AbbVie and Gilead Get European Recommendation for New Hepatitis C Combos

Maviret and Vosevi were highly effective and well tolerated in clinical trials.

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The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) last week recommended approval of two new combination treatments for all genotypes of hepatitis C.

AbbVie's coformulation of glecaprevir and pibrentasvir will be sold in Europe under the brand name Maviret. Gilead Sciences' coformulation of sofosbuvir, velpatasvir and voxilaprevir will be marketed in Europe as Vosevi.

As part of the EMA, CHMP plays a regulatory role similar to that of the U.S. Food and Drug Administration. FDA approval of these two combination pills is expected this summer. Final European approval is expected in the fall.

Maviret and Vosevi contain direct-acting antivirals (DAAs) that attack different steps of the hepatitis C virus (HCV) life cycle. Both were found to be effective against HCV genotypes 1 through 6 in Phase III clinical trials, including hard-to-treat genotype 3.

Both Maviret and Vosevi are well tolerated and are used without interferon or ribavirin, which often cause side effects. Maviret is administered as three tablets taken once daily, while Vosevi is taken as a single once-daily pill. A majority of people should be eligible for an eight-week course of treatment, but some harder-to-treat patients may do better with 12 weeks.

The two drugs in the Maviret combination pill—the HCV protease inhibitor glecaprevir and the NS5A inhibitor pibrentasvir—are both new.

A pooled analysis of data from seven studies showed that 97 percent of hepatitis C patients without liver cirrhosis who took Maviret for eight weeks achieved sustained virological response at 12 weeks post-treatment (SVR12, considered a cure).

In the EXPEDITION-1 trial, Maviret taken for 12 weeks cured 99 percent of people with HCV

genotypes 1, 2, 4, 5 or 6 who had compensated cirrhosis. Looking specifically at the most challenging genotype, the ENDURANCE-3 trial found that 95 percent of newly treated people with genotype 3 were cured with either eight or 12 weeks of Maviret. The combination also works well in people with HIV and HCV coinfection.

The Vosevi coformulation includes the HCV polymerase inhibitor sofosbuvir (sold alone as Sovaldi), the NS5A inhibitor velpatasvir (combined with sofosbuvir in the Epclusa coformulation) and the new protease inhibitor voxilaprevir.

The POLARIS-2 trial found that 95 percent of previously untreated people with all HCV genotypes, with or without cirrhosis, were cured with eight weeks of Vosevi. In POLARIS-3, 96 percent of people with genotype 3 and cirrhosis achieved SVR12.

Two other studies (POLARIS-1 and POLARIS-4) showed that a 12-week course of Vosevi cured 97 percent of people with all HCV genotypes who did not respond to previous treatment with DAAs.

If approved, Maviret and Vosevi will offer new highly effective and well-tolerated options for treating all types of hepatitis C.

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