Simeprevir Is Safe and Effective for Hep C Patients With Advanced Fibrosis

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The new hepatitis C virus (HCV) therapy simeprevir is generally safe and well-tolerated among hep C patients with advanced liver fibrosis and improves treatment outcomes when added to the standard regimen of pegylated interferon and ribavirin, HIVandHepatitis.com reports. Fred Poordad from Cedars-Sinai Medical Center in Los Angeles presented results at a meeting of the American Association for the Study of Liver Diseases (AASLD) in Boston. He and his colleagues conducted two randomized Phase IIb studies—called PILLAR and ASPIRE—analyzing the safety and efficacy of the protease inhibitor simeprevir (formerly TMC-435) taken in combination with pegylated interferon and ribavirin by genotype 1-infected hep C patients with advanced liver fibrosis.

The PILLAR trial included 386 treatment-naïve hep C patients, a portion of whom had advanced fibrosis; they took simeprevir for 12, 24 or 48 weeks along with pegylated interferon and ribavirin for 24 or 48 weeks. Patients with early sustained virologic responses (SVR, considered a cure) were allowed to stop the treatment at the 24-week mark. Otherwise, they continued on pegylated interferon and ribavirin through 48 weeks. A group taking a placebo with pegylated interferon and ribavirin continued for 48 weeks.

The ASPIRE trial included 462 patients with prior treatment experience, including patients with advanced fibrosis or cirrhosis. The structure of the subgroups was similar to that of the PILLAR trial, except patients assigned to the 12- or 24-week regimens of simeprevir stopped the drug regardless of virologic response at their respective benchmarks and continued with the pegylated interferon and ribavirin through week 48.

Both trials showed statistically significant increased cure rates when simeprevir is added to pegylated interferon and ribavirin. Most notably, 79 percent of those in the PILLAR study who took simeprevir had an SVR 24 weeks after completing treatment, compared with 71 percent of patients in the placebo group who maintained an SVR. These differences were magnified for treatment-experienced patients in the ASPIRE trial. Furthermore, for those patients with stage F3 liver fibrosis, 56 percent achieved a cure on the triple combination therapy, compared with only 4 percent on the placebo (which represents a single partial responder). For patients with stage F4 fibrosis, 62 percent on the simeprevir combination were cured, compared with none in the control group.

To read the HIVandHepatitis.com story, click here.

To read the AASLD presentation, click here.

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