Mavyret Cures Hep C at High Rates in Historically Underserved Groups

This includes people who use drugs, those with psychiatric disorders and those with a history of alcohol use.

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People in historically underserved groups achieve a hepatitis C virus (HCV) cure at high rates when treated with Mavyret (glecaprevir/pibrentasvir).

Such historically underserved individuals with HCV include people who use drugs (PWUD); people with psychiatric disorders, a history of alcohol use (at least two drinks per day on average) or low adherence to HCV treatment; and people who are unemployed or have a low level of education.

Mavyret is approved to treat all genotypes of HCV.

Pietro Lampertico, MD, PhD, of the Università degli Studi di Milano, and colleagues conducted a pooled analysis of Mavyret treatment among 1,892 people from historically underserved groups in nine countries. He presented findings at The Liver Meeting, the Annual Meeting of the American Association for the Study of Liver Diseases, in Boston this month.

The analysis included adults with genotypes 1 through 6 of HCV, including those without cirrhosis or who had compensated cirrhosis (the milder form of the advanced liver disease) and those who had or had not been treated for HCV previously.

The study focused on patient-reported outcomes according to the 36-Item Short-Form Health Survey, including the mental (MCS) and physical component scores (PCS), which were assessed upon individuals' entry into their respective studies, at the end of their HCV treatment and at the 12-week post-treatment mark, at which point it is determined whether the virus is cured.

A total of 1,656 people (87.5%) did not have cirrhosis and 1,632 (86.5%) had not previously been treated for HCV.

One hundred forty-nine individuals (8.0%) were PWUD, 185 (9.8%) had a psychiatric disorder, 296 (18.3%) had a history of alcohol use, 16 (0.9%) had low adherence to previous treatment, 506 (27.8%) were unemployed and 445 (26.7%) had a low level of education.

A total of 1,585 people (83.8%) were assigned to receive eight weeks of Mavyret, while 271 (14.3%) were assigned to receive 12 weeks and 36 (1.9%) were assigned to receive 16 weeks of treatment.

The study categorized the overall population of 1,892 as the safety, or total, population. From that group, 111 people were excluded from what the researchers called the core population of 1,781 people, including 94 who received treatment with Mavyret that was not in keeping with its label's guidelines and 17 who had previously taken direct-acting antivirals (DAAs).

Three hundred four people from the core population were excluded from the final analysis, including 78 who were lost to follow-up, four who discontinued treatment without having a fully suppressed hep C viral load because of adverse health events, seven who discontinued treatment for other reasons and one who withdrew consent. For 214 others, data were missing to determine whether they were cured, including those who may not yet have reached the 12-week post-treatment mark.

This left 1,477 people for the final analysis; this group was called the core population with sufficient follow-up (CPSFU).

The overall hep C cure rate in the CPSFU was 98.6% (1,456 of 1,477). This included cure rates of 98.0% (98 of 100) among PWUD, 99.3% (140 of 141) among people with psychiatric disorders, 96.5% (195 of 202) among people with a history of alcohol use, 90.0% (10 of 11) among people who took less than 90% of their Mavyret doses, 98.3% (354 of 360) among those who were unemployed and 98.2% (322 of 328) among those with low education.

All 150 of those with cirrhosis (who were treated for 12 weeks) and 98.5% (1,275 of 1,294) of those without cirrhosis (who were treated for eight weeks) were cured.

A total of 47.8% of participants experienced an improvement in their MCS scores and 42.0% experienced an improvement in their PCS scores.

A total of 244 (12.9%) of the participants experienced any adverse health event, 138 (7.3%) experienced DAA-related adverse health events, 18 (1.0%) experienced drug-related serious adverse health events, one (less than 0.1%) experienced a DAA-related serious adverse health event and 10 (0.5%) experienced adverse health events leading to discontinuation of treatment.

Ten people (0.3) died during the studies.

The most common side effects occurring in at least 1% of participants were weakness or lack of energy (2.2%), fatigue (2.1%), headache (2.0%) and nausea (1.0%).

The study authors concluded that Mavyret is a highly effected and well-tolerated treatment for people with hep C who have been historically underserved.

To read the conference abstract, click here.