Theratechnologies Receives Refusal to File Letter for Trogarzo® Intramuscular Method of Administration sBLA from FDA

Feb 27, 2024

MONTREAL, Feb. 27, 2024 (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 issued a refusal to file letter (RTF) regarding the Company’s supplemental Biologics License Application (sBLA) for an intramuscular (IM) method of administration for the maintenance dose of Trogarzo® (ibalizumab-uiyk). The sBLA filing was announced on January 2, 2024.

Upon preliminary review, the FDA determined that the sBLA was not sufficiently complete to permit a substantive review. The RTF states that the sBLA did not contain the data required to establish the pharmacokinetic bridge between the IM and the intravenous infusion route of administration of Trogarzo®.

“While we are disappointed to receive this letter from the FDA, we were aware that the approval of this sBLA for Trogarzo ® IM administration could be challenging based on the results shared in October 2023 from the TMB-302 study, even though viral suppression was maintained throughout the study,” said Christian Marsolais, Ph.D., Senior Vice President and Chief Medical Officer at Theratechnologies. “We will now assess our options regarding this application.”

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 (IV) 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 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 Company’s assessment of its options regarding the IM method of administration of Trogarzo®. 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. 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 decision by the Company not to pursue the approval of the IM method of administration for the maintenance dose of Trogarzo®, or the non-approval of this method of

administration by the FDA even if a new sBLA is filed. We refer current and potential investors to the “Risk Factors” section of our Form 20-F dated February 21, 2024 available on SEDAR+ at www.sedarplus.ca and on EDGAR at www.sec.gov 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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