

## [New Drug Approvals](#)

### Generic Name (Trade Name—Company)

March 6, 2018

### **Ibalizumab-uiyk**

### **(Trogarzo—TaiMed Biologics)**

### **New HIV treatment approved for patients with limited treatment options**

### Uses/Notes

FDA approved [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).

Ibalizumab-uiyki is administered intravenously once every 14 days by a trained medical professional and used in combination with other antiretroviral medications.

Safety and efficacy the agent 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 ibalizumab-uiyk was added to their failing antiretroviral regimens. After 24 weeks of ibalizumab-uiyk plus other antiretroviral drugs, 43% 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 ibalizumab-uiyk 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 ibalizumab-uiyk development program.

The most common adverse reactions were diarrhea, dizziness, nausea and rash. Severe adverse effects included rash and changes in the immune system.

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