Hep C Drug Harvoni OK for HIV Population

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The U.S. Food and Drug Administration (FDA) has given the thumbs up to new uses for Gilead Sciences' hepatitis C virus (HCV) treatment Harvoni (ledipasvir/sofosbuvir): to treat the virus in those who have genotypes 4, 5 or 6 of hep C, and in those coinfected with HIV. Additionally, the FDA approved Harvoni plus ribavirin as an alternative to 24 weeks of Harvoni for people with genotype 1 and cirrhosis who have failed a previous hep C cure attempt.

Harvoni was approved in October 2014 to treat those with genotype 1.

Gilead's FDA application for Harvoni's new uses was based on various trials that showed cure rates between 93 and 96 percent. The Phase III study that looked at HIV-coinfected participants in particular included individuals with genotype 1 or 4; 96 percent were cured of HCV after 12 weeks of treatment.

"This FDA approval accurately reflects the science and is terrific news for treatment of our HIV-infected patients," says Daniel Fierer, MD, an infectious disease specialist at Mount Sinai Hospital in New York City. "FDA approval has become a political necessity in some cases, to combat [insurers'] refusals to pay for treatment."

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