Gilead’s Sovaldi-Ledipasvir Pill Safe With Major HIV Drugs

May 28, 2014

Gilead Sciences' fixed-dose combination pill of Sovaldi (sofosbuvir) and ledipasvir to treat hepatitis C virus (HCV) does not have a clinically significant impact on five common HIV antiretrovirals, the National AIDS Treatment Advocacy Project (NATAP) reports. Currently pending U.S. Food and Drug Administration approval—a decision is expected October 10—the combination pill of the analog polymerase inhibitor Sovaldi and the NS5A inhibitor ledipasvir has boasted near-perfect cure rates in recent trials.

Gilead conducted three multidose randomized crossover trials to look for drug-drug interactions between the combination hep C treatment and Isentress (raltegravir), Atripla (efavirenz/emtricitabine/tenofovir) and Complera (rilpivirine/emtricitabine/tenofovir).

Atripla was found to lower concentrations of ledipasvir by about 30 percent, and Sovaldi/ledipasvir lowered Isentress concentrations less than 20 percent. However, Gilead determined that neither of these effects was clinically relevant. Sovaldi/ledipasvir raised tenofovir levels about 1.8- to 2.6-fold when tenofovir was in Atripla and 1.3- to 1.9-fold when the drug was in Complera. Nevertheless, the researchers concluded that the tenofovir dose needed no adjusting.

Gilead found that the hep C combo pill may be prescribed in combination with Atripla, Complera, Isentress or Truvada (emtricitabine/tenofovir) without the need for adjusting any of the medications' dosages.

To read the NATAP report, click here.

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