



## Theratechnologies files New Drug Submission for *EGRIFTA*<sup>®</sup> with Health Canada

**Montreal, Canada – June 20, 2011** – Theratechnologies Inc. (TSX: TH) (NASDAQ: THER) today announced that it has filed a New Drug Submission (NDS) with the Therapeutic Products Directorate of Health Canada for *EGRIFTA*<sup>®</sup> (tesamorelin for injection).

*EGRIFTA*<sup>®</sup> is an analogue of the growth hormone-releasing factor (GRF) proposed for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy. Currently, there are no approved treatments for lipodystrophy in HIV patients available in Canada.

“Following the launch of *EGRIFTA*<sup>®</sup> in the U.S., Theratechnologies continues to pursue additional regulatory filings in major markets around the world. As a Canadian-based company, we are pleased to move forward with a regulatory filing in our home country,” stated Mr. John-Michel T. Huss, President and Chief Executive Officer of Theratechnologies. “Theratechnologies’ filing with Health Canada is part of our commitment to maximize the commercial potential of *EGRIFTA*<sup>®</sup> and to help address currently unmet medical needs here in Canada,” concluded Mr. Huss.

The NDS is based on the positive results from two Phase 3 clinical trials, which enrolled more than 800 patients, and follows a marketing approval for *EGRIFTA*<sup>®</sup> by the U.S. Food and Drug Administration received in November 2010.

On June 6, 2011, Theratechnologies announced that its partner, Ferrer Internacional S.A., filed a Marketing Authorization Application (MAA) with the European Medicines Agency for tesamorelin. If approved, tesamorelin will receive marketing authorization for the 27 European Union member countries as well as in Iceland, Liechtenstein and Norway.

### **About *EGRIFTA*<sup>®</sup>**

*EGRIFTA*<sup>®</sup>, a once-daily injection, is a novel, stabilized analogue of GRF. GRF is a hypothalamic peptide that acts on the pituitary cells in the brain to stimulate the synthesis and pulsatile release of endogenous growth hormone (GH). GH has been shown to play an important role in regulating lipid metabolism and body composition (e.g., increasing muscle mass and reducing fat)<sup>1</sup>.

### **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 accumulation of excess abdominal fat accumulation, which is known as abdominal lipohypertrophy.

## **About Theratechnologies**

Theratechnologies (TSX: TH) (NASDAQ: THER) is a specialty pharmaceutical company that discovers and develops innovative therapeutic peptide products, with an emphasis on growth-hormone releasing factor peptides. Its first product, *EGRIFTA*<sup>®</sup> (tesamorelin for injection), was approved by the United States Food and Drug Administration in November 2010. To date, *EGRIFTA*<sup>®</sup> is the only approved therapy for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. *EGRIFTA*<sup>®</sup> has not been approved in Canada.

*EGRIFTA*<sup>®</sup> is currently marketed in the United States by EMD Serono pursuant to a collaboration and licensing agreement executed in October 2008. In addition, Theratechnologies has signed distribution and licensing agreements with a subsidiary of Sanofi granting them the exclusive commercialization rights for *EGRIFTA*<sup>®</sup> for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy in Latin America, Africa and the Middle East and with Ferrer Internacional S.A. granting them the exclusive commercialization rights for *EGRIFTA*<sup>®</sup> for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy in Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries.

## **Additional Information about Theratechnologies**

Further information about Theratechnologies is available on the Company's website at [www.theratech.com](http://www.theratech.com). Additional information, including the Annual Information Form and the Annual Report, is also available on SEDAR at [www.sedar.com](http://www.sedar.com) and on the Securities and Exchange Commission's website at [www.sec.gov](http://www.sec.gov).

## **Forward-Looking Information**

This press release contains certain statements that are considered "forward-looking information" within the meaning of applicable securities legislation, which statements may contain such words as "may", "would", "could", "will", "intend", "plan", "anticipate", "believe", "estimate", "expect" and similar expressions. This forward-looking information includes, but is not limited to, information regarding the potential approval of *EGRIFTA*<sup>®</sup> for the treatment of excess abdominal fat in adult HIV-infected patients with lipodystrophy in Canada and in other jurisdictions.

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 Theratechnologies' control that could cause actual results to differ materially from those that are disclosed in or implied by such forward-looking information. These assumptions include, but are not limited to, that Health Canada and other regulatory agencies in other jurisdictions will approve *EGRIFTA*<sup>®</sup> for the treatment of excess abdominal fat in adult HIV-infected patients with lipodystrophy and that no additional clinical trials will be required by Health Canada and other regulatory agencies in other jurisdictions in order to approve *EGRIFTA*<sup>®</sup>. These risks and uncertainties include, but are not limited to, the risk that Health Canada and other regulatory agencies in other jurisdictions do not approve *EGRIFTA*<sup>®</sup> for the treatment of excess abdominal fat in adult HIV-infected patients with lipodystrophy or that Health Canada or other regulatory agencies in other jurisdictions

require additional clinical studies prior to make any decision regarding the approval or non-approval of *EGRIFTA*<sup>®</sup>.

Theratechnologies refers potential investors to the "Risks and Uncertainties" section of its Annual Information Form (AIF) dated February 22, 2011. The AIF is available at [www.sedar.com](http://www.sedar.com) and at [www.sec.gov](http://www.sec.gov) under Theratechnologies' 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 Theratechnologies' expectations as of that date.

Theratechnologies 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.

<sup>1</sup>*Grunfeld C et al. J Acquir Immune Defic Syndr; 45:286-297 (2007). Lo J et al. JAMA, 300: 509518 (2008).*

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