Theratechnologies' Trogarzo® (Ibalizumab-uiyk) Shortens Time to HIV Undetectability and Extends Durability of Undetectability and Viral Suppression in a Matched Treatment Comparison

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- *First-of-its-Kind Study in HIV Compares Ibalizumab Clinical Trial Experience to Matched Real-World Non-Ibalizumab OPERA® Cohort*
- *Data Presented at ACTHIV ™ Conference Highlight Improved Clinical Outcomes of Ibalizumab for Heavily Treatment-Experienced People with HIV*

MONTREAL, May 04, 2023 (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 presented data from a landmark study in which the use of ibalizumab, a monoclonal antibody antiretroviral therapy (ART) commercialized as Trogarzo®, was associated with favorable virologic outcomes compared to non-ibalizumab regimens used in routine care in heavily treatment-experienced people with HIV. In the study, which was presented at the 17th Annual American Conference for the Treatment of HIV™ (ACTHIV™) in Phoenix, Ariz., use of ibalizumab resulted in a statistically significant doubling of the likelihood of viral undetectability, as well as a much longer duration of undetectability and viral suppression, compared to a real-world, non-ibalizumab control group from the Observational Pharmaco-Epidemiology Research & Analysis (OPERA®) database.

Developed by epidemiologists at Epividian®, OPERA® is a large electronic health record (EHR) database containing patient-level data without identifiers and collected at the point of care for about 14% of the total U.S. HIV population. The ibalizumab study is thought to be the first matching-adjusted indirect treatment comparison (MAIC) study in HIV, an approach designed to facilitate a closely matched comparison from a synthesized, real-world population, when randomization to a control arm would be impractical or unethical.

"We are proud of our collaboration with the Epividian ® team on this MAIC analysis, which shows superior outcomes of Trogarzo®-based regimens in heavily treatment-experienced people with HIV, as compared to the real-world standard of care," said Christian Marsolais, Ph.D., Senior Vice President and Chief Medical Officer of Theratechnologies. "This is the largest dataset and longest follow-up for Trogarzo ® since our Phase 3 study, and reinforces its importance in a patient population that historically has had limited novel treatment options."

"The OPERA® cohort has the benefit of large numbers of patients contributing rich clinical and resistance data over a long period of time," explained Michele Jonsson-Funk, Ph.D., member of the Epividian® Epidemiology and Clinical Advisory Board and Assistant Professor in the Department of Epidemiology at the University of North Carolina, Chapel Hill. "With those details, it was possible to align the groups on inclusion criteria and key clinical factors in order to understand the impact of ibalizumab."

"Comparing the ibalizumab clinical trial experience to a well-matched real-world cohort provides us with additional validation of ibalizumab's efficacy," said Michael Wohlfeiler, M.D., of the AIDS Healthcare Foundation and a co-author of the study. "The potency and durability of ibalizumab, as observed in this latest analysis, bolster the clinical rationale for its use in regimens for heavily treatment-experienced patients and could have important clinical benefits for these individuals."

The study evaluated data from 76 participants in two clinical trials (Phase 2b and Phase 3) who received 800 mg of ibalizumab every two weeks (treatment arm), and compared those data to outcomes from 65 individuals treated with non-ibalizumab-containing regimens as routine care in the OPERA® cohort (control arm). Standardized mortality rate (SMR) weighting ensured balance between the treatment and control groups in terms of baseline age, CD4 cell count, viral load (VL), and susceptibility to specific ART agents.

Despite ibalizumab trial participants having more severe disease at baseline than non-ibalizumab controls, ibalizumab was associated with superior virologic outcomes. At 24 weeks, investigators observed a statistically significant doubling of the likelihood of viral undetectability (defined as VL <50 c/mL) in the treatment arm versus the control arm (SMR-weighted hazard ratio [HR]: 1.98; 95% confidence interval [CI]: 1.02, 3.69). Achievement of viral suppression (defined as VL <200 c/mL) was also more likely with ibalizumab, though this finding did not reach statistical significance (SMR-weighted HR: 1.28; 95% CI: 0.82, 2.06).

Among those who achieved undetectability on ibalizumab, 95% maintained undetectability through the end of follow-up, compared to 27% of those on non-ibalizumab regimens (SMR-weighted HR: 16.08; 95% CI: 3.99, 64.78). Additionally, the same significance emerged for maintaining viral suppression, which was 18 times lower for real-world non-ibalizumab regimens compared to ibalizumab. For both durability analyses, confidence intervals were wide but statistically significant (SMR-weighted HR: 18.36; 95% CI: 2.48, 135.68).

The abstract and poster can be found on Theratechnologies' website.

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.

Trogarzo® is administered by intravenous (IV) infusion 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. In October 2022, the Trogarzo® maintenance dose was approved by the U.S. Food and Drug Administration (FDA) to 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 healthcare provider or nurse, or get medical help right away if you get any symptoms of an allergic reaction. Before you receive Trogarzo®, tell your healthcare 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 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.

About Epividian®

Epividian® advances the mission of medicine by developing novel technologies and empowering clinical practice, clinical research, academic, public health and regulatory efforts. Our mission is to advance the mission of medicine: solving complex problems to improve the health of individuals and the public.

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 favorable virologic outcomes of using ibalizumab, likelihood of viral undetectability, as well as longer duration of undetectability and viral suppression from the use of ibalizumab, and clinical benefits of using ibalizumab. 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 all heavily treatment-experience patients with HIV will experience the same clinical benefits as those shown in the study. 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 the uncertainty that heavily treatment-experienced patients with HIV will experience the same clinical benefits as those discussed in this press release. We refer current and potential investors to the “Risk Factors” section of our Annual Information Form dated February 27, 2023 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 28, 2023 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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