Theratechnologies Announces 48-Week Efficacy and Safety Results for Ibalizumab Presented at IDWeek 2017™

HIV Monoclonal Antibody and Long-Acting Investigational Antiretroviral Ibalizumab with Optimized Background Regimen Maintained High Viral Suppression and was Well Tolerated Through Week 48 in Patients with Multidrug Resistant HIV

Montreal, Canada – October 4, 2017 – Theratechnologies Inc. (Theratechnologies) (TSX: TH) today announced 48-week efficacy and safety results for ibalizumab in patients infected with multidrug resistant HIV-1 who completed the 24-week Phase III study (TMB-301) and continued treatment in the Expanded Access Program study (TMB-311). These data are being presented in an oral presentation at IDWeek 2017™ in San Diego (abstract #1686).

Of the 27 patients who completed the 24-week treatment period of TMB-301 in the U.S., all entered TMB-311, where patients continued to receive ibalizumab at 800 mg every 2 weeks for up to 48 weeks. The virologic suppression observed at week 24 was sustained through week 48; median viral load reduction from baseline was 2.5log10 at weeks 24 and 48. In TMB-311, all 15 patients with an undetectable viral load at week 24 maintained suppression to week 48. Another patient in TMB-311 reached less than 50 copies/mL at week 48 after having a detectable viral load at week 24. A total of 17 patients (63%) achieved a viral load less than 200 copies/mL.

“As we await an FDA decision for ibalizumab, this long-term data reinforces the critical role ibalizumab could have for patients struggling with multidrug resistant HIV,” said Luc Tanguay, President and Chief Executive Officer, Theratechnologies Inc. “With the dramatic progress made over the past two decades in treating HIV, the crucial need for new treatments for these very vulnerable patients is often overlooked. At Theratechnologies, focusing on these unmet needs is what we are committed to doing, and ibalizumab is a prime example of that. We thank both the patients and investigators for participating in this important study.”

In TMB-311, ibalizumab plus optimized background regimen (OBR) was well tolerated; of the 27 patients in the study, 24 (89%) continued to receive treatment until week 48 and 3 patients discontinued early due to non ibalizumab-related reasons. No new or unexpected safety concerns emerged between weeks 24 and 48. The most common adverse reactions were diarrhea, dizziness, nausea and rash.

“The participants enrolled in the Phase III study were highly treatment experienced with limited antiretroviral options due to drug resistance. As clinicians treating these patients, having access to an agent with a novel mechanism of action was critical,” said Dr. Brinda Emu, Assistant Professor of Medicine, Infectious Diseases, Yale School of Medicine, New Haven, CT. “Seeing sustained virologic response out to 48 weeks is heartening and emphasizes the potential benefit that ibalizumab may bring to HIV patients in need of new treatment options.”

About Study TMB-311
Of the 27 patients who completed the 24-week treatment period in TMB-301 in the U.S., 27 entered TMB-311, the ibalizumab Expanded Access Program, where patients continued to receive ibalizumab at 800 mg every 2 weeks for up to 48 weeks. Additionally, 59% and 33% of the patients in the study had exhausted at least three or four antiretroviral (ARV) classes, respectively, and 15% had HIV-1 resistant to all approved ARVs.

The Expanded Access Program is ongoing and enrolling patients. For more information about TMB-311 (NCT02707861), please refer to the ClinicalTrials.gov website (www.clinicaltrials.gov) or the study website (www.ibalizumab-eap.com).

TMB-301 was a 24-week open-label study investigating the efficacy and safety of ibalizumab plus OBR in highly treatment experienced patients with multidrug resistant HIV.

About ibalizumab

Ibalizumab is an investigational humanized monoclonal antibody being developed for the treatment of multidrug resistant 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 T cells while preserving normal immunological function.

Ibalizumab is currently under accelerated review by the FDA following the acceptance of a Biologics License Application on June 30, 2017. The FDA target action date to complete the review of ibalizumab is January 3, 2018.

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 approval of ibalizumab as a treatment for HIV patients and the benefits of using 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: the FDA will approve ibalizumab, patients and physicians will accept ibalizumab as a treatment for HIV-infected patients (if approved), treatment with
ibalizumab will have the same effects as those observed during the clinical trials and the Company will have set-up on time the necessary infrastructure to launch ibalizumab as a drug (if and when approved). These risks and uncertainties include, but are not limited to, the risk that the FDA does not approve ibalizumab for commercialization, that the effect of a treatment using ibalizumab (if approved) will differ from those observed during the clinical trials and that the Company is unable to set-up its infrastructure on time to successfully launch ibalizumab (if and when approved by the FDA).

We refer potential investors to the “Risk Factors” section of our Annual Information Form dated February 7, 2017 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 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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