Looking Back, Focusing Forward: The Year in Hep News

The approval of two hepatitis C protease inhibitors, the first evidence of interferon-free regimens curing hep C, and a handful of studies touting the potential health benefits of coffee all make the top 20 list of viral hepatitis news in 2011.

December 14, 2011 By Tim Horn

Hep C Infection Rates Slow to Decline Among Injection Drug Users

The substantial decline in new HIV cases among injection drug users (IDUs) in Baltimore has not been matched by reductions in the number of new hepatitis C cases, according to a study published in the March issue of *The Journal of Infectious Diseases*. Likely reasons? The prevalence of hepatitis C virus (HCV) is four times that of HIV in the United States—roughly 4 million compared with 1.2 million living with HIV—and the fact that the risk of passing along HCV is roughly 10 times that of HIV. Sharing needles even once can be enough to transmit hep C, making it a much greater threat to those who make only intermittent use of sterile needles and needle exchange programs. Adding insult to injury, experts note, is that harm reduction measures such as needle exchange and opioid substitution treatment don't get enough support and aren't sufficiently accessible to drug users.

Treatment for Depression Increases Hep C Adherence

Depression isn't just feeling blue—it can be debilitating, and it can seriously sabotage efforts to effectively treat hepatitis C. New data confirm what experts have long suspected, that antidepressants can significantly boost treatment adherence rates in people living with hepatitis C, notably those being treated with interferon—a drug known to cause and exacerbate depression. "All health care professionals, including pharmacists, need to know how to detect depression and work together to support safe, effective and affordable treatments," the researchers conclude.

Breakthrough: Non-Interferon/Ribavirin Regimen Can Cure Hep C

In what was heralded as a research breakthrough, preliminary data reported in April suggested that at least some cases of chronic HCV infection can be cured without the use of either pegylated interferon or ribavirin. The study combined Bristol-Myers Squibb's protease inhibitor asunaprevir (BMS-650032) and NS5A inhibitor daclatasvir (BMS-790052), without interferon and ribavirin, and managed to cure four of 11 people with otherwise difficult-to-treat genotype 1 HCV and who had not responded favorably to earlier therapy attempts. It was the first study to indicate that interferon- and ribavirin-free regimens could work—findings that raised the stakes for all other

drug companies with promising HCV agents in development.

FDA Approves Merck's Hep C Drug Victrelis (Boceprevir)
FDA Approves Incivek (Telaprevir), Second New Hep C Drug

The era of "direct acting antivirals" was officially ushered in with the May 12 and May 23 approvals of two long-awaited hep C protease inhibitors: Victrelis (boceprevir) and Incivek (telaprevir). When they're used in combination with pegylated interferon and ribavirin, people with genotype 1 HCV stand a 70 percent chance of clearing the virus, sometimes with as little as six months of treatment.

"With the approval of [Victrelis and Incivek], there are now two important new treatment options for hepatitis C that offer a greater chance at a cure for some patients with this serious condition," said Edward Cox, MD, MPH, director of the Office of Antimicrobial Products at the FDA's Center for Drug Evaluation and Research. "The availability of new therapies that significantly increase responses while potentially decreasing the overall duration of treatment is a major step forward in the battle against chronic hepatitis C infection."

Fair Pricing Coalition Voices Concern About High Cost of Merck's Victrelis
Fair Pricing Coalition Says Vertex's Incivek Price "Outrageous"

Soon after Victrelis and Incivek were approved by the U.S. Food and Drug Administration, activists sounded the alarm regarding the drugs prices. In separate statements five days apart, the Fair Pricing Coalition (FPC) said that Incivek's price tag of $49,200 per 12-week course and Victrelis's $1,100 weekly cost would adversely affect the ability of people with HCV to access the drugs, while also setting an excessively unreasonable future price point for the many hepatitis C drugs in the pipeline. "If each of the new drugs costs $50,000, we are looking at regimens that will ultimately cost between $150,000 and $200,000 in the very near future," said FPC member Murray Penner. "This is unsustainable and will unacceptably limit access to the regimens."

HHS Launches Viral Hepatitis Action Plan

In May, the U.S. Department of Health and Human Services (HHS) issued its long-awaited Combating the Silent Epidemic of Viral Hepatitis: Action Plan for the Prevention, Care and Treatment of Viral Hepatitis—the government's blueprint outlining plans to fight viral hepatitis in the United States. By 2020, the goals of the plan include: increase the number of people who are aware they have hepatitis B from 33 percent to 66 percent; increase the number of people who are aware they have hepatitis C from 45 percent to 66 percent; reduce new cases of hep C by 25 percent; and eliminate mother-to-child transmission of hep B.

Drinking Coffee Doubles Hep C Treatment Responses
Coffee Helps Minimize Hepatitis C Treatment Side Effects
Coffee Slows Progression of Hep C Liver Disease

Is there anything a good cup of coffee (or three) can't do? Not only does coffee consumption slow liver disease progression and increase the chances of success while undergoing treatment for chronic hepatitis C infection, but drinking three or more cups a day also appears to reduce the incidence of hep C treatment side effects by more than 80 percent.

Curing Hepatitis C Reduces Death From Any Cause
Higher Rates of Non-Liver-Related Deaths in Chronic Hep C

People who have been treated for chronic hepatitis C virus (HCV) infection—and cured—are not only much less likely to die of liver failure or liver cancer, but they are also less likely to die from non-liver-related health problems, according to June 2011 research findings. The drop in death rates from any cause is an unexpected benefit from curing hepatitis C, especially because another study published this summer found that chronic hepatitis C doubles the risk of death from all causes.

Hepatitis C in the U.S. May Be Underestimated by Over a Million

The number of people who have been infected with hepatitis C virus (HCV) may have been undercounted by a whopping 1.1 million, according to new estimates from a paper published in the September 2011 edition of Liver International. Epidemiologists believe that at least 5.2 million people in the United States are HCV antibody positive—meaning that they were infected at one time, although they may not have developed chronic hepatitis C—an increase of 1.1 million over The National Health and Nutrition Examination Survey (NHANES) estimate of 4.1 million cases.

Hep C Inhibitor PSI-7977 Goes Interferon-Free in Phase III Studies
HIV Drug Giant Gilead Acquires Pharmasset, a Hep C Drug Development Leader
12 Weeks Interferon-Free PSI-7977 Regimen Cures 100 Percent Hep C Genotype 2/3

Princeton, New Jersey–based Pharmasset—recently acquired by pharmaceutical giant Gilead Sciences—announced in November that it is putting its lead experimental hepatitis C nucleotide inhibitor PSI-7977 to the test in three late-stage clinical trials exploring the drug's safety and efficacy as a component of a regimen that only needs to be taken for three months and that doesn't include pegylated interferon. The high-stakes decision is based, in part, on preliminary results from a Phase II study in which 10 out of 10 people with genotype 2 or 3 HCV infection were cured after 12 weeks of treatment with a regimen that included PSI-7977 and ribavirin, but not pegylated interferon. If all goes well in the studies, the company will petition the U.S. Food and Drug Administration to begin the process of reviewing PSI-7977 for approval sometime in the second half of 2013.

Five-Year Viread Follow-Up: Long-Term Hep B Suppression, Plus Fibrosis and Cirrhosis Improvements

Data continue to mount, indicating that not only can hepatitis B virus (HBV) medications work for many years, but they can also help reverse liver fibrosis and even cirrhosis in people living with the infection. According to new study results presented at the 62nd annual meeting of the American Association for the Study of Liver Diseases (AASLD), held in San Francisco in November, Viread (tenofovir) maintained long-term viral suppression of HBV—over a period of five years for the majority of participants enrolled in two clinical trials—with 88 percent experiencing improvements in liver health measurements.

Testing All Baby Boomers for Hep C Would Find 86% of Infections

Testing all U.S. baby boomers—individuals born between 1945 and 1965—for hep C infection would help identify more than 800,000 people living with the virus, or roughly 86 percent of those

who are infected and at risk for potentially fatal liver disease but don’t yet know it. This idea is based on data reported at AASLD, along with the suggestion that testing all baby boomers is a cost-effective first step in the prevention of serious HCV-related disease.

OraQuick HCV Test Gets Clearance for Wider Use

Good news for doctor’s offices, outreach clinics and community-based organizations looking to use OraSure Technologies’ rapid test for hepatitis C virus (HCV): According to a December announcement, the test has been granted a CLIA waiver, meaning that its use is no longer limited to professionals who have received laboratory certification from the U.S. Department of Health and Human Services. OraQuick’s assay remains the only U.S. Food and Drug Administration–approved rapid test to detect antibodies to HCV, which causes liver disease. The test, using fingerstick or vein-drawn blood specimens, provides results in 20 minutes. “The CLIA waiver will enable health care providers, those on the front lines of fighting this devastating disease, to use this simple and accurate test in physician offices and outreach settings so more individuals infected with hepatitis C can be diagnosed and treated,” said Douglas Michels, president and chief executive officer of OraSure Technologies.

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