

Theratechnologies Announces New Data from the Pivotal Phase III Trial of HIV Monoclonal Antibody and Long-Acting Investigational Antiretroviral Ibalizumab

Ibalizumab Maintains Significant Viral Load Reduction and Increases CD4⁺ T cells in Patients with Multidrug Resistant HIV-1 over 24 Weeks

Results Presented in Late-Breaker Session at CROI 2017 Support Upcoming FDA Submission

Montreal, Canada – February 14, 2017 – Theratechnologies Inc. (Theratechnologies) (TSX: TH) announced today that additional secondary efficacy and safety endpoint results from the 24-week ibalizumab Phase III trial, TMB-301, were presented at a late-breaker session at the Conference on Retroviruses and Opportunistic Infections (CROI) 2017. Preliminary secondary efficacy and safety endpoint results were announced on November 10, 2016.

The new data showed that patients with multidrug resistant (MDR) HIV-1 infection experienced a mean increase in CD4⁺ T cell of 48 cells/ μ L after 24 weeks of treatment with ibalizumab plus an optimized background regimen (OBR). These data supplement previously reported findings, where 83% of patients achieved a $\geq 0.5 \log_{10}$ decrease in viral load from baseline seven days after the single loading dose of 2000 mg of ibalizumab (primary endpoint) and a mean reduction in viral load of 1.6 \log_{10} over the 24 week treatment period with more than 48% of patients experiencing a viral load reduction of more than 2.0 \log_{10} .

“CD4⁺ T cells play an important role in protecting the body from infection. The higher the CD4⁺ T cell count, the better able you are to fight HIV and other infections,” said Dr. Brinda Emu, Assistant Professor of Medicine, Infectious Diseases, Yale School of Medicine, New Haven, CT. “This meaningful increase in CD4⁺ T cell counts is particularly important for patients with multidrug resistant virus, as they often have the most advanced disease. These data suggest that for these patients, ibalizumab could be an important new treatment option,” added Dr. Emu.

Patients enrolled in this Phase III trial experienced a significant decrease in viral load after receiving a single loading dose of ibalizumab 2,000 mg intravenously (IV) in addition to their failing ART (or no therapy). Viral load decreases were maintained during the 24-week trial. At the end of the treatment period, the proportion of study participants with undetectable viral load (HIV-1 <50 copies/mL) was 43% (mean viral load reduction of 3.1 \log_{10}) and 50% of patients had a viral load lower than 200 copies/mL.

Total CD4⁺ T cell increases varied according to baseline levels of CD4⁺ T cells. Patients with baseline CD4⁺ T cells lower than 50 cells/ μ L (17 patients) had an increase of 9 cells/ μ L, those with CD4⁺ T cells between 50 and 200 cells/ μ L (10 patients) had an increase of 75 cells/ μ L and those with CD4⁺ T cells higher than 200 cells/ μ L (13 patients) had an increase of 78 cells/ μ L. Similar efficacy was observed, in a subgroup of 17 patients infected with HIV-1 that was resistant to all FDA approved ART and for whom the only other active agent that could be included in the OBR was another investigational drug.

The safety results in this Phase III trial are consistent with the ones previously observed in the Phase IIb trial. Other than for one case of immune reconstitution inflammatory syndrome, an inflammatory response in HIV-infected patients that may be triggered after changing to more active ART, no serious adverse events were considered to be related to ibalizumab. Most treatment-emergent adverse events reported were mild to moderate in severity. No notable trends in laboratory abnormalities were observed. Additionally, no anti-ibalizumab antibodies were detected in blood samples from patients.

“There is an urgent need for a drug with a new mechanism of action for patients infected with multidrug resistant HIV-1,” said Christian Marsolais, Ph.D., Senior Vice President and Chief Medical Officer, Theratechnologies Inc. “These results continue to support the submission of a Biologics License Application (BLA) to the FDA, and if approved by the FDA, ibalizumab will be the first antiretroviral treatment with a new mechanism of action to be approved in close to 10 years.”, added Dr. Marsolais.

Additional Study Information

Patients enrolled in the Phase III trial had high pre-existing levels of drug resistance and advanced clinical disease. Patients had a mean HIV-1 viral load of 100,287 copies/mL, with 18% having viral loads above 100,000 copies/mL. The median CD4⁺ T cell count was 73 cells/ μ L and 30% had less than 10 CD4⁺ T cells/ μ L. Close to 90% of patients had more than one identified mutation conferring resistance to the Nucleoside Reverse Transcriptase Inhibitors (NRTI), Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI) or Protease Inhibitors (PI) and more than 60% of patients had resistance to at least one Integrase Inhibitor (INI). Patients enrolled in the trial were infected with HIV-1 resistant to more than 75% of all drugs in the NRTI, NNRTI and PI classes and to 1-2 drugs from the INI class, on average. Finally, just over 50% of patients had HIV-1 with resistance to all available drugs from at least three classes of ART, 35% from 4 ART classes and 15% from all approved ARTs.

A total of 9 patients (23%) discontinued the Phase III trial prior to the completion of the 24 week trial treatment (4 non-drug related deaths, 3 withdrawals, and 2 lost to follow-up). The statistical analysis method used for efficacy, intent-to-treat – missing equals failure (ITT-MEF), represents the most stringent and most conservative data handling convention. The ITT-MEF analysis methodology considers all patients enrolled in the trial and any missing values are treated as failure (or no change) in the analysis of the results.

About TMB-301, ibalizumab Phase III study

TMB-301 was a single arm, 24-week study of ibalizumab plus optimized background regimen (OBR) in treatment-experienced patients infected with multidrug resistant HIV-1. The primary objective of the study was to demonstrate the antiviral activity of ibalizumab seven days after the first dose of ibalizumab. Patients receiving their current failing antiretroviral therapy (ART), or no therapy, were monitored during a seven-day control period. Thereafter, a single loading dose of 2,000 mg of intravenous (IV) ibalizumab was the only ART added to their regimen. The primary efficacy endpoint was the proportion of patients achieving a $\geq 0.5 \log_{10}$ decrease in HIV-1 RNA seven days after initiating ibalizumab therapy, day 14 of the study. Ibalizumab was continued at doses of 800 mg IV every two weeks through 24 weeks on study treatment. A total of 40 patients have been

enrolled in the study. After completion of treatment, patients were offered participation in the expanded access study (TMB-311). Study TMB-311 is also open for US patients with limited options. For more information about TMB-301 (NCT 02475629) and TMB-311 (NCT02707861), please refer to the ClinicalTrials.gov website (www.clinicaltrials.gov).

About Ibalizumab

Ibalizumab is an investigational humanized monoclonal antibody currently being developed for the potential treatment of MDR HIV-1 infection. Unlike other antiretroviral agents, ibalizumab binds primarily to the second extracellular domain of the CD4+ T cell receptor, away from major histocompatibility complex II molecule binding sites. It potentially prevents HIV from infecting CD4+ immune cells while preserving normal immunological function. Ibalizumab is active against HIV-1 resistant to all approved antiretroviral agents. Ibalizumab has been tested in Phase I and II clinical trials and the Phase III trial is the last pivotal clinical study necessary for the completion of a BLA expected to be filed with the FDA.

Ibalizumab has received “Breakthrough Therapy” designation from the FDA. This designation is given if a therapy may provide a substantial improvement over what is currently available to address a serious and life-threatening condition. Ibalizumab also received “Orphan Drug” designation by the FDA.

About Theratechnologies

Theratechnologies (TSX: TH) is a specialty pharmaceutical company addressing unmet medical needs to promote healthy living and an improved quality of life among HIV patients. Further information about Theratechnologies is available on the Company's website at www.theratech.com and on SEDAR at www.sedar.com.

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 belief 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, the completion and filing of a BLA with the FDA for ibalizumab and the approval of ibalizumab as a treatment for patients with MDR HIV-1 infection.

Forward-looking statements are based upon a number of assumptions and 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 information. These assumptions include but are not limited to, the following: all data required to file a BLA with the FDA will be available to support such filing, ibalizumab will be approved by the FDA as a treatment for MDR HIV-1 infection, and, if ibalizumab is approved, Theratechnologies will have set-up on time the necessary infrastructure to launch and commercialize ibalizumab in the United States. These risks and uncertainties include, but are not limited to, the risk that all data required to file a BLA with the FDA are not satisfactory enough to proceed with such filing, that the

FDA does not approve ibalizumab as a treatment for MDR HIV-1 infection, or if approved, impose a significant limitation of its use, that the FDA requires additional clinical trials to be conducted and that Theratechnologies is unable to have all the necessary infrastructure in place to successfully launch and commercialize ibalizumab in the United States.

We refer potential investors to the "Risk Factors" section of our Annual Information Form (AIF) dated February 7, 2017 for additional risks and uncertainties about Theratechnologies. The AIF is available on the Corporation's website at www.theratech.com and on SEDAR at www.sedar.com.

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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