Trogarzo™ (ibalizumab-uiyk) Injection, the First HIV-1 Inhibitor and Long-Acting Monoclonal Antibody for Multidrug Resistant HIV-1

Most people living with HIV in the modern antiretroviral therapy (ART), are doing well, there is a small proportion that have developed an extensively resistant virus and hence are unable to achieve an undetectable viral load.

Ibalizumab or Trogarzo was approved by the FDA on March 6th 2018. In combination with other ARTs, Trogarzo™ is indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen. Ibalizumab is a monoclonal antibody that targets a human protein rather than attacking the virus directly. Ibalizumab binds domain 2 of the CD4 receptor and does not interfere with MHC class II binding at domain 1. It does not appear to be immunosuppressive . Ibalizumab does not inhibit HIV gp120 binding to domain 1, but, through steric interference, blocks post-CD4 binding events leading to cell entry

The efficacy of Trogarzo was 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 researchers looked at how many people experienced at least a 0.5 log10 drop in viral load by day 7 after receiving a 2,000 mg loading dose of Trogarzo™ and no adjustment to the failing background regimen. The loading dose of ibalizumab led to declines in plasma HIV-1 RNA more than 0.5 log in 83% of participants at 1 week. An optimised background regimen with at least one other active drug was then added , as determined by resistance testing and patient received a second lower-dose infusion of 800mg ibalizumab on day 21 and then every other week until the six-month mark. The average viral load reduction after 24 weeks was 1.6 log10 with 43% of patients achieving undetectable viral loads.

The most common drug-related adverse reactions (incidence ≥ 5%) were diarrhea (8%), dizziness (8%), nausea (5%) and rash (5%). No drug-drug interactions were reported with other ARTs or medications, and no cross-resistance with other ARTs were observed.

DOSAGE AND ADMINISTRATION

TROGARZO is administered intravenously (IV) 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.