Just One of the Pills in AbbVie’s Hep C Regimen Cures 95% of 1b’s

February 9, 2015

AbbVie’s combination tablet of ombitasvir, paritaprevir and ritonavir cured 95 percent of treatment-naive Japanese adults with genotype 1b of hepatitis C virus (HCV) who did not have cirrhosis. The tablet is one of two that make up AbbVie’s recently approved Viekira Pak (ombitasvir/paritaprevir/ritonavir; dasabuvir), a regimen that for some also requires ribavirin.

With intentions to announce further results at an upcoming medical meeting, AbbVie has announced these topline results from the Phase III, placebo-controlled GIFT-1 study of the combination tablet of the NS5A inhibitor ombitasvir, the NS3/4A protease inhibitor paritaprevir, and the HIV protease inhibitor Norvir (ritonavir), given for 12 weeks to 363 Japanese adults with genotype 1b of hep C. The results announced at this time derive from a subgroup of the study that included 112 treatment-naive, non-cirrhotic people with genotype 1b who had a viral load of at least 100,000.

Ninety-five percent (106) of the participants achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure).

Among the non-cirrhotic participants in GIFT-I, the most commonly reported side effects were the common cold (16.7 percent in the active drug group vs. 13.2 percent in the placebo group), headache (8.8 percent vs. 9.4 percent) and peripheral edema—swelling of tissues, typically in the lower limbs (5.1 percent vs. 0 percent). Two participants (0.9 percent) stopped treatment because of adverse side effects.

There were no virologic failures while the participants in the subgroup were taking treatment. A total of 2.8 percent (3 of 109) of the remaining participants experienced relapse after completing treatment.

To read a press release on the study, click here.

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