Theratechnologies Presents Results From Trogarzo® IV Push Administration Study at CROI 2022

February 16, 2022

- *No difference in pharmacokinetics between IV Push and IV Infusion*
- *No serious adverse events observed*
- *No difference in viral load between IV Push and IV Infusion and no anti-drug antibodies detected*

MONTREAL, Feb. 16, 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 the presentation of positive results from the Phase 3 study evaluating an intravenous (IV) push method of administration of Trogarzo® for the treatment of human immunodeficiency virus type 1 (HIV-1). The results, presented as a poster at the Conference on Retroviruses and Opportunistic Infections (CROI) held virtually February 12–16, 2022, demonstrated that there was no significant difference in pharmacokinetics between IV Push and IV Infusion of Trogarzo®.

“We are pleased to present the positive results of our Trogarzo® IV Push study to the scientific community,” said Christian Marsolais, Ph. D., Senior Vice President and Chief Medical Officer of Theratechnologies. “With the recently submitted supplemental Biologics License Application, we are optimistic that this more convenient IV push mode of administration will improve convenience for both patients and health care providers, thereby allowing patients to benefit from long-acting protection against HIV-1 when Trogarzo® is administered with other antiretrovirals.”

Key data and conclusions from the poster include:

- The Phase 3 study met the primary endpoint with a 90% confidence interval of the ratio of IV Push to IV Infusion, within the target value of 0.80–1.25 (0.9478–1.1226);
- The proportion of subjects with mean trough serum drug concentration equal or exceeding the target concentration was 18/19 (94.7%) for both forms of administration;
- No serious adverse events (AEs) were observed, and only one treatment-related adverse event was observed. All AEs were considered mild to moderate. Additionally, there were no clinically significant differences in the occurrence of AEs during IV Infusion or IV Push; and
- Two secondary endpoints were also achieved, demonstrating no difference in HIV-1 viral load due to the change from IV Infusion to IV Push and no detection of anti-Trogarzo® antibodies.

Poster Presentation Details

Presentation Title: IV Push Administration of Ibalizumab: Pharmacokinetics, Safety and Efficacy
Poster number: 429
Session: G01 – What's New in Pharmacokinetics, Pharmacogenetics, And Drug Interactions
Presenter: Edwin DeJesus, MD

The TMB-302 Phase 3 study, conducted by the Company’s partner, TaiMed Biologics (TaiMed), evaluated the safety and comparability of the current Trogarzo® IV Infusion mode of administration with a more convenient IV Push form of administration that can be infused within 30 seconds without dilution compared to the 15-minute infusion time of the original IV Infusion. The Company submitted a supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA) based on these results in December 2021. We are pleased to announce that the FDA has accepted our filing and has provided a target action date of October 3, 2022 in accordance with the Prescription Drug User Fee Act (PDUFA).

A copy of the Poster will be available on our website shortly.

About Trogarzo®(ibalizumab-uiyk) Injection
Trogarzo® is a CD4-directed post-attachment HIV-1 inhibitor. Trogarzo® is approved for commercialization in the United States and in the European Union. 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 (MDR) HIV-1 infection failing their current antiretroviral regimen. In Europe, 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.

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, or, 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 expected improvement of the IV push mode of administration for patients.

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 FDA will approve the sBLA seeking the approval of the IV push mode of administration of Trogarzo®, patients and physicians will accept the IV push mode of administration of Trogarzo®, the current pandemic will not adversely affect the access of patients to their physicians and to their treatments, and Trogarzo® will not be subject to any recall.

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 adverse impact of the ongoing COVID-19 pandemic on patients' access to physicians and clinics, non-approval by the FDA of the sBLA, recall of Trogarzo® and non-acceptance by patients and physicians of this new mode of administration.

We refer current and potential investors to the "Risk Factors" section of our Annual Information Form dated February 24, 2021 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 25, 2021 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.

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