Theratechnologies Submits Supplemental Biologics License Application to FDA Advancing Development of IV Push Trogarzo® for Patients Living With HIV

December 6, 2021

sBLA submission with FDA follows on the back of recently announced positive TMB-302 study results

MONTREAL, Dec. 06, 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 the submission of a supplemental biologics license application (sBLA) to the U.S. Food and Drug Administration (FDA) for the Company's intravenous (IV) push form of administration of Trogarzo®. The IV Push Trogarzo® program continues the Company's commitment to improving the lives and treatment outcomes for patients living with HIV.

The FDA submission is the next step in the advancement of Theratechnologies' Trogarzo ® IV Push program. As recently announced, **TMB-302 study** demonstrated that there was no difference in pharmacokinetics (PK) between IV Push and IV Infusion and was conducted by the Company's partner, TaiMed Biologics (TaiMed). Trogarzo® IV Push, a more convenient form of administration, can be infused within 30 seconds without dilution compared to the 15-minute infusion time of the original IV Infusion. Theratechnologies believes this mode of administration will represent a marked improvement for patients.

Additionally, TMB-302 also demonstrated that 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. There were also no anti-Trogarzo® antibodies or immunogenicity concerns of Trogarzo® detected.

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.

Important Safety Information

Before you receive Trogarzo®, tell your healthcare provider 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 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 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 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, 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 form 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, patients and physicians will accept the IV push form 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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