4 Weeks of Merck's Hep C Meds Plus Sovaldi Fails; 8 Weeks Does Well

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A four-week regimen of Merck's fixed-dose combination therapy grazoprevir/elbasvir (MK-5172/MK-8742, MK-5172A) plus Gilead Sciences' Sovaldi (sofosbuvir) posted poor interim results in treating people with genotype 1 of hepatitis C virus (HCV), FierceBiotech reports. A six-week regimen has yielded better, if still not ideal, results, while eight weeks of treatment among people with cirrhosis appears likely to achieve about a 95 percent cure rate once the follow-up period of the study is completed.

The C-SWIFT proof-of-concept study gave Merck's once-daily, fixed-dose, single-pill of the NS3/4A protease inhibitor grazoprevir and the NS5A replication complex inhibitor elbasvir along with the nucleotide analog polymerase inhibitor Sovaldi to 102 treatment-naive people with genotype 1 of hep C. Non-cirrhotic participants were randomized to take the regimen for either four, six or eight weeks. The cirrhotic participants were randomized to take therapy for six or eight weeks. Results were presented at the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in Boston.

"These interim data provide a compelling proof-of-concept for the potential of an eight- or six-week triple therapy course in treatment-naive patients with genotype 1 [of HCV], including cirrhotic patients," Eric Lawitz, MD, vice president, scientific and research development at the Texas Liver Institute in San Antonio, Texas, and C-SWIFT's lead investigator, said in a press release. "These findings will inform the design of larger studies aimed at understanding the potential of short-duration triple therapy across multiple patient types."
Of the non-cirrhotics, just 38.7 percent (12 out of 31) of those who took therapy for four weeks achieved a sustained virologic response either four or eight weeks after completing therapy. (This is called SVR4/8, which indicates a high likelihood that they will make it to SVR12 and be pronounced cured. The participants are still in the follow-up period of the trial; some have only made it four weeks past therapy and others only eight.) As for the non-cirrhotics who were treated for six weeks, 86.7 percent (26/30) achieved an SVR4/8. Among the cirrhotics, 80 percent (26/30) of those treated for six weeks achieved an SVR4/8 and 94.7 percent (18/19) of those treated for eight weeks achieved an SVR4/8. However, the investigators adjusted the eight-week results: There were initially 21, not 19, participants in that segment of the trial, but two discontinued. Merck issued the results as "modified intent to treat" data. One of those two partcipants took his medication on day one but then did not return and the other dropped out at week for personal reasons.

The regimen proved generally safe and well-tolerated. The most common adverse side effects were headache (4 percent), fatigue (2 percent) and nausea (2 percent).

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