FDA News Release

FDA approves new HIV treatment for patients who have limited treatment options

For Immediate Release

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Release

Español (/NewsEvents/Newsroom/ComunicadosdePrensa/ucm599714.htm)

Today, the U.S. Food and Drug Administration approved Trogarzo (ibalizumab-uiyk), a new type of antiretroviral medication for adult patients living with HIV who have tried multiple HIV medications in the past (heavily treatment-experienced) and whose HIV infections cannot be successfully treated with other currently available therapies (multidrug resistant HIV, or MDR HIV).Trogarzo is administered intravenously once every 14 days by a trained medical professional and used in combination with other antiretroviral medications.

“While most patients living with HIV can be successfully treated using a combination of two or more antiretroviral drugs, a small percentage of patients who have taken many HIV drugs in the past have multidrug resistant HIV, limiting their treatment options and putting them at a high risk of HIV-related complications and progression to death,” said Jeff Murray, M.D., deputy director of the Division of Antiviral Products in the FDA’s Center for Drug Evaluation and Research. “Trogarzo is the first drug in a new class of antiretroviral medications that can provide significant benefit to patients who have run out of HIV treatment options. New treatment options may be able to improve their outcomes.”

The safety and efficacy of Trogarzo were evaluated in a clinical trial of 40 heavily treatment-experienced patients with MDR HIV-1 who continued to have high levels of virus (HIV-RNA) in their blood despite being on antiretroviral drugs. Many of the participants had previously been treated with 10 or more antiretroviral drugs. The majority of participants experienced a significant decrease in their HIV-RNA levels one week after Trogarzo was added to their failing antiretroviral regimens. After 24 weeks of Trogarzo plus other antiretroviral drugs, 43 percent of the trial’s participants achieved HIV RNA suppression.

The clinical trial focused on the small patient population with limited treatment options and demonstrated the benefit of Trogarzo in achieving reduction of HIV RNA. The seriousness of the disease, the need to individualize other drugs in the treatment regimen, and safety data from other trials were considered in evaluating the Trogarzo development program.

A total of 292 patients with HIV-1 infection have been exposed to Trogarzo IV infusion. The most common adverse reactions to Trogarzo were diarrhea, dizziness, nausea and rash. Severe side effects included rash and changes in the immune system (immune reconstitution syndrome).

The FDA granted this application Fast Track (/ForPatients/Approvals/Fast/ucm405399.htm), Priority Review (/ForPatients/Approvals/Fast/ucm405405.htm) and Breakthrough Therapy (/ForPatients/Approvals/Fast/ucm405397.htm) designations. Trogarzo also received Orphan Drug (/ForIndustry/DevelopingProductsforRareDiseasesConditions/HowtoapplyforOrphanProductDesignation/default.htm) designation, which provides incentives to assist and encourage the development of drugs for rare diseases.

The FDA granted approval of Trogarzo to TaiMed Biologics USA Corp.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The Agency is also 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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