

### THERATECHNOLOGIES ANNOUNCES NEW DATA DEMONSTRATING TESAMORELIN'S POSITIVE EFFECT ON IMMUNE RESPONSE LINKED TO LIVER INFLAMMATION

# Data presented at ENDO 2021

**Montreal, Canada – March 20, 2021 –** Theratechnologies Inc. (Theratechnologies) (TSX: TH) (NASDAQ: THTX), a biopharmaceutical company focused on the development and commercialization of innovative therapies, is pleased to announce that new data, demonstrating the positive effect of tesamorelin on the circulation of immune activation markers associated with liver inflammation, was presented today at The Endocrine Society's annual meeting, ENDO 2021.

Dr. Takara L. Stanley, Assistant Professor of Pediatrics, Harvard Medical School, Assistant Pediatrician, Massachusetts General Hospital and Program Director, Pediatric Endocrine Fellowship Program, MGHfC, authored the poster presented at ENDO 2021.

The data comes from a sub-analysis of a double-blind, randomized, 12-month investigator-initiated trial studying the effect of tesamorelin on liver fat in 61 people infected with HIV with nonalcoholic fatty liver disease (NAFLD) which was conducted by Dr. Steven Grinspoon, Professor of Medicine, Harvard Medical School, Chief of the Metabolism Unit at Massachusetts General Hospital. Dr. Grinspoon's findings were published in The Lancet HIV in October 2019.

The sub-analysis concludes that treatment with tesamorelin for 12 months decreased circulating markers of T-cell and monocyte/macrophage activity. A corresponding downregulation of immune pathways in the liver was also observed. These conclusions suggest that treatment with tesamorelin may contribute to better regulated immune activation in a population with metabolic dysregulation and systemic inflammation.

"The data presented at ENDO 2021 highlights tesamorelin's unique mechanism of action that addresses the underlying cause of liver disease and further supports the Phase 3 development of this novel medicine for the potential treatment of NASH," said Dr. Christian Marsolais, Senior Vice President and Chief Medical Officer at Theratechnologies.

The presentation abstract is available at: <u>https://www.abstractsonline.com/pp8/#!/9188/presentation/2240</u>

## Phase 3 clinical trial

The proposed Phase 3 clinical trial design will enroll participants with liver-biopsy confirmed NASH and stage 2 or 3 fibrosis. Participants will be randomized 1:1 to receive 2 mg of tesamorelin or placebo. A second liver biopsy will be performed after 18 months of treatment for the first 900 participants, approximately. These data will form the basis for filing an sBLA with the U.S. Food and Drug Administration (FDA) to seek accelerated approval. The primary endpoint used to seek accelerated approval will be the percentage of participants achieving NASH resolution and no worsening of fibrosis

compared to placebo. Participants will remain in the Phase 3 trial for a total of 60 months. Subject to additional discussions with regulatory agencies, approximately 2,000 participants in total are expected to be enrolled, including a cohort of approximately 75 to 100 participants with HIV.

In late December 2020, the Company received a "Study May Proceed" letter for the Phase 3 trial from the FDA with a recommendation that the Company requests a meeting to discuss questions and comments provided on certain aspects of the proposed trial design. The Company has formally requested a meeting with the FDA to ensure alignment with current regulatory expectations for the late-stage development of treatments for NASH. The Company is assessing its strategy regarding a filing with the EMA to initiate a Phase 3 clinical trial of tesamorelin for the treatment of NASH in the European Union.

The Company plans to initiate the Phase 3 clinical trial by the end of the third quarter of calendar year 2021. The timing of the trial initiation and the final number of patients enrolled are dependent upon any adjustments to the protocol and trial design as recommended by the FDA and EMA. The Company has retained the services of a global, large-scale contract research organization, or CRO, with experience in implementing large and late-stage clinical trials to assist with the execution of its Phase 3 clinical trial in NASH.

#### About NAFLD /NASH

According to the National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health, experts estimate that 20 percent of Americans with NAFLD have NASH. It is believed that 3 to 12 percent of adult Americans have NASH.<sup>1</sup>

NAFLD is an umbrella term for a spectrum of liver conditions that begin with a build-up of hepatic fat, which can set the stage for inflammation that may promote scarring known as fibrosis. Over time, fibrosis can progress to potentially fatal cirrhosis and even a form of liver cancer called hepatocellular carcinoma.

Usually, NAFLD and NASH are silent diseases with few or no symptoms. A patient may not show symptoms even if they develop cirrhosis due to NASH.

There is currently no approved treatment for NAFLD and NASH in the North America and Europe.

#### About Theratechnologies

Theratechnologies (TSX: TH) (NASDAQ: THTX) is a biopharmaceutical company focused on the development and commercialization of innovative therapies addressing unmet medical needs. Further information about Theratechnologies is available on the Company's website at www.theratech.com, on SEDAR at <u>www.sedar.com</u> and on EDGAR at <u>www.sec.gov</u>.

<sup>&</sup>lt;sup>1</sup> <u>https://www.niddk.nih.gov/health-information/liver-disease/nafld-nash/definition-</u>

facts#:~:text=Experts%20estimate%20that%20about%2020%20percent%20of%20people%20with%20NAFLD%20hav e%20NASH.&text=Between%2030%20and%2040%20percent,the%20United%20States%20have%20NASH.

### 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 beliefs 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 development of tesamorelin for the treatment of NASH, the timelines related to the beginning of the Phase 3 clinical trial the enrollment of patients and the study duration, as well statements regarding the number of U.S. patients suffering from NASH.

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: tesamorelin will be shown as a safe and effective drug for the treatment of NASH in the general population, tesamorelin data and results monitored to date will continue to be observed in the Phase 3 trial, the various timelines set forth in this press release will be met, the Phase 3 study protocol will be approved by both the FDA and the European regulatory agencies, we will succeed in enrolling a sufficient number of patients to conduct the Phase 3 trial and we will have enough funds to conduct the Phase 3 development of tesamorelin in the general population suffering from NASH and to execute on our business plan.

The risks and uncertainties include, among others, the risk that tesamorelin does not prove to be a safe and effective drug for the treatment of NASH, that we do not meet the endpoints of the Phase 3 trial, that we are unable to enroll a sufficient number of patients to show clinical benefits from the use of tesamorelin, that unknown side effects of tesamorelin are discovered, that our intellectual property is challenged and held to be invalid or infringing upon third parties' intellectual property, that we do not have enough funds to finance the Phase 3 trial and our business plan, that competing drugs are or may become available and more successful, that performance of third-party suppliers and manufacturers we are relying on may be deficient, that expenses, revenues and capital requirements vary from our estimates, that conditions may be imposed by regulatory authorities on the marketing approvals of our products, that we are unable to adequately service the markets for our products, and that there is a poor rate and degree of market acceptance of our products.

We refer potential investors to the "Risk Factors" section of our annual information form dated February 24, 2021 and to our Form 40-F dated February 25, 2021 filed on EDGAR for additional risks regarding the conduct of our business and Theratechnologies. 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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