

***Theratechnologies Announces Results from the Last Pivotal Phase III Trial of HIV Long Acting Biologic (LAB) Investigational Antiretroviral Ibalizumab.***

*Ibalizumab Maintains Significant Reduction of Viral Load in Patients with Multi-Drug Resistant HIV-1 Over 24 Weeks.*

*Results from the Study Support the Regulatory Submission of the BLA to the US FDA.*

**Montreal, Canada – November 10, 2016** – Theratechnologies Inc. (Theratechnologies) (TSX: TH) today announced that it has been notified by its partner, TaiMed Biologics, Inc., of the preliminary results for the safety and efficacy secondary endpoints of the 24-week Phase III trial with ibalizumab in patients with multi-drug resistant (MDR) HIV-1 (TMB-301). This Phase III trial confirms the safety and efficacy results of ibalizumab observed in the previously completed Phase IIb study, despite the fact that the patient population in the Phase III trial had higher levels of MDR HIV-1 and more advanced disease at time of enrollment.

In the Phase III trial, after 24 weeks of treatment, the mean reduction in viral load was 1.6 log<sub>10</sub> and a total of 48% of patients had a reduction in viral load of more than 2.0 log<sub>10</sub> during this period. At the end of the treatment period using ibalizumab with optimized background regimen (OBR), the proportion of study participants with undetectable viral load (HIV-1 <50 copies/mL) was 43% (mean viral load reduction of 3.1 log<sub>10</sub>) and 53% of patients had a viral load lower than 400 copies/mL. The mean viral load of patients at baseline was 100,287 copies/mL. As previously announced, the preliminary results also indicated that 83% of patients enrolled in the Phase III trial (33/40, p<0.0001) have met the primary endpoint of a decrease of ≥ 0.5 log<sub>10</sub> in viral load following a 7-day treatment period with ibalizumab.

The safety results in this Phase III trial are consistent with the ones previously observed in the Phase IIb study. 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 antiretroviral therapy (ART), no serious adverse events (SAEs) 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.

“The results of the Phase III trial of ibalizumab in MDR HIV-1 patients are particularly exciting, they confirm what we had previously observed with ibalizumab, but in a patient population with higher antiretroviral drug resistance and more advanced disease.” said Dr. Jacob Lalezari, Medical Director, Quest Clinical Research, a division of eStudySite. “If approved by the FDA, ibalizumab would be the first long-acting and the first biologic product to show such efficacy in patients with highly resistant HIV-1,” added Dr. Lalezari.

“We are very pleased with the safety and efficacy results observed in the Phase III trial,” said Christian Marsolais, Ph.D., Senior Vice President and Chief Medical Officer, Theratechnologies Inc. “These results support the submission of the Biologics License Application (BLA) to the US FDA and the next step is the completion of the regulatory submission by our partner TaiMed Biologics, Inc.,” 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 count was 73 cells/mm<sup>3</sup> and nearly 30% had less than 10 CD4 cells/mm<sup>3</sup>. More than 85% 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). 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, just over 50% of patients had HIV-1 with resistance to all available drugs from at least three classes of ART.

A total of 9 patients (23%) discontinued the Phase III trial prior to the completion of the 24 week study treatment (4 non-drug related deaths, 3 withdrawals, and 2 lost to follow-up). The statistical analyses 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 study 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 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  $\geq 0.5 \log_{10}$  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](http://www.clinicaltrials.gov)).

## **About Ibalizumab**

Ibalizumab is a humanized monoclonal antibody being 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 virus 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 a Biologics License Application (BLA) to be filed with the United States Food and Drug Administration (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](http://www.theratech.com) and on SEDAR at [www.sedar.com](http://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 HIV patients.

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 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 the other 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 HIV, 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 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 the Corporation's website at [www.theratech.com](http://www.theratech.com) and on SEDAR at [www.sedar.com](http://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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