



Theratechnologies Presents New Tesamorelin Data Demonstrating Improvement of Metabolic Syndrome in People with HIV

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- *Presentation at Conference on Retroviruses and Opportunistic Infections (CROI) demonstrates association between excess visceral abdominal fat (EVAF) reduction and decreased prevalence of metabolic syndrome with tesamorelin treatment*
- *Data provide further evidence of potential utility of tesamorelin in addressing metabolic syndrome and complement research in fatty liver diseases*

MONTREAL, Feb. 22, 2023 (GLOBE NEWSWIRE) -- Theratechnologies Inc. ("Theratechnologies" or the "Company") (TSX: TH) (NASDAQ: THTX), a biopharmaceutical company focused on the development and commercialization of innovative therapies, today presented data suggesting that tesamorelin may improve metabolic profiles in people with HIV (PWHIV) by reducing excess visceral abdominal fat (EVAF). In a presentation at the 30th Conference on Retroviruses and Opportunistic Infections (CROI) in Seattle, Wash., researchers reported an association between EVAF reduction and positive change in metabolic syndrome classification in PWHIV treated with tesamorelin, a growth hormone-releasing hormone analogue.

Metabolic syndrome is a condition characterized by central adiposity, high levels of fasting blood glucose, high blood levels of triglycerides, low blood levels of high-density lipoprotein (HDL) cholesterol, and hypertension (high blood pressure). Metabolic syndrome is associated with increased risk of cardiovascular disease, stroke, and type 2 diabetes. EVAF, an important component of central adiposity contributes to obesity-related disorders and is associated with ectopic (abnormal) fat accumulation in the liver, including nonalcoholic fatty liver disease (NAFLD). Some individuals with liver fat can develop nonalcoholic steatohepatitis (NASH), an aggressive form of fatty liver disease, which is marked by liver inflammation and may progress to advanced scarring (cirrhosis) and liver failure.

"Our findings of EVAF reduction and reversal of metabolic syndrome classification following treatment with tesamorelin are consistent with previous data indicating an association between visceral fat reduction and improved metabolic profiles in PWHIV," stated lead investigator Roger Bedimo, MD, professor of internal medicine at The University of Texas Southwestern Medical Center. "Given the relationship between EVAF and metabolic syndrome, these data appear to suggest that tesamorelin could improve metabolic profiles in individuals with HIV who have central adiposity."

Study Overview

Researchers conducted a post-hoc analysis of data from two Phase III trials of tesamorelin in PWHIV with EVAF. Trial participants were randomized to receive a 2-mg dose of tesamorelin or placebo subcutaneously for 26 weeks. In an analysis of 400 participants assigned to receive tesamorelin the investigators defined responders as those with a reduction in EVAF of at least 8%. They evaluated and classified for metabolic syndrome by its five components – elevated waist circumference, high triglycerides, low HDL cholesterol, increased blood pressure, and elevated fasting blood glucose – according to guidelines issued by the National Cholesterol Education Program (NCEP) and the International Diabetes Federation (IDF).

At baseline, more than a third (37%) of participants had metabolic syndrome; the prevalence did not differ significantly between responders and non-responders (34.2% vs. 43.8%, respectively, by NCEP; $p=0.077$). However, following 26 weeks of tesamorelin treatment, the prevalence of metabolic syndrome decreased in responders, resulting in a significantly lower prevalence compared to non-responders (30.8% vs. 48.5%; $p<0.001$). While the overall prevalence of metabolic syndrome was lower when evaluated and classified according to IDF guidelines versus NCEP guidelines, the positive tesamorelin treatment effect remained consistent across both definitions. Differences in metabolic syndrome status were driven predominantly by resolution of triglycerides (17.5% in responders vs. 8.0% in non-responders; $p=0.026$) and waist circumference decrease (13.3% vs. 5.8%; $p=0.034$).

"Since our scientists discovered tesamorelin in 1995, Theratechnologies has pursued the development and use of this innovative treatment for lipodystrophy – specifically excess visceral abdominal fat - in people with HIV," commented Christian Marsolais, Ph.D., Senior Vice President and Chief Medical Officer of Theratechnologies. "Given tesamorelin's unique ability to target ectopic fat, these latest data bolster our confidence as we continue to explore its potential as a treatment for NASH in the general population."

Results from an Investigator Sponsored Trial, supported by Theratechnologies and led by Dr. Giada Sebastiani and a team at the McGill University Health Centre examining the relationship between visceral adiposity and NAFLD were also presented at CROI. The findings show that NAFLD diagnosed by controlled attenuation parameter is associated with visceral abdominal fat in PWHIV independently of anthropometric measures of obesity.

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 potential benefits related to the use of tesamorelin for the improvement of

metabolic profiles in PWHIV, and the potential use of tesamorelin for the treatment of NASH and its development for such disease. Forward-looking statements are based upon a number of assumptions and include, but are not limited to, the following: that results stemming from the post-hoc analysis would be the same for all PWHIV receiving tesamorelin; and data gathered using tesamorelin would justify investigating its use for the potential treatment of NASH. 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 uncertainty include, but are not limited to, the risk that tesamorelin does not provide the same results in all PWHIV as those reported herein, and the risk that results observed from its use on metabolic conditions may not be conclusive evidence for the potential treatment of NASH in the general population. We refer potential investors to the "Risk Factors" section of our annual information form dated February 23, 2022 available on SEDAR at www.sedar.com and on EDGAR at www.sec.gov as an exhibit to our report on Form 40-F dated February 24, 2022 under Theratechnologies' public filings 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

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