FDA OKs Major New Hepatitis C Drug, Sovaldi (Sofosbuvir)

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The U.S. Food and Drug Administration has approved Gilead Sciences' hotly anticipated Sovaldi (sofosbuvir), a once-daily oral nucleotide analog polymerase inhibitor to treat people with hepatitis C virus (HCV), including those coinfected with HIV and those who have liver cancer and are awaiting a transplant. For those with genotypes 2 and 3 of the virus, Sovaldi offers the first-ever opportu

nity for treatment with an interferon-free drug regimen. Those with genotypes 1 and 4, however, will in most cases still require the injectable interferon, which causes flu-like side effects.

Sovaldi must be taken in combination with ribavirin regardless of genotype. The recommended treatment duration is 12 weeks for genotypes 1, 2 and 4, and 24 weeks for genotype 3.

Gilead also states that those with genotype 1 who are ineligible to take interferon "can be considered" to receive Sovaldi and ribavirin for 24 weeks of treatment. Also, for those awaiting a liver transplant, the same combination should be given for up to 48 weeks before transplantation to prevent post-transplant infection with the virus.

"Today's approval represents a significant shift in the treatment paradigm for some patients with chronic hepatitis C," Edward Cox, MD, director of the office of antimicrobial products in the FDA's center for drug evaluation and research, said in a release.

A four-week supply of Sovaldi will cost $28,000. For the same supply, the price tag for Janssen's NS3/4A protease inhibitor Olysio (simeprevir), which the FDA approved on November 22, will be $22,120.

Sovaldi leads the pack in the race for highly effective all-oral, interferon- and even ribavirin-free hep C therapies, and many expect the drug to become a major blockbuster. The release of Sovaldi and Olysio, however, is really only a warm-up round. The real clincher won't come until late 2014 when the crucial NS5A inhibitors will likely hit the market. Gilead is hoping to gain approval for a single, coformulated pill of Sovaldi and the company's NS5A inhibitor ledipasvir, which has boasted near-perfect cure results in recent trials.

In the meantime, physicians may choose to prescribe Sovaldi off-label in combination with Olysio. Phase II studies of the pair, given both with and without ribavirin, have yielded cure rates in the mid-90 percent range.

"Today marks a landmark advance in the treatment of hepatitis C, opening up new opportunities to stop the spread of this virus and the ravages of this disease," John Ward, MD, director of the Centers for Disease Control and Prevention's (CDC) division of viral hepatitis,

said in a release. “However, new therapies only work if people receive treatment—the potential of these and other treatment advances hinges entirely on our ability to get more people screened and into care. Right now, most Americans with hepatitis C don’t access treatment because they have no idea they’re infected.”

The FDA’s approval of Sovaldi was based on data from four Phase III studies, NEUTRINO, FISSION, POSITRON and FUSION. Between 50 and 90 percent of study participants taking Sovaldi-based treatments achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure).

Sovaldi has proved well tolerated, with typically mild adverse events among study participants and few treatment discontinuations because of side effects. The most common adverse side effects, found in at least one in five of participants taking Sovaldi with ribavirin and interferon, were fatigue, headache, nausea, insomnia and anemia.