



Theratechnologies Announces FDA Approval of Trogarzo® 90-Second Intravenous (IV) Push Loading Dose

Dec 13, 2023

- Updated label means new Trogarzo® patients no longer require initiation of treatment by 30-minute infusion
- Complete IV push method enables easier and more convenient administration of Trogarzo® for heavily treatment-experienced adults with HIV

This news release constitutes a “designated news release” for the purposes of the Company’s prospectus supplement dated December 16, 2021 to its short form base shelf prospectus dated December 14, 2021.

MONTREAL, Dec. 13, 2023 (GLOBE NEWSWIRE) -- Theratechnologies Inc. (“Theratechnologies” or the “Company”) (TSX: TH) (NASDAQ: THTX), a biopharmaceutical company focused on the development and commercialization of innovative therapies, today announced that the United States Food and Drug Administration (FDA) has approved the company’s Labelling Prior Approval Supplement to include a 2000-mg intravenous (IV) push loading dose for Trogarzo® (ibalizumab-uiyk). IV push is a method by which the undiluted medication is “pushed” by syringe for faster administration into the body’s circulation and is designed to make Trogarzo® administration easier and more convenient for people with HIV and their health care providers. As a result, more clinics will be able to initiate new patients and provide ongoing treatment.

In the U.S., Trogarzo®, in combination with other antiretrovirals (ARVs), is indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug-resistant virus failing their current ARV regimen. The label update follows [FDA approval](#) of the IV push maintenance dose in October 2022. With the new label, Trogarzo® administration can now take only 90 seconds for the loading dose, as opposed to a 30-minute infusion, and 30 seconds for a maintenance dose every two weeks.

“The approved updated label further simplifies the administration of Trogarzo® for heavily treated people with HIV, allowing them to initiate treatment within their own clinics,” said Christian Marsolais, Ph.D., Senior Vice President and Chief Medical Officer at Theratechnologies. “This new administration option for the Trogarzo® loading dose is the latest innovation in our ongoing efforts to enhance the convenience of non-oral therapy for this important group of people who have limited treatment options and have been taking oral HIV medication for a long time, many for decades,” added Dr. Marsolais.

Theratechnologies is currently finalizing its application to the FDA for an intramuscular (IM) method of administration of the Trogarzo® maintenance dose.

About Trogarzo®

Trogarzo® (ibalizumab-uiyk) is a long-acting, CD4-directed, post-attachment HIV-1 inhibitor. In the United States, Trogarzo®, in combination with other antiretroviral(s), is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen. Trogarzo® is not approved in Canada.

Trogarzo® is administered by intravenous infusion as a single loading dose of 2,000 mg followed by a maintenance dose of 800 mg every two weeks after dilution in 250 mL of 0.9% Sodium Chloride Injection, USP. The Trogarzo® loading dose can also be administered as an undiluted intravenous (IV) push over 90 seconds, and the maintenance dose can be administered as an undiluted IV push over 30 seconds.

Important Safety Information

Do not receive Trogarzo® if you have had an allergic reaction to Trogarzo® or any of the ingredients in Trogarzo®. Trogarzo® can cause allergic reactions, including serious reactions, during and after infusion. Tell your healthcare provider or nurse, or get medical help right away if you experience any symptoms of an allergic reaction. Before you receive Trogarzo®, tell your healthcare provider about all of your medical conditions, including if you are pregnant or plan to become pregnant as it is not known if Trogarzo® may harm your unborn baby, or if you are breastfeeding or plan to breastfeed as it is not known if Trogarzo® passes into breast milk. Tell your healthcare provider about all the medicines you take, including all prescription and over-the-counter medicines, vitamins, and herbal supplements.

Changes in your immune system (immune reconstitution inflammatory syndrome) can happen when you start taking HIV-1 medicines. Your immune system might get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you start having new symptoms after starting your HIV-1 medicine. The most common side effects of Trogarzo® include diarrhea, dizziness, nausea, and rash. Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of Trogarzo®. For more information, ask your healthcare provider or pharmacist.

Full prescribing information is available at www.trogarzo.com.

About Theratechnologies

Theratechnologies (TSX: TH) (NASDAQ: THTX) is a biopharmaceutical company focused on the development and commercialization of innovative therapies addressing unmet medical needs. Further information about Theratechnologies is available on the Company’s website

at www.theratech.com, on SEDAR+ at www.sedarplus.ca and on EDGAR at www.sec.gov. Follow Theratechnologies on [LinkedIn](#) and [Twitter](#).

Forward-Looking Information

This press release contains forward-looking statements and forward-looking information (collectively, the “Forward-Looking Statements”) within the meaning of applicable securities laws, that are based on management’s beliefs and assumptions and on information currently available to it. You can identify forward-looking statements by terms such as “may”, “will”, “should”, “could”, “promising”, “would”, “outlook”, “believe”, “plan”, “envisage”, “anticipate”, “expect” and “estimate”, or the negatives of these terms, or variations of them. The Forward-Looking Statements contained in this press release include, but are not limited to, statements regarding the ease of administration of the Trogarzo[®] loading dose and the finalization of the Company’s application to the FDA for an IM method of administration of the Trogarzo[®] maintenance dose. Although the Forward-Looking Statements contained in this press release are based upon what the Company believes are reasonable assumptions in light of the information currently available, investors are cautioned against placing undue reliance on these statements since actual results may vary from the Forward-Looking Statements contained in this press release. These assumptions include, without limitation, the market acceptance of the IV push loading dose for Trogarzo[®] by patients and physicians and the perceived ease of use of this IV push loading dose, and the finalization of the application to the FDA for the filing of the IM method of administration of the Trogarzo[®] maintenance dose. Forward-Looking Statements assumptions are subject to a number of risks and uncertainties, many of which are beyond the Company’s control, that could cause actual results to differ materially from those that are disclosed in or implied by such Forward-Looking Statements. These risks and uncertainties include, but are not limited to, the lack of market acceptance of the IV push loading dose for Trogarzo[®] by patients and physicians, the difficulty in switching patients from the current method of administration of the loading dose to a new one, the lack of sales growth in Trogarzo[®] despite the introduction of this new method of administration of the loading dose and a delay in filing the IM method of administration of the Trogarzo[®] maintenance dose with the FDA. We refer current and potential investors to the “Risk Factors” section of our Annual Information Form dated February 27, 2023, available on SEDAR+ at www.sedarplus.ca and on EDGAR at www.sec.gov as an exhibit to our report on Form 40-F dated February 28, 2023, under Theratechnologies’ public filings. The reader is cautioned to consider these and other risks and uncertainties carefully and not to put undue reliance on forward-looking statements. Forward-looking statements reflect current expectations regarding future events and speak only as of the date of this press release and represent our expectations as of that date.

We undertake no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise, except as may be required by applicable law.

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