

Trogarzo[™] (ibalizumab-uiyk) – New orphan drug approval

- On March 6, 2018, the [FDA announced](#) the approval of [Theratechnologies](#) and [TaiMed Biologics'](#) [Trogarzo \(ibalizumab-uiyk\)](#), in combination with other antiretroviral(s) for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug resistant (MDR) HIV-1 infection failing their current antiretroviral regimen.
- Approximately 25,000 Americans with HIV are currently MDR. About 12,000 of them are in urgent need of a new treatment option because their current treatment regimen is failing them and their viral load has risen to detectable levels, jeopardizing their health and making HIV transmittable.
- Trogarzo is the first biologic drug in a new class of antiretroviral medications. It is a HIV-1 inhibitor that binds to CD4+ receptors on host cells and blocks the HIV virus from infecting the cells.
- The efficacy of Trogarzo was demonstrated in study of 40 heavily treatment-experienced HIV-1 infected patients with MDR HIV-1. Fifty-three percent of the participants had previously been treated with 10 or more antiretroviral drugs.
 - Eighty-three percent (95% CI: 67%, 93%) of patients achieved the study's primary endpoint, at least a 0.5 log₁₀ (or 70%) viral load reduction from baseline seven days after receiving a 2,000 mg loading dose of Trogarzo vs. 3% (95% CI: 0.06%, 13%) of patients achieving a viral load reduction from baseline prior to receiving Trogarzo therapy.
 - The average viral load reduction after 24 weeks was 1.6 log₁₀ with 43% of patients achieving undetectable viral loads.
- A warning and precaution of Trogarzo is immune reconstitution inflammatory syndrome.
- The most common adverse reactions (≥ 5%) with Trogarzo use were diarrhea, dizziness, nausea and rash.
- The recommended dosage of Trogarzo is administered intravenously as a single loading dose of 2,000 mg followed by a maintenance dose of 800 mg every 2 weeks after dilution in 250 mL of 0.9% sodium chloride injection.
- Patients can get assistance and expert support regarding their Trogarzo therapy by contacting THERA patient support[™] at 1-833-23-THERA (84372).
- The annual wholesale acquisition [cost](#) of Trogarzo will be \$118,000.
- Theratechnologies plans to launch Trogarzo within the next six weeks. Trogarzo will be available as a single-dose 2 mL vial containing 200 mg/1.33 mL.