolam. Caution is advised when taken with warfarin, clarithromycin, or erythromycin. Okay to take with methadone, but monitoring of methadone levels and patient discomfort is recommended as some may need a dose increase due to reduced concentrations of methadone.

More information
There’s not a whole lot to say about this drug, as it’s not going to be prescribed any longer and the AASLD/IDSA no longer recommend its use. It was great when it came on the scene, especially when compared to the effectiveness of pegylated interferon and ribavirin dual therapy for the treatment of GT 1, but it just doesn’t stand up to the new and forthcoming HCV drugs in terms of pill burden and dosing, as well as SVR rates and side effects. Incivek is “response-guided therapy”: Treatment should be stopped if one has a detectable HCV viral load greater than 1000 IU/mL at week 4 or 12, or a detectable viral load of any level at week 24.

Approved treatment durations for Incivek

<table>
<thead>
<tr>
<th>HCV RNA LEVELS DURING TREATMENT</th>
<th>INCIVEK, PEGYLATED INTERFERON, AND RIBAVIRIN</th>
<th>PEGYLATED INTERFERON AND RIBAVIRIN</th>
<th>TOTAL TREATMENT DURATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Undetected at weeks 4 and 12</td>
<td>Take for 12 weeks</td>
<td>Additional 12 weeks</td>
<td>24 weeks</td>
</tr>
<tr>
<td>Detectable at weeks 4 and 12 (see below)</td>
<td>Take for 12 weeks</td>
<td>Additional 36 weeks</td>
<td>48 weeks</td>
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Prior partial and null responder patients

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<tr>
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<th>INCIVEK, PEGYLATED INTERFERON, AND RIBAVIRIN</th>
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<tbody>
<tr>
<td>All patients</td>
<td>Take for 12 weeks</td>
<td>Additional 36 weeks</td>
<td>48 weeks</td>
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</table>
PREZISTA® (darunavir) is a prescription medicine. It is one treatment option in the class of HIV (human immunodeficiency virus) medicines known as protease inhibitors.

PREZISTA® is always taken with and at the same time as ritonavir (Norvir®), in combination with other HIV medicines for the treatment of HIV infection in adults. PREZISTA® should also be taken with food.

PREZISTA® does not cure HIV infection or AIDS and you may continue to experience illnesses associated with HIV-1 infection, including opportunistic infections. You should remain under the care of a doctor when using PREZISTA®.

Please read Important Safety Information below, and talk to your healthcare provider to learn if PREZISTA® is right for you.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about PREZISTA®?

- **PREZISTA® can interact with other medicines and cause serious side effects.** See “Who should not take PREZISTA®?”
- **PREZISTA® may cause liver problems.** Some people taking PREZISTA® together with Norvir® (ritonavir), have developed liver problems which may be life-threatening. Your healthcare provider should do blood tests before and during your combination treatment with PREZISTA®. If you have chronic hepatitis B or C infection, your healthcare provider should check your blood tests more often because you have an increased chance of developing liver problems.
- **Tell your healthcare provider if you have any of these signs and symptoms of liver problems: dark (tea-colored) urine, yellowing of your skin or whites of your eyes, palecolored stools (bowel movements), nausea, vomiting, pain or tenderness on your right side below your ribs, or loss of appetite.**
- **PREZISTA® may cause severe or life-threatening skin reactions or rash.** Sometimes these skin reactions and skin rashes can become severe and require treatment in a hospital. You should call your healthcare provider immediately if you develop a rash. However, **stop taking PREZISTA® and ritonavir combination treatment and call your healthcare provider immediately if you develop any skin changes with these symptoms: fever, tiredness, muscle or joint pain, blisters or skin lesions, mouth sores or ulcers, red or inflamed eyes, like “pink eye.” Rash occurred more often in patients taking PREZISTA® and raltegravir together than with either drug separately, but was generally mild.

Who should not take PREZISTA®?

- **Do not take PREZISTA® if you are taking the following medicines:** afluzosin (Uroxatral®), dihydroergotamine (D.H.E.45®, Embolen®, Migranal®), ergotamine (Catapres® Ergomar®), methylergonovine (Cispide® Propulsid®), pimozide (Orap®), oral midazolam (Versed®), trizolam (Halcion®), the herbal supplement St. John’s wort (Hypericum perforatum), lovastatin (Mevacor® Atorvastatin, Lipitor®), simvastatin (Zocor®, Simcor® Vytorin®), rifampin (Rifadin® Rifter®, Rifamate®, Rimactane®), sildenafil (Revatio®) when used to treat pulmonary arterial hypertension, indinavir (Crixivan®), lopinavir/ritonavir (Kaletra®), saquinavir (Invirase®), boceprevir (Victrelis®), or telaprevir (Incivek®), or if you are taking any of the following medicines with PREZISTA®.

- **Before taking PREZISTA®, tell your healthcare provider if you are taking sildenafil (Viagra®, Revatio®), vardenafil (Levitra®, Staxyn®), tadalafil (Cialis®, Adcirca®), atorvastatin (Lipitor®), rosuvastatin (Crestor®), pravastatin (Pravachol®), or colchicine (Colcrys®, Col-Probenecid®).** Tell your healthcare provider if you are taking estrogen-based contraceptives (birth control). PREZISTA® might reduce the effectiveness of estrogen-based contraceptives. You must take additional precautions for birth control, such as condoms.

Serious problems can happen if you or your child takes any of these medicines with PREZISTA®.

This is not a complete list of medicines. Be sure to tell your healthcare provider about all the medicines you are taking or plan to take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Do not start any new medicines while you are taking PREZISTA® without first talking to your healthcare provider.

What should I tell my doctor before I take PREZISTA®?

- **Before taking PREZISTA®, tell your healthcare provider if you have any medical conditions, including liver problems (including hepatitis B or C), allergy to sulfa medicines, diabetes, or hemophilia.**
- **Tell your healthcare provider if you are pregnant or planning to become pregnant, or are breastfeeding.**
  - The effects of PREZISTA® on pregnant women or their unborn babies are not known. You and your healthcare provider will need to decide if taking PREZISTA® is right for you.
  - Do not breastfeed. It is not known if PREZISTA® can be passed to your baby in your breast milk and whether it could harm your baby. Also, mothers with HIV should not breastfeed because HIV can be passed to your baby in the breast milk.

What are the possible side effects of PREZISTA®?

- **High blood sugar, diabetes or worsening of diabetes, and increased bleeding in people with hemophilia have been reported in patients taking protease inhibitor medicines, including PREZISTA®.**
- **Changes in body fat have been seen in some patients taking HIV protease inhibitor medicines, including PREZISTA®.**
- **Changes in your immune system can happen when you start taking HIV medications, including PREZISTA®.** The cause and long-term health effects of these conditions are not known at this time.
- **Changes in your immune system can happen when you start taking HIV medicines. Your immune system may get stronger and begin to fight infections that have been hidden.**
- **The most common side effects related to taking PREZISTA® include diarrhea, nausea, rash, headache, stomach pain, and vomiting.** This is not a complete list of all possible side effects. If you experience these or other side effects, talk to your healthcare provider. Do not stop taking PREZISTA® or any other medicines without first talking to your healthcare provider.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please refer to the ritonavir (Norvir®) Product Information (PI and PPI) for additional information on precautionary measures.

Please see accompanying full Product Information for more details.
PREZISTA® is always taken with and at the same time as ritonavir (Norvir®), as protease inhibitors. PREZISTA® does not cure HIV infection or AIDS and you may continue to develop new infections. You should remain under the care of a doctor when using PREZISTA®.

IMPORTANT SAFETY INFORMATION

Please read Important Safety Information below, and talk to your healthcare provider to learn if PREZISTA® is right for you.

PREZISTA® (darunavir) is a prescription medicine. It is one treatment option in combination with other HIV medicines for the treatment of HIV infection in adults. PREZISTA® should also be taken with food.

• Do not take PREZISTA® with tobacco or alcohol.
• Tell your healthcare provider if you have any of these signs and symptoms:
  - Rash occurred more often in patients taking PREZISTA® and raltegravir
  - Swelling of lymph glands
  - Swelling of the ankles or feet
  - Palpitations
  - Changes in body fat
• High blood sugar, diabetes or worsening of diabetes, and increased risk of developing liver problems.
• Changes in your immune system can happen when you start taking HIV medicines. It is important to take your HIV medicines as directed on a daily basis to help keep your HIV under control. Call your healthcare provider immediately if you develop any skin changes with your HIV medicines.
• Serious problems can happen if you or your child takes any of these medicines together. For additional information on precautionary measures.
• In some patients taking HIV medicines, an increased chance of developing liver problems has been reported when used in combination with other medicines. Your healthcare provider should check your blood tests more often because you have developed liver problems which may be life-threatening. Your healthcare provider should stop PREZISTA® and ritonavir combination treatment and call your healthcare provider immediately if you develop any skin changes with your HIV medicines.
• The effects of PREZISTA® on pregnant women or their unborn babies are not known. You and your healthcare provider will need to decide if PREZISTA® is right for you.
• Do not breastfeed.

PREZISTA® Experience isn’t just an HIV treatment. It’s an HIV treatment experience as unique as you.

Please read the Important Safety Information and Patient Information on adjacent pages.

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05/14 014606-140430
PREZISTA (pre-ZIS-ta)
(darunavir)
Oral Suspension

PREZISTA (pre-ZIS-ta)
(darunavir)
Tablets

Read this Patient Information before you start taking PREZISTA and each time you get a refill. There may be new information. This provider does not take the place of talking to your healthcare provider about your medical condition or your treatment.

Also refer to the Patient Information leaflet for NORVIR® (ritonavir).

What is the most important information I should know about PREZISTA?

• PREZISTA can interact with other medicines and cause serious side effects. It is important to know the medicines that should not be taken with PREZISTA. See the section “Who should not take PREZISTA?”

• PREZISTA may cause liver problems. Some people taking PREZISTA in combination with NORVIR® (ritonavir) have developed liver problems which may be life-threatening. Your healthcare provider should do blood tests before and during your combination treatment with PREZISTA. If you have chronic hepatitis B or C infection, your healthcare provider should check your blood tests more often because you have an increased chance of developing liver problems.

• Tell your healthcare provider if you have any of the below signs and symptoms of liver problems.
  • Dark (tea colored) urine
  • yellowing of your skin or whites of your eyes
  • pale colored stools (bowel movements)
  • nausea
  • vomiting
  • pain or tenderness on your right side below your ribs
  • loss of appetite

PREZISTA may cause severe or life-threatening skin reactions or rash. Sometimes these skin reactions and skin rashes can become severe and require treatment in a hospital. You should call your healthcare provider immediately if you develop a rash. However, stop taking PREZISTA and ritonavir combination treatment and call your healthcare provider immediately if you develop any skin changes with symptoms below:
  • fever
  • tiredness
  • muscle or joint pain
  • blisters or skin lesions
  • mouth sores or ulcers
  • red or inflamed eyes, like “pink eye” (conjunctivitis)

Rash occurred more often in people taking PREZISTA and raltegravir together than with either drug separately, but was generally mild.

See “What are the possible side effects of PREZISTA?” for more information about side effects.

What is PREZISTA?

PREZISTA is a prescription anti-HIV medicine used with ritonavir and other anti-HIV medicines to treat adults with human immunodeficiency virus (HIV-1) infection. PREZISTA is a type of anti-HIV medicine called a protease inhibitor. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

When used with other HIV medicines, PREZISTA may help to reduce the amount of HIV in your blood (called “viral load”). PREZISTA may also help to increase the number of white blood cells called CD4 (T) cell which help fight off other infections. Reducing the amount of HIV and increasing the CD4 (T) cell count may improve your immune system.

This may reduce your risk of death or infections that can happen when your immune system is weak (opportunistic infections).

PREZISTA does not cure HIV infection or AIDS and you may continue to experience illnesses associated with HIV-1 infection, including opportunistic infections. You should remain under the care of a doctor when using PREZISTA.

Avoid doing things that can spread HIV-1 infection.

• Do not share needles or other injection equipment.

• Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.

• Do not have any kind of sex without protection.

Always practice safe sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

Ask your healthcare provider if you have any questions on how to prevent passing HIV to other people.

Who should not take PREZISTA?

Do not take PREZISTA with any of the following medicines:

• alfuzosin (Uroxatral®)
• ergot-containing medicines: dihydroergotamine (D.H.E. 45®, Embolex®, Migranal®), ergotamine (Cafergot®, Ergomar®), methylergonovine
• cisapride
• pimozide (Orap®)
• oral midazolam (Versed®), triazolam (Halcion®)
• the herbal supplement St. John’s Wort (Hypericum perforatum)
• the cholesterol lowering medicines lovastatin (Mevacor®, Atoprev®), simvastatin (Zocor®, Simcor®, Vytorin®)
• rifampin (Rifadin®, Rifater®, Rifamate®, Rimactane®)
• sildenafil (Revatio®) only when used for the treatment of pulmonary arterial hypertension.

Serious problems can happen if you take any of these medicines with PREZISTA.

What should I tell my doctor before I take PREZISTA?

PREZISTA may not be right for you. Before taking PREZISTA, tell your healthcare provider if you:

• have liver problems, including hepatitis B or hepatitis C
• are allergic to sufa medicines
• have high blood sugar (diabetes)
• have hemophilia
• are pregnant or planning to become pregnant. It is not known if PREZISTA will harm your unborn baby.

Pregnancy Registry: You and your healthcare provider will need to decide if taking PREZISTA is right for you. If you take PREZISTA while you are pregnant, talk to your healthcare provider about how you can be included in the Antiretroviral Pregnancy Registry. The purpose of the registry is follow the health of you and your baby.

• are breastfeeding or plan to breastfeed. Do not breastfeed. We do not know if PREZISTA can be passed to your baby in your breast milk and whether it could harm your baby. Also, mothers with HIV-1 should not breastfeed because HIV-1 can be passed to the baby in the breast milk.

Tell your healthcare provider about all the medicines you take including prescription and nonprescription medicines, vitamins, and herbal supplements. Using PREZISTA and certain other medicines may affect each other causing serious side effects. PREZISTA may affect the way other medicines work and other medicines may affect how PREZISTA works.

Especially tell your healthcare provider if you take any of the medicines listed below. The generic name is provided, followed by examples of possible brand names for the drug product:

• medicine to treat HIV
• estrogen-based contraceptives (birth control). PREZISTA might reduce the effectiveness of estrogen-based contraceptives. You must take additional precautions for birth control such as a condom.
• medicines to prevent organ transplant rejection such as cyclosporine (Gengraf®, Sandimmune®, Neoral®), tacrolimus (Prograf®, sirolimus (Rapamune®)
• amiodarone (Pacerone®, Cardarone®)
• artemether/lumeonafarine (Coartem®)
• atorvastatin (Liptor®)
• bepridil (Bepadin®)
• red or inflamed eyes, like “pink eye” (conjunctivitis)
• the herbal supplement St. John’s Wort (Hypericum perforatum)
• clofibrate (Atromid-S®, Atromid®, Orpharen®)
• colchicine (Colcrys®, Col-Probenecid®)
• desipramine (Norpramin®)
• dexamethasone (Dexamethasone, Ondrex®)
• digoxin (Lanoxin®)
• sildenafil (Revatio®) only when used for the treatment of pulmonary arterial hypertension.
• phenobarbital

• digoxin (Lanoxin®)
• lidocaine (Xylocaine Viscous®)
• paroxetine (Paxil®)
• pimozide (Orap®)
• oral midazolam (Versed®), triazolam (Halcion®)
• the herbal supplement St. John’s Wort (Hypericum perforatum)
• the cholesterol lowering medicines lovastatin (Mevacor®, Atoprev®, Simcor®, Vytorin®)
• rifampin (Rifadin®, Rifater®, Rifamate®, Rimactane®)
• sildenafil (Revatio®) only when used for the treatment of pulmonary arterial hypertension.

Serious problems can happen if you take any of these medicines with PREZISTA.

What should I tell my doctor before I take PREZISTA?

PREZISTA may not be right for you. Before taking PREZISTA, tell your healthcare provider if you:

• have liver problems, including hepatitis B or hepatitis C
• are allergic to sufa medicines
• have high blood sugar (diabetes)
• have hemophilia
• are pregnant or planning to become pregnant. It is not known if PREZISTA will harm your unborn baby.

Pregnancy Registry: You and your healthcare provider will need to decide if taking PREZISTA is right for you. If you take PREZISTA while you are pregnant, talk to your healthcare provider about how you can be included in the Antiretroviral Pregnancy Registry. The purpose of the registry is follow the health of you and your baby.

• are breastfeeding or plan to breastfeed. Do not breastfeed. We do not know if PREZISTA can be passed to your baby in your breast milk and whether it could harm your baby. Also, mothers with HIV-1 should not breastfeed because HIV-1 can be passed to the baby in the breast milk.

Tell your healthcare provider about all the medicines you take including prescription and nonprescription medicines, vitamins, and herbal supplements. Using PREZISTA and certain other medicines may affect each other causing serious side effects. PREZISTA may affect the way other medicines work and other medicines may affect how PREZISTA works.

Especially tell your healthcare provider if you take any of the medicines listed below. The generic name is provided, followed by examples of possible brand names for the drug product:

• medicine to treat HIV
• estrogen-based contraceptives (birth control). PREZISTA might reduce the effectiveness of estrogen-based contraceptives. You must take additional precautions for birth control such as a condom.
• medicines to prevent organ transplant rejection such as cyclosporine (Gengraf®, Sandimmune®, Neoral®), tacrolimus (Prograf®, sirolimus (Rapamune®)
• amiodarone (Pacerone®, Cardarone®)
• artemether/lumeonafarine (Coartem®)
• atorvastatin (Liptor®)
• bepridil (Bepadin®)
• red or inflamed eyes, like “pink eye” (conjunctivitis)
• the herbal supplement St. John’s Wort (Hypericum perforatum)
• clofibrate (Atromid-S®, Atromid®, Orpharen®)
• colchicine (Colcrys®, Col-Probenecid®)
• desipramine (Norpramin®)
• dexamethasone (Dexamethasone, Ondrex®)
• digoxin (Lanoxin®)
• sildenafil (Revatio®) only when used for the treatment of pulmonary arterial hypertension.
• phenobarbital

• digoxin (Lanoxin®)
• lidocaine (Xylocaine Viscous®)
• paroxetine (Paxil®)
• pimozide (Orap®)
• oral midazolam (Versed®), triazolam (Halcion®)
• the herbal supplement St. John’s Wort (Hypericum perforatum)
• the cholesterol lowering medicines lovastatin (Mevacor®, Atoprev®, Simcor®, Vytorin®)
• rifampin (Rifadin®, Rifater®, Rifamate®, Rimactane®)
• sildenafil (Revatio®) only when used for the treatment of pulmonary arterial hypertension.

Serious problems can happen if you take any of these medicines with PREZISTA.
• phenytoin (Dilantin®, Phenytek®)
• pravastatin (Pravachol®)
• propafenone (Rythmol®)
• quinidine (Nuedexta®)
• rifabutin (Mycobutin®)
• risperidone (Risperdal®)
• rosuvastatin (Crestor®)
• salmeterol (Advair®, Serevent®)
• sertraline (Zoloft®)
• sildenafil (Viagra®, Revatio®)
• tadalafil (Cialis, Adcirca®)
• telaprevir (Incivek®)
• thioridazine (MellanilTM)
• timolol (Cosopt®, Betimol®, Timoptic®, Isaltol®, Combigan®)
• trazodone (Oleptro, Desyrel®)
• warfarin (Coumadin®, Jantoven®)
• vardenafil (Levitra, Staxyn®)
• voriconazole (VFend®)

This is not a complete list of medicines that you should tell your healthcare provider or your pharmacist if you are not sure if your medicine is one that is listed above. Know the medicines you take. Keep a list of them to show your doctor or pharmacist when you get a new medicine. Do not start any new medicines while you are taking PREZISTA without first talking with your healthcare provider.

How should I take PREZISTA?

• Take PREZISTA every day exactly as prescribed by your healthcare provider.
• You must take ritonavir (NORVIR®) at the same time as PREZISTA.
• Do not change your dose of PREZISTA or stop treatment without talking to your healthcare provider first.
• Take PREZISTA and ritonavir (NORVIR®) with food.
• Swallow PREZISTA tablets whole with a drink. If you have difficulty swallowing PREZISTA tablets, PREZISTA oral suspension is also available. Your health care provider will help decide whether PREZISTA tablets or oral suspension is right for you.
• PREZISTA oral suspension should be given with the supplied oral dosing syringe. Shake the suspension well before each use. See the Instructions for Use that come with PREZISTA oral suspension for information about the right way to prepare and take a dose.
• If your prescribed dose of PREZISTA oral suspension is more than 6 mL, you will need to divide the dose. Follow the instructions given to you by your pharmacist or pharmacist of your healthcare provider. Do not divide the dose. Ask your healthcare provider or pharmacist if you are not sure.
• If you take too much PREZISTA, call your healthcare provider or go to the nearest hospital emergency room right away.

What should I do if I miss a dose?

People who take PREZISTA one time a day:
• If you miss a dose of PREZISTA by less than 12 hours, take your missed dose of PREZISTA right away. Then take your next dose of PREZISTA at your regularly scheduled time.
• If you miss a dose of PREZISTA by more than 12 hours, wait and then take the next dose of PREZISTA at your regularly scheduled time.

People who take PREZISTA two times a day:
• If you miss a dose of PREZISTA by less than 6 hours, take your missed dose of PREZISTA right away. Then take your next dose of PREZISTA at your regularly scheduled time.
• If you miss a dose of PREZISTA by more than 6 hours, wait and then take the next dose of PREZISTA at your regularly scheduled time.

If a dose of PREZISTA is skipped, do not double the next dose. Do not take more or less than your prescribed dose of PREZISTA at any one time.

What are the possible side effects of PREZISTA?

PREZISTA can cause side effects including:
• See “What is the most important information I should know about PREZISTA?”
• Diabetes and high blood sugar (hyperglycemia). Some people who take protease inhibitors including PREZISTA can get high blood sugar, develop diabetes, or your diabetes can get worse. Tell your healthcare provider if you notice an increase in thirst or urine often while taking PREZISTA.
• Changes in body fat. These changes can happen in people who take antiretroviral therapy. The changes may include an increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the back, chest, and stomach area. Loss of fat from the legs, arms, and face may also happen. The exact cause and long-term health effects of these conditions are not known.
• Changes in your immune system (Immune Reconstitution Syndrome) can happen when you start taking HIV medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Call your healthcare provider right away if you start having new symptoms after starting your HIV medicine.
• Increased bleeding for hemophiliacs. Some people with hemophilia have increased bleeding with protease inhibitors including PREZISTA.

The most common side effects of PREZISTA include:
• diarrhea
• headache
• nausea
• abdominal pain
• rash
• vomiting

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of PREZISTA. For more information, ask your health care provider.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

How should I store PREZISTA?
• Store PREZISTA oral suspension and tablets at room temperature (77°F [25°C]).
• Do not refrigerate or freeze PREZISTA oral suspension.
• Keep PREZISTA away from high heat.
• PREZISTA oral suspension should be stored in the original container.

Keep PREZISTA and all medicines out of the reach of children.

General information about PREZISTA

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use PREZISTA for a condition for which it was not prescribed. Do not give PREZISTA to other people even if they have the same condition you have. It may harm them.

This leaflet summarizes the most important information about PREZISTA. If you would like more information, talk to your healthcare provider. You can ask your healthcare provider or pharmacist for information about PREZISTA that is written for health professionals.

For more information, call 1-800-526-7736.

What are the ingredients in PREZISTA?
Active ingredient: darunavir
Inactive ingredients:
PREZISTA Oral Suspension: hydroxypropyl cellulose, microcrystalline cellulose, sodium carboxymethylcellulose, methylparaben sodium, citric acid monohydrate, sucrose, masking flavor, strawberry cream flavor, hydrochloric acid (for pH adjustment), purified water.
PREZISTA 75 mg and 150 mg Tablets: colloidal silicon dioxide, crospovidone, magnesium stearate, microcrystalline cellulose. The film coating contains: OPADRY® White (polyethylene glycol 3350, polyvinyl alcohol-partially hydrolyzed, talc, titanium dioxide).
PREZISTA 600 mg Tablets: colloidal silicon dioxide, crospovidone, magnesium stearate, microcrystalline cellulose. The film coating contains: OPADRY® Orange (FD&C Yellow No. 6, polyethylene glycol 3350, polyvinyl alcohol-partially hydrolyzed, talc, titanium dioxide).
PREZISTA 800 mg Tablets: colloidal silicon dioxide, crospovidone, magnesium stearate, microcrystalline cellulose, hypromellose. The film coating contains: OPADRY® Dark Red (iron oxide red, polyethylene glycol 3350, polyvinyl alcohol-partially hydrolyzed, talc, titanium dioxide).

This Patient Information has been approved by the U.S. Food and Drug Administration.

Product of Ireland
Manufactured by:
PREZISTA Oral Suspension Janssen Pharmaceutica, N.V.
Beere, Belgium
PREZISTA Tablets Janssen Ortho LLC,
Gurabo, PR 00778

Manufactured for:
Janssen Therapeutics, Division of Janssen Products, LP, Titusville NJ 08560

Revised: April 2014
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014859-140506
Potential side effects and adverse events
Olysio is associated with a rash and photosensitivity. The rash was generally mild, with very few people experiencing a severe rash. The photosensitivity is considered mild to moderate, and anyone taking Olysio should wear sunscreen and take other protective measures. Other side effects include pruritus (itching), nausea, myalgia (muscle pain) and shortness of breath. Since Olysio is taken with pegylated interferon and ribavirin, additional side effects related to those medications include fatigue, headaches, nausea, fever, chills, and joint pain. For more information on the side effects of each of these medications, see their respective drug pages. Pegylated interferon and ribavirin, additional side effects related to these conditions, talk to your provider before starting HCV treatment. Since Olysio is used with ribavirin, pregnant women or women who are trying to become pregnant cannot take it; women of childbearing age and their male sexual partners must use two forms of birth control throughout treatment and for six months after treatment. Changes in hematological (blood) values are common, and routine blood testing to look for anemia, neutropenia, and other blood conditions is recommended.

Potential drug interactions
Talk to your medical provider and/or pharmacist about any and all medications you are taking whether they’re prescribed, over-the-counter, or illicit. Olysio interacts with many other medications, and this is not a complete list. For a more detailed review of drug interactions, see the package insert. Olysio should not be taken with any HIV protease inhibitors (PIs), the non-nucleoside reverse transcriptase inhibitors (NNRTIs) Sustiva (efavirenz, also in Atripla) or Viramune (nevirapine) or Intelence (etravirine), or with cobicistat-boosted regimens (Stribild). Olysio can be taken with Edurant (rilpivirine), Isentress (raltegravir), Tivicay (dolutegravir), and the nucleoside reverse transcriptase inhibitors including Truvada, Ziden (abacavir), Emtriva (emtricitabine), Epivir (lamivudine), Epzicom, and Viread (tenofovir). Olysio boosts the levels of erectile dysfunction drugs (Viagra, Cialis, and Levitra). Start with the lowest dose possible and increase as needed. Do not use with the herbs milk thistle (silymarin) or St. John’s wort. Anticonvulsants such as phenobarbital, carbamazepine, phenytoin, and oxcarbazepine should not be used as they reduce the concentrations of Olysio, thus reducing its effectiveness. Rifampin, rifabutin, and rifapentine should not be taken. Antibiotics erythromycin, clarithromycin, and telithromycin increase levels of Olysio so they should be avoided, as should the antifungals fluconazole, voriconazole, itraconazole, ketoconazole, and posaconazole. Antiarrhythmics such as Tambocor and Cordarone should not be taken; no interactions with methadone and buprenorphine.

More information
GT 1 can be treated with Sovaldi and Olysio with or without ribavirin in what is called “off-label” (not FDA-approved) use based on the results of the “COSMOS” study, which saw high SVR (cure) rates and minimal side effects for both treatment-naive and prior non-responders. For individuals who need treatment now, but cannot tolerate interferon, this is an excellent option. In May 2014, Janssen submitted this combination for FDA approval.

TWO IMPORTANT COMPONENTS OF OLYSIO TREATMENT
1. People with genotype 1a need a blood test called a “Q80K polymorphism”, for a resistant strain of HCV. This polymorphism reduces treatment effectiveness and other medications should be considered.
2. Olysio is “response-guided therapy”: Treatment should be stopped if one has a detectable HCV viral load of any level at weeks 4, 12, or 24.

<table>
<thead>
<tr>
<th>Approved treatment durations for Olysio</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PATIENT TREATMENT HISTORY</strong></td>
</tr>
<tr>
<td>Treatment-naive; or viral relapers (including those with cirrhosis)</td>
</tr>
<tr>
<td>Prior non-responder (including partial and null responders)</td>
</tr>
</tbody>
</table>
FDA STATUS: Approved

CLASS: Nucleotide analog NS5B polymerase inhibitor

GENOTYPE: 1, 2, 3, 4, 5, 6

Approved for HIV/HCV co-infection.

DOSAGE: Take one 400 mg tablet once daily with or without food; must be taken in combination with either ribavirin or pegylated interferon and ribavirin (see below for more details). Sovaldi should never be taken by itself. Take your missed dose as soon as possible, unless it is closer to the time of your next dose. Never double your dose. The chart on this page summarizes the various treatment regimens.

MANUFACTURER: Gilead Sciences, Inc.

AWP: $7,250 per week

Sovaldi has a lot of “firsts”: first drug of its class; first drug to receive FDA approval for use without interferon, and first DAA to receive FDA approval for use in HIV/HCV co-infected patients. It immediately became the most popular HCV medicine, achieving the status of preferred treatment regimen in the AASLD/IDSA guidelines and is becoming one of the fastest prescribed medicines ever. Given the history of HCV treatment and the desire for regimens that are easier to take, along with its treatment effectiveness and the fact that it can be used without interferon for GT 2 and 3 (and in some cases, even 1), and its use and effectiveness in co-infected people, it’s no wonder it has become so widely used. Sovaldi has also been approved for use with ribavirin in people who have hepatocellular carcinoma (liver cancer) and are awaiting a liver transplant. It’s also becoming common to see medical providers treat GT 1 with Sovaldi and Olysio with or without ribavirin in “off-label” (not FDA-approved) use based on the results of a clinical trial called “COSMOS.” The results were very promising, with high SVR rates and minimal side effects for both treatment-naïve and prior non-responders. In April 2014, AASLD recommended this regimen for HIV/HCV co-infected patients who were previous non-responders or ineligible for interferon treatment. For individuals who need treatment now, but cannot tolerate the side effects of interferon, this is an excellent option. By the end of 2014, we are likely to see other potential combinations: Upon FDA approval, Gilead will release a fixed dose combination of Sovaldi and ledipasvir (see drug page for more information on this combination). The approval of the BMS drug, daclatasvir (see page 49), a drug that has also been shown to be highly effective when used with Sovaldi, will also create new treatment opportunities.

Potential side effects and adverse events
Since Sovaldi is taken with pegylated interferon and ribavirin or ribavirin alone, the most common side effects reported by people taking this regimen are related to those two medications: fatigue, headaches, nausea, fever, chills, and arthralgia (joint pain). For more information on the side effects of each of these medications, see their respective drug pages. Pegylated interferon has been associated with depression, anxiety, and in rare cases, suicidal thoughts. If you have a history of any of these conditions, talk to your provider before starting HCV treatment (it does not mean you can’t take HCV treatment, you just want to watch for signs and be able to take preventative actions ahead of time). When Sovaldi is used with ribavirin, pregnant women or women who are trying to become pregnant cannot take it; women of childbearing age and their male partners must use two forms of birth control throughout treatment and for six months after treatment. Changes in hematological (blood) values are also common, and routine blood testing to look for anemia, neutropenia, and other blood conditions is recommended.

Potential drug interactions
Sovaldi may interact with other drugs: Be sure to tell your medical provider or pharmacist about all the medications, supplements, and herbs you take, whether prescribed, over-the-counter, or illicit, before starting this regimen, and inform them of any changes as they happen. Sovaldi is safe to take with HIV antivirals except Aptivus/Norvir (tipranavir/ritonavir), with no clinically relevant changes or dose adjustments necessary. Sovaldi has no interactions with methadone.

The following cannot be taken with Sovaldi: St. John’s wort, rifabutin, or rifapentine. Anticonvulsants such as phenobarbital, carbamazepine, phenytoin, and oxcarbazepine should not be used as they reduce the concentrations of Sovaldi, thus reducing its therapeutic effectiveness.

More information

### Approved treatment durations for Sovaldi

<table>
<thead>
<tr>
<th>HCV MONO-INFECTED AND HIV/HCV CO-INFECTED</th>
<th>TREATMENT</th>
<th>DURATION OF TREATMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype 1 and 4</td>
<td>Sovaldi + pegylated interferon + ribavirin</td>
<td>12 weeks</td>
</tr>
<tr>
<td>Genotype 2</td>
<td>Sovaldi + ribavirin</td>
<td>12 weeks</td>
</tr>
<tr>
<td>Genotype 3</td>
<td>Sovaldi + ribavirin</td>
<td>24 weeks</td>
</tr>
</tbody>
</table>
FDA STATUS:
A fixed dose combination submitted for approval; ruling expected Fall 2014

CLASS:
ledipasvir: NS5A inhibitor; sofosbuvir: Nucleotide analog NS5B polymerase inhibitor

GENOTYPE: 1 (possibly 3)
Being studied in HIV/HCV co-infection; has shown promising results in clinical studies

DOSAGE:
Still investigational.
A fixed dose combination (FDC) of ledipasvir 90 mg/sofosbuvir 400 mg. Take one tablet once daily with or without food; may or may not be taken in combination with ribavirin (see chart for more details). Take your missed dose as soon as possible, unless it is closer to the time of your next dose. Never double your dose. Duration of therapy not yet determined, but the submission for approval to the FDA was based on the following clinical trial data, which gives a sense of what the final approval will look like. The chart summarizes the various treatment regimens for these studies.

MANUFACTURER:
Gilead Sciences

Potential side effects and adverse events
In the ledipasvir/sofosbuvir regimens taken without ribavirin, the most commonly reported side effects are fatigue, headache, nausea, and diarrhea; less frequently reported side effects include insomnia, rash, and pruritis (itching). In all cases, the side effects were considered mild and no one in the ION studies had to stop treatment because of them. It is also notable that there were no cases of anemia in any ribavirin-free group, and only two people experienced any hematologic (blood) abnormalities. In the regimens containing ribavirin, the side effects were similar, with higher rates of fatigue, insomnia, and anemia. There were more cases of hematologic abnormalities, and routine blood testing to look for anemia, neutropenia, and other blood conditions is recommended. No one in this group had to stop the treatment due to side effects. When this combination is used with ribavirin, pregnant women or women who are trying to become pregnant cannot take it; women of childbearing age and their male sexual partners must use two forms of birth control throughout treatment and for six months after treatment.

Potential drug interactions
Ledipasvir does not appear to have any significant drug interactions. Sofosbuvir may interact with other drugs: Be sure to tell your medical provider or pharmacist about all the medications, supplements, and herbs you take, whether they are prescribed, over-the-counter, or illicit, before starting this regimen, and inform them of any changes as they happen. It is safe to take with HIV antivirals except Aptivus/Norvir (tipranavir/ritonavir), with no clinically relevant changes or dose adjustments necessary; there are no interactions with methadone. The following cannot be taken with Sovaldi (sofosbuvir): St. John’s wort, tipranavir/ritonavir, rifampin, rifabutin, and rifampentine. Anticonvulsants such as phenobarbital, carbamazepine, phenytoin, and oxcarbazepine should not be used as they reduce the concentrations of Sovaldi, thus reducing its therapeutic effectiveness.

More information
This combination may be a real game-changer for treating HCV GT 1: One pill, once daily potentially curing HCV in eight weeks is an astounding achievement. It is also worth noting that the combination of sofosbuvir with another NS5A inhibitor, BMS’ daclatasvir, also cures people at very high rates with minimal side effects. We will get a better sense of its indications and dosing once it gets FDA approval, but in addition to treating GT 1, this combination has shown very promising results for people with the more difficult to treat GT 3, as well as in HIV/HCV co-infected individuals. Sofosbuvir alone is already approved, as Sovaldi.

Phase III clinical trial results for ledipasvir/sofosbuvir

<table>
<thead>
<tr>
<th>STUDY</th>
<th>PATIENT GROUP</th>
<th>TREATMENT</th>
<th>DURATION</th>
<th>SVR 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>ION-1</td>
<td>GT 1 treatment-naïve (including 15.7% with cirrhosis)</td>
<td>SOF/LDV</td>
<td>12 weeks</td>
<td>97.7%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SOF/LDV + RBV</td>
<td>12 weeks</td>
<td>97.2%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SOF/LDV</td>
<td>24 weeks</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SOF/LDV + RBV</td>
<td>24 weeks</td>
<td>N/A</td>
</tr>
<tr>
<td>ION-2</td>
<td>GT 1 treatment-experienced (including 20% with cirrhosis)</td>
<td>SOF/LDV</td>
<td>12 weeks</td>
<td>93.6%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SOF/LDV + RBV</td>
<td>12 weeks</td>
<td>96.4%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SOF/LDV</td>
<td>24 weeks</td>
<td>99.1%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SOF/LDV + RBV</td>
<td>24 weeks</td>
<td>99.1%</td>
</tr>
<tr>
<td>ION-3</td>
<td>GT 1 treatment-naïve, no cirrhosis</td>
<td>SOF/LDV</td>
<td>8 weeks</td>
<td>94%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SOF/LDV + RBV</td>
<td>8 weeks</td>
<td>93.1%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SOF/LDV</td>
<td>12 weeks</td>
<td>95.4%</td>
</tr>
</tbody>
</table>
FDA STATUS:
daclatasvir and asunaprevir: Submitted for approval; ruling expected Fall 2014
BMS-791325: Not yet submitted for approval

CLASS:
daclatasvir: NS5A replication complex inhibitor
asunaprevir: NS3/4A protease inhibitor
BMS-791325: Non-nucleoside NS5B polymerase inhibitor

GENOTYPE: 1, 2, 3, 4 (depending upon regimen)

Being studied in HIV/HCV co-infection; under study for use with sofosbuvir

DOSAGE:
Still investigational.
Take one daclatasvir 60 mg tablet once daily; take one asunaprevir 100 mg softgel capsule twice daily; take one 75 mg or 150 mg BMS-791325 tablet twice daily. When taken with Sovaldi (sofosbuvir) take one daclatasvir 60 mg tablet once per day and one Sovaldi 400 mg orally with or without weight-based ribavirin, taken twice daily. Take your missed dose as soon as possible, unless it’s too close to your next dose. Never double dose.

MANUFACTURER:
Bristol-Myers Squibb

Potential side effects and adverse events
As this drug has not yet been FDA-approved, side effects data come from conference presentations and peer-reviewed scientific papers published in medical journals. A complete listing of side effects will be included in the package insert. The most commonly reported side effects from the daclatasvir/sofosbuvir combination are fatigue, headache, and nausea, but all were considered to be mild to moderate in intensity; when ribavirin is included, there is an increased risk of these side effects. For more information on the side effects of ribavirin, refer to its drug page. When this regimen is used with ribavirin, pregnant women or women who are trying to become pregnant cannot take it; women of childbearing age and their male sexual partners must use two forms of birth control throughout treatment and for six months post-treatment. Changes in hematological (blood) values were also seen in the clinical trials, and routine blood testing to look for anemia, neutropenia, and other blood conditions are recommended; the side effects associated with the daclatasvir/asunaprevir combination include nasopharyngitis, elevated liver enzymes, headaches, diarrhea, and pyrexia (fever); the side effects reported in the daclatasvir/asunaprevir/BMS-791325 combination include headache, diarrhea, fatigue, and nausea.

Potential drug interactions
There is limited data on the drug interactions with either daclatasvir or asunaprevir. More detailed information will be available upon FDA approval, and you can then refer to the package insert for more information. Daclatasvir is thought to have a low potential for drug interactions overall; it has no known interactions and is safe to use with other HCV DAAs, including asunaprevir, BMS-791325, Sovaldi (sofosbuvir), and MK-5172 (NS3/4A PI from Merck). Limited data has shown that there are no dose adjustments necessary with some HIV medications. There are no available data on drug interactions between asunaprevir and other drugs at the time of writing as the studies are ongoing, but as it is a protease inhibitor, it is likely to interact with the HIV PIs as well, but be suitable for use with the NRTIs, rilpivirine, integrase inhibitors, and maraviroc. There are no available data on the interactions of BMS-791325, but studies are underway.

More information
Before Gilead bought sofosbuvir (Sovaldi) from Pharmasset and decided to pursue the combination of ledipasvir/sofosbuvir, the combination of daclatasvir/sofosbuvir had generated quite a buzz in the HCV community due to its high level of cure rates. Gilead suspended working with BMS, much to the criticism, from many advocates and people with HCV, but the potential for this combination remains high. The combination of daclatasvir/sofosbuvir has shown excellent treatment response rates in this population, but also in the more difficult to treat GT 3 patients. It remains to be seen if the FDA will approve this use, or if clinicians will have to use them off-label. Similarly, the daclatasvir/asunaprevir combination has been shown to be effective against GT 1b, which is the most common strain of HCV world-wide. Daclatasvir is also being investigated for its use in HIV/HCV co-infected people.

### Phase II clinical trial results for daclatasvir + asunaprevir + BMS-791325

<table>
<thead>
<tr>
<th>STUDY NAME</th>
<th>DRUG REGIMEN</th>
<th>GENOTYPE</th>
<th>NUMBER OF PARTICIPANTS</th>
<th>SVR 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>AI443-014</td>
<td>Daclatasvir + asunaprevir + BMS-791325 75 mg</td>
<td>1a and 1b (included some people with cirrhosis)</td>
<td>77</td>
<td>92.2% (71/77)</td>
</tr>
<tr>
<td>AI443-014</td>
<td>Daclatasvir + asunaprevir + BMS-791325 150 mg</td>
<td>1a and 1b (included some people with cirrhosis)</td>
<td>84</td>
<td>91.7% (77/84)</td>
</tr>
</tbody>
</table>
Potential side effects and adverse events
As this drug has not yet been FDA-approved, side effects data come from conference presentations and peer-reviewed scientific papers published in medical journals. A complete listing of side effects will be included in the package insert. The most commonly experienced were headaches, fatigue, nausea, asthenia (loss of strength), insomnia, pruritus (itching), diarrhea, dyspnea (difficulty breathing), cough, and myalgia (muscle pain); all side effects were considered mild. When taken with ribavirin, there is an increased risk of fatigue, nausea, headaches, and pruritus. For more information on the side effects of ribavirin, refer to its drug page. When this regimen is used with ribavirin, pregnant women or women who are trying to become pregnant cannot take it; women of childbearing age and their male sexual partners must use two forms of birth control throughout treatment and for six months post-treatment. Changes in hematological (blood) values were also seen in the clinical trials, and routine blood testing to look for anemia, neutropenia, and other blood conditions are recommended.

Potential drug interactions
There is limited data on the drug interactions with this regimen; more detailed information will be available upon FDA approval, and you can then refer to the package insert for more information. There is a small sample of people who were on methadone or buprenorphine, and there were no clinically relevant drug interactions. As ABT-450/r is a protease inhibitor (boosted with ritonavir), there may be other drug interactions that you will need to be aware of, especially when used with HIV medicines.

More information
The results from the clinical trials of this regimen are very promising for both GT 1a and 1b. FDA approval is pending, but it looks like this regimen has higher SVR (cure) rates for GT 1a when ribavirin is used. GT 1b does not look like it will need ribavirin, which is good news for the rest of the world as GT 1b is the most common genotype across the globe. Research studies are underway to see how this regimen works for people co-infected with HIV/HCV and in people with post-liver transplants.

| Phase III clinical trial results for ABT-450/r; ombitasvir + dasabuvir |
|-----------------|-----------------|-----------------|-----------------|
| STUDY           | GENOTYPE, PATIENT TYPE | NUMBER | TREATMENT |
| PEARL-II        | GT 1b, treatment experienced | 179    | ABT-450/r-ombitasvir + dasabuvir + RBV |
|                 |                   |        | 97% (85/88) |
|                 |                   |        | ABT-450/r-ombitasvir + dasabuvir |
|                 |                   |        | 100% (91/91) |
| PEARL-II        | GT 1b, treatment naive | 419    | ABT-450/r-ombitasvir + dasabuvir + RBV |
|                 |                   |        | 99% (209/210) |
|                 |                   |        | ABT-450/r-ombitasvir + dasabuvir |
|                 |                   |        | 99% (207/209) |
| PEARL-IV        | GT 1a treatment naive | 305    | ABT-450/r-ombitasvir + dasabuvir + RBV |
|                 |                   |        | 97% (97/100) |
|                 |                   |        | ABT-450/r-ombitasvir + dasabuvir |
|                 |                   |        | 90% (185/205) |
| TURQUOISE-II 12 & 24 weeks | GT 1 treatment naive and treatment experienced with compensated cirrhosis | 380    | ABT-450/r-ombitasvir + dasabuvir + RBV for 12 weeks |
|                 |                   |        | 92% (191/208) |
|                 |                   |        | ABT-450/r-ombitasvir + dasabuvir + RBV for 24 weeks |
|                 |                   |        | 96% (165/172) |
| SAPPHIRE-I      | GT 1, treatment naive | 631    | ABT-450/r-ombitasvir + dasabuvir + RBV |
|                 |                   |        | 96% (455/473) |
| SAPPHIRE-II     | GT 1, treatment experienced | 394    | ABT-450/r-ombitasvir + dasabuvir + RBV |
|                 |                   |        | 96% (286/297) |
You can talk to us.
We’re Help-4-Hep, and one of our phone counselors is ready to help you meet the challenges of hepatitis C head-on...where to get tested, how to get treatment, or help paying for lab work and medicines. All from someone who’s had hepatitis C touch their own life.
HCV resources, services, and information

**HELP-4-HEP**
877-435-7443 toll-free
National hepatitis C support line staffed by trained peer counselors. Health education, resources, referrals for testing and treatment, and emotional support. Monday–Friday, 9 am–7pm EST.

**HIV Health InfoLine**
800-822-7422 toll-free
Staffed by trained Project Inform operators and staff, many of whom also live with or are impacted by HIV. Call-back service Monday–Friday, 10 am–4 pm PST.

**AIDS/HIV Nightline**
800-628-9240 toll-free
Operates 5 pm–5 am and is run by the San Francisco Suicide Prevention hotline. Very strong on offering emotional support and health education.

**The HCV Advocate**
hcvadvocate.org

**Hep C Association**
hepcasssoc.org
An excellent source for HCV news and information.

**Hep C Connection**
hepc-connection.org
Array of services for people throughout Colorado. Excellent site for news and information.

**Caring Ambassadors**
hepcchallenge.org
Array of services and advocacy around HCV. They also publish *Hepatitis C Choices*.

**Project Inform**
projectinform.org
Advocates for issues related to HIV, HCV and health care access. Up-to-date information on HIV and HCV care and health care reform.

**Treatment Action Group**
treatmentactiongroup.org
National advocacy, research, and policy think tank on HIV, hepatitis C and tuberculosis. Fact sheets, policy papers and annual *Pipeline Report*.

**Test Positive Aware Network**
tpan.com
Offers an array of services for people in the Chicago area, including HIV and HCV testing. Publishes bi-monthly *POSITIVELY AWARE* magazine as well as annual HIV drug and HCV drug guides.

**National AIDS Treatment Advocacy Project**
natap.org
Excellent website for scientific results from HIV and HCV conferences and academic articles.

**HIVandHepatitis.com**
Provides high quality and accurate news coverage on the prevention and treatment of HIV, HCV, and HIV/HCV co-infection.

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An estimated 25% of the 1.1 million HIV-positive people in the U.S. are co-infected with HCV.

HIV CO-INFECTION
MORE THAN TRIPLES THE RISK FOR LIVER DISEASE, LIVER FAILURE, AND LIVER-RELATED DEATH FROM HCV.

Source: CDC
YOUR DOLLARS AT WORK.

The Ride for AIDS Chicago, July 12–13, is an annual two-day, 200-mile bicycling fundraising event and anti-stigma campaign produced by TPAN, a Chicago-based HIV/AIDS community organization and publisher of POSITIVELY AWARE. In the 11 years since the Ride began, more than $2 million has been raised to support HIV/AIDS programs.

Your donation of:

$30 covers one hepatitis C test with pre- and post-test counseling.

$50 pays for one two-hour group therapy session with a licensed therapist.

$100 covers the cost of one therapy session with a licensed therapist.

DONATE AND GET MORE INFORMATION AT www.rideforaids.org.
PHOTOGRAPHY: Sandro Dancer Andrew Murdock, Hubbard Street Dance Chicago

5pm Hilton Chicago’s Grand Ballroom
8pm Auditorium Theatre of Roosevelt University

PERFORMANCES BY Giordano Dance Chicago, Hubbard Street Dance Chicago, Joffrey Ballet, River North Dance Chicago, Ensemble Español Spanish Dance Theater and Visceral Dance Chicago

WORLD PREMIERES BY Randy Duncan, and Harrison McEldowney & Jeremy Plummer

BENEFICIARIES AIDS Foundation of Chicago, The Dancers’ Fund, Making A Daily Effort and Agape Missions Inc.

GALA TICKETS $250-$600  PERFORMANCE ONLY TICKETS $25-$75

www.DanceforLifeChicago.org  312-922-5812 /DanceForLifeChicago @danceforlifeChi

MEDIA PARTNERS:

Saturday, August 16, 2014