Theratechnologies Unveils Study Design and Baseline Characteristics of PROMISE-US Trial of Ibalizumab in Heavily Treatment-Experienced People with HIV and Multidrug Resistance

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Baseline Data Show More Frequent Selection of Ibalizumab in Patients with Lower CD4 Counts and Higher Viral Loads, Compared to Other Regimens

MONTREAL, Oct. 17, 2024 (GLOBE NEWSWIRE) -- Theratechnologies Inc. (“Theratechnologies” or the “Company”) (TSX: TH) (NASDAQ: THTX), a biopharmaceutical company focused on development and commercialization of innovative therapies, today disclosed the study design and baseline characteristics of participants in the Prospective Observational Study of Multidrug-Resistant Patient Outcomes with and without Ibalizumab in a Real-World Setting: United States (PROMISE-US). The study seeks to fill a critical gap in long-term clinical outcomes for heavily treatment-experienced (HTE) people with HIV (PWH), while illuminating factors contributing to maintenance of virologic control.

In a poster presentation at IDWeek 2024 in Los Angeles, Calif., PROMISE-US investigators reported that ibalizumab, a CD4-directed post-attachment inhibitor of HIV, was more frequently selected for use in advanced, HTE participants with lower CD4 cell counts and higher viral loads, compared to regimens not containing ibalizumab. Despite the use in more advanced patients, ibalizumab demonstrated good durability, with the majority of subjects staying on therapy for more than 24 months.

“The phenomenon of multidrug resistance is most prevalent in persons with HIV with extensive prior exposure to antiretroviral therapies, making it challenging to establish and maintain virologic control, due to the limited availability of medications for constructing a fully suppressive regimen,” stated presenting author, Charlotte-Paige Rolle, M.D., MPH, Director of Research Operations, Orlando Immunology Center. “Given the need for more options to treat this subset of PWH and to understand how they respond to treatment, we designed PROMISE-US to compare the long-term efficacy and safety of ibalizumab-based regimens to other regimens used in heavily treatment-experienced individuals in the real-world setting.”

PROMISE-US (ClinicalTrials.gov identifier: NCT05388474) is a phase 4, multicenter, retrospective and prospective, observational, non-interventional registry study. The study is designed to assess risk factors and predictors of virologic and immunologic response in HTE PWH and specific sub-populations and is the first real-world registry study that captures patient-reported outcomes such as satisfaction and adherence to treatment in this specific patient population.

The study’s primary objective is to evaluate the long-term efficacy and durability of ibalizumab in combination with other antiretroviral (ARV) therapies by comparing the clinical outcomes of patients receiving ibalizumab (Cohort 2) versus matched patients not receiving ibalizumab (Cohort 1).

As of November 2023, a total of 114 participants were enrolled: 70 in Cohort 1, 42 on ibalizumab, and two screen failures. Baseline characteristics, including race, ethnicity, sex, gender, and time since diagnosis, were well matched between both cohorts. The use of ibalizumab was associated with HTE patients with higher viral loads ($p = 0.0629$) and declining CD4 T cells ($p = 0.001$), compared to those subjects not taking ibalizumab.

The PROMISE-US researchers also investigated the use of the capsid inhibitor lenacapavir, for HTE PWH, in combination with ibalizumab. This subset of Cohort 2 exhibited the highest viral loads and lowest CD4 counts at baseline, although the sample size is small ($n = 12$). As of the time of analysis, 80% of participants ($n = 21$) in Cohort 2 had remained on ibalizumab for greater than 12 months. Ibalizumab was well tolerated, with no infusion reactions reported.

“As more agents with novel mechanisms of action become available and HIV researchers and clinicians are paying increasing attention to multidrug resistance, we continue to analyze data from PROMISE-US to understand the long-term safety and efficacy of ibalizumab, particularly with regard to its suitability for combination with long-term injectable therapies,” said Christian Marsolais, Ph.D., Senior Vice President and Chief Medical Officer of Theratechnologies. “We also seek further understanding of the factors that contribute to maintaining virologic response in heavily treatment-experienced individuals with HIV, a population with a high unmet need for reliable, sustainable antiretroviral therapy. We are proud to be the first company to establish a registry to capture long-term clinical outcomes for heavily treatment-experienced patients with multidrug-resistant HIV-1 in a real-world setting and look forward to sharing additional data from this ongoing study.”

IDWeek 2024 is the joint annual meeting of the Infectious Diseases Society of America, the Society for Healthcare Epidemiology of America, the HIV Medicine Association, the Pediatric Infectious Diseases Society, and the Society of Infectious Diseases Pharmacists.

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 the long-term safety and efficacy of ibalizumab, particularly with regard to its suitability for combination with long-term injectable therapies and our understanding of the factors that contribute to maintaining virologic response in heavily treatment-experienced individuals with HIV. Forward-looking statements involve a number of assumptions, risks and uncertainties. The Company refers current and potential investors to the “Risk Factors” section of its Annual Information Form filed under the Company’s Form 20-F dated February 21, 2024 available on SEDAR+ at www.sedarplus.ca and on EDGAR at www.sec.gov 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 the Company's expectations as of that date.

The Company undertakes 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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