# Trogarzo Maintains Viral Load Suppression for Nearly 10 Years

Extended follow-up confirms that the long-acting monoclonal antibody works well for people with highly resistant HIV.

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Trogarzo (ibalizumab), a long-acting monoclonal antibody infusion, suppressed HIV for up to 9.5 years in people with extensive prior treatment experience and highly resistant virus, according to a report this week at the virtual IDWeek conference.

Although only a small number of people used Trogarzo for that long, these findings show that it can be an effective component of long-term antiretroviral therapy for people with few remaining treatment options, the researchers concluded.

Trogarzo is a monoclonal antibody administered by IV infusions once every two weeks, making it the first antiretroviral that does not require daily dosing. Instead of attacking HIV directly, it attaches to the CD4 receptor on T cells and interferes with a protein shape change that allows viral entry. Theratechnologies, the company that developed the drug, calls it a post-attachment HIV inhibitor.

The Food and Drug Administration approved Trogarzo in 2018 for people with HIV who have limited treatment options because they have tried numerous prior therapies and have developed multidrug-resistant virus.

The approval was based on results from the Phase III TMB-301 trial, which enrolled people on a failing regimen who were resistant to three or more classes of antiretrovirals but had at least one fully active drug still available to construct an optimized background regimen. First, they added Trogarzo to their failing regimen. Then, after seven days, their treatment was optimized based on resistance testing. As reported at IDWeek 2016, 43% had an undetectable viral load (below 50) after 24 weeks of treatment.

For the current analysis, researchers analyzed long-term outcomes among people with multidrug-resistant HIV in an earlier Phase IIb trial (TMB-202), which ran from October 2008 through January 2011. The participants were randomly assigned to receive Trogarzo at a dose of 800 milligrams every two weeks or 2,000 mg every four weeks plus an optimized background regimen for 24 weeks.

Of the 113 people in that study, 56 transferred to an investigational new drug protocol after the trial ended. Twelve of them—along with participants from the Phase III trial—later enrolled in an expanded access program (TMB-311) and remained on treatment with ongoing monitoring until Trogarzo became commercially available in March 2018.

All 12 of the long-term participants were men, and all but one were white. When they enrolled in TMB-202, the median age was 55, more than 80% were over 50 and they had been living with HIV for a median of 22 years. Upon entry into that study, the median viral load was about 25,000 copies, the median CD4 count was 135 and a quarter had a count below 50, indicating advanced immune suppression. Five had been randomized to the 800 mg dose of Trogarzo, and seven received the 2,000 mg dose.

At the completion of TMB-202, eight of the 12 had an undetectable viral load (under 50), and all but one met the study's definition of viral suppression (under 200). At the last TMB-311 follow-up visit—which occurred 7.8 to 9.5 years after initial enrollment in TMB-202—11 had a viral load below 50, and all 12 were below 200.

Eight participants maintained viral suppression without any additional antiretrovirals, including two who were able to simplify their treatment. The other four added medications, but in two of these cases, the only change was the addition of a ritonavir booster.

Treatment also led to immunologic recovery. At the end of TMB-202, the participants had gained an average of 64 CD4 cells, and by week 96 of TMB-311, the mean gain had increased to 99 cells.

Trogarzo was generally safe and well tolerated. No one withdrew from TMB-311 or was lost to follow-up. Half of the participants experienced severe adverse events, but none were considered related to Trogarzo. There were two deaths from unrelated causes.

"In treatment-experienced patients with limited options, these data demonstrate the durability of viral suppression when combining the long-acting antiretroviral ibalizumab with short-acting oral agents," the researchers concluded.

Click here to view the IDWeek 2020 program.

Click here to read about one person's experience using Trogarzo.

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