Tivicay (Dolutegravir) Is Approved in Europe

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The European Commission has approved ViiV Healthcare's integrase inhibitor Tivicay (dolutegravir) to treat HIV-positive adults and adolescents older than 12 in all nations of the European Union. Already approved by the U.S. Food and Drug Administration (FDA), Tivicay was studied in both treatment-experienced and treatment-naive people with HIV, including those with resistance to another integrase inhibitor, Isentress (raltegravir).

The approval was based on four pivotal Phase III clinical trials of 2,557 adults who received either Tivicay or Isentress in combination with other antiretrovirals (ARVs). A fifth study also examined Tivicay's effects in children age 12 and older. The studies found Tivicay statistically superior to Isentress in two of the studies and non-inferior in a third.

Just 1 percent to 3 percent of participants discontinued Tivicay because of adverse side effects. The most common side effects were nausea (15 percent), diarrhea (16 percent) and headache (14 percent).

"Today's approval of Tivicay is an important advance, opening the door to new treatment combinations for people living with HIV in Europe," Dominique Limet, MD, chief executive officer of ViiV Healthcare, said in a release. "Tivicay's clinical development program was only possible through partnerships with the people living with HIV and healthcare professionals who participated in it, and we aim to move forward together with them based on an absolute commitment to the HIV/AIDS global response."

To read the ViiV release, click here.

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