Theratechnologies Trogarzo® Data at AIDS 2022 Shows Potential for Improved Treatment Regimens

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- *New sub-analysis on Trogarzo clinical trial patients demonstrates that long-term viral suppression is not influenced by partially active agents.*
- *Predictive pharmacokinetic modelling shows that new methods of administration could provide similar kinetics to intravenous infusion.*
- *Additional data highlights synergistic activities between Trogarzo and dolutegravir, etravirine, tenofovir alafenamide and lenacapavir, a long-acting investigational antiretroviral therapy (ARV).*

MONTREAL, July 28, 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 data from two poster presentations at the 24th International AIDS Conference (“AIDS 2022”), being held from July 29 to August 2 in Montreal, Canada and virtually. The new data provide key understandings on the potential of Trogarzo® (ibalizumab) to evolve treatment paradigms for heavily treatment-experienced HIV populations on complex regimens.

“Our sub-analysis showed that the combination of the fully active ARVs with ibalizumab most influenced virologic control with or without the partially active ARVs in combination,” said Dr. Jason Leider, MD PhD, Professor of Medicine at Albert Einstein College of Medicine, and lead author on ***Ibalizumab long-term efficacy is not impacted by partially active antiretrovirals***. “We know that complex resistance profiles often limit the number of fully active agents available. These results demonstrate our focus should be on utilizing all available fully active agents, which could lead to simpler regimens for this heavily treatment-experienced population.”

This continuous genotypic susceptibility score (cGSS) analysis, using the Stanford HIVdb (database), sought to understand the contribution of partially active ARVs on durability of response to Trogarzo with optimized background regimens (OBRs). Trogarzo in combination with at least one fully active ARV remained effective across a range of cGSS scores through week 96, demonstrating its durability treating multidrug-resistant (MDR) virus despite combination with compromised agents. The abstract was selected as a top 300 abstract by AIDS 2022.

The second poster presentation at AIDS 2022 entitled ***Pharmacokinetic (PK) modeling and simulation of intramuscular and subcutaneous ibalizumab delivery*** highlights results from population PK modeling to simulate intramuscular (IM) and subcutaneous (SC) dosing based on seven past clinical studies with people living with HIV. The modelling was completed using IM and SC administration to deliver 400 mg weekly or 800 mg biweekly in 100 simulations. Both methods of administration maintained trough concentrations greater than 0.3 µg/mL, which has been previously correlated with efficacy. These data support the proof of concept that administration of Trogarzo via both IM and SC injection weekly or every two weeks are potential future improvements in convenience and accessibility. The PK and safety of Trogarzo IM administration are currently being evaluated in an open-label non-randomized phase 3 study.

The two AIDS 2022 scientific presentations come on the heels of data presented at the Italian Conference on AIDS and Antiviral Research (ICAR) entitled ***Evaluation of the in vitro combinatorial activity of Ibalizumab and HIV-1 antivirals***, which was supported by an independent grant. In vitro combination activity between Trogarzo and nine other ARVs, seven commercially available and two investigational, demonstrated the additive or synergistic effects seen between each pairing. Of note, synergistic activities were seen with dolutegravir, etravirine, tenofovir alafenamide and lenacapavir, a long-acting investigational ARV.

“We are proud to continue to investigate improving treatment for people living with HIV on complex treatment regimens. It is exciting to see new developments for this group, many of whom have been taking numerous ARVs for years. The data being presented at AIDS 2022 builds on the results shared at ICAR; highlighting the need for further research so that more people living with treatment-experienced HIV could ultimately benefit from convenient regimens with long-acting agents,” said Dr. Christian Marsolais, Chief Medical Officer, Theratechnologies.

Posters can be found at www.aids2022.org and will be available following the conference at www.theratech.com.

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.

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 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 improvement of treatment for people living with HIV on complex treatment regimens and the need for further research so that more people living with treatment-experienced HIV could ultimately benefit from convenient regimens with long-acting agents. 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: improved treatments for people living with HIV on complex treatment regimens will be discovered, the IM formulation of Trogarzo® will prove to be safe and effective and the FDA will approve the IM formulation of Trogarzo®.

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 failure of the Phase 3 study to demonstrate safe and effective IM mode of administration of Trogarzo® and the non-approval by the FDA of such IM 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.

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