Theratechnologies Announces Results from Trogarzo® (Ibalizumab-uiyk) Intramuscular Administration Study

Oct 13, 2023

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, Oct. 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 results from a study evaluating an intramuscular (IM) method of administration for Trogarzo® (ibalizumab-uiyk), a monoclonal antibody antiretroviral therapy (ART) for the treatment of heavily treatment-experienced adults with multidrug-resistant (MDR) HIV-1 infection failing their current antiretroviral regimen.

The TMB-302 study, conducted in partnership with TaiMed Biologics, enrolled 21 subjects (7 HIV-positive and 14 HIV-negative) to assess the pharmacokinetics, efficacy, and safety of IM administration of Trogarzo® as compared to intravenous (IV) infusion.

Mean Trogarzo® trough concentrations were greater than 15 µg/mL, suggesting that IM injection was sufficient at maintaining the drug trough concentration above the therapeutic level of 0.3 µg/mL. The mean trough concentrations were comparable between IV infusion and IM injection in HIV-positive subjects. However, the primary endpoint measuring a 90% confidence interval of the ratio of IM injection to IV infusion (0.69, 1.08) did not meet the equivalence limits (0.8, 1.25). Viral suppression, a key secondary clinical endpoint, was maintained in all HIV-positive subjects throughout the IM phase and the overall study.

Each study subject received IM maintenance doses for eight weeks of treatment and a total of 152 IM injections were administered, which were well tolerated. One subject reported injection-site pruritus (itching) at a single time point, and no subjects reported injection-site pain when Trogarzo® was administered intramuscularly.

With the TMB-302 data in hand, Theratechnologies is seeking expert advice prior to completing a regulatory submission of the Trogarzo® IM administration maintenance dose to the U.S. Food and Drug Administration (FDA). The FDA is currently reviewing the Company's submission for the loading dose of the Trogarzo® IV push method of administration and a decision is expected in mid-December.

About Trogarzo® (ibalizumab-uiyk)

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. In October 2022, the Trogarzo® maintenance dose was approved by the FDA to also 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 our management's beliefs and assumptions and on information currently available to our management. 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 completion of a regulatory submission of the Trogarzo® IM administration maintenance dose with the FDA and the timelines about expected decision of the FDA on the Company's submission for the IV push method of administration of the Trogarzo® loading dose. Certain assumptions made in preparing the Forward-Looking Statements include that: we will file the regulatory submission of the Trogarzo® IM administration maintenance dose with the FDA in the last calendar quarter of 2023; the FDA will approve the IM administration of Trogarzo® option for the maintenance dose and the IV push method of administration of the Trogarzo® loading dose; sales of Trogarzo® will increase with the addition of those two methods of administration; and Trogarzo® will continue being reimbursed by private and public payors. Forward-Looking Statements are subject to a number of risks and uncertainties, many of which are beyond Theratechnologies' 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, those related to or arising from: a delay in the filing of the regulatory submission of the Trogarzo® IM administration maintenance dose to the FDA; the non-filing of the IM administration maintenance dose of Trogarzo® with the FDA if experts recommend against it; the non-approval by the FDA of the Trogarzo® IM administration maintenance dose and/or the IV push method of administration of the Trogarzo® loading dose; and, sales of Trogarzo® do not increase despite the approval by the FDA of both or any one of those new methods of administration of Trogarzo® . 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 for additional risks involved in our business. 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.

Contacts:

Investor inquiries:
Phillipe Dubuc
Senior Vice President and Chief Financial Officer
pdubuc@theratech.com
438-315-6608

Media inquiries:
Julie Schneiderman
Senior Director, Communications & Corporate Affairs
communications@theratech.com
1-514-336-7800