FDA Approves Gilead's Vitekta (Elvitegravir) to Treat HIV

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On September 24, the U.S. Food and Drug Administration approved Gilead Sciences' integrase strand transfer inhibitor Vitekta (elvitegravir) for treatment-experienced HIV-positive adults. The drug is indicated for combination use with a protease inhibitor coadministered with Norvir (ritonavir) plus one or more antiretrovirals (ARVs). It should be taken with food.

Vitekta was approved in 85 milligram or 150 mg tablets. The 85 mg tablet is recommended to be taken once daily along with either: 300 mg of Reyataz (atazanavir) plus 100 mg of Norvir, each taken once daily; or 400 mg of lopinavir plus 100 mg of Norvir, each taken twice daily (lopinavir and Norvir are the components of Kaletra). The 150 mg Vitekta tablet is recommended to be taken once daily along with either: 600 mg of Prezista (darunavir) plus 100 mg of Norvir, each taken twice daily; 700 mg of Lexiva (fosamprenavir) plus 100 mg of Norvir, each taken twice daily; or 500 mg of Aptivus (tipranavir) plus 200 mg of Norvir, each taken twice daily.

The approval was based upon results from the Phase III Study 145, in which 712 treatment-experienced people took either Vitekta (354 people) or Isentress (raltegravir) (358 people), each of which was given with a fully active protease inhibitor that was coadministered with Norvir and one or more other ARVs. Throughout 96 weeks of treatment, outcomes were similar between the two groups. Those taking Vitekta had a mean increase of 205 CD4s while those on Isentress experienced a mean increase of 198 cells.

Just 3 percent of the participants taking Vitekta discontinued participation in the study because of adverse side effects, compared with 4 percent of those taking Isentress. The most common side effects of Vitekta and Isentress, respectively, were diarrhea (7 percent vs. 5 percent), nausea (4 percent vs. 3 percent) and headache (3 percent each).

Vitekta should not be given with protease inhibitors that are coadministered with cobicistat, Gilead's new "boosting agent," which operates similarly to Norvir in that it raises the drug levels of other ARVs. The FDA approved cobicistat on September 24 as well, although more information about the drug is still pending.

Vitekta also should not be taken with other drugs that contain elvitegravir (the drug's generic name), including Stribild.

To read the FDA press release, click here.

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