Theratechnologies' Ibalizumab Demonstrates Cost-Effectiveness as an Addition to Routine Clinical Care in Heavily Treatment-Experienced People with HIV

Oct 19, 2023

- *Data presented at AMCP Nexus 2023 highlight implications for U.S. payers based on cost-effectiveness and improved outcomes*

This news release constitutes a "designated news release" for the purposes of the Company's prospectus supplement dated December 16, 2021 to its short form base shelf prospectus dated December 14, 2021.

MONTREAL, Oct. 19, 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 shared data demonstrating the cost-effectiveness of ibalizumab, a monoclonal antibody antiretroviral therapy (ART) commercialized in the U.S. under the trade name Trogarzo®, as an addition to optimized background regimens (OBR) in heavily treatment-experienced (HTE) people with HIV. The analysis, which was presented at the Academy of Managed Care Pharmacy (AMCP) Nexus 2023 conference in Orlando, Fla., suggests that adding ibalizumab to routine clinical care may provide payers with a cost-effective treatment option that can substantially improve outcomes for HTE individuals with HIV.

"As there is an increasing urgency for closer management of healthcare costs in the U.S., payers should prioritize therapies that can clearly demonstrate cost-effectiveness," said John Leasure, Global Commercial Officer at Theratechnologies. "Although adding ibalizumab to optimized background regimens increases the costs of care, it also increases quality-adjusted life-years, making this therapy a cost-effective component of HIV for those who are heavily treatment experienced."

Researchers employed a Markov model to estimate the cost per quality-adjusted life-year (QALY) gained following the addition of ibalizumab to OBR from a U.S. payer perspective. They derived estimates of comparative effectiveness through a standardized mortality rate (SMR)-weighting comparison of data from two ibalizumab clinical trials to those from a real-world, non-ibalizumab control group in 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 for about 14% of the total U.S. HIV population. The analysis encompassed numerous costs, including those for treatment acquisition and administration, monitoring, adverse events, opportunistic infections, and terminal care. Mortality assumptions and health-state utility values were based on disease-specific published literature and clinical trial data.

Over a lifetime horizon, the addition of ibalizumab to OBR increased the time patients' HIV remained undetectable (less than 50 copies/ml) or suppressed (between 50 and 200 copies/ml). The addition of ibalizumab also extended patients' QALYs compared to OBR alone. Researchers calculated a base-case incremental cost-effectiveness ratio (ICER) of U.S. $169,103 for ibalizumab versus OBR, a ratio that fell within an acceptable cost-effectiveness range for the population size. Deterministic and probabilistic scenario analyses indicated that the result was robust to changes to structural or parameter uncertainty.

The abstract was awarded a Bronze Medal by the conference peer reviewers, who used a 1-5 scale of the same five criteria used by the *Journal of Managed Care Pharmacy* to evaluate manuscripts: relevance, originality, quality, bias, and clarity. Only 20% of the submitted abstracts were given an award.

Complete abstract and poster details are available on the Company's website .

About Trogarzo® (ibalizumab-uiyk)

Trogarzo® (ibalizumab-uiyk) is a long-acting, CD4-directed, post-attachment HIV-1 inhibitor. 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. Trogarzo® is not approved in Canada.

Trogarzo® is administered by intravenous 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 FDA to also be administered as an undiluted IV 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 experience 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 healthcare 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.sedarplus.ca and on EDGAR at www.sec.gov. Follow Theratechnologies on LinkedIn and Twitter.

Forward-Looking Information

This press release contains forward-looking statements and forward-looking information (collectively, the “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", “promising”, “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 increases in quality-adjusted life-years, the addition of ibalizumab to routine clinical care providing payers with a cost-effective treatment option, and the use of ibalizumab improving outcomes for HTE individuals with HIV. Certain assumptions made in preparing the Forward-Looking Statements include that: the addition of ibalizumab increases quality-adjusted life-years, in all cases the addition of ibalizumab will be cost-effective treatment option, and ibalizumab improves the outcomes for all HTE patients with HIV. Forward-Looking Statements 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 non-acknowledgement by public and private payers that ibalizumab is cost-effective, and variations in outcomes among HTE individuals with HIV using ibalizumab. 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.sedarplus.ca 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 involved in our business. 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.

Contacts:

Media inquiries:
Julie Schneiderman
Senior Director, Communications & Corporate Affairs
communications@theratech.com
1-514-336-7800

Investor inquiries:
Phillipe Dubuc
Senior Vice President and Chief Financial Officer
pdubuc@theratech.com
438-315-6608