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FDA Approves 'Game Changer' Hepatitis C Drug Sofosbuvir

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The US Food and Drug Administration (FDA) has approved the first-in-kind nucleotide analog inhibitor sofosbuvir (*Sovaldi*, Gilead Sciences, Inc) for the treatment of adults with chronic hepatitis C virus (HCV) infection, a widely anticipated move that is expected to dramatically improve outcomes for many patients.

Data presented earlier this year at an FDA advisory committee meeting support the use of sofosbuvir in combination with ribavirin (RBV) for all-oral dual therapy of infections with HCV genotypes 2 and 3, as well as in triple therapy along with injected pegylated interferon (pegIFN) and RBV for treatment-naive patients with HCV genotypes 1 and 4.

The availability of the first all-oral, interferon-free regimen is a first and a major advance, experts say.

"This is a very exciting time in liver diseases," Greg Fitz, MD, president of the American Association for the Study of Liver Diseases, said at a news conference held last month during The Liver Meeting 2013, at which sofosbuvir was discussed extensively and new data were presented.

"I think the move away from interferon and toward a high probability of success is remarkably encouraging for all of us.... Suddenly, it's realistic to think we can cure most patients with hepatitis C," Dr. Fitz told reporters.

"Sofosbuvir is a game-changer and will allow high cure rates with just 12-week regimens," David R. Nelson, MD, assistant vice president for research, professor of medicine, and associate dean of clinical research at the College of Medicine, University of Florida, Gainesville, told *Medscape Medical News*.

Indeed, liver expert Norah A. Terrault, MD, told *Medscape Medical News* that sofosbuvir holds numerous advantages over current therapy because of its efficacy profile, safety, and tolerability across many different patient populations and HCV genotypes, as well as its dosing simplicity.

"And of course, the first all-oral option for patients with HCV is also a large step forward in terms of principal, to show that you can eradicate HCV without interferon being part of the treatment cocktail.... It's a huge and major advance," said Dr. Terrault, professor of medicine and surgery and director of the Viral Hepatitis Center at the University of California, San Francisco.

Data supporting licensure for sofosbuvir came from 6 clinical trials consisting of 1947 participants, some in trials of sofosbuvir plus RBV with HCV genotype 2 or 3 (including both treatment-naive patients and those who had failed or could not tolerate previous therapy) and others taking the triple combination of sofosbuvir, RBV, and pegIFN in 3 treatment-naive patients infected with HCV genotypes 1, 4, 5, or 6.

At the advisory committee hearing, Gilead scientists reported sustained viral clearance at 12 weeks (SVR12) ranging from 89% to 95% for genotype 2 and 61% to 63% for genotype 3. For

HCV genotype 1, which accounts for about 70% of all HCV in the United States, sofosbuvir-based triple therapy including pegIFN produced an SVR12 of 89%.

Dr. Terrault noted that although there has been a published trial showing efficacy of sofosbuvir and RBV without IFN for HCV genotype 1, the SVR12 was inferior to the triple therapy regimen.

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