

FDA Approves *EGRIFTA*[™] (tesamorelin for injection): The First and Only Treatment for the Reduction of Excess Abdominal Fat in HIV-Infected Patients with Lipodystrophy

- **Clinical Trials Demonstrate Reduction in VAT and Waist Circumference**
 - **Important Milestone Payments To Be Received**

Montréal, Canada – November 11, 2010 - Theratechnologies (TSX: TH) announced today that the U.S. Food and Drug Administration (“FDA”) has approved *EGRIFTA*[™] (tesamorelin for injection) as the first and only treatment indicated to reduce excess abdominal fat in HIV-infected patients with lipodystrophy (abdominal lipohypertrophy). *EGRIFTA*[™] (tesamorelin for injection) was developed by Theratechnologies and will be exclusively commercialized in the U.S. by EMD Serono, Inc. (“EMD Serono”), an affiliate of Merck KGaA, of Darmstadt, Germany, under the terms of a collaboration and licensing agreement.

There are limitations of use associated with *EGRIFTA*[™] (tesamorelin for injection). Since the long-term cardiovascular safety and potential long-term cardiovascular benefit of *EGRIFTA*[™] (tesamorelin for injection) treatment have not been studied and are not known, careful consideration should be given whether to continue *EGRIFTA*[™] (tesamorelin for injection) treatment in patients who do not show a clear efficacy response as judged by the degree of reduction in visceral adipose tissue (“VAT”) measured by waist circumference (“WC”) or CT scan. *EGRIFTA*[™] (tesamorelin for injection) is not indicated for weight loss management (weight neutral effect). There are no data to support improved compliance with antiretroviral therapies in HIV-positive patients taking *EGRIFTA*[™] (tesamorelin for injection).

“Theratechnologies is very pleased to receive marketing approval for *EGRIFTA*[™] from the FDA. We are one of the very few Canadian biotechnology companies to have successfully discovered, developed and brought a drug to the market on our own. This milestone represents a significant achievement which will benefit both patients and our shareholders,” commented Yves Rosconi, President and CEO of Theratechnologies.

“We are confident that EMD Serono will successfully commercialize *EGRIFTA*[™] in the United States, given their track record and expertise with other metabolic disorders,” noted Paul Pommier, Chairman of the Board of Directors of Theratechnologies. “Theratechnologies will continue to focus on signing partnerships outside of the United States in order to access additional markets for *EGRIFTA*[™] in HIV-infected patients with excess abdominal fat associated with lipodystrophy,” Mr. Pommier concluded.

“While antiretroviral therapy is extremely important in the management of patients with HIV infection, some patients are experiencing excess abdominal fat associated with lipodystrophy, which can be difficult to manage,” said Fereydoun Firouz, President and CEO, EMD Serono. “EMD Serono has maintained a commitment to advancing science and medicine in this area of unmet medical need, and it will continue to remain a focus for the organization. We are committed to making a difference in people's lives, and look forward to making *EGRIFTA*[™] available for patients as soon as possible.”

In 2008, Theratechnologies entered into a collaboration and licensing agreement with EMD Serono, for the exclusive commercialization rights to *EGRIFTA*[™] (tesamorelin for injection) in the United States for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy. Under the terms of this agreement, the FDA marketing approval is associated with milestone payments totaling US\$25 million (approximately CAN\$25 million). *EGRIFTA*[™] is the proposed brand name to be used globally.

The efficacy and safety of *EGRIFTA*[™] (tesamorelin for injection) was evaluated in two Phase 3 multi-center, randomized, double-blind, placebo-controlled clinical trials, which demonstrated statistically significant decreases in VAT and WC versus placebo in HIV-infected patients who suffer from excess abdominal fat associated with lipodystrophy.

The FDA has requested the following three post-marketing requirements: a long-term observational safety study for tesamorelin acetate (*EGRIFTA*[™]), a single vial formulation - the development of a new presentation of the same formulation, and a clinical trial to assess whether *EGRIFTA*[™] (tesamorelin for injection) has an impact on diabetic retinopathy in diabetic HIV-infected patients with lipodystrophy and excess abdominal fat.

“Having a FDA-approved treatment available for this condition is an important goal for the HIV population,” said Steven Grinspoon, M.D., Professor of Medicine at Harvard Medical School, Director of the Massachusetts General Hospital Program in Nutritional Metabolism, and lead investigator for *EGRIFTA*[™] (tesamorelin for injection) trials in the U.S. “Although lifestyle modification could be a valuable first step for HIV patients with abdominal fat accumulation, results to date from lifestyle and exercise studies have been inconsistent with respect to the reduction in abdominal lipohypertrophy. Until today, physicians did not have access to approved drug options to treat this complication,” added Dr. Grinspoon. “Having been involved in the clinical development of *EGRIFTA*[™] over the past 7 years, I am pleased that we have published data demonstrating that *EGRIFTA*[™] reduces VAT, with no adverse effects on subcutaneous adipose tissue. It is also important to monitor IGF-1 levels and impaired glucose tolerance in patients receiving *EGRIFTA*[™]. I am encouraged that, for the first time, patients in the United States with this serious condition will have a FDA-approved treatment option available to them,” concluded Dr. Grinspoon.

About *EGRIFTA*[™] (tesamorelin for injection) Phase 3 Trials

The FDA approval of *EGRIFTA*[™] (tesamorelin for injection) was based on two multi-center, randomized, double-blind, placebo-controlled Phase 3 studies consisting of a 26-week main phase and a 26-week extension phase of 816 HIV-infected patients with excess abdominal fat associated with lipodystrophy.

The primary endpoint of the 26-week main phase was the percent change in VAT from baseline, as assessed by computed tomography (“CT”) scan at the L4-L5 vertebral level.

In both Phase 3 studies, patients received either *EGRIFTA*[™] (tesamorelin for injection) or placebo for 26 weeks. Patients initially randomized to *EGRIFTA*[™] (tesamorelin for injection) were then re-randomized to receive either *EGRIFTA*[™] (tesamorelin for injection) or placebo for an additional 26-week treatment period, whereas patients receiving placebo were switched to *EGRIFTA*[™] (tesamorelin for injection). In the first study, at baseline, mean VAT was 178 cm² for the patients who received *EGRIFTA*[™] (tesamorelin for injection) and was 171 cm² for the patients who received placebo. In the second study, at baseline, mean VAT was 186 cm² for the patients who received *EGRIFTA*[™] (tesamorelin for injection) and was 195 cm² for the patients who received placebo. Patients treated with

EGRIFTA[™] (tesamorelin for injection) experienced a statistically significant least-squares mean decrease from baseline in VAT of 27 cm² compared to an increase of 4 cm² for patients on placebo [(95% CI for the mean treatment difference of -31 cm² (-39 cm², -24 cm²)] in the first study, and a statistically significant decrease from baseline in VAT of 21 cm² compared to no change in VAT for patients on placebo [(95% CI for the mean treatment difference of -21 cm² (-29 cm², -12 cm²)] in the second study during the 26-week main phase. This represents a statistically significant least-squares mean decrease from baseline in VAT of 18% for patients treated with *EGRIFTA*[™] (tesamorelin for injection) compared to an increase of 2% for patients on placebo [(95% CI for the mean treatment difference of -20% (-24%, -15%)] in the first study, and a statistically significant decrease from baseline of 14% for patients treated with *EGRIFTA*[™] (tesamorelin for injection) compared to a decrease of 2% for patients on placebo [(95% CI for the mean treatment difference of -12% (-16%, -7%)] in the second study during the 26-week main phase.

In the first study, at baseline, mean waist circumference was 104 cm for the patients who received *EGRIFTA*[™] (tesamorelin for injection) and was 105 cm for the patients who received placebo. In the second study, at baseline, mean waist circumference was 105 cm for the patients who received *EGRIFTA*[™] (tesamorelin for injection) and for the patients who received placebo. Treatment with *EGRIFTA*[™] (tesamorelin for injection) resulted in a statistically significant least-squares mean decrease from baseline in waist circumference of -3 cm compared to a decrease of -1 cm for patients on placebo [(95% CI for the mean treatment difference of -2 cm (-2.8 cm, -0.9 cm)] in the first study, and a statistically significant decrease from baseline of -2 cm compared to a decrease of -1 cm for patients on placebo [(95% CI for the mean treatment difference of -1 cm (-2.5 cm, -0.3 cm)] in the second study during the 26-week main phase. The decreases in VAT and waist circumference observed after 26 weeks of treatment were sustained in patients who received *EGRIFTA*[™] (tesamorelin for injection) over 52 weeks.

Important Risk Information

EGRIFTA[™] (tesamorelin for injection) is contraindicated in women who are pregnant, in patients with disruption of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, head irradiation or head trauma, in patients with known hypersensitivity to tesamorelin and/or mannitol (excipient) and in patients with active malignancies (either newly diagnosed or recurrent). Any preexisting malignancy should be inactive and its treatment complete prior to instituting therapy with *EGRIFTA*[™] (tesamorelin for injection). If pregnancy occurs, *EGRIFTA*[™] (tesamorelin for injection) therapy should be discontinued.

EGRIFTA[™] (tesamorelin for injection) induces the release of endogenous growth hormone ("GH"), a known growth factor, thus, patients with active malignancy should not be treated with *EGRIFTA*[™] (tesamorelin for injection). For patients with a history of non-malignant neoplasms, *EGRIFTA*[™] (tesamorelin for injection) therapy should be initiated after careful evaluation of the potential benefit of treatment. For patients with a history of treated and stable malignancies, *EGRIFTA*[™] (tesamorelin for injection) therapy should be initiated only after careful evaluation of the potential benefit of treatment relative to the risk of re-activation of the underlying malignancy. In addition, the decision to start treatment with *EGRIFTA*[™] (tesamorelin for injection) should be considered carefully based on the increased background risk of malignancies in HIV-positive patients.

EGRIFTA[™] (tesamorelin for injection) stimulates GH production and increases serum IGF-I. Given that IGF-I is a growth factor and the effect of prolonged elevations in IGF-I levels

on the development or progression of malignancies is unknown, IGF-I levels should be monitored closely during *EGRIFTA*[™] (tesamorelin for injection) therapy. Careful consideration should be given to discontinuing *EGRIFTA*[™] (tesamorelin for injection) in patients with persistent elevations of IGF-I levels (e.g., >3 SDS), particularly if the efficacy response is not robust (e.g., based on visceral adipose tissue changes measured by waist circumference or CT scan). During the clinical trials, patients were monitored every three months. Among patients who received *EGRIFTA*[™] (tesamorelin for injection) for 26 weeks, 47.4% had IGF-I levels greater than 2 standard deviation score (SDS), and 35.6% had SDS >3, with this effect seen as early as 13 weeks of treatment. Among those patients who remained on *EGRIFTA*[™] (tesamorelin for injection) for a total of 52 weeks, at the end of treatment 33.7% had IGF-I SDS >2 and 22.6% had IGF-I SDS >3.

Fluid retention may occur during *EGRIFTA*[™] (tesamorelin for injection) therapy and is thought to be related to the induction of GH secretion. It manifests as increased tissue turgor and musculoskeletal discomfort resulting in a variety of adverse reactions (e.g., edema, arthralgia, carpal tunnel syndrome) which are either transient or resolve with discontinuation of treatment.

EGRIFTA[™] (tesamorelin for injection) treatment may result in glucose intolerance. During the Phase 3 clinical trials, the percentages of patients with elevated HbA1c ($\geq 6.5\%$) from baseline to Week 26 were 4.5% and 1.3% in the *EGRIFTA*[™] (tesamorelin for injection) and placebo groups, respectively. An increased risk of developing diabetes with *EGRIFTA*[™] (tesamorelin for injection) (HbA1c level $\geq 6.5\%$) relative to placebo was observed [intent-to-treat hazard ratio of 3.3 (CI 1.4, 9.6)]. Therefore, glucose status should be carefully evaluated prior to initiating *EGRIFTA*[™] (tesamorelin for injection) treatment. In addition, all patients treated with *EGRIFTA*[™] (tesamorelin for injection) should be monitored periodically for changes in glucose metabolism to diagnose those who develop impaired glucose tolerance or diabetes. Diabetes is a known cardiovascular risk factor and patients who develop glucose intolerance have an elevated risk for developing diabetes. Caution should be exercised in treating HIV-positive patients with lipodystrophy with *EGRIFTA*[™] (tesamorelin for injection) if they develop glucose intolerance or diabetes, and careful consideration should be given to discontinuing *EGRIFTA*[™] (tesamorelin for injection) treatment in patients who do not show a clear efficacy response as judged by the degree of reduction in visceral adipose tissue by waist circumference or CT scan measurements. Since *EGRIFTA*[™] (tesamorelin for injection) increases IGF-I, patients with diabetes who are receiving ongoing treatment with *EGRIFTA*[™] (tesamorelin for injection) should be monitored at regular intervals for potential development or worsening of retinopathy.

Hypersensitivity reactions may occur in patients treated with *EGRIFTA*[™] (tesamorelin for injection). Hypersensitivity reactions occurred in 3.6% of patients with HIV-associated lipodystrophy treated with *EGRIFTA*[™] (tesamorelin for injection) in the Phase 3 clinical trials. These reactions included pruritus, erythema, flushing, urticaria, and other rash. In cases of suspected hypersensitivity reactions, patients should be advised to seek prompt medical attention, and treatment with *EGRIFTA*[™] (tesamorelin for injection) should be discontinued immediately.

EGRIFTA[™] (tesamorelin for injection) treatment may cause injection site reactions, including injection site erythema, pruritus, pain, irritation, and bruising. The incidence of injection site reactions was 24.5% in *EGRIFTA*[™] (tesamorelin for injection)-treated patients and 14.4% in placebo-treated patients during the first 26 weeks of treatment in the Phase 3 clinical trials. For patients who continued *EGRIFTA*[™] (tesamorelin for injection)

for an additional 26 weeks, the incidence of injection site reactions was 6.1%. In order to reduce the incidence of injection site reactions, it is recommended to rotate the site of injection to different areas of the abdomen.

Increased mortality in patients with acute critical illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure has been reported after treatment with pharmacologic amounts of growth hormone. *EGRIFTA*[™] (tesamorelin for injection) has not been studied in patients with acute critical illness. Since *EGRIFTA*[™] (tesamorelin for injection) stimulates growth hormone production, careful consideration should be given to discontinuing *EGRIFTA*[™] (tesamorelin for injection) in critically ill patients.

EGRIFTA[™] (tesamorelin for injection) is contraindicated in pregnant women. During pregnancy, visceral adipose tissue increases due to normal metabolic and hormonal changes. Modifying this physiologic change of pregnancy with *EGRIFTA*[™] (tesamorelin for injection) offers no known benefit and could result in fetal harm. Tesamorelin acetate administration to rats during organogenesis and lactation resulted in hydrocephalus in offspring at a dose approximately two and four times the clinical dose, respectively, based on measured drug exposure (AUC). If pregnancy occurs, discontinue *EGRIFTA*[™] (tesamorelin for injection) therapy. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.

Because of both the potential for HIV-1 infection transmission and serious adverse reactions in nursing infants, mothers receiving *EGRIFTA*[™] (tesamorelin for injection) should be instructed not to human milk-feed. It is not known whether *EGRIFTA*[™] (tesamorelin for injection) is excreted in human milk.

Safety and effectiveness in pediatric patients have not been established. *EGRIFTA*[™] (tesamorelin for injection) should not be used in children with open epiphyses, among whom excess GH and IGF-I may result in linear growth acceleration and excessive growth.

There is no information on the use of *EGRIFTA*[™] (tesamorelin for injection) in patients greater than 65 years of age with HIV and lipodystrophy.

Safety, efficacy, and pharmacokinetics of *EGRIFTA*[™] (tesamorelin for injection) in patients with renal or hepatic impairment have not been established.

The most commonly reported adverse reactions (>5% and more frequent than placebo) are arthralgia [13.1% of patients receiving *EGRIFTA*[™] (tesamorelin for injection) and 11.0% of patients receiving placebo], pain in extremity [6.1% of patients receiving *EGRIFTA*[™] (tesamorelin for injection) and 4.6% of patients receiving placebo], myalgia [5.5% of patients receiving *EGRIFTA*[™] (tesamorelin for injection) and 1.9% of patients receiving placebo], injection site erythema [8.5% of patients receiving *EGRIFTA*[™] (tesamorelin for injection) and 2.7% of patients receiving placebo], injection site pruritus [7.6% of patients receiving *EGRIFTA*[™] (tesamorelin for injection) and 0.8% of patients receiving placebo], and peripheral edema [6.1% of patients receiving *EGRIFTA*[™] (tesamorelin for injection) and 2.3% of patients receiving placebo].

During the first 26 weeks of treatment (main phase), discontinuations as a result of adverse reactions occurred in 9.6% of patients receiving *EGRIFTA*[™] (tesamorelin for injection) and

6.8% of patients receiving placebo. Apart from patients with hypersensitivity reactions identified during the studies and who were discontinued per protocol (2.2%), the most common reasons for discontinuation of *EGRIFTA*[™] (tesamorelin for injection) treatment were adverse reactions due to the effect of GH (4.2%) and local injection site reactions (4.6%).

About *EGRIFTA*[™] (tesamorelin for injection)

EGRIFTA[™] (tesamorelin for injection) is a synthetic analogue of the human growth hormone releasing factor (“GRF”) shown to reduce visceral fat in HIV-infected patients with excess abdominal fat associated with lipodystrophy. GRF is a hypothalamic peptide that acts on the pituitary cells in the brain to stimulate the synthesis and release of endogenous growth hormone.

EGRIFTA[™] (tesamorelin for injection) is approved for sale in the United States only.

About HIV-Associated Lipodystrophy

Several factors, including a patient’s antiretroviral drug regimen and the HIV virus itself are thought to contribute to HIV-associated lipodystrophy, which is characterized by body composition changes. The changes in body composition may include excess abdominal fat accumulation, which is known as abdominal lipohypertrophy.

Please see full prescribing information for *EGRIFTA*[™] (tesamorelin for injection) at www.emdserono.com.

Conference Call and Webcast

Theratechnologies will hold a conference call and webcast today at 8:30 a.m. (Eastern Standard Time) to discuss the approval of *EGRIFTA*[™] (tesamorelin for injection) by the FDA.

To participate, please dial: 1-416-981-9005 or 1-800-931-6427 (toll free). Please dial in five minutes prior to the conference in order to ensure your participation. The webcast will be accessible at the following links: www.gowebcasting.com/2099 and www.theratech.com/.

A replay of the conference call will be available from 10:30 a.m. today, November 11, 2010, until November 26, 2010 at 11:59 p.m. at the following number: 1-416-626-4100, pass code 21488561# or 1-800-558-5253, pass code 21488561#. The webcast will be posted for 30 days at the links indicated above.

About Theratechnologies

Theratechnologies (TSX: TH) is a Canadian biopharmaceutical company that discovers and develops innovative therapeutic products, with an emphasis on peptides, for commercialization. The Company targets unmet medical needs in specialty markets where it can retain all or part of the commercial rights to its products. Its most advanced compound, tesamorelin, is an analogue of the human growth hormone releasing factor. Tesamorelin will be exclusively commercialized in the U.S. by EMD Serono under the brand name *EGRIFTA*[™]. The Company’s growth strategy is centered on the commercialization of *EGRIFTA*[™] (tesamorelin for injection) in the United States through an agreement with EMD Serono, Inc. for the reduction of excess abdominal fat associated with lipodystrophy in HIV-infected patients. Moreover, Theratechnologies’ growth strategy will also derive from the commercialization of *EGRIFTA*[™] (tesamorelin for injection) in

other markets for HIV-associated lipodystrophy, as well as the development of clinical programs for *EGRIFTA*[™] (tesamorelin for injection) in other medical conditions.

For more information, please visit www.theratech.com

About EMD Serono, Inc.

EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany, is a leader in the US biopharmaceutical arena, integrating cutting-edge science with unparalleled patient support systems to improve people's lives. The company has strong market positions in neurodegenerative diseases, with Rebif® (interferon beta-1a), as well as in endocrinology, with Saizen® (somatropin (rDNA origin) for injection) and Serostim® (somatropin (rDNA origin) for injection). EMD Serono is a leader in reproductive health, with Gonal-f® (follitropin alfa for injection), Luveris® (lutropin alfa for injection) and Ovidrel® Prefilled Syringe (choriogonadotropin alfa injection). In addition, EMD Serono is growing its expertise and presence in the area of oncology, with more than 10 projects currently in development. With a clear focus on the patient and a leadership presence in the biopharmaceutical industry, EMD Serono's US footprint continues to grow, with more than 1100 employees around the country and fully integrated commercial, clinical and research operations in the company's home state of Massachusetts.

For more information, please visit www.emdserono.com

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 receipt of milestone payments by EMD Serono as a result of the obtaining of marketing approval for *EGRIFTA*[™](tesamorelin for injection), the efficacy of *EGRIFTA*[™](tesamorelin for injection) in selectively reducing VAT, the capacity of the Company to obtain regulatory approval and commercialize *EGRIFTA*[™](tesamorelin for injection) in additional markets, the growth of Theratechnologies through the development of *EGRIFTA*[™](tesamorelin for injection) in additional clinical programs in other medical conditions and the capacity of the Company to enter into commercial agreements with partners for the commercialization of *EGRIFTA*[™](tesamorelin for injection) in additional markets. The Company disclaims any liability resulting from the statements made by EMD Serono in this press release and under the section "About EMD Serono, Inc."

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, and, accordingly, 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 risk that the Company may not receive the regulatory milestones under the collaboration and licensing agreement entered into with EMD Serono, that the administration of *EGRIFTA*[™](tesamorelin for injection) does not have the same effect in reducing VAT on all patients, that *EGRIFTA*[™](tesamorelin for injection) is not approved for commercial sale by regulatory agencies in geographies other than the United States, that the design of additional clinical programs may not be begun or, if begun, must be suspended, or that the Company will not find additional partners or that, if and when found, it will not be able to enter into commercialization agreements with such partners on reasonable and commercially-acceptable terms.

Certain assumptions made in preparing the forward-looking information include, among others, that EMD Serono will meet its obligations under the collaboration and licensing agreement and that the Company will receive these milestones, that patients administered with *EGRIFTA*[™](tesamorelin for injection) will benefit from a reduction in VAT, that regulatory agencies in other geographies will also approve *EGRIFTA*[™](tesamorelin for injection), that results from additional clinical programs will be positive, and that the Company, by itself or through third parties, will be able to commercialize *EGRIFTA*[™](tesamorelin for injection) in additional markets.

All of the forward-looking information is qualified by the foregoing cautionary statements. Forward-looking information reflects current expectations regarding future events only as of the date of release of this press release. The Company refers potential investors to the "Risks and Uncertainties" section of its Annual Information Form (the "AIF") dated February 23, 2010. The AIF is available at www.sedar.com under the Company's public filings. 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 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.

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