

Bristol hep C drug helps cure 97 pct of HIV coinfecting patients-study

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Feb 26 (Reuters) - Ninety-seven percent of hepatitis C patients also infected with HIV were cured of the liver-destroying virus after 12 weeks of treatment with Bristol-Myers Squibb's daclatasvir and Gilead Sciences' Sovaldi, according to data from a study presented on Thursday.

The results could help put Bristol's hepatitis C program back on track in the United States, following a setback last year.

In the Ally-2 study, including new patients and those not helped by prior treatment, 149 of 153 were deemed cured of hepatitis C regardless of what other anti-viral regimens they were on for HIV, the virus that causes AIDS.

"The results of Ally-2 signaled that nearly all HIV-HCV coinfecting patients in the study could be cured of hepatitis C with a 12-week regimen on daclatasvir and sofosbuvir," Dr. David Wyles, the study's lead investigator, said in a statement, using the chemical name for Sovaldi.

There were no reported serious side effects related to the hepatitis drugs, and patients did not require any alteration of HIV medications over potential drug-drug interactions.

"This is a paramount consideration for clinicians treating this patient population," added Wyles, who presented the data at the Conference on Retroviruses and Opportunistic Infections (CROI) meeting in Seattle.

About 300,000 Americans with HIV also suffer from hepatitis C, according to the Centers for Disease Control and Prevention, making them prone to more rapid progression to liver damage.

Daclatasvir is approved in Europe, Brazil and Japan as part of combination therapy, but has fallen behind rivals in the world's most lucrative market. In November, the U.S. Food and Drug Administration declined to approve daclatasvir in combination with other antiviral drugs.

The company had sought FDA permission to market daclatasvir in combination with another Bristol drug, asunaprevir. But Bristol abandoned its U.S. marketing application for asunaprevir due to potential competition from more potent drugs, leaving the FDA without data to gauge the effectiveness of daclatasvir as part of a combination regimen.

The FDA asked for new data on daclatasvir with other drugs, which the Ally results could help satisfy.

Sovaldi is part of Gilead's market-leading hepatitis C franchise and half of its own one-pill-per-day combination treatment Harvoni.

All 26 patients in the Ally-2 study with the less common genotypes 2, 3 and 4 of the virus were cured by the combination. A shorter eight-week regimen tested among 50 patients led to a 75 percent cure rate.