Two New Drugs Provide Hope for More Cures

The U.S. Food and Drug Administration (FDA) has approved two new drugs; telaprevir (Incivek, Vertex) and boceprevir (Victrelis, Merck) to be used with peginterferon plus ribavirin for the treatment of Hepatitis C virus (HCV) infection, thereby providing new hope for patients who are infected. Both drugs are serine protease inhibitors and cannot be used as monotherapy.

**Incivek** (telaprevir) is approved for the treatment of chronic hepatitis C genotype 1 infection, in combination with peginterferon and ribavirin, in patients aged 18 years and older with compensated liver disease, including cirrhosis, who are treatment-naive or who have been previously treated with interferon-based treatment. Patients who received 750 mg of Incivek every 8 hours with meals along with the conventional treatment of peginterferon plus ribavirin had a significantly higher rate of sustained virologic response (SVR) of 79%, considerably higher than the rate observed in patients receiving conventional therapy. The SVR response rate for all patients across all studies and all patient groups, was 20% to 45% higher than the current standard of care. Treatment with Incivek is limited to 12 weeks with peginterferon plus ribavirin, and then the peginterferon and ribavirin are continued for an additional 12 weeks for a total of 24 weeks of treatment in most patients. Some patients, about 40%, will require longer therapy with peginterferon and ribavirin. Patients who had relapsed from prior therapy achieved a SVR of 86%, while those with a partial response had a SVR of 59% and so-called null responders had the lowest SVR of 32%. Anemia was a common adverse effect and serious skin reactions with telaprevir occurred in less than 1% of patients.

**Victrelis** (boceprevir), also approved for the treatment of genotype 1 chronic hepatitis C patients with compensated liver disease, including cirrhosis, who are over 18 years of age, is given four weeks after beginning the combination of peginterferon plus ribavirin in a lead-in phase. The dose of 800 mg is given orally with food every 7 to 9 hours. Victrelis may be given for 24 weeks together with peginterferon plus ribavirin, following the four-week lead-in phase, in about 45% of patients, and for 44 weeks in the remainder, based on HCV RNA levels measured at weeks 8 and 24. For naive patients, SVR was achieved in 63-66% of patients. Patients who previously had relapsed or had a partial response when treated with peginterferon and ribavirin, achieved a SVR of 70-75% and 40-52%, respectively. Null responders, defined as individuals in whom HCV RNA levels failed to decline by at least 2 logs at week 12 of previous treatment were not included in Phase III studies but in earlier studies, SVR rates were less than 15%. Adverse effects of concern include: anemia, neutropenia and thrombocytopenia, but serious skin reactions were not seen.

As with conventional treatment, patients need to be warned that both treatment regimens have the potential to cause depression, suicidal ideation and, if taken during pregnancy, birth defects. Because of drug-drug interactions, it is essential that all medications be carefully reviewed before beginning either therapy.

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Medical Writer’s Workshop Empowers Writers with Creative Ideas

Writers and publishers who attended the Viral Hepatitis Cutting Edge Update – Reaching Out to the Silent Sufferers workshop or webcast learned about the advances being made in the development of new treatments for hepatitis C and the need to identify the millions of Baby Boomers who are unaware of their hepatitis B and C infection.Highlighting the need for additional education that empowers individuals to assess their
Church Leaders Learn About Liver Health and Prevention

Concerned about the high incidence of Hepatitis, HIV and drugs use and abuse among African Americans, Cynthia Newbille, Councilwoman Richmond City Council, East End 7th District in collaboration with the Family Resource Center in Richmond Virginia, created the 7th District Health & Wellness Initiative.

One of the major components of this Wellness Initiative included the Foundation for Decision Making Training of Black Faith Leaders in ways to promote liver health, healthy lifestyles and prevention of liver damaging behaviors among members of their congregations.

Reverend Dr. J. Elisha Burke, Director of Men and Health Ministry, Baptist General Convention of Virginia was fascinated by the liver wellness approach and said “It would be very helpful in reaching out to health ministries and their constituents with appropriate videos and materials to enhance their efforts to engage individuals in adopting healthier lifestyle behaviors.”

Declared as “eye openers”, participants reported learning new and vitally important information and techniques to engage young and old alike to avoid behaviors that could expose them to hepatitis and HIV viruses and the tragic life threatening consequences of both diseases. Several nurse/health ministers welcomed filling in informational gaps in their personal understanding of the important role the liver plays in hundreds of life maintaining functions on a daily basis.

HFI Jump Starts Viral Hepatitis Action Plan

The Hepatitis Foundation International (HFI) applauds the U.S. Department of Health and Human Services (HHS) for its Action Plan to Prevent, Care and Treat Viral Hepatitis, a silent and underestimated public health problem. However, implementation of the plan depends on government support to be effective. HFI understands the urgency to make this action plan happen, especially the need to identify the large at-risk population of Baby Boomers of whom many are unaware of their infection. For many years the Foundation has developed programs and worked to engage healthcare providers, and community and corporate leaders to promote liver health/wellness programs and empower individuals to assess their own risk of infection, seek testing and take advantage of new treatments and subsequent cures.

To promote liver health education, missing in most prevention programs, HFI continues to reach and engage leading organizations including Georgia Power/Southern Company and The Coca Cola Company to join Partners in Liver Wellness, HFI’s initiative to encourage liver health education in the workplace. Georgia Power/Southern Company executives, who was impressed with HFI’s liver health program that promotes healthy lifestyle behaviors and avoidance of liver damaging activities, provided their liver health information to its 9,000 employees through their Safety Education Program. Their medical director, Dr. Rob Harshman said, “I am happy to hear there is growing momentum to educate people in protecting their livers through healthy lifestyles. It is a message we have to continually revisit.”

“We cannot afford to wait until people get sick. Understanding the important role the liver plays is essential to enable individuals to avoid liver related debilitating chronic illnesses that include hepatitis, fatty liver, obesity, diabetes and alcohol and drug misuse and abuse”, says Dr. Raymond Koff, hepatologist and clinical professor at University of Connecticut Health Sciences Center. Prevention depends on individuals making healthy lifestyle choices. Liver health education is the key.

Continued from previous page
FDA Advises Acetaminophen Recall

The US Food and Drug Administration (FDA) has made some important recommendations in response to reports about the misuse and accidental overdose of acetaminophen that can lead to acute liver damage and fatalities. Of major concern are infant and children’s liquid products with potential manufacturing deficiencies which may affect quality, purity or potency. McNeil Consumer Healthcare, a subsidiary of Johnson and Johnson, has ceased production of liquid infant Tylenol containing acetaminophen in response to FDA’s concerns to insure their products are safe, effective and of the highest quality. FDA advises consumers who have purchased these recalled products to discontinue use and anticipates requiring boxed warnings be added to all acetaminophen prescription products in the future.

Few parents realize that the infant dose of acetaminophen is three times stronger than the elixir recommended for young children. Tragically, uninformed parents or caregivers have inadvertently provided their children with an overdose of acetaminophen causing severe liver damage necessitating a liver transplant or having fatal outcomes.

Baltimore Viral Hepatitis Summit Hits the Mark

Nearly 100 healthcare providers, addictions professionals and others attended the Baltimore Viral Hepatitis Summit on May 6, 2011. Attendees agreed that this type of education was needed to help them better assist patients and clients in assessing their risk of becoming infected with viral hepatitis and helping infected patients adhere to treatment. The consistent message echoed by all of the presenters was that individuals need to be empowered and motivated to take control of their own health care, to be aware of the activities that could put them at risk of becoming infected, to encourage them to seek testing of the status of their liver health, and if infected to consider treatment options.

This program was generously supported by educational grants from Vertex Pharmaceuticals, Inc., Genentech, a Member of the Roche Company and Gilead Sciences.

HFI Mourns Loss of Hepatitis Advocate and Friend

HFI is deeply saddened by the recent loss of Kathryn L. White, MT, RN, BSN as the result of a tragic car accident. Kathy was a dear and valued friend for decades. As the Hepatitis Prevention Coordinator for the Nebraska Department of Health and Human Services, she was always helpful with her sage advice and counsel. Her suggestions and support as a founding member of the National Nurses Advisory Council – Liver Wellness and Viral Hepatitis, created a link to other professionals in promoting quality care for patients that was so close to her heart.

Kathy knew how to make things happen and how to put policy and action together to achieve the best outcomes. Always with an ear to the ground, she had a heart of gold reaching out to newcomers, prisoners, teachers, nurses and everyone she encountered in her daily rounds. It was an honor and privilege to have her as a close friend and colleague. She was a gift to all of us and to the many silent sufferers whose lives she touched. Kathy was a precious gift to the world around her and will be sorely missed.

Kathy had asked HFI to put on a Viral Hepatitis Summit in Omaha on September 20, 2011 and we were in the midst of planning this event with her. We will continue to hold this event as a tribute to Kathy, our dear friend and colleague.

Alarming Increase of HCV Among Young Adults

A report from the Massachusetts Department of Health showed an alarming increase in the rate of Hepatitis C infection among young adults age 15 – 24. This was nearly double the rate between 2002 and 2009. According to state officials, this new wave of disease is attributed to the rise in abuse of percocet and oxicodone leading to participation in intravenous drugs use by young adults. The increase is purported to be linked to sharing infected needles to inject the drugs.

“We cannot afford to wait until young adults are infected to address this increasing health problem,” comments Dr. Raymond Koff, hepatologist and clinical professor at University of Connecticut Health Sciences Center. “Educating children at an early age about the important role the liver plays and how drugs and alcohol can impact their health and life itself is essential to empower young people to make informed choices and avoid the life altering impact of being hepatitis C infected.”

Absent in most primary and secondary school curricula is information about liver health and adoption of healthy lifestyle behaviors. Extensive surveys by the Hepatitis Foundation International (HFI) show that the majority of teachers
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Liver Transplants Out of Reach for Many

We often hear the lament that liver transplants are out of the reach for many who are uninsured or underinsured. It is a “do or die” situation if you do not have sufficient insurance or $250,000 or more to pay for a new liver plus the additional cost of $2,000 to $5,000 monthly for postoperative anti-rejection medications. One underinsured, middle income mother who had cirrhosis resulting from a genetic disorder was advised by a social worker to get a divorce so she would be indigent and eligible for welfare that would cover the cost of a liver transplant. Married for three decades with two children, this was not an acceptable option for this woman. A sad and next to impossible decision to make.

Currently, 50% of liver transplants are being performed on patients who have hepatitis C, a disease that is called the Silent Killer and totally preventable. Because the liver is a non complaining organ, an estimated 75% of Americans are currently unaware of their infection that can lead to cirrhosis and cancer of the liver. The most vulnerable population is Baby Boomers. The challenge we face is encouraging them to seek testing and if infected to obtain new and more effective treatments. With the approval of new HCV medications this disease can be cured in about 80% of cases avoiding the necessity for a liver transplant. Preventing hepatitis C must play an essential role in controlling escalating costs and avoiding the tragic consequences and loss of lives due to the inability to pay the high cost of treatment and a liver transplant.

Non Invasive Screening for Liver Disease

Elastography and serum markers are two non invasive diagnostic options to detect cirrhosis. Liver biopsy, the gold standard for determining the stage of fibrosis/cirrhosis is on the decline. Drawbacks to liver biopsy include pain or bleeding, inaccurate staging from sampling error, and variability of biopsy interpretations, is the most widely used worldwide. Several studies have confirmed that Fibrotest, an indirect serum marker to be reliable in detecting stage 4 fibrosis (cirrhosis). Imaging techniques such as ultrasound-based transient elastography (TE) have been found to be 90% accurate in diagnosing cirrhosis. Evaluations of magnetic resonance elastography (MRE) have shown 85% accuracy for detecting stages 2 - 4 fibrosis.

Prenatal Screening Provides Opportunities to Reach Vulnerable Populations

A recent study at Columbia Presbyterian Medical Center in New York reported on the high rates of chronic Hepatitis B infection (HBV) found in pregnant minority and immigrant women with the majority not receiving education, appropriate follow-up testing or referral that is considered to the standard of care. Researchers also found that subpopulations of largely young immigrant and underserved patients are living with chronic hepatitis B that they know little about and are unlikely to receive care in terms of surveillance and treatments. Immigrant populations not listed as “high risk” under current guidelines may in fact have high rates of chronic HBV. Prenatal testing provides a golden opportunity to identify HBV infected young mothers and engage them with intervention and prevention messages to avoid spreading this disease to others.

Please remember HFI in your WILL.