

# THERATECHNOLOGIES REPORTS POSITIVE 52-WEEK PHASE 3 RESULTS FOR ITS LEAD DRUG CANDIDATE TESAMORELIN

Safety and efficacy profile of tesamorelin consistent with previous results

Montreal, Canada – Monday October 1, 2007 – Theratechnologies (TSX:TH) today announced positive 52-week results of its Phase 3 clinical trial, evaluating the long-term safety profile of the Company's lead compound, tesamorelin (TH9507), in patients with HIV-associated lipodystrophy. 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. In addition, tesamorelin's efficacy is confirmed as patients on treatment for 52 weeks lost 18% of their visceral adipose tissue (VAT) compared to baseline.

"Our objective was to demonstrate long-term safety, and we have clearly achieved this. In addition, we continue to differentiate tesamorelin from other compounds being evaluated in HIV-associated lipodystrophy as having a favorable risk/benefit profile for patients," commented Mr. Yves Rosconi, President and Chief Executive Officer of Theratechnologies. "The long-term safety profile provides strong evidence that tesamorelin can be used safely to significantly reduce VAT, which is a risk factor for cardiovascular disease and Type 2 diabetes," Mr. Rosconi stated.

"The long-term treatment is very encouraging for patients treated with tesamorelin for 52 weeks and shows that tesamorelin when administered long term does not compromise its safety profile," commented Dr. Christian Marsolais, Vice President, Clinical Research for Theratechnologies.

"There does not appear to be a significant impact on glucose tolerance, which is important for the long-term treatment of HIV lipodystrophy. The results are important as no treatment is currently on the market and approved to reduce visceral adiposity in this population," commented Dr. Steve Grinspoon, Associate Professor of Medicine, Harvard Medical School, Director of the Massachusetts General Hospital Program in Nutritional Metabolism, and Lead Investigator for the tesamorelin trial in the United States.

"The data demonstrate that one year treatment with tesamorelin results in sustained VAT reduction. This provides a great deal of hope for patients with symptoms of HIV-associated lipohypertrophy," stated Dr. Julian Falutz, Director, HIV Metabolic Clinic, Montreal General Hospital, Assistant Professor, McGill University Medical School, and Lead Investigator for Canada.

## **Trial Design**

For the first 26 weeks of the study, patients were either treated with tesamorelin (2mg per day) or placebo. Those patients receiving tesamorelin for the first portion of the study were re-randomized to receive either tesamorelin or placebo for an additional 26 weeks, generating a group of patients that have been treated for a total of 52 weeks. All patients who received placebo in the first 26 weeks were treated

with tesamorelin from weeks 26 to 52. It is important to note that there is no patient group that received placebo for 52 weeks and therefore there is no direct placebo comparator for the group of patients that were treated for 52 weeks.

# Safety Results

The primary objective for the extension phase of the study was to evaluate the safety profile of tesamorelin over a 52-week period. The safety profile in this extension phase replicated the safety data disclosed after 26 weeks of treatment. As experienced for the first six months of treatment, no issues related to glycemic control were observed after 52 weeks. The drop out rate for the patients treated with tesamorelin for 52 weeks of treatment was 16% as compared to 23% for the first six months of treatment.

### **Efficacy Results**

Although the primary objective of the trial was to determine the long-term (52 weeks) safety profile of tesamorelin, additional interesting data emerged regarding the efficacy of tesamorelin. Those patients that were treated for 52 weeks experienced a total reduction of 18% VAT compared to baseline (p<0.001). Patients treated with tesamorelin for the first 26 weeks experienced a total of 15% VAT reduction (p<0.001). Finally, patients treated with tesamorelin for 26 weeks followed by placebo for 26 weeks regained VAT to levels comparable to their baseline values (-1.6%, p<0.191).

#### **Additional Data**

The analysis of additional data and secondary endpoints is ongoing and will be reported in future publications and scientific meetings. The first such meeting will be the European AIDS Conference in Madrid later this month.

# **Conference Call and Webcast**

The Company will hold a conference call and webcast today at 8:00 a.m. to discuss the results.

To participate, please dial: 1-416-644-3415 or 1-800-733-7571 (toll free). Please dial in five minutes prior to the teleconference in order to ensure your participation. The webcast will be accessible at the following links: <a href="https://www.investorcalendar.com">www.investorcalendar.com</a> and <a href="https://www.theratech.com">www.theratech.com</a>.

A replay of the conference call will be available from 10:00am today, October 1, 2007, until October 8, 2007 at 11:59pm at the following number: 1-416-640-1917, pass code 21248622# or 1-877-289-8525, pass code 21248622#. The webcast will be posted for 90 days at the links indicated above.

## **HIV-associated Lipodystrophy**

HIV-associated lipodystrophy is characterized by a change in the distribution of adipose tissue (fat containing tissue), dyslipidemia and glucose intolerance. VAT 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 found in patients with HIV-associated lipodystrophy. 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, which has recently completed patient recruitment for its confirmatory Phase 3 clinical trial for a serious metabolic disorder known as HIV-associated lipodystrophy. Tesamorelin could be the first compound on the market to threat 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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