



Theratechnologies Announces Positive Results for Trogarzo® IV Push Administration Study

September 22, 2021

- TMB-302 study results demonstrate that there was no difference in pharmacokinetics between IV Push and IV Infusion -

- No serious adverse events observed -

- sBLA filing planned for Q4 2021 -

MONTREAL, Sept. 22, 2021 (GLOBE NEWSWIRE) -- Theratechnologies Inc. (Theratechnologies, or Company) (TSX: TH) (NASDAQ: THTX), a biopharmaceutical company focused on the development and commercialization of innovative therapies, is pleased to announce that a study evaluating an intravenous (IV) push form of administration of Trogarzo® for the treatment of human immunodeficiency virus type 1 (HIV-1) infection achieved consistent and statistically significant results demonstrating that there was no difference in pharmacokinetics (PK) between IV Push and IV Infusion. Based on these results, a supplemental Biologics License Application (sBLA) is expected to be filed with the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2021.

The TMB-302 study was conducted by the Company's partner, TaiMed Biologics (TaiMed), to evaluate 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.

"These results confirm that the IV Push method of administration of Trogarzo® is an effective alternative to the current IV Infusion administration," said Paul Levesque, President and Chief Executive Officer of Theratechnologies. "This more convenient IV Push mode of administration also offers patients a rapid infusion time and requires only two quick infusions per month. We are confident that this faster infusion may further increase patient compliance, allowing patients to benefit from long-acting protection against HIV-1 when Trogarzo® is administered with other antiretrovirals."

The primary endpoint measuring a 90% confidence interval of the ratio of IV Push to IV Infusion was within the target value. The proportion of subjects with mean trough serum drug concentration equal or exceeding the target concentration was also the same for both forms of administration. Additionally, there were no serious adverse events observed and drug-related adverse events were considered mild to moderate.

Secondary endpoints were also achieved confirming no difference in HIV-1 viral load due to the change from IV Infusion to IV Push. Additionally, there were no anti-Trogarzo® antibodies or immunogenicity concerns of Trogarzo® detected.

Theratechnologies and TaiMed are currently evaluating an intramuscular (IM) method of administration for Trogarzo® as part of the TMB-302 study with patient screening planned for the fourth quarter of 2021. The study will be conducted and funded by Theratechnologies with support from TaiMed.

Under the terms of the agreement with TaiMed, Theratechnologies is entitled to commercialize the new IV Push and IM methods of administration of Trogarzo® if, and when, approved.

About Trogarzo®

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 HIV-1 infection failing their current antiretroviral 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 filing of an sBLA with the FDA and the timing of such filing, the convenience of the IV Push method of administration, the increase in patient compliance and seeking approval of the IV Push mode of administration, the development of the IM method of administration for Trogarzo® and the timelines to initiate same.

Although the forward-looking information contained in this press release is based upon what the Company believes are reasonable assumptions in light of the information currently available, investors are cautioned against placing undue reliance on this information since actual results may vary from the forward-looking information. Certain assumptions made in preparing the forward-looking statements include that: the current COVID-19 pandemic will have limited adverse effect on the Company's operations; sales of Trogarzo® in the United States and Europe will increase over time; the IV Push method of administration will be approved by the FDA and, if approved, will be accepted by the marketplace; the long-term use of Trogarzo® will not change its safety profile; no recall or market withdrawal of Trogarzo® will occur; no laws, regulation, order, decree or judgment will be passed or issued by a governmental body negatively affecting the marketing, promotion or sale of Trogarzo® in countries where such products are commercialized; continuous supply of Trogarzo® will be available; the timelines set forth in this press release will be met; the Company's relations with

third-party suppliers of its products will be conflict-free and such third-party suppliers will have the capacity to manufacture and supply the Company's products to meet market demand on a timely basis; and the Company's business plan will not be substantially modified.

Forward-looking information 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 information. These risks and uncertainties include, but are not limited to, those related to or arising from: the adverse impact of the COVID-19 pandemic on (a) the Company's sales efforts and sales initiatives, (b) the capacity of the Company's suppliers to meet their obligations vis-à-vis the Company, (c) the Company's research and development activities, (d) the health of the Company's employees and its capacity to rely on its resources, as well as (e) global trade; the non-approval by the FDA of the IV Push method of administration; delays in filing the sBLA seeking approval of the IV Push method of administration and delays in initiating the development of the IM method of administration for Trogarzo[®] as part of the TMB-302 study; the Company's ability and capacity to grow the sales of Trogarzo[®] successfully in the United States and in Europe; the Company's capacity to meet supply and demand for its products; the market acceptance of the IV Push method of administration of Trogarzo[®], if and when approved, in the United States; the Company's expectations regarding its financial performance, including revenues, expenses, gross margins, profitability, liquidity, capital expenditures and income taxes; and the Company's estimates regarding its capital requirements.

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. 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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