Trogarzo (ibalizumab-uiyk)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Trogarzo
- **Generic name:** Ibalizumab-uiyk
- **Pharmacological class:** CD4-directed post-attachment HIV-1 inhibitor
- **Strength and Formulation:** 200mg/1.33mL
- **Manufacturer:** Theratechnologies, Inc.
- **How supplied:** Singled-dose vials (2mL)—2
- **Legal Classification:** Rx

Indications

- In combination with other antiretroviral(s) for **HIV-1 infection in heavily treatment-experienced adults** with multidrug resistant HIV-1 infection failing their current antiretroviral regimen

Trogarzo


Package contains two vials.
Single-dose vial.
NDC 62064-122-02
Rx only
Trogarzo™
(ibalizumab-uiyk)
Injection
200 mg/1.33 mL (150 mg/mL)
For Intravenous Infusion Only.
Single-dose vial. Discard unused portion.
THERA technologies
Distributed by: Theratechnologies Inc.
2015 Peel Street, 5th Floor
Montréal, Québec Canada H3A 1T8
Trogarzo
(ibalizumab-uiyk)
Injection
200 mg/1.33 mL (150 mg/mL)
For Intravenous Infusion
Single-dose vial.
Discard unused portion.

Dosage & Administration

- Give as IV infusion over ≥30mins for 1st infusion; may reduce to ≥15mins for subsequent infusions if no infusion-associated adverse reactions have occurred
- 2000mg as single loading dose followed by 800mg maintenance dose every 2 weeks

Considerations for Special Populations

- **Pregnancy:** Inadequate data to establish risk to pregnancy outcomes
- **Nursing mothers:** Not recommended
  Pediatric: Not established
- **Elderly:** No studies conducted in geriatric patients

Warnings/Precautions

- **Do not** give as IV push or bolus
- **Observe** patient for 1hr post-infusion; may reduce to 15mins thereafter if no infusion-associated adverse reactions have occurred
- Immune reconstitution inflammatory syndrome

Adverse Reactions

- Diarrhea
- Dizziness
- Nausea
- Rash

Mechanism of Action

- Ibalizumab-uiyk, a recombinant humanized monoclonal antibody, blocks HIV-1 from infecting CD4+ T cells by binding to domain 2 of CD4 and interfering with post-attachment steps required for the entry of HIV-1 virus particles into host cells and preventing the viral transmission that occurs via cell-cell fusion
  - Ibalizumab-uiyk blocks viral entry into host cells without causing immunosuppression

Clinical Studies

- **TMB-301** was a single-arm, multicenter trial that enrolled 40 heavily treatment-experienced HIV-infected patients with multidrug resistant HIV-1

Clinical Studies

- Patients were required to have a **viral load** >1000 copies/mL and documented resistance to ≥1 antiretroviral drug from each of the 3 classes (eg, NRTI, NNRTI, PI)
- Patients must have been treated with antiretrovirals for **≥6 months** and be failing or had recently failed therapy (eg, in the last 8 weeks)

Clinical Studies

- **Day 0−6 (Control period)**
  - Patients were either monitored on current failing therapy or received no therapy if they failed and stopped treatment within the 8 weeks before screening
- **Day 7−13 (Functional monotherapy period)**
  - Patients received Trogarzo 2000mg loading dose
  - Patients on a failing ART regimen continued their failing regimen in addition to the loading dose

Clinical Studies

- **Day 14 to Week 25** (Maintenance period)
  - Viral load was assessed and the background regimen was optimized to include ≥1 drug to which the virus was susceptible
- **Starting Day 21**
  - Trogarzo 800mg was given every 2 weeks as maintenance starting Week 3 through 25

Clinical Studies

- The **primary efficacy endpoint** was the proportion of patients achieving a ≥0.5$\log_{10}$ decrease in viral load from the beginning to the end of the “Functional monotherapy period” vs patients achieving the same decrease from the beginning to the end of the “Control period”

Clinical Studies

- At the end of the **Control** period, 3% of patients achieved a ≥0.5$\log_{10}$ decrease in viral load (95% CI, 0.06%, 13%; *P* <.0001)
- At the end of the **Functional monotherapy** period, 83% of patients achieved a ≥0.5$\log_{10}$ decrease in viral load (95% CI, 67%, 93%; *P* <.0001)

Clinical Studies

- At Week 25, viral load **<50** and **<200** HIV-1 RNA copies/mL was achieved in 43% and 50% of patients, respectively
- 55% of subjects had a ≥1$\log_{10}$ reduction in viral load, and 48% of subjects had a ≥2$\log_{10}$ reduction in viral load at Week 25
- An increase in the mean and median number of CD4+ T-cells (44 cells/mm^3 and 17 cells/mm^3, respectively) was observed from baseline to Week 25

Clinical Studies

- Regarding safety, **13%** of study patients discontinued treatment due to adverse events or death

- For more clinical data info, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/trogarzo/drug/34819/