News Release

THERATECHNOLOGIES TO DEVELOP TESAMORELIN FOR THE TREATMENT OF NASH IN THE GENERAL POPULATION

Phase 3 protocol to be filed in Q4 2020; trial expected to begin early 2021

Clinical study to include HIV cohort

Montreal, Canada – September 10, 2020 – Theratechnologies Inc. (Theratechnologies) (TSX: TH) (NASDAQ: THTX), a biopharmaceutical company focused on the development and commercialization of innovative therapies, is pleased to announce that it plans to pursue Phase 3 clinical development of tesamorelin for the treatment of Non-Alcoholic Steatohepatitis (NASH) in the general population.

"After careful review of our file and discussions with our scientific advisers, we made the decision to pursue the Phase 3 development of tesamorelin for the treatment of NASH in the general population," said Mr. Paul Lévesque, President and Chief Executive Officer, Theratechnologies.

"From 10 years of real-life experience, the safety profile of tesamorelin in HIV patients with lipodystrophy is well established. Based on current scientific evidence showing a reduction in liver fat and delayed progression of liver fibrosis in patients with HIV infection and NAFLD or NASH, combined with robust intellectual property, a new investigational formulation and the development of a multi-dose pen injector, we believe that we have a potential best-in-class candidate for the treatment of NASH in the general population," added Mr. Lévesque.

It was recently published in JCI Insight, a peer-reviewed medical journal, that in HIV-associated NAFLD/NASH, tesamorelin has a positive effect on gene expression related to oxidative phosphorylation, decreased gene expression related to inflammation, tissue repair and cell division while improving gene expression associated with favorable hepatocellular carcinoma (HCC) prognosis. Based on its unique mode of action, tesamorelin is designed to work upstream to reduce the accumulation of liver fat, which can lead to NASH.

"Given that tesamorelin improves critical mechanistic NASH pathways common to both the general population and in people living with HIV, we believe tesamorelin could bring favorable results in both patient populations," said Dr. Steven Grinspoon, Professor of Medicine, Harvard Medical School, Chief of the Metabolism Unit at Massachusetts General Hospital and study Principal Investigator.

“NASH is a silent killer that affects a growing number of people each year worldwide. There is a dire need for safe and effective treatments for NASH as patients and physicians currently do not have access to any approved drugs. Given its clinical history, recent positive data in patients with HIV-associated NAFLD and its mode of action, we believe tesamorelin has the potential to reverse NASH and NASH related fibrosis in the Phase 3 trial for the management of this serious and deadly condition,” said Dr. Rohit Loomba, Professor of Medicine (with tenure) in the Division of Gastroenterology, and Adjunct Professor in the Division of Epidemiology at the University of California, San Diego.

Phase 3 clinical trial

Theratechnologies intends to submit its Phase 3 study protocol to the United States Food and Drug Administration (FDA) and the European regulatory agencies in the coming weeks. Subject to feedback from the regulatory agencies, the trial would involve approximately 650 patients with fibrosis scores of 2 and 3 and with a NAS score of at least 4 and also include a cohort of 50 people living with HIV. The enrollment of patients is planned for the first quarter of 2021. Patients will be treated for a period of 18 months. As per published regulatory guidelines, the primary endpoints will assess NAS score normalisation and absence of worsening of fibrosis stage, or fibrosis improvement ≥ 1 stage and no worsening of NAS.

Theratechnologies intends to use a new investigational formulation of tesamorelin, known as “F8”, for the Phase 3 trial in NASH. In addition, a supplemental Biologics License Application (sBLA) is expected to be filed with the FDA in early 2022 in HIV-associated lipodystrophy using a convenient, multi-dose pen injector currently being developed for this new formulation.

The F8 is patent protected in the U.S. until 2033 and until 2034 in major European countries.

Furthermore, a notice of allowance was issued by the United States Patent and Trademark Office on a pending US patent application filed by the Massachusetts General Hospital (MGH) in March 2020 relating to the treatment of hepatic disease using GHRH or analogues thereof. This patent application claims, amongst other things, a method for the treatment of NAFLD or NASH in a patient via the administration of tesamorelin. Theratechnologies has an exclusive license with the MGH to this patent application.

Theratechnologies continues to explore the filing of additional patent applications in the NAFLD/NASH field.

Investigator-initiated study results published in The Lancet HIV

On October 11, 2019, results from an investigator-initiated randomized, double-blind, multicenter study assessing the effect of tesamorelin on liver fat and histology in people living with HIV with NAFLD/NASH were published in The Lancet HIV. This publication followed prior data published in the Journal of Clinical Endocrinology and Metabolism showing that tesamorelin also significantly reduced ectopic adipose tissue in non-HIV patients.

At baseline, liver biopsies revealed that 43% of patients had liver fibrosis and 33% had NASH. A total of 61 patients received 2mg of tesamorelin daily or an identical placebo for a period of 12 months. The primary endpoint of the study was a change in hepatic fat fraction. After 12 months of treatment, liver fat in patients on tesamorelin had decreased by 32% while it had increased by 5% in placebo patients, from baseline, (p=0.02), amounting to a 37% relative reduction in liver fat. Furthermore, 35% of patients in the tesamorelin group returned to liver fat values below 5% in comparison to only 4% of patients on placebo (p=0.007). The study concluded that only 10.5% of patients in the tesamorelin group experienced progression of liver fibrosis compared to 37.5% in patients receiving a placebo (p=0.04). Exploratory analyses showed that the higher the baseline NASH score was, the more change was seen among the tesamorelin-treated individuals (r=-0.48, P=0.04), whereas a similar relationship was not observed in the placebo group (r=-0.14, P=0.52). The safety profile of tesamorelin in this study was comparable to that observed in HIV patients with lipodystrophy.

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.[1]

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.

[1] https://www.niddk.nih.gov/health-information/liver-disease/nafld-nash/definition-facts#:~:text=Experts%20estimate%20that%20about%2020%20percent%20of%20people%20with%20NAFLD%20have%20NASH.&text=Between%2030%20and%2040%20percent,the%20United%20States%20have%20NASH.

Conference Call Details

A conference call and webcast will be held on September 10, 2020 at 8:30 a.m. (ET) to discuss the announcement. The call will be hosted by Paul Lévesque, President and Chief Executive Officer of Theratechnologies, and will include Christian Marsolais, Senior Vice President and Chief Medical Officer, Dr. Steven Grinspoon and Dr. Rohit Loomba. A question and answer period, open exclusively to financial analysts, will follow their presentation. Investors and members of the media may participate on a listen-only basis.

To access the call, please dial 1-877-223-4471 (North America) or 1-647-788-4922 (International). The conference call will also be webcast live at https://onlinexperiences.com/Launch/QReg/ShowUUID=38B2592A-4FD1-441C-B11F-A65C5AE94FDC . An audio replay of the conference call will be available, as of 12:00 (EST) September 10, 2020 and until 23:59 (EST) October 10, 2020, by dialing 1-800-585-8367 (North America) or 1-416-621-4642 (International) and by entering the playback code 6228838.

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 www.sedar.com and on EDGAR at www.sec.gov.

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 filing of a Phase 3 study protocol, a sBLA for the F8 formulation with regulatory agencies, the enrollment of patients and the study duration, as well statements regarding the development of a multi-dose pen using a new formulation of tesamorelin, expectations about the common effect of tesamorelin on both the general population and in people living with HIV and expectations about the potential of tesamorelin on the reversal of NASH and NASH related fibrosis in the Phase 3 trial.

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, the F8 formulation will be approved for use by the FDA for the treatment of lipodystrophy and by the FDA and the EMA in connection with the Phase 3 trial, we will succeed in enrolling a sufficient number of patients to conduct the Phase 3 trial, the development of the multi-dose injection pen will be successful, 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 the FDA and European regulatory agencies do not allow us to proceed with a Phase 3 trial without conducting a Phase 2b or earlier study in the general NASH population, 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 the development of a multi-dose pen is not successful, that the F8 formulation is not approved by the FDA for use in lipodystrophy or by the FDA and the EMA in connection with the Phase 3 trial, that we are unable 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 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 for our products, that we are unable to adequately service the markets for our products, and 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, 2020 and to our Form 40-F dated February 25, 2020 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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