AbbVie ‘3D’ Regimen Highly Effective for Transplantees

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Preliminary results in a small study of 24 weeks of AbbVie’s “3D” combination regimen have shown near-perfect results in treating people with recurrent infection of genotype 1 of hepatitis C virus (HCV) following a liver transplant, HIVandHepatitis reports. Results from the ongoing Phase II M12-99 trial were presented at the 49th annual meeting of the European Association for the Study of the Liver (EASL) in London.

The 3D regimen consists of a daily dose of the fixed-dose combination of the protease inhibitor ABT-450 and ritonavir coformulated with the NS5A inhibitor ombitasvir (ABT-267), as well as a twice-daily dose of the non-nucleoside polymerase inhibitor dasabuvir (ABT-333). In this study the regimen was given with ribavirin.

Thirty-four participants with recurrent genotype 1 infection post-liver transplant received the regimen for 24 weeks. The liver transplants were conducted at least a year before participants began the study, and no one had undergone treatment for hep C since the their operations.

All 34 of the participants experienced a rapid virologic response, which is an undetectable viral load four weeks into treatment. Every participant also had an undetectable viral load at the end of treatment, known as the end of treatment virologic response. So far, 32 out of 33 (97 percent) of them have achieved a sustained virologic response four weeks after completing therapy (SVR4, which indicates a high likelihood that they will be cured). A total of 25 out of 26 (96.2 percent) of them have made it eight weeks further from the end of treatment to achieve an SVR12, which is considered a cure.

The most common adverse side effects, reported in more than 25 percent of participants, were headache, fatigue, cough and insomnia.

AbbVie filed for approval of the 3D regimen with the U.S. Food and Drug Administration on April 22.

To read the HIVandHepatitis story, click here.