Interferon-free Treatment Options Abound in the Hep C Pipeline

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Just a few years ago, treatment options were bleak for people living with hepatitis C virus (HCV)—especially those with advanced liver disease, who most urgently need a cure. Attempting to rid the body of the virus meant rolling dice loaded with dreary odds for success and spending a year suffering through flu-like side effects from the dreaded weekly injectable drug interferon.

In 2011, the first pair of direct-acting antivirals (DAAs) to treat hep C were released. These drugs upped cure rates and lowered treatment times, although they still had to be taken with interferon. Then, at the end of 2013, the U.S. Food and Drug Administration (FDA) approved Gilead Sciences' Sovaldi (sofosbuvir) and Janssen's Olysio (simeprevir), two DAAs that have kick-started a revolution in hep C care that will only accelerate during the coming year or two.

"This is a time when spectacular results in curing HCV are the norm," said Douglas T. Dieterich, MD, a professor of medicine at the Icahn School of Medicine at Mount Sinai in New York City. "In addition, these treatments require a shorter duration of therapy and often have less toxicity."

Current guidelines typically recommend 12 to 24 weeks of treatment with Sovaldi, interferon and the drug ribavirin. This offers an 85 percent to 95 percent chance of a cure in most cases. Those with genotype 1 of the virus who are ineligible to take interferon—which some clinicians argue includes those who simply do not want to take the drug—may opt for 12 weeks of Olysio, Sovaldi and ribavirin or 24 weeks of Sovaldi and ribavirin.

There is also good news for those who are coinfected with hep C and HIV. Not only is Sovaldi the first DAA specifically approved for use in coinfected people, but recent research also shows that this population's chances of a cure are no different than those without HIV. Also, in most cases Sovaldi can be paired safely with HIV meds.

Thanks to the pent-up demand for treatment and Sovaldi's $84,000 price tag for 12 weeks of therapy, Gilead made $2.3 billion in sales during the first three months of 2014, about $2 billion of it in the United States. This obliterated the record for any drug's entire first year on the market. By comparison, during the same period Janssen sold $354 million of Olysio, which costs $66,360 for 12 weeks.

With so much at stake, a handful of pharmaceutical companies are locked in a competitive race to

bring new combination therapies to market that will drive success rates into the 95 percent-plus range for most people, while further lowering treatment times and doing away with interferon for good, not to mention ribavirin, which can cause anemia, among other side effects. Between February and May, Gilead, Janssen, Bristol-Myers Squibb and AbbVie all submitted applications to the FDA for new interferon-free hep C combination regimens. This means that in all likelihood the last few months of 2014 will produce more dramatic changes in the treatment landscape. According to Daniel Fierer, MD, an assistant professor of medicine in infectious diseases, also at Mount Sinai, present treatment priority should be for those with cirrhosis; others should probably hold off for this more golden opportunity.

In addition, the resulting competition could drive down prices as companies try to chip away at Gilead’s supremacy, providing much-needed relief to overtaxed insurers, both public and private.

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