

## Health Canada Accepts to Review Theratechnologies' New Drug Submission for *EGRIFTA*<sup>®</sup>

**Montreal, Canada – August 16, 2011** – Theratechnologies Inc. (TSX: TH) (NASDAQ: THER) today announced that the Therapeutic Products Directorate of Health Canada has accepted to review its New Drug Submission (NDS) for *EGRIFTA*<sup>®</sup> (tesamorelin for injection) filed in late June.

"We are pleased that Health Canada has completed the screening of our NDS for *EGRIFTA*<sup>®</sup> and has accepted to move forward with the technical review," stated Mr. John-Michel T. Huss, President and Chief Executive Officer of Theratechnologies. "We look forward to working with Health Canada throughout the review process," added Mr. Huss.

*EGRIFTA*<sup>®</sup>, or tesamorelin, 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 is no approved treatment for lipodystrophy in HIV patients available in Canada.

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. Additional applications for tesamorelin for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy are currently under review with regulatory agencies in Europe and Israel.

### **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>. For more information about *EGRIFTA*<sup>®</sup>, including its U.S. Food and Drug Administration approved indications, limitations of use and complete risk profile, please consult the full U.S. Prescribing Information available at [www.egrifta.com/Pdfs/Prescribing\\_Information.pdf](http://www.egrifta.com/Pdfs/Prescribing_Information.pdf). *EGRIFTA*<sup>®</sup> has not been approved in Canada.

### **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, which is known as abdominal lipohypertrophy.

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## 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> 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 an affiliate of Sanofi, granting them the exclusive commercialization rights for tesamorelin 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 tesamorelin 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.

Theratechnologies is also looking to develop tesamorelin for the treatment of patients suffering from muscle wasting associated with Chronic Obstructive Pulmonary Disease (COPD). Tesamorelin has been shown to increase muscle mass, which makes it a potential treatment for muscle wasting. The COPD clinical program is expected to begin in September 2011.

## 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, the timing of the beginning of the COPD clinical program and the development of tesamorelin for the treatment of patients suffering from muscle wasting associated with COPD.

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, 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>, that all elements will be in place to begin the COPD clinical program in September 2011, and that the development of tesamorelin for the treatment of patients suffering from muscle wasting associated with COPD will be successful. 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, that Health Canada or other regulatory agencies in other jurisdictions require additional clinical studies prior to making any decision regarding the approval or non-approval of *EGRIFTA*<sup>®</sup>, that the beginning of the COPD clinical program is delayed, or that the results of clinical studies using tesamorelin to treat patients suffering from muscle wasting associated with COPD are negative and lead to a delay in pursuing such studies or a termination thereof.

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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