

Ibalizumab (*Trogarzo*)

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Drug Summary

Ibalizumab is a humanized monoclonal IgG-4 antibody that prevents HIV cell entry by binding to the domain 2 region of the host CD4 receptor, which is a distinct from the domain 1 region where the HIV gp120 bind to the CD4 receptor. Ibalizumab is referred to as a post-attachment inhibitor because its inhibition of HIV entry occurs after the initial HIV gp120-CD4 cell receptor binding has taken place; the ibalizumab binding to the domain 2 region of the CD4 receptor prevents the normal structural shift in the HIV gp120 that is required for the next step in viral entry—the HIV gp120-host cell coreceptor binding. Ibalizumab has been studied in combination with at least one other active antiretroviral medication in treatment-experienced individuals with extensive resistance. Ibalizumab is not affected by resistance to other classes of antiretroviral medications, nor it is impacted by HIV tropism status (CCR5 versus CXCR4), or renal insufficiency, and there are no significant drug interactions. This medication requires administration via intravenous infusion. It is given as an initial loading dose, followed by a 15-30 minute intravenous infusion every 14 days. Based on the need to give ibalizumab via an intravenous infusion and its high cost, the use of this agent will likely be reserved for rare instances in which an adult has developed multiclass antiretroviral drug resistance and for whom a complete regimen cannot be crafted using other available options.

Key Clinical Trials

In a single-arm, open-label, phase 3 trial [[TMB-301](#)], 40 treatment-experienced adults were enrolled. All participants had multiclass ARV resistance but at least one active drug remaining. All participants were monitored on their failing antiretroviral therapy for 7 days, then received a loading dose of ibalizumab (2,000 mg by IV infusion) and were monitored for another 7 days, then their background regimen was optimized (including at least one other active ARV), and then they continued this optimized background regimen along with ibalizumab 800 mg by IV infusion every 2 weeks. At 7 days after the loading dose of ibalizumab, the proportion of participants with at least a 0.5 log drop in HIV RNA level was 83% (the primary outcome) and the proportion with at least a 1 log drop was 60%. After 24 weeks, the mean viral load decrease from baseline was 1.6 log, 24% achieved an undetectable viral load, and 50% achieved a viral load below 200 copies/mL. There was only one drug-related adverse event leading to treatment discontinuation. Twenty-seven individuals completed this study and enrolled in an open-label extension [[TMB-311](#)] and continued ibalizumab

infusions every 2 weeks plus optimized background regimen until completing 48 weeks of therapy. By that time point, 3 had discontinued for non-drug-related reasons, 59% achieved an undetectable HIV RNA level, and 63% achieved an HIV RNA level below 200 copies/mL.

Adverse Effects

With the use of ibalizumab, there is a risk of infusion-related adverse events and it is recommended to monitor patients for at least 1 hour after the initial loading dose and, assuming no adverse events occur, for at least 15 minutes after each maintenance dose. The drug has also been reported to cause diarrhea, rash, nausea, or dizziness.

Use In Pregnancy

Ibalizumab is not recommended for use in pregnancy.

Key Drug Interactions

For complete information on ibalizumab-related drug interactions, see the [Drug Interactions section in the Ibalizumab \(Trogarzo\) Prescribing Information](#).
