

FDA Grants Priority Review to HIV Monoclonal Antibody and Long-Acting Investigational Antiretroviral Ibalizumab

Biologics License Application (BLA) Accepted for Review with a Target Action Date of January 3, 2018

Ibalizumab Expanded Access Program (EAP) Currently Enrolling New Patients

Montreal, Canada – June 30, 2017 – Theratechnologies Inc. (Theratechnologies) (TSX: TH) today announced that it has been notified by its partner, TaiMed Biologics, Inc., that the U.S. Food and Drug Administration (FDA) has accepted for review the Biologics License Application (BLA) for ibalizumab as a treatment for 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.

"We are excited to be one step closer to potentially bringing an important new treatment, with a new mechanism of action, to patients whose virus has become resistant to therapies in multiple classes and have limited treatment options for the long-term management of their condition," said Luc Tanguay, President and Chief Executive Officer, Theratechnologies Inc. "The granting of Priority Review status is important since it confirms that, if approved, ibalizumab would represent a significant improvement in the treatment of this serious condition," added Mr. Tanguay.

The FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of January 3, 2018, for the ibalizumab application. Priority Review status accelerates FDA review time from 10 months to a goal of six months from the day of acceptance. In addition, ibalizumab received Breakthrough Therapy designation from the FDA in 2015, 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 in 2014.

The BLA, submitted on May 3, 2017, 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 who had high pre-existing levels of drug resistance and advanced clinical disease.

The ibalizumab Expanded Access Program (EAP), or study TMB-311, 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).

As HIV multiplies in the body, the virus may mutate to produce drug-resistant strains. Viral mutations may mean that HIV medicines that previously controlled a person's virus are no longer effective, causing treatment to fail. There are approximately 20,000 to 25,000 Americans with HIV-1 that are resistant to at least one drug out of the three different classes of antiretroviral therapies. 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.

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.

About Theratechnologies

Theratechnologies (TSX: TH) is a specialty pharmaceutical company addressing unmet medical needs to promote healthy ageing 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 statements that are considered forward-looking information ("FLI") within the meaning of 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 in the United States for the treatment of MDR HIV-1 infected patients, the target action date based on PDUFA, the approximate number of HIV Americans resistant to at least one drug out of three classes of antiretroviral therapies, the number of patients experiencing a virological failure and the growth of Theratechnologies based on such approval.

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: 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, the target action date is accurate, the data obtained on the number of HIV Americans resistant to at least one drug out of three classes of antiretroviral therapies and the number of patients experiencing a virological failure are accurate and ibalizumab, if approved, will be well received by the marketplace. These risks and uncertainties include, but are not limited to, the risk 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, our data regarding the number of HIV Americans resistant to at least one drug out of three classes of antiretroviral therapies and the number of patients experiencing a virological failure are not accurate which could result in a smaller market for 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 Company’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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