

Theratechnologies Reports 52-Week Results in Its Confirmatory Phase 3 Trial with Tesamorelin

Safety and efficacy profile of tesamorelin consistent with previous Phase 3 trial

Montreal, Canada – December 15, 2008 – Theratechnologies (TSX:TH) today announced 52-week results of its confirmatory Phase 3 clinical trial, evaluating the long-term safety profile of the Company's lead compound, tesamorelin, in patients with HIV-associated lipodystrophy. The results of the confirmatory trial announced today are consistent with the safety profile observed in the first Phase 3 trial. In addition, patients lost 18% of their visceral adipose tissue (VAT) after 52 weeks of treatment, while losing 11% after 26 weeks of treatment, compared to baseline.

"With the conclusion of our Phase 3 program in HIV-associated lipodystrophy, we now have a complete profile for tesamorelin. These data, over a one-year period, will allow us to submit a strong data package to the FDA for their consideration," commented Mr. Yves Rosconi, President and Chief Executive Officer of Theratechnologies. "These data will be an important part of our upcoming NDA submission," concluded Mr. Rosconi.

"The conclusion of the Phase 3 program in HIV-associated lipodystrophy is an important milestone for us," commented Dr. Christian Marsolais, Vice President, Clinical Research and Medical Affairs for Theratechnologies. "As such, we would like to acknowledge our employees, collaborators, and principal investigators. Most importantly, we would like to sincerely thank all of the patients who participated in both Phase 3 trials for their dedication and commitment," noted Dr. Marsolais.

"The changes regarding the following glucose parameters were 0.00 ± 0.89 in fasting blood glucose, -0.08 ± 2.10 in two-hour oral glucose tolerance test, and -37.6 ± 180 in fasting insulin levels after 52 weeks of treatment, and these are similar to what was seen in the previous Phase 3 study. These data are important as over a third of patients with HIV-associated lipodystrophy are glucose intolerant," commented Dr. Steven Grinspoon, 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. "Furthermore, tesamorelin selectively reduces VAT without affecting SAT: which may be important for those patients that suffer from both lipoatrophy and excess abdominal fat accumulation," concluded Dr. Grinspoon.

"We are pleased with the consistency of results across both Phase 3 trials. The development of lipohypertrophy in treated HIV patients is a serious complication that significantly affects the quality of life of many patients, and for which there is no currently approved treatment," 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 both the first and confirmatory Phase 3 trials, patients were either treated with tesamorelin (2 mg per day) or placebo and results were evaluated at 26 and 52 weeks. Those patients receiving tesamorelin for the first 26 weeks of the studies 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 are no patient groups that received placebo for 52 weeks and therefore there are no direct placebo comparators for the group of patients that were treated for 52 weeks in both Phase 3 studies.

Safety Results

The primary objective for the extension phase (weeks 26-52) of both Phase 3 studies was to evaluate the safety profile of tesamorelin over a 52-week period. The safety profile in the extension phase of the confirmatory Phase 3 trial replicated the safety data disclosed in the first Phase 3 trial (both at 26 and 52 weeks). The following glucose parameters were observed after 52 weeks of treatment: changes in fasting blood glucose, two-hour oral glucose tolerance test, and fasting insulin levels were 0.00 ± 0.89 , -0.08 ± 2.10 , and -37.6 ± 180 , respectively. The drop out rate for the patients treated with tesamorelin from weeks 26 to 52 of treatment in the confirmatory trial was 13% as compared to 25% for the first six months of treatment.

Efficacy Results

Although the primary objective of the Phase 3 trials was to determine the long-term (52 weeks) safety profile of tesamorelin, the data regarding the efficacy of tesamorelin in this confirmatory trial replicated what was observed in the first Phase 3 trial. Those patients that were treated for 52 weeks in the confirmatory trial experienced a total reduction of 18% VAT compared to baseline ($p < 0.001$) which is consistent with the results observed at 52 weeks in the first trial. Patients treated with tesamorelin for the first 26 weeks in the confirmatory trial experienced a total of 11% VAT reduction ($p < 0.001$). Further aligned with these results, patients who were on the placebo arm for the first 26 weeks and were crossed over to treatment from weeks 26 to 52 had a decrease of 14% in VAT compared to baseline ($p < 0.001$). Finally, patients treated with tesamorelin for 26 weeks followed by placebo for 26 weeks regained VAT to levels comparable to their baseline values (+1%, $p = 0.432$).

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: 1-416-644-3418 or 1-800-732-9303 (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: www.investorcalendar.com and www.theratech.com.

A replay of the conference call will be available from 10:00 a.m. today, December 15, 2008, until December 22, 2008 at 11:59 p.m. at the following number: 1-416-640-1917, pass code 21292496# or 1-877-289-8525, pass code 21292496#. The webcast will be posted for 30 days at the links indicated above.

About HIV-Associated Lipodystrophy

Several factors including the antiretroviral drug regimen and the virus itself are thought to contribute to HIV-associated lipodystrophy which is characterized by body composition changes, dyslipidemia and glucose intolerance. The changes in body composition include excess abdominal fat accumulation. There is currently no approved treatment available for the excess abdominal fat related to HIV-associated lipodystrophy, a condition that can stigmatize patients and discourage HIV treatment adherence.

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 concluded a confirmatory Phase 3 clinical trial for a serious metabolic disorder involving excess abdominal fat in HIV patients with lipodystrophy. The Company also has other projects at earlier stages of development.

Forward-Looking Information

This press release contains certain statements that are considered "forward-looking information" within the meaning of applicable securities legislation. This forward-looking information includes, but is not limited to: information regarding the safety profile of tesamorelin for long-term use of the product; the completion of the Company's regulatory file, which includes tesamorelin's product

monograph; and the submission of a New Drug Application. (“NDA”) for tesamorelin with US regulatory agencies. Words such as “will”, “may”, “could”, “should”, “outlook”, “believe”, “plan”, “envisage”, “anticipate”, “expect” and “estimate”, or the negatives of these terms or variations of them and the use of the conditional tense as well as similar expressions denote forward-looking information.

Forward-looking information is based upon a number of assumptions and is subject to a number of risks and uncertainties, many of which are beyond the Company’s control, that could cause actual results to differ materially from those that are disclosed in or implied by such forward-looking information. These risks and uncertainties include, but are not limited to: the effect of tesamorelin may vary from one individual to the other, the delay in completing the regulatory file, a delay in submitting the NDA, or the delay in approval or the non-approval of tesamorelin by the applicable regulatory authorities. The Company refers potential investors to the “Risks and Uncertainties” section of its Annual Information Form (the “AIF”) dated January 29, 2008. The AIF is available at www.sedar.com under the Company’s public filings. The reader is cautioned that the foregoing list of risks and uncertainties is not exhaustive of the risks and uncertainties that may affect any of the Company’s forward-looking statements. The reader is also cautioned to consider these and other risks and uncertainties carefully and not to put undue reliance on forward-looking statements.

Although the forward-looking information contained in this press release is based upon what the Company believes are reasonable assumptions, actual results may vary from the forward-looking information contained herein. Certain assumptions made in preparing the forward-looking information include, but are not limited to: that the inclusion of the 52-week data in the product monograph will allow long-term use of tesamorelin, that the applicable regulatory authorities will approve tesamorelin for commercialization within the customary delay after the filing of the NDA; and that there will be an interest on the part of patients and physicians in using tesamorelin for the treatment of HIV-associated lipodystrophy.

Consequently, all of the forward-looking information contained in this press release is qualified by the foregoing cautionary statements, and there can be no guarantee that the results or developments anticipated by the Company will be realized or, even if substantially realized, that they will have the expected consequences or effects on the Company, its business, financial condition or results of operation. Furthermore, the forward-looking information reflects current expectations regarding future events and speaks only as of the date of this press release and represents the Company’s expectations as of that date. The Company does not undertake to update or amend such forward-looking information whether as a result of new information, future events or otherwise, except as may be required by applicable law.

Contact:

Andrea Gilpin
Vice President, IR & Communications
Theratechnologies Inc.
Phone: 514 336-7800, ext. 205
communications@theratech.com