

# Results of HIV Biologic and Long-Acting Investigational Antiretroviral Ibalizumab to be Presented in Late-Breaker Session at IDWeek 2016<sup>TM</sup>

Phase III Study Primary Endpoint Results Show Ibalizumab Significantly Reduced Viral Load in Patients with Multi-Drug Resistant HIV-1

**Montreal, Canada – Oct. 28, 2016** – Theratechnologies Inc. (Theratechnologies) (TSX: TH) announced additional results related to the primary endpoint of the ibalizumab Phase III pivotal study, TMB-301. The initial results were announced on May 24, 2016.

Patients with multi-drug resistant (MDR) HIV-1 experienced a significant decrease in viral load after receiving a loading dose of ibalizumab 2,000 mg intravenously (IV) in addition to their failing antiretroviral therapies (ART) (or no therapy), according to new data from the TMB-301 study to be presented Saturday, October 29, 2016 by Theratechnologies' partner, TaiMed Biologics, in an oral presentation at IDWeek  $2016^{TM}$ . A total of 40 patients were enrolled in the study. Seven days after the loading dose, 83% of patients achieved a  $\geq 0.5 \log_{10}$  decrease from baseline compared with 3% during the seven-day control period. These results were statistically significant (p<0.0001).

During the same period, 60% of patients achieved a decrease of  $\geq$  1.0  $\log_{10}$  (p<0.0001). The average viral load decrease for the total population was 1.1  $\log_{10}$  (p<0.0001). There were no treatment-related serious adverse events or discontinuations reported during the initial seven-day treatment period.

More than 85% of patients had at least 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). Study patients 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, 50% of patients had HIV-1 with resistance to all available drugs from at least three classes of ART.

Since the first HIV-1 infection was identified 35 years ago, the medical community has made strides in developing treatments to manage the disease and keep patients alive longer. While many patients can control the infection with currently approved treatments, some are in dire need of new treatment options because of HIV-1 MDR. As HIV multiplies in the body, the virus sometimes mutates to produce drug-resistant strains. When this occurs, HIV medicines that previously controlled a person's virus may no longer be effective, causing treatment to fail. Taking medication as directed can reduce the risk of drug resistance.

"These results are particularly exciting as ibalizumab, if approved by the FDA, would be the first long-acting biologic to show such efficacy in patients with highly resistant HIV-1," said Dr. Jacob Lalezari, Medical Director, Quest Clinical Research, a division of eStudySite. "The study suggests that when combined with other agents, ibalizumab could help these patients in dire need of new treatments options, and could change the way multi-drug resistant HIV is managed in the future."

Ibalizumab has received "Breakthrough Therapy" designation from the U.S. Food and Drug Administration (FDA). This designation is given if a therapy may provide a substantial improvement over what is currently available to address a serious and lifethreatening condition. Ibalizumab also received "Orphan Drug" designation by the FDA. The current ibalizumab Phase III study is the last pivotal clinical trial required for the submission of the Biologics License Application (BLA). This study was completed on October 24, 2016, and topline results of safety and secondary efficacy endpoints for the 24-week treatment period will be announced in the coming weeks.

"We understand the challenges faced by people living with HIV and are committed to improving their lives," said Luc Tanguay, President and Chief Executive Officer, Theratechnologies Inc. "We are excited about the potential benefits ibalizumab represents in the fight against HIV, and we will continue to work with our partner, TaiMed Biologics, towards the potential launch of ibalizumab in a timely manner."

## About TMB-301, ibalizumab Phase III study

TMB-301 is a single arm, 24-week study of ibalizumab plus optimized background regimen (OBR) in treatment-experienced patients infected with multi-drug resistant HIV-1. The primary objective of the study is 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 loading dose of 2,000 mg of intravenous (IV) ibalizumab was the only ART added to their regimen. The primary efficacy endpoint is the proportion of patients achieving a  $\geq$  0.5 log<sub>10</sub> decrease in HIV-1 RNA seven days after initiating ibalizumab therapy, day 14 of the study. Ibalizumab is 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 are offered participation in the expanded access study (TMB-311). For more information about TMB-301 and TMB-311, please refer to the ClinicalTrials.gov website (www.clinicaltrials.gov).

#### **About ibalizumab**

Ibalizumab is a humanized monoclonal antibody developed for the potential treatment of HIV-1 infection. Unlike other antiretroviral agents, ibalizumab binds primarily to the second extracellular domain of the CD4 receptor, away from Major Histocompatibility Complex II molecule (MHC II) 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 study is the last pivotal clinical study necessary for the completion of the BLA.

#### **About Theratechnologies**

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

## 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 approval of ibalizumab as a treatment for HIV patients, the filing of a BLA with the FDA for ibalizumab, the announcement of topline results of safety and secondary efficacy endpoints for the 24-week treatment period related to the study and the launch of ibalizumab as a drug. 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: no delay will occur in the analysis of the topline results of the safety and secondary efficacy endpoints for the 24-week treatment period of the study, results from the phase III study will allow the filing of a BLA with the FDA, ibalizumab will be approved by the FDA as a treatment for HIV, and, if ibalizumab is approved, Theratechnologies will have set-up on time the necessary infrastructure to launch ibalizumab. These risks and uncertainties include, but are not limited to, the risk that results from the phase III study are not good enough to file a BLA with the FDA, that the FDA does not approve ibalizumab as a treatment for HIV, that the FDA requires additional clinical trials to be conducted and that Theratechnologies is unable to have all the necessary infrastructure set-up to successfully launch ibalizumab, if approved by the FDA. We refer potential investors to the "Risk Factors" section of our Annual Information Form (AIF) dated February 24, 2016 for additional risks and uncertainties about Theratechnologies. The AIF is available 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 forwardlooking 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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