

# HEALTH CANADA APPROVES EGRIFTA<sup>™</sup> (tesamorelin for injection) AND THERATECHNOLOGIES REGAINS CANADIAN COMMERCIALIZATION RIGHTS TO EGRIFTA<sup>™</sup>

**Montreal, Canada – April 30, 2014** – Theratechnologies Inc. (Theratechnologies) (TSX: TH) is pleased to announce that it has received a notice of compliance (regulatory approval) from Health Canada for  $EGRIFTA^{TM}$  (tesamorelin for injection).

"This represents yet another important milestone for Theratechnologies and we are pleased that Canadian authorities have approved a drug developed in our country," said Luc Tanguay, President and CEO, Theratechnologies Inc.

Consistent with its previously announced decision to resume production of *EGRIFTA*<sup>™</sup> (tesamorelin for injection) in its 1mg/vial presentation, the Company will file a supplementary new drug submission (sNDS) with Health Canada to obtain authorization to commercialize this presentation.

 $EGRIFTA^{TM}$  (tesamorelin for injection) was first approved by the United States Food and Drug Administration in November 2010. Since then, hundreds of patients have been treated with  $EGRIFTA^{TM}$  in this country.

# Theratechnologies to market *EGRIFTA*<sup>™</sup> in Canada

The approval of *EGRIFTA*<sup>™</sup> in Canada comes as Theratechnologies completed discussions with Actelion Pharmaceuticals Canada Inc. (Actelion) to regain marketing rights in Canada. Theratechnologies and Actelion entered into a termination agreement on April 30, 2014, pursuant to which the Company regained all rights under the supply, distribution and licensing agreement entered into in February 2012 (Original Agreement). Consistent with the terms of the Original Agreement pursuant to which no upfront payment was made by Actelion to the Company, the termination agreement does not provide for financial compensation to any of the parties involved. As a result, Theratechnologies will develop its own marketing strategy for Canada which will benefit from key learning experience in the United States.

"After regaining all commercialisation rights for *EGRIFTA*<sup>™</sup> (tesamorelin for injection) in the United States, we came to the conclusion that it would be desirable and preferable for Theratechnologies to assume all commercialisation activities in Canada. As we develop and implement our marketing plan in Canada, we will benefit from synergies stemming from our operations in the United States, and maximise the potential value of that territory for our shareholder," added Luc Tanguay.

### **Indication in Canada**

 $EGRIFTA^{TM}$  is indicated for the treatment of excess visceral adipose tissue, as assessed by waist circumference  $\ge 95$  cm for men and  $\ge 94$  cm for women, and confirmed by a visceral adipose tissue (VAT) level > 130 cm<sup>2</sup> by CT scan, in treatmentexperienced adult HIV-infected patients.  $EGRIFTA^{TM}$  is not indicated for weight loss management. Treatment with  $EGRIFTA^{TM}$  should be limited to patients who failed to reduce excess VAT using diet and exercise. Since the long-term cardiovascular safety and potential long-term cardiovascular benefit of  $EGRIFTA^{TM}$  treatment have not been studied and are not known, careful consideration should be given whether to continue  $EGRIFTA^{TM}$  treatment in patients who do not show a clear efficacy response, as judged by the degree of reduction in visceral adipose tissue measured by waist circumference or CT scan. There are no data to support improved compliance with anti-retroviral therapies in HIV-positive patients taking  $EGRIFTA^{TM}$ .

## About Theratechnologies

Theratechnologies (TSX: TH) is a specialty pharmaceutical company addressing unmet medical needs in metabolic disorders to promote healthy ageing and improved quality of life. Further information about Theratechnologies is available on the Company's website at www.theratech.com, on SEDAR at www.sedar.com and on the SEC's website at <u>www.sec.gov</u>.

### 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 Theratechnologies' growth, information regarding the availability of the drug to Canadian patients, information regarding the filing of a sNDS and information regarding the capacity of the Company to commercialise  $EGRIFTA^{TM}$  (tesamorelin for injection) in Canada.

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, the fact that Theratechnologies will resume the manufacture of  $EGRIFTA^{TM}$  with the 1mg/vial presentation, will file a sNDS with Health Canada and that such sNDS will be approved by Health Canada and the fact that  $EGRIFTA^{TM}$  will be eligible for reimbursement by third-party payors and the various provinces in Canada.

These risks and uncertainties include, but are not limited to, the risk that Theratechnologies is unable to resume the production of  $EGRIFTA^{TM}$  or that material delays to resume production is encountered, the risk that batches of the 1mg/vial presentation of  $EGRIFTA^{TM}$  are not within specifications, the risk that Health Canada does not approve the sNDS which would prevent the commercialization of  $EGRIFTA^{TM}$  in Canada with the 1mg/vial presentation, the risk that  $EGRIFTA^{TM}$  is not reimbursed by third-party payors and the provinces in Canada resulting in a low demand for  $EGRIFTA^{TM}$ .

We refer potential investors to the "Risk Factors" section of our Annual Report on Form 20-F dated February 27, 2014 available at <u>www.sedar.com</u>, <u>www.sec.gov</u> and <u>www.theratech.com</u>. 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 statements reflect current expectations regarding future events and speak only as of the date of this press release and represent our expectations as of that date.

We undertake 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.

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