High Marks for Merck's Hep C Treatment in Those With HIV

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Merck's investigational hepatitis C virus (HCV) treatment grazoprevir/elbasvir cured high rates of the virus among individuals coinfected with HIV, aidsmap reports. Final results from the Phase III C-EDGE Coinfection study of the fixed-dose combination tablet of the NS3/4 protease inhibitor grazoprevir and the NS5A inhibitor elbasvir were presented at the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in San Francisco.

Merck expects a decision in the coming weeks from the U.S. Food and Drug Administration (FDA) on the approval of grazoprevir/elbasvir.

The study included 218 treatment-naive individuals with HIV and HCV, including those with genotypes 1a (66 percent), 1b (20 percent), 4 (13 percent) and 6 (1 percent).

The participants were either not receiving HIV treatment while maintaining a CD4 count greater than 500, or were on stable antiretroviral (ARV) treatment with more than 200 CD4s and an undetectable HIV viral load. ARVs the participants were taking included Isentress (raltegravir), Tivicay (dolutegravir) or Edurant (rilpivirine). For the most part, the partcipants also took either Viread (tenofovir) or Ziagen (abacavir).

A total of 93.1 percent of the participants achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure), with similar results among genotypes 1a, 1b and 4. Both people with genotype 6 were cured. The analysis counted two individuals who were reinfected as not having been cured. A second analysis that excluded those two people found that the overall cure rate was 97.6 percent.

All 34 of the participants with cirrhosis were cured, along with 96 percent of the non-cirrhotic participants.

The treatment was generally safe and well tolerated. None of the participants experienced serious adverse health problems or stopped taking treatment for that reason. The most common side effects included fatigue, headache and nausea.

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