FDA Approves Antibody Treatment Trogarzo for Multidrug-Resistant HIV

The intravenously infused medication, which should be used with standard antiretrovirals, has a wholesale acquisition cost of $118,000 per year.

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The Food and Drug Administration (FDA) has approved the humanized monoclonal antibody treatment for HIV Trogarzo (ibalizumab-uiyk) for the treatment of multidrug-resistant HIV among those with extensive experience with standard antiretrovirals (ARVs) whose current regimen is failing.

The new biweekly intravenously infused treatment, which is manufactured by Theratechnologies and its partner, TaiMed Biologics, is the first approved HIV treatment in a decade to belong to a new drug class: It is a CD4-directed post-attachment HIV-inhibitor, or an HIV-1 inhibitor for short. The antibody works by binding to the surface of CD4 cells and blocking HIV from attaching to and infecting the immune cells.

In a move that acknowledged Trogarzo had the potential to improve upon already-approved therapies for HIV, the FDA had previously granted the antibody treatment priority review status and breakthrough therapy and orphan drug designations.

Trogarzo's wholesale acquisition cost is $118,000 per year.

According to Theratechnologies, approximately 25,000 U.S. residents are living with multidrug-resistant HIV, and 12,000 of them are out of effective treatment options and thus likely good candidates for Trogarzo.

The approval is based on a Phase III trial in which Trogarzo, added to a regimen of standard ARVs, significantly reduced the viral load of participants on failing ARV regimens. Forty-three percent achieved an undetectable viral load after 24 weeks. The study members' average CD4 count rose by 44 by the end of this period.

Common drug-related adverse reactions, occurring in at least 5 percent of participants, included diarrhea (8 percent), dizziness (8 percent), nausea (5 percent) and rash (5 percent). There were no apparent drug-drug interactions between Trogarzo and other ARVs or medications. Nor did the participants' resistance to any ARVs seem to lead to cross-resistance to Trogarzo.

For information on a patient assistance program to help with the cost of Trogarzo, call 800.238.4372.

To read a press release about the study, click here.

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