

## VISCERAL FAT IS A PREDICTOR OF LIVER FIBROSIS AND FIBROSIS PROGRESSION IN PEOPLE LIVING WITH HIV

- New sub-analysis of MGH Study presented at CROI 2020 -

**Montreal, Canada – March 11, 2020** – Theratechnologies Inc. (Theratechnologies) (TSX: TH) (NASDAQ: THTX), a commercial-stage biopharmaceutical company, is pleased to announce that Dr. Lindsay Fourman, from Harvard Medical School, presented data demonstrating that visceral fat is a clinical predictor of liver fibrosis and liver fibrosis progression in an oral presentation during CROI 2020. These findings highlight the critical role played by excess visceral adiposity in the progression of fibrosis among HIV-infected patients with nonalcoholic fatty liver disease. This information may further inform the field as to the development of prediction tools and therapeutic strategies for hepatic fibrosis in this population.

This finding comes from a sub-analysis of the recent study led by Dr Steven Grinspoon and conducted at the Massachusetts General Hospital and the National Institute of Allergy and Infectious Diseases and funded by the NIH, to assess the effect of tesamorelin on NAFLD/NASH in patients living with HIV. The study was published in the October 2019 issue of *The Lancet HIV* Journal.

## Visceral fat: a predictor of liver fibrosis

Results from the sub-analysis presented during the CROI conference demonstrate a significant association between liver fibrosis and visceral fat.

This sub-analysis from biopsied patients (n=58) demonstrated that visceral fat at baseline was higher (284 ± 91 cm<sup>2</sup>) in the 25 patients with hepatic fibrosis (stage 1, 2, and 3) compared to the 33 patients who did not present with fibrosis (212 ± 95 cm<sup>2</sup>) (P = 0.005). Of note, there was no difference in subcutaneous fat and body mass index between the groups.

The sub-analysis also demonstrated that 37.5% of the 24 patients with paired biopsies (at the beginning and at the end of the trial) in the placebo group had fibrosis progression. Higher visceral fat was also the only clinical predictor of liver fibrosis progression. Baseline liver fibrosis and its progression were not associated to age, sex, race, duration of HIV infection and CD4 count.

"Visceral adiposity was found to be a novel clinical predictor of accelerated hepatic disease, which suggests that therapies to reduce visceral fat may be particularly effective in HIV-associated NAFLD" said Dr. Steve Grinspoon Professor of Medicine at Harvard Medical School, Chief of the Metabolism Unit at the Massachusetts General Hospital, and a scientific advisor to Theratechnologies Inc.

"Findings of this new sub-analysis are particularly interesting as they support the clinical relevance of visceral adipose tissue as a potential noninvasive marker for the diagnosis of liver fibrosis and the importance of treating visceral adiposity," said Dr. Christian Marsolais, Senior Vice President and Chief Medical Officer, Theratechnologies Inc.

The randomized, double-blind, multicenter trial, from which the data were drawn, assessed the effect of tesamorelin on liver fat and histology in people living with HIV with NAFLD. At baseline, liver biopsies revealed that 43% of patients had liver fibrosis and 33% had NASH. A total of 61 patients received 2 mg 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 = 0.016), 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 = 0.0069).

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).

## **About Theratechnologies**

Theratechnologies (TSX: TH) (NASDAQ: THTX) is a specialty pharmaceutical company addressing unmet medical needs by bringing to market specialized therapies for people with orphan medical conditions, including those living with HIV. Further information about Theratechnologies is available on the Company's website at <u>www.theratech.com</u>, on SEDAR at <u>www.sedar.com</u>, 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 visceral adiposity being a predictor of accelerated hepatic disease, therapies to reduce visceral fat may be effective in HIV-associated NAFLD and visceral adipose tissue is a potential noninvasive marker for the diagnosis of liver fibrosis.

Forward-looking statements are based upon a number of assumptions and include, but are not limited to, the following: the reduction of visceral adipose has benefits to treat NAFLD, tesamorelin is a peptide suited to treat NAFLD and patients being administered tesamorelin will respond to the drug and will incur a reduction in visceral adipose tissue.

Forward-looking statements are subject to a variety of risks and uncertainties, many of which are beyond our control that could cause our actual results to differ materially from those that are disclosed in or implied by the forward-looking statements contained in this press release. These risks and uncertainties include, among others, that results from the study may not be applicable to a larger patient population, patients may not respond to tesamorelin and see no results such as the one seen in the study and regulatory

agencies may disagree with the fact that visceral adipose tissue is a marker of liver fibrosis.

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.

-30-

For media inquiries: Denis Boucher Vice President, Communications and Corporate Affairs 514-336-7800