Theratechnologies Announces Decision by the FDA to Extend the Ibalizumab Review Period to April 3, 2018

Montreal, Canada – November 13, 2017 – Theratechnologies Inc. (Theratechnologies) (TSX: TH) announced that it was notified today by its partner, TaiMed Biologics, Inc. (“TaiMed”), that the U.S. Food and Drug Administration (FDA) will extend its review of the Biologics License Application (“BLA”) for ibalizumab. In a notice received today by TaiMed from the FDA, the Prescription Drug User Fee Act (“PDUFA”) target action date has been extended to April 3, 2018. The three-month extension period is the FDA’s standard extension period.

On October 25, 2017, at the FDA’s request, TaiMed submitted additional documentation related to the manufacturing section of the BLA, and the FDA subsequently decided it constituted a major amendment that required an extension to the target action date, to provide time for a full review of the submission. The FDA did not request any additional information from TaiMed in this notice.

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 priority review by the FDA following the acceptance of a BLA on June 30, 2017. The FDA target action date to complete the review of ibalizumab is April 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 timing of the target action date.
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 not change the target action date, the FDA will meet the announced target action date and the FDA will approve ibalizumab as a treatment for HIV-infected patients. These risks and uncertainties include, but are not limited to, the risk that the FDA does not meet the announced target action date and/or does not approve ibalizumab for commercialization.

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](http://www.sedar.com) for additional risks and uncertainties about Theratechnologies and its business. 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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