

FDA NEWS RELEASE

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FDA approves new drug to treat HIV infection

The U.S. Food and Drug Administration today approved Tivicay (dolutegravir), a new drug to treat HIV-1 infection.

Tivicay is an integrase strand transfer inhibitor that interferes with one of the enzymes necessary for HIV to multiply. It is a pill taken daily in combination with other antiretroviral drugs.

Tivicay is approved for use in a broad population of HIV-infected patients. It can be used to treat HIV-infected adults who have never taken HIV therapy (treatment-naïve) and HIV-infected adults who have previously taken HIV therapy (treatment-experienced), including those who have been treated with other integrase strand transfer inhibitors. Tivicay is also approved for children ages 12 years and older weighing at least 40 kilograms (kg) who are treatment-naïve or treatment-experienced but have not previously taken other integrase strand transfer inhibitors.

“HIV-infected individuals require treatment regimens personalized to fit their condition and their needs,” said Edward Cox, M.D., M.P.H., director of the Office of Antimicrobial Products in the FDA’s Center for Drug Evaluation and Research. “The approval of new drugs like Tivicay that add to the existing options remains a priority for the FDA.”

About 50,000 Americans become infected with HIV each year and about 15,500 died from the disease in 2010, according to the Centers for Disease Control and Prevention.

Tivicay’s safety and efficacy in adults was evaluated in 2,539 participants enrolled in four clinical trials. Depending on the trial, participants were randomly assigned to receive Tivicay or Isentress (raltegravir), each in combination with other antiretroviral drugs, or Atripla, a fixed-dose combination of efavirenz, emtricitabine and tenofovir. Results showed Tivicay-containing regimens were effective in reducing viral loads.

A fifth trial established the pharmacokinetics, safety and activity of Tivicay as part of treatment regimens for HIV-infected children ages 12 years and older weighing at least 40 kg who have not previously taken integrase strand transfer inhibitors.

Common side effects observed during clinical studies include difficulty sleeping (insomnia) and headache. Serious side effects include hypersensitivity reactions and abnormal liver function in participants co-infected with hepatitis B and/or C. The Tivicay label gives advice on how to monitor patients for the serious side effects.

Tivicay is manufactured by GlaxoSmithKline, based in Research Triangle Park, N.C. Isentress is marketed by Whitehouse Station, N.J.-based Merck, and Atripla is marketed by San Francisco, Calif.-based Gilead.

For more information:

- [FDA: HIV and AIDS Activities](http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/HIVandAIDSActivities/default.htm) (<http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/HIVandAIDSActivities/default.htm>)
- [FDA: Antiretroviral drugs used in the treatment of HIV infection](http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/HIVandAIDSActivities/ucm118915.htm) (<http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/HIVandAIDSActivities/ucm118915.htm>)
- [FDA: Drug Innovation](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/default.htm) (<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/default.htm>)
- [CDC: HIV/AIDS](http://www.cdc.gov/hiv/) (<http://www.cdc.gov/hiv/>)
- [NIH: AIDS Information](http://www.aidsinfo.nih.gov/) (<http://www.aidsinfo.nih.gov/>)
- [HHS: AIDS News and Resources](http://www.aids.gov/) (<http://www.aids.gov/>)

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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