Eight Weeks of AbbVie's G/P Cures Almost All Those With Genotype 3 of Hep C

The investigational glecaprevir/pibrentasvir was tested among people with genotype 3 of hepatitis C virus who did not have cirrhosis.

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An eight-week regimen of AbbVie's investigational glecaprevir/pibrentasvir, known as G/P, cured a high rate of those with genotype 3 of hepatitis C virus (HCV) who had not been treated for the virus before and did not have cirrhosis according to a recent study. Additionally, the study found that 12 weeks of G/P treated this demographic as well as 12 weeks of Sovaldi (sofosbuvir) plus Daklinza (daclatasvir).

AbbVie applied for FDA approval of G/P in February. A decision is expected in late June.

The Phase III open-label, active-controlled ENDURANCE-3 study included 505 people with genotype 3 of hep C who were randomized to receive either 12 weeks of G/P (233 people) or 12 weeks of Sovaldi plus Daklinza (115 people). Those who enrolled in the study at a later point were given eight weeks of G/P (157 people).

Findings were presented at the 52nd International Liver Congress in Amsterdam.

Of the non-randomized individuals receiving eight weeks of G/P, 95 percent (149 of 157) achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure).

Among the randomized participants, 95 percent of those receiving 12 weeks of G/P (222 of 233) were cured, as were 97 percent of those receiving 12 weeks of Sovaldi plus Daklinza (111 of 115). The researchers judged that 12 weeks of G/P is non-inferior to, or as effective as, 12 weeks of Sovaldi plus Daklinza.

The rate of virologic failure among those who received 12 weeks of G/P was 1.7 percent (4 of 233), 0.9 percent (1 of 115) among those who received 12 weeks of Sovaldi plus Daklinza and 3.8 percent (6 of 157) among those who were given eight weeks of G/P without being randomized.

None of those who received eight weeks of G/P stopped treatment because of adverse health

events. Seventy-one percent of the adverse health events were mild among both those receiving eight and 12 weeks of the regimen. The most common adverse events among those receiving eight and 12 weeks of G/P, occurring in more than 10 percent of participants, were headache (20 percent and 26 percent, respectively), fatigue (13 percent and 19 percent) and nausea (12 percent and 14 percent). Among those who received 12 weeks of Sovaldi plus Daklinza, 20 percent experienced headache, 14 percent experienced

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