FDA Approves HIV Drug Tivicay (Dolutegravir)

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The U.S. Food and Drug Administration (FDA) has approved ViiV Healthcare's Tivicay (dolutegravir), the second approved antiretroviral (ARV) in the integrase strand transfer class after Isentress (raltegravir), MedPage Today reports. The FDA declined to approve a third drug, elvitegravir, as an individual agent in the same class. It has already been approved as a component of the "Quad" pill, Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir), and may eventually be approved as an individual agent.

The FDA gave the green light for Tivicay's use in both treatment-naive as well as treatment-experienced people with HIV, including those who have taken Isentress. The agency also approved the ARV for use in children ages 12 and up who weigh at least 40 kilograms (88 pounds) and have not taken integrase inhibitors before.

Before making its decision, the FDA considered four Phase III clinical trials including 2,557 participants who were randomly given Tivicay or Isentress in combination with other ARVs, or they were given Atripla (efavirenz/emtricitabine/tenofovir).

Tivicay suppressed HIV at rates equivalent to or better than Isentress. Tivicay is considered a promising alternative because of its once-a-day, 50 milligram dosing, compared with twice-a-day, 400 mg dosing for Isentress.

Tivacy's common side effects included insomnia and headache. Serious side effects included hypersensitivity reactions and abnormal liver function among those coinfected with HIV and hepatitis B or C.

ViiV Healthcare is a joint effort of GlaxoSmithKline and Pfizer, established in 2009 to pursue advancements in HIV care.

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