

***Theratechnologies Partner Submits Biologics License Application for HIV Monoclonal Antibody and Long-Acting Investigational Antiretroviral Ibalizumab***

*Potential New Treatment Option for People Living with Multidrug Resistant HIV-1*

**Montreal, Canada – May 3, 2017** – Theratechnologies Inc. (Theratechnologies) (TSX: TH) today announced that its partner, TaiMed Biologics, Inc., has completed the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for ibalizumab for the treatment of multidrug resistant Human Immunodeficiency Virus-1 (MDR HIV-1). If approved, ibalizumab will be the first antiretroviral treatment (ART) with a new mechanism of action to be introduced in nearly 10 years and the only treatment that does not require daily dosing. As ibalizumab has received the Breakthrough Therapy and Orphan Drug Designations, TaiMed has requested Priority Review for the application.

The ibalizumab BLA is based on data from the phase III TMB-301 study, a single arm, 24-week study of ibalizumab plus an optimized background regimen (OBR) in treatment-experienced patients infected with MDR HIV-1. Full results from the trial were recently presented at the Conference on Retroviruses and Opportunistic Infections (CROI) 2017.

“The BLA submission is an important milestone for patients, physicians and everyone who has worked tirelessly to bring this much-needed medicine to people living with MDR HIV-1,” said Luc Tanguay, President and Chief Executive Officer, Theratechnologies Inc. “This is a significant step toward the expansion of our product portfolio, which reinforces our mission to improve the lives of people living with HIV,” added Mr. Tanguay.

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. Approximately 20,000 to 25,000 Americans with HIV-1 are currently resistant to at least one drug in three different classes of antiretroviral therapies, and up to 12,000 of these patients experience a virological failure over a period of 48 weeks of treatment, requiring their physician to modify their treatment.

“While some people can suppress their viral loads with currently-approved treatments, there is an urgent need for new options among those with multidrug resistance,” said Christian Marsolais, Ph.D., Senior Vice President and Chief Medical Officer, Theratechnologies Inc.

“We understand that some people living with HIV-1 have special needs, and we will continue to bring solutions to help them live healthier lives,” concluded Mr. Tanguay.

**About ibalizumab**

Ibalizumab is an investigational humanized monoclonal antibody being developed for the 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 received “Breakthrough Therapy” designation from the FDA, which is given if a therapy may provide a substantial improvement over what is currently available to address a serious and life-threatening condition. The FDA also granted “Orphan Drug” designation.

### **About TMB-301, ibalizumab Phase III study**

TMB-301 was a single arm, 24-week study of ibalizumab plus optimized background regimen (OBR) in 40 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<sub>10</sub> 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. After completion of treatment, patients were offered participation in the expanded access study (TMB-311). Study TMB-311 is also open for U.S. 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](http://www.clinicaltrials.gov)) or visit [ibalizumab-eap.com](http://ibalizumab-eap.com).

### **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 approval of ibalizumab for the treatment of MDR HIV-1 infected patients, the growth of Theratechnologies based on such approval and the sales of ibalizumab in the United States, the number of patients currently resistant to at least one drug in three different classes of antiretroviral therapies and the number of patients who will experience a virological failure over a period of 48 weeks of treatment.

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: the BLA submission will be accepted for review by the FDA, all data obtained from the conduct of the Phase I, II and III clinical trials will be sufficient to demonstrate the safety and efficacy of ibalizumab and no other clinical trial will need to be conducted, ibalizumab will be approved by the FDA for the treatment of MDR HIV-1 infected patients and, if 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 the data obtained so far from the Phase I, II and III clinical trials do not allow the FDA to approve ibalizumab, that the number of patients resistant to at least one drug in three different classes of antiretroviral therapies and the number of patients who will experience a virological failure over a period of 48 weeks of treatment be lower than disclosed herein, that additional studies need to be conducted prior to the FDA approving ibalizumab, that the FDA does not approve ibalizumab as a treatment for MDR HIV-1 infection and, if approved, that the FDA imposes a significant limitation on its use resulting in a smaller patient population who could benefit from ibalizumab.

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](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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