Theratechnologies' Trogarzo® Approved by FDA for 30-Second Intravenous (IV) Push, Simplifying HIV Treatment for Heavily Treatment-Experienced Population

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- *Reduces maintenance dose from a 15-minute IV infusion to a 30-second, undiluted IV push every two weeks*
- *Safety profile of Trogarzo® IV push similar to that of IV infusion*
- *New method of administration designed to make maintenance dosing easier for patients and health care providers and allow more clinics to administer treatment*

MONTREAL, Oct. 03, 2022 (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) approved Trogarzo® (ibalizumab-uiyk) for administration by intravenous (IV) push, a method by which the undiluted medication is "pushed" by syringe for faster administration into the body's circulation. In the U.S., Trogarzo ®, in combination with other antiretrovirals (ARVs), is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug-resistant virus failing their current ARV regimen.

The FDA originally approved Trogarzo®, a novel, long-acting monoclonal antibody, in March 2018 to be administered intravenously as a single loading dose followed by a 15-minute maintenance dose every two weeks. Following today's approval, the maintenance dose can be administered as an undiluted IV push over 30 seconds.

"Today marks an important milestone in our journey to improve the lives of people living with HIV who have been heavily treated," said Dr. Christian Marsolais, Chief Medical Officer, Theratechnologies. "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. We are proud of our long-term commitment to bring much needed non-oral innovations to help shift the treatment paradigm for heavily treatment-experienced people living with HIV."

"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). "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."

The approval of the Trogarzo® IV push method of administration is based on study TMB-302, a Phase 3 trial that evaluated the safety and pharmacokinetic (PK) profile of an 800-mg dose of Trogarzo® once every two weeks administered via IV push. Results show that the safety and PK profile of Trogarzo® administered via IV push are similar to that of IV infusion administration. These findings were observed in the Phase 3 TMB-301 trial, which evaluated the safety and efficacy of Trogarzo® in treatment-experienced patients with multidrug-resistant HIV-1. In the TMB-301 trial, patients receiving Trogarzo®, in combination with other ARVs, experienced significant reductions in viral load and a clinically significant increase in CD4+ (T-cell) count. A total of 350 subjects have received Trogarzo® in the clinical development program, including 19 subjects who received Trogarzo® via IV push. Trogarzo® is also being studied for intramuscular injection administration in the continuation of the TMB-302 study. The study is now fully enrolled, with the last patient visit scheduled for November 2022.

About Trogarzo®

Trogarzo® is a long-acting, CD4-directed, post-attachment HIV-1 inhibitor. In the United States, Trogarzo® (ibalizumab-uiyk), 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 (MDR) HIV-1 infection failing their current antiretroviral regimen. In the European Union, Trogarzo® is approved for the treatment of adults infected with MDR HIV-1 for whom it is otherwise not possible to construct a suppressive antiviral regimen.

Trogarzo® is administered intravenously (IV) 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® maintenance dose can also be administered as an undiluted intravenous 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 health care provider or nurse, or get medical help right away if you get any symptoms of an allergic reaction. Before you receive Trogarzo®, tell your health care 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 health care 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 health care 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 health care 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 health care 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.sedar.com, and on EDGAR at www.sec.gov.

Forward-Looking Information

This press release contains forward-looking statements and forward-looking information (collectively, “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", “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 simplification and improvement of treatment for people living with HIV, the increase in the number of clinics that could administer Trogarzo®, the last patient visit scheduled for November 2022 related to the open-label intramuscular Phase 3 study and the expected results from such Phase 3 study administering Trogarzo® intramuscularly. 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. Certain assumptions made in preparing the Forward-Looking Statements include that: the IV-push method of administration of the maintenance dose of Trogarzo® will be found to be simpler and more convenient and will allow more clinics to administer Trogarzo®, the timeline described therein for the last patient visit will be met, the results to be derived from the open-label intramuscular Phase 3 study using Trogarzo® will be at least equal or superior to those observed with the IV-push method of administration and, if and when filed to the FDA, the intramuscular administration of Trogarzo® will be approved by the FDA. Forward-Looking Statements assumptions 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 the non-acceptance by the marketplace of the IV-push mode of administration of Trogarzo®, the number of clinics administering Trogarzo® remains unchanged, a delay occurs in connection with the visit of the last patient, the failure of the Phase 3 study to demonstrate the safe and effective use of the intramuscular mode of administration of Trogarzo® and the non-approval by the FDA of such intramuscular mode of administration. We refer current and potential investors to the “Risk Factors” section of our Annual Information Form dated February 23, 2022 available on SEDAR at www.sedar.com and on EDGAR at www.sec.gov as an exhibit to our report on Form 40-F dated February 24, 2022 under Theratechnologies’ public filings for additional risks related to the Company. 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:

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

Investor inquiries:
Elif McDonald
Senior Director, Investor Relations
ir@theratech.com
1-438-315-8563