FDA OKs Faster Administration Method for Trogarzo

The long-acting monoclonal antibody, approved for people with highly resistant HIV, can now be administered in 30 seconds.

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The Food and Drug Administration (FDA) has approved a quicker administration method for Trogarzo (ibalizumab), allowing the long-acting IV treatment to be delivered in 30 seconds rather than 15 minutes every two weeks.

“The evolution of Trogarzo administration from intravenous infusion to intravenous push means less preparation and treatment time in clinics for patients and their health care providers, possibly allowing for more clinics to administer this treatment,” Theratechnologies chief medical officer Christian Marsolais, PhD, said in a press release.

Trogarzo is a long-acting monoclonal antibody that works as a post-attachment HIV entry inhibitor. Instead of attacking the virus directly, it binds to CD4 receptors on T cells and interferes with a protein shape change that enables viral entry.

The FDA approved Trogarzo in 2018 for heavily treatment-experienced people with multidrug-resistant HIV who have trouble achieving viral suppression on their current regimen. Administered by IV infusion every two weeks, Trogarzo was the first antiretroviral that did not require daily pills. Since then, in 2021, the FDA authorized Cabenuva (injectable cabotegravir and rilpivirine) as the first complete HIV treatment regimen that does not require daily dosing.

The approval of Trogarzo was based on results from a Phase III trial that enrolled people whose HIV was resistant to three or more classes of antiretrovirals and who were on a failing regimen at study entry. They first added Trogarzo to their existing regimen for a week, and their regimen was then optimized based on resistance testing.

As reported at IDWeek 2016, 43% of study participants had an undetectable viral load (below 50) after 24 weeks of treatment. At IDWeek 2019, researchers reported that Trogarzo suppressed HIV for 48 weeks in people with highly resistant HIV who received the drug through an expanded access program, reflecting the population that would use it in the real world. Further follow-up showed that people treated with Trogarzo plus an optimized background regimen maintained viral suppression for nearly 10 years.

Until now, ongoing treatment required slow intravenous infusions of diluted Trogarzo every two weeks, which typically took about 15 minutes. The new administration method—known as an IV push—uses a syringe to push undiluted medication into the bloodstream in about 30 seconds. The FDA approval is based on a study showing that the IV push method was safe and resulted in drug levels similar to those achieved with the original slower administration method.

IV administration, even using the faster method, is still a bigger challenge than popping a daily pill, but this change offers a benefit for people with highly resistant HIV who have few treatment options.

“We are grateful for continued innovation to help people living with HIV, and it is comforting to know that this group, which is rarely the focus of treatment advancements, now has a proven, more convenient treatment option,” said Nelson Vergel, founder of the Program for Wellness Restoration (PoWeR), who participated in a trial and still uses Trogarzo. “The availability of treatments that are easier to administer is of real importance to all people with HIV, and this advancement could make it easier to suppress the virus and maintain undetectability.”

Click here for more news about Trogarzo.

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