Eight Weeks of Harvoni Works Well in the Real World, Even in Some Not Approved For Such Short Treatment

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Real-world results of eight weeks of the hepatitis C virus (HCV) treatment Harvoni (ledipasvir/sofosbuvir) are excellent, and some people who do not qualify for such a short treatment length have still succeed with it, Medscape reports. Researchers compared results from the ION-3 clinical trial of the eight-week regimen to five real-world studies, including the HCV-TARGET, TRIO, VA-Ohio, GECCO and Buggisch studies.

Results were presented at the International Conference on Viral Hepatitis 2016 in San Francisco.

According to the U.S. Food and Drug Administration (FDA), an eight-week treatment with Harvoni is a possibility for those with genotype 1 of the virus who have not been treated before, who do not have cirrhosis, and who have a viral load below 6 million.

In ION-3, 123 people qualified for and were treated with eight weeks of Harvoni. A matched cohort of 126 people took 12 weeks of the treatment. A respective 97 percent and 96 percent achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure).

Some of the ION-3 participants did not qualify for an eight-week treatment but received it anyway. Among those with a viral load above 6 million, 95 percent of those who took ribavirin with Harvoni were cured, as were all of those who did not take ribavirin. Such cure rates were just as high for those who had up to stage 3 of fibrosis.

A total of 323 of the participants in TARGET qualified for eight weeks of treatment. Nevertheless, 192 of these individuals took 12 weeks of treatment under the instruction of their physicians. Ninety-seven percent of both groups of people were cured. Fourteen of those treated for eight weeks did not actually fit the criteria for such short treatment: Six had cirrhosis and eight had been treated for hep C before.

Eight of the 263 people in TRIO had a viral load greater than 6 million.

In GECCO, seven people were coinfected with HIV, three had cirrhosis, 12 had been treated before, and nine had a viral load above 6 million. They were all cured.

In the five real-world studies, cure rates among those receiving eight weeks of treatment were 97 percent or greater.

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