

# Theratechnologies and TaiMed Biologics sign exclusive Marketing and Distribution Agreement for Ibalizumab

MONTRÉAL, Québec - March 18, 2016 – Theratechnologies inc. (TSX: TH) and TaiMed Biologics, Inc. today announced a 12-year collaboration agreement to market and distribute ibalizumab in the United States and in Canada. Ibalizumab is a novel CD4-directed HIV entry-inhibitor and is the first humanized monoclonal antibody in clinical trials for the treatment of HIV.

Ibalizumab is currently in a late-stage Phase III clinical trial, the last step before submitting the product for regulatory approval to the Food and Drug Administration in the United States ("FDA"). Over two-thirds of patients required for the open-label, 24-week trial have been enrolled. Patient screening for this study is anticipated to close later this month. The objective of this study is to reduce viral replication in patients with multi-drug resistant HIV infection. The primary endpoint of the Phase III trial is the proportion of patients achieving a 0.5 log<sub>10</sub> decrease in viral load 7 days after initiating treatment.

Once the Phase III trial is completed, ibalizumab will be evaluated under the FDA's priority review process which is expected to be completed within six months of the application or during the first half of 2017.

Ibalizumab was designated a "Breakthrough Therapy" by the FDA based on preliminary clinical evidence indicating that it may represent a substantial improvement over existing therapies on one or more clinically significant endpoints. In a Phase IIb clinical trial, conducted on 113 patients, the product significantly reduced viral load in multi-drug resistant HIV-infected patients.

The US FDA has also granted ibalizumab Orphan Drug designation. This status is given to drugs and biologics that are intended for the safe and effective treatment of rare diseases/disorders that affect fewer than 200,000 persons.

Under the *Biologics Price Competition and Innovation Act of 2009,* ibalizumab will be granted 12 years of marketing exclusivity.

Ibalizumab is currently administered as a bi-monthly (once every two weeks) intravenous injection. TaiMed is conducting clinical trials with the same formulation for bi-monthly intramuscular injection (IM) and monthly IM administration. Theratechnologies has also secured exclusive rights to market and distribute the drug for the IM route of administration.

"Ibalizumab represents a perfect fit for our organization. It is a niche, breakthrough treatment for multi-drug resistant HIV patients. These individuals are followed by the

same physicians that treat patients suffering from HIV-associated lipodystrophy. Ibalizumab fits very well within our existing commercial infrastructure, as we can leverage our salesforce, our Medical Science Liaison team as well as our Managed Markets group and call center. This is the type of products we want to add to our portfolio as they hold the potential to generate additional revenues while keeping focused on our core business," said Luc Tanguay, President and CEO, Theratechnologies inc.

"Partnering with Theratechnologies for the commercialization of ibalizumab makes perfect sense. They bring experience and knowledge of the world's largest market for our product. On our side, we will stay focused on our R&D expertise and further develop ibalizumab. We have made a transaction which will allow us to rapidly bring our product to market and to generate revenues for our company," said James Chang, Chief Executive Officer, TaiMed Biologics, Inc.

## Transaction terms

The terms of the transaction include a US\$2 million payment obligation, of which US\$1 million was paid in cash at the signature of the agreement and US\$1million will be paid at the commercial launch through the issuance of 957,169 common shares of Theratechnologies.

A further US\$8.5 million will become due at commercial launch, subject to certain conditions. This amount will be payable as follows: US\$2 million in common shares of Theratechnologies at a price to be determined upon FDA approval and US\$1 million in common shares of Theratechnologies at a price to be determined upon commercial launch, based on the volume-weighted average trading price of Theratechnologies' common shares on the TSX prior to each of these dates and US\$5.5 million, payable in quarterly installments based on a predetermined percentage of net sales during that quarter.

Once sales have reached an aggregate amount of US\$20 million over 4 consecutive quarters, Theratechnologies will make a US\$7 million milestone payment (payable in two installments over one year). Theratechnologies will also pay additional sales related milestones; US\$10 million once annual sales of ibalizumab reach US\$200 million, US\$40 million once annual sales reach US\$500 million, and US\$100 million once annual sales reach US\$500 million, and US\$100 million once annual sales reach US\$500 million.

Theratechnologies will also pay development milestones to TaiMed. A US\$3 million milestone is due upon the approval of the twice-monthly (once every two weeks) intramuscular route of administration, again payable in two installments over one year. TaiMed will also be planning a larger Phase III trial with the once-monthly (once every four weeks) intramuscular or subcutaneous route of administration, to address a much broader patient population. This development milestone will consist of an upfront milestone payment of up to US\$50 million, depending on the size of the newly targeted

population, which will be paid quarterly, based on a percentage of net sales generated by the product.

Pursuant to the terms of the agreement, Theratechnologies has exclusive rights to commercialize ibalizumab in the United States and in Canada. TaiMed will continue to be responsible for development of ibalizumab and seek approval from the FDA whereas Theratechnologies will be responsible to obtain the approval from Health Canada. TaiMed will manufacture and supply ibalizumab to Theratechnologies at a transfer price of 52% of net sales of the product.

## **Conference Call, Webcast and Slide Presentation Details**

A conference call will be held today at 8:00 a.m. (ET) to discuss the transaction. The call will be hosted by Luc Tanguay, President and Chief Executive Officer. The conference call will be open to questions from financial analysts. Media and other interested individuals are invited to participate in the call on a "listen-only" basis.

The conference call can be accessed by dialing 1-877-223-4471 (North America) or 1-647-788-4922 (International). The conference call will also be accessible via webcast and will be supported by a slide presentation at http://www.gowebcasting.com/7368.

Audio replay of the conference call will be available two hours after the call's completion until April 1, 2016, by dialing 1-800-585-8367 (North America) or 1-416-621-4642 (International) and by entering the playback code 67672037.

### About Theratechnologies

Theratechnologies (TSX: TH) is a specialty pharmaceutical company addressing unmet medical needs in metabolic disorders to promote healthy ageing and an improved quality of life. Further information about Theratechnologies is available on the Company's website at <u>www.theratech.com</u> and on SEDAR at www.sedar.com

## **About TaiMed Biologics**

TaiMed Biologics, Inc. is a publicly held Taiwanese biotechnology company with the mission to discover, develop and deliver for the global market innovative medicines that help patients prevail over serious infectious diseases. For more information, please visit the company's website at www.taimedbiologics.com.

### **Forward-Looking Information**

This press release contains forward-looking statements and forward-looking information, or, collectively, forward-looking statements, 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, statements regarding the approval of ibalizumab, the timelines related to the review of the application by the FDA and the revenue growth to Theratechnologies generated by the commercialization of ibalizumab.

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; the timelines disclosed in this press release to obtain the issuance of a decision from the FDA is accurate; if, and once approved, ibalizumab will be accepted by physicians and patients as a new treatment; and revenues generated from the sale of ibalizumab will grow our business and create shareholders value.

These risks and uncertainties include, but are not limited to, the risk that the Phase III trial does not generate positive data resulting in halting the development of ibalizumab or having to begin new clinical trials; the FDA does not approve ibalizumab; delays occur in completing the Phase III trial, the filing of the BLA, the issuance of the decision by the FDA and/or the commercial launch of ibalizumab; if approved, physicians and patients do not accept ibalizumab as a new treatment and, if and when approved, sales of ibalizumab do not allow us to generate enough revenues to significantly grow our business.

We refer potential investors to the "Risk Factors" section of our Annual Information Form dated February 24, 2016 available at www.sedar.com for additional risks regarding the Company and its operation. The reader is cautioned to consider these and other risks and uncertainties carefully and not to put undue reliance on forwardlooking 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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