FDA News Release

FDA approves first two-drug regimen for certain patients with HIV

For Immediate Release

November 21, 2017

Summary

FDA approved Juluca, the first complete treatment regimen containing only two drugs to treat certain adults with human immunodeficiency virus type 1 (HIV-1).

Release

Español (/NewsEvents/Newsroom/ComunicadosdePrensa/ucm586308.htm)

The U.S. Food and Drug Administration today approved Juluca, the first complete treatment regimen containing only two drugs to treat certain adults with human immunodeficiency virus type 1 (HIV-1) instead of three or more drugs included in standard HIV treatment. Juluca is a fixed-dose tablet containing two previously approved drugs (dolutegravir and rilpivirine) to treat adults with HIV-1 infections whose virus is currently suppressed on a stable regimen for at least six months, with no history of treatment failure and no known substitutions associated with resistance to the individual components of Juluca.

“Limiting the number of drugs in any HIV treatment regimen can help reduce toxicity for patients,” said Debra Birnkrant, M.D., director of the Division of Antiviral Products in the FDA’s Center for Drug Evaluation and Research.

HIV weakens a person’s immune system by destroying important cells that fight disease and infection. According to the Centers for Disease Control and Prevention, an estimated 1.1 million people in the United States are living with HIV, and the disease remains a significant cause of death for certain populations.

Juluca's safety and efficacy in adults were evaluated in two clinical trials of 1,024 participants whose virus was suppressed on their current anti-HIV drugs. Participants were randomly assigned to continue their current anti-HIV drugs or to switch to Juluca. Results showed Juluca was effective in keeping the virus suppressed and comparable to those who continued their current anti-HIV drugs.

The most common side effects in patients taking Juluca were diarrhea and headache. Serious side effects include skin rash and allergic reactions, liver problems and depression or mood changes. Juluca should not be given with other anti-HIV drugs and may have drug interactions with other commonly used medications.

The FDA granted approval of Juluca to ViiV Healthcare.

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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