

# Theratechnologies announces publication of its 26-week Phase 3 data with tesamorelin in the *New England Journal of Medicine*

Montreal, Canada – December 5, 2007 – Theratechnologies (TSX: TH) today announced that the results from its first Phase 3 clinical trial, using tesamorelin (TH9507), are published in the December 6, 2007 New England Journal of Medicine (www.nejm.org). The study entitled, "Metabolic Effects of a Growth Hormone-Releasing Factor in Patients with HIV" outlines, in detail, the 26-week data of the trial. Top-line results of this Phase 3 trial were initially disclosed in December 2006.

"All of the data we have presented thus far indicate that tesamorelin may offer an attractive combination of efficacy and safety with potential advantages over other approaches," commented Mr. Yves Rosconi, President and Chief Executive Officer of Theratechnologies. "The publication in the *New England Journal of Medicine* attests to the rigour and to the high quality data generated from this study. We acknowledge our clinical and regulatory teams, our dedicated principal investigators, and the patients involved in the trial, as being paramount in the achievement of this publication," noted Mr. Rosconi.

"The results published today in the *New England Journal of Medicine* suggest that tesamorelin is among the most promising strategies to date to improve excess visceral fat in HIV-infected patients with lipodystrophy," commented Dr. Steve Grinspoon, Professor of Medicine, Harvard Medical School, Director of the Massachusetts General Hospital Program in Nutritional Metabolism, Lead Investigator for the tesamorelin trial in the United States and corresponding author for the NEJM publication. "Furthermore, tesamorelin not only significantly improved visceral fat, but also significantly improved dyslipidemia, which may also help to improve the cardiovascular risk profile in such patients. The tesamorelin program continues to be very exciting and the results of this study are only the beginning of what we might see in other indications," Dr. Grinspoon noted.

"Publication of this paper supports the importance of lipohypertrophy to the overall well-being of HIV patients with metabolic complications," commented Dr. Julian Falutz, Director, HIV Metabolic Clinic, McGill University Health Centre, Assistant Professor, McGill University Medical School, and Lead Investigator for Canada. "This clinical trial is the largest to date studying lipohypertrophy and these positive results bring hope that treatment for lipodystrophy may become available," Dr. Falutz noted.

An extension phase of the above Phase 3 trial was performed to understand the safety profile of tesamorelin over a period of 52 weeks. Positive top-line data for the 52-week results were announced in October 2007 and presented at the 11<sup>th</sup> European AIDS conference in Madrid, Spain. The 52-week results are consistent with the safety profile observed in the first 26 weeks of treatment and show that tesamorelin is well tolerated.

A confirmatory Phase 3 trial is currently underway for which the last patient has been randomized. We recently announced that the recruitment of this 404-patient, multi-

center, double-blind, randomized, placebo-controlled study, conducted in 48 centers in North America and Europe, had been completed. This trial is designed to confirm the results of the above mentioned Phase 3 trial by examining the safety and efficacy of a daily administration of 2 mg of tesamorelin for 26 weeks. In August 2006, the protocol for this confirmatory Phase 3 trial was reviewed by the Food and Drug Administration (FDA) in the United States through the Special Protocol Assessment (SPA) process. Top-line data of the confirmatory Phase 3 trial is expected in the first half of 2008.

## HIV-associated Lipodystrophy

HIV-associated lipodystrophy is characterized by a change in the distribution of adipose tissue (fat containing tissue), dyslipidemia and glucose intolerance. Visceral adipose tissue accumulation with its concomitant metabolic profile is known to be a risk factor for cardiovascular diseases. The changes in fat distribution include visceral fat accumulation and/or loss of subcutaneous fat, generally in the limbs and in the face. There is no treatment available for the accumulation of visceral fat (lipohypertrophy) found in patients with HIV-associated lipodystrophy. According to market research that was conducted by Verispan in 2005 by interviewing 100 individual physicians and 50 payers, it is estimated that approximately 250,000 HIV-infected patients in North America and Europe suffer an excessive accumulation of visceral fat.

# **About Theratechnologies**

Theratechnologies (TSX:TH) is a Canadian biopharmaceutical company that discovers innovative drug candidates in order to develop them and bring them to market. The Company targets unmet medical needs in financially attractive specialty markets. Its most advanced program is tesamorelin, now in a confirmatory Phase 3 clinical trial for a serious metabolic disorder known as HIV-associated lipodystrophy. The Company also has other projects at earlier stages of development.

### **Forward-looking statements**

This press release contains forward-looking statements regarding the conduct of the Company's clinical program. By their very nature, these statements involve uncertainties and inherent risks, both general and specific, which give rise to the possibility that the predictions will not materialize. We refer you to pages 15 to 19 of the 2006 Annual Information Form, which contain a more exhaustive analysis of the risks and uncertainties connected to the business of the Company. We have no obligation whatsoever to update forward-looking statements and we do not undertake to do so.

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