FDA Green Lights AbbVie's Technivie for Genotype 4 of Hepatitis C

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The U.S. Food and Drug Administration (FDA) has approved AbbVie's single-tablet combination regimen Technivie (ombitasvir/paritaprevir/ritonavir) plus ribavirin to treat genotype 4 of hepatitis C virus among those without cirrhosis. This is the first time the FDA has approved an all-oral, interferon-free treatment for genotype 4.

Twelve weeks of treatment are recommended.

Technivie comprises one of the two tablets in AbbVie's Viekira Pak (ombitasvir/paritaprevir/ritonavir; dasabuvir), which was approved to treat genotype 1 of hep C in December 2014. Paritaprevir is a protease inhibitor, ombitasvir is an NS5A inhibitor ombitasvir and Norvir (ritonavir) is an HIV antiretroviral used to boost body's levels of the other two drugs.

About 1 percent of Americans with hep C have genotype 4. Its highest prevalence is in the metropolitan areas of Southern California and in the Northeast Corridor.

Perhaps looking to avoid the particular brand of public relations nightmare Gilead Sciences incurred when it priced Sovaldi (sofosbuvir) at the round number of $1,000 per pill ($84,000 for a 12-week treatment), AbbVie has set the price of Technivie at the odd number of $76,653 for the recommended 12-week therapy. Viekira Pak costs $83,319 for the same treatment length. (Putting daily cost at $991.89 for Viekira Pak and $912.54 for Technivie, with a $79.35 difference between them.)

Technivie is not recommended for individuals with moderate liver impairment, specifically the Child-Pugh B- or C-level classification.

Technivie's approval was based on data from the Phase IIb PEARL-1 study, in which 100 percent of 42 treatment-naive and 49 treatment-experienced participants without cirrhosis achieved a sustained virologic response 12 weeks after completing treatment (SVR12, considered a cure). They were treated with Technivie and ribavirin for 12 weeks. Another 44 treatment-naive participants took Technivie without ribavirin, also for 12 weeks. Forty of them (91 percent) were cured.

Technivie should not be taken with the HIV antiretroviral Sustiva (efavirenz), which is included in

Atripla (efavirenz/tenofovir/emtricitabine).

To read a press release from AbbVie, click here.

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