Theratechnologies IDWeek Presentations Highlight the Impact of Excess Visceral Abdominal Fat (EVAF) on Cardiovascular Disease (CVD) Risk in People with HIV

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Data Show Tesamorelin May Reduce CVD Risk by Reducing EVAF

MONTREAL, Oct. 17, 2024 (GLOBE NEWSWIRE) -- Theratechnologies Inc. (“Theratechnologies” or the “Company”) (TSX: TH) (NASDAQ: THTX), a biopharmaceutical company focused on development and commercialization of innovative therapies, today announced data from two poster presentations, focusing on the association between excess visceral abdominal fat (EVAF) and cardiovascular disease (CVD) risk in people with HIV (PWH), and on the use of tesamorelin to reduce such risk.

In a poster presentation at IDWeek 2024 in Los Angeles, Calif., investigators from the Visceral Adiposity Measurement and Observations Study (VAMOS) reported that EVAF is one of several risk factors that contribute to heightened CVD risk in PWH who are on modern anti-retroviral therapy (ART) regimens. In a separate poster presentation, researchers demonstrated that the EVAF-lowering properties of tesamorelin, a growth hormone-releasing factor (GHRF), enable a reduction in CVD risk in PWH.

“The two studies presented at IDWeek 2024 suggest that excess visceral abdominal fat is an overlooked risk factor for cardiovascular disease in people with HIV, and that use of tesamorelin for visceral abdominal fat reduction may contribute to lowering cardiovascular disease risk,” said Christian Marsolais, Ph.D., Senior Vice President and Chief Medical Officer of Theratechnologies. “We hope greater awareness of EVAF, and of strategies to address this risk factor, lead to improved outcomes in people with HIV being treated with ART medicines.”

VAMOS Data

VAMOS, a cross-sectional, multicenter observational study, is the first trial designed to improve the understanding of the impact of EVAF on CVD, steatotic liver disease, insulin resistance, and other metabolic parameters in PWH who are on modern ART regimens. The investigators examined the impact of EVAF (defined as visceral fat surface area ≥130 cm^2 by CT scan) on traditional CVD risk factors and overall cardiovascular (CV) risk in 170 participants with HIV. The prevalence of EVAF in the study was 58%, and the mean visceral fat area was 148 cm^2. Among participants with EVAF, values for the Homeostatic Model Assessment for Insulin Resistance (HOMA-IR; $p \leq 0.0001$) and triglyceride:high-density lipoprotein (TG:HDL) ratios ($p=0.0013$) were higher than in those without EVAF. Investigators noted a positive correlation between EVAF and HOMA-IR ($\rho=0.43$, $p \leq 0.0001$) and TG:HDL ratios ($\rho=0.33$, $p \leq 0.0001$).

Importantly, greater EVAF was associated with a higher 10-year atherosclerotic cardiovascular disease (ASCVD) risk ($p \leq 0.0001$). The investigators also found that increasing visceral fat surface area was inversely associated with growth hormone (GH) levels ($\rho=-0.17$, $p=0.03$), and that participants with EVAF had lower GH levels overall ($p=0.05$).

“Excess visceral abdominal fat, or EVAF, is the key characteristic of central adiposity, a condition that is still prevalent in today’s population of people living with HIV, even among those who were never exposed to earlier anti-retroviral agents,” commented VAMOS investigator, John Koethe M.D., Associate Professor of Medicine at Vanderbilt University. “As the quantity of visceral fat rises, 10-year ASCVD risk scores increase, as well as traditional risk factors including insulin resistance and lipid levels. Together, these factors contribute to the heightened risk of cardiovascular disease we see in people with HIV, which is a particular concern among aging individuals. Additionally, the relationship we observed between EVAF and decreased growth hormone levels appears to support a focus on the growth hormone axis to impact EVAF.”

Tesamorelin CV Risk Data

Researchers examined data from two phase 3 randomized studies to assess the impact of tesamorelin-induced reduction of EVAF on CVD outcomes in 543 PWH. They calculated 10-year ASCVD risk scores for participants at baseline and at 26 weeks of tesamorelin treatment. The percentages of participants on lipid-lowering therapies, antihypertensive treatment, or diabetes medications were 44%, 37%, and 18%, respectively.

Although most participants had low CVD risk at baseline, 44% had borderline to high CVD risk. Participants on tesamorelin tended toward a modest reduction in 10-year ASCVD risk scores, with an estimated change of -0.4% (95% confidence interval [CI] -0.89%, 0.05%). The reduction in CVD risk was relatively larger among subjects with higher CVD risk at baseline ($p=0.038$ for the overall trend among all participants). These reductions in ASCVD risk scores were driven primarily by reductions in total cholesterol, independent of lipid-lowering therapies.

“Our analysis provides evidence that tesamorelin may contribute to a reduction in forecasted cardiovascular disease risk in persons with HIV, particularly among individuals at the highest baseline risk,” stated investigator Lindsay Fourman, M.D., Massachusetts General Hospital and Harvard Medical School. “Given the high prevalence of obesity and central adiposity in this population, a strategy that selectively reduces excess visceral abdominal fat may be particularly effective in CVD risk management.”

IDWeek 2024, taking place October 16-19, is the joint annual meeting of the Infectious Diseases Society of America, the Society for Healthcare Epidemiology of America, the HIV Medicine Association, the Pediatric Infectious Diseases Society and the Society of Infectious Diseases Pharmacists.

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.sedarplus.ca and on EDGAR at www.sec.gov. Follow Theratechnologies on Linkedin and Twitter.

Forward-Looking Information

This press release contains forward-looking statements and forward-looking information (collectively, the “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", “promising”, “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 use of tesamorelin for visceral abdominal fat reduction contributing to lowering cardiovascular disease risk and attention to targeting excess visceral abdominal fat when considering CVD risk management. Forward-looking statements involve a number of assumptions, risks and uncertainties. Some of these assumptions include, but are not limited to, the fact that people living with HIV taking tesamorelin for visceral abdominal fat reduction will lower the risk of cardiovascular disease. The Company refers current and potential investors to the “Risk Factors” section of the Company’s Annual Information Form filed on Form 20-F dated February 21, 2024 available on SEDAR+ at www.sedarplus.ca and on EDGAR at www.sec.gov under Theratechnologies’ public filings for the risks associated with the business of 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 the Company’s expectations as of that date.

The Company undertakes 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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