

# ews Release

# Theratechnologies Announces New Findings with the Investigational Antiretroviral Ibalizumab and with EGRIFTA® (tesamorelin for injection)

Results Presented at 9th IAS Conference on HIV Science (IAS 2017) in Paris, France

Montreal, Canada – July 24, 2017 – Theratechnologies Inc. (Theratechnologies) (TSX: TH) announced today that results on HIV susceptibility to ibalizumab from the Phase IIb trial, TMB-202, along with new findings for EGRIFTA® (tesamorelin for injection), are being presented during poster sessions at the 9<sup>th</sup> IAS Conference on HIV Science (IAS 2017) in Paris, France.

# **Ibalizumab**

The Phase II data for ibalizumab, a long-acting monoclonal antibody, show no significant difference in susceptibility (measured by maximum percent inhibition or ICHALFMAX Fold Change) in patient HIV isolates that were either sensitive or resistant to other antiretroviral agents, including nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors, protease inhibitors, integrase strand transfer inhibitors, enfuvirtide and maraviroc.

"HIV drug resistance is a key topic at the IAS conference this year, and these findings are particularly important as they suggest that ibalizumab is equally active against HIV whether it is resistant or responsive to approved antiretroviral agents," said Steve Weinheimer, Vice President, Biological Sciences at TaiMed Biologics USA. "On the heels of the BLA acceptance for priority review, these data provide additional support for ibalizumab as a potential tool for the treatment of multidrug resistant HIV-1," added Mr. Weinheimer.

# **EGRIFTA®**

In a retrospective analysis of datasets from two, multicenter, randomized placebocontrolled trials of EGRIFTA® among HIV-infected adults with lipodystrophy, fat in trunk muscles decreased and trunk muscle area increased over 26 weeks in patients with excess visceral adipose tissue (VAT, abdominal fat) who had shown a clinical response to EGRIFTA® (VAT decrease of 8 percent or more). These results were seen across a number of trunk muscle groups and were independent of the change in amount of VAT for many of the measures.

"This is the first study to evaluate changes in trunk muscle fat (both abdominal and spine musculature) in HIV patients who have responded to tesamorelin," said Kristine Erlandson, MD, Assistant Professor of Medicine, Divisions of Infectious Disease and Geriatric Medicine, University of Colorado. "We are pleased to continue to uncover new information on the potential effects of tesamorelin in HIV patients with excess abdominal fat," added Dr. Erlandson.

EGRIFTA® is not indicated for trunk muscle fat decrease.

### About ibalizumab

Ibalizumab is an investigational humanized monoclonal antibody being developed for the treatment of multidrug resistant HIV-1 infection. Unlike other antiretroviral agents, ibalizumab binds primarily to the second extracellular domain of the CD4+ T cell receptor, away from major histocompatibility complex II molecule binding sites. It potentially prevents HIV from infecting CD4+ immune cells while preserving normal immunological function.

Ibalizumab is active against HIV-1 resistant to all approved antiretroviral agents.

Ibalizumab is currently under review by the FDA following the acceptance of a Biologics License Application on June 30, 2017.

# INDICATION AND IMPORTANT RISK INFORMATION FOR EGRIFTA®

### Indication

*EGRIFTA*<sup>®</sup> is indicated for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

### Limitations of Use:

- The impact and safety of EGRIFTA® on cardiovascular health have not been studied
- EGRIFTA® is not indicated for weight loss management.
- It is not known whether taking EGRIFTA® helps improve compliance with antiretroviral medications.

### Contraindications:

Do not use EGRIFTA® if you:

- Have pituitary gland tumor, pituitary gland surgery or other problems related to your pituitary gland.
- Have active cancer, either newly diagnosed or recurrent, or are receiving treatment for cancer.
- Are allergic to tesamorelin or any of the ingredients in EGRIFTA<sup>®</sup>.
- Are pregnant or become pregnant. If you become pregnant, stop using *EGRIFTA*® and talk with your healthcare provider.

### Warnings and Precautions

- **Neoplasms:** *EGRIFTA*<sup>®</sup> therapy should be initiated after careful evaluation of the potential benefit of treatment in patients with a history of non-malignant neoplasms or treated and stable malignancies.
- Elevated IGF-1: IGF-1 levels should be monitored closely during EGRIFTA®
  therapy. Careful medical consideration should be given to discontinuing EGRIFTA®
  in patients with persistent elevations of IGF-1 levels (eg, >3 SDS).

- **Fluid Retention:** Fluid retention, manifesting as increased tissue turgor and musculoskeletal discomfort, may occur during *EGRIFTA*® therapy.
- **Glucose Intolerance:** *EGRIFTA*<sup>®</sup> treatment may result in glucose intolerance. Glucose status should be carefully evaluated prior to initiating *EGRIFTA*<sup>®</sup> treatment and monitored periodically for changes in glucose metabolism.
- Hypersensitivity Reactions: Hypersensitivity reactions may occur in patients treated with EGRIFTA<sup>®</sup>. In cases of suspected hypersensitivity reactions, patients should be advised to seek prompt medical attention and treatment with EGRIFTA<sup>®</sup> should be discontinued immediately
- **Injection Site Reactions:** *EGRIFTA*® treatment may cause injection site reactions, including injection site erythema, pruritus, pain, irritation, and bruising.
- Acute Critical Illness: EGRIFTA® has not been studied in patients with acute critical illness. 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. Since EGRIFTA® stimulates growth hormone production, careful consideration should be given to discontinuing EGRIFTA® in critically ill patients.

# **Drug Interactions**

- Cytochrome P450-Metabolized Drugs: EGRIFTA® had no significant impact on the pharmacokinetic profiles of simvastatin in healthy subjects; however, careful monitoring is advisable when EGRIFTA® is administered in combination with other drugs known to be metabolized by CYP450 liver enzymes.
- Growth hormone is known to inhibit 11β-hydroxysteroid dehydrogenase type 1 or 11βHSD-1, a microsomal enzyme required for conversion of cortisone to its active metabolite, cortisol, in hepatic and adipose tissue. Because tesamorelin stimulates growth hormone production, patients receiving glucocorticoid replacement for previously diagnosed hypoadrenalism may require an increase in maintenance or stress doses following initiation of EGRIFTA®, particularly in patients treated with cortisone acetate and prednisone because conversion of these drugs to their biologically active metabolites is dependent on the activity of 11βHSD-1.

## **Immunogenicity**

 Anti-tesamorelin IgG antibodies were detected in approximately half of patients treated with EGRIFTA® and generally disappeared over time after discontinuation of treatment. Antibodies did not appear to impact the efficacy of EGRIFTA®

### Use in Specific Populations.

- Nursing Mothers: Because of both the potential for HIV-1 infection transmission and serious adverse reactions in nursing infants, mothers receiving EGRIFTA® should be instructed not to human breast-feed
- Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

- **Geriatric Use:** There is no information on the use of *EGRIFTA*® in patients greater than 65 years of age with HIV and lipodystrophy
- Renal and Hepatic Impairment: Safety, efficacy, and pharmacokinetics of EGRIFTA® in patients with renal or hepatic impairment have not been established
- Pregnancy: EGRIFTA® 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® offers no known benefit and could result in fetal harm.

### **Adverse Reactions**

In clinical trials, the most common *EGRIFTA*® adverse reactions occurring in >5% of patients during the 26-week main phase of the combined studies included hypersensitivity reactions, reactions due to the effect of GH including arthralgia, extremity pain, peripheral edema, and myalgia, and injection site reactions including injection site erythema and pruritis.

For complete disclosure of *EGRIFTA*® product information, please read the <u>Full</u> <u>Prescribing Information</u>, <u>Patient Information</u>, and <u>Patient Instructions for Use</u>.

For more information about *EGRIFTA*<sup>®</sup>, contact the *EGRIFTA ASSIST*<sup>™</sup> toll-free at 1-844-347-EGRIFTA or 1-844-347-4382. To report suspected adverse reactions, contact the *EGRIFTA ASSIST*<sup>™</sup> toll-free or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

# **About Theratechnologies**

Theratechnologies (TSX: TH) is a specialty pharmaceutical company addressing unmet medical needs to promote healthy ageing and an improved quality of life among HIV patients. Further information about Theratechnologies is available on the Company's website at www.theratech.com and on SEDAR at <a href="https://www.sedar.com">www.sedar.com</a>.

### **Forward-Looking Information**

This press release contains statements that are considered forward-looking information ("FLI") within the meaning of securities laws that are based on our management's belief and assumptions and on information currently available to our management. You can identify forward-looking statements by terms such as "may", "will", "should", "could", "would", "outlook", "believe", "plan", "envisage", "anticipate", "expect" and "estimate" or the negatives of these terms, or variations of them. The forward-looking statements contained in this press release include, but are not limited to, the approval of ibalizumab in the United States for the treatment of MDR HIV-1 infected patients, the effect of ibalizumab to treat HIV and, more particularly, the treatment of multidrug resistant HIV-1, and the growth of Theratechnologies based on such approval.

Forward-looking statements are based upon a number of assumptions and are 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 following: ibalizumab will be approved by the FDA for the treatment of MDR

HIV-1 infected patients and, if approved, Theratechnologies will have set-up on time the necessary infrastructure to launch and commercialize ibalizumab in the United States, and ibalizumab will be well received by the marketplace. These risks and uncertainties include, but are not limited to, the risk that the FDA does not approve ibalizumab as a treatment for MDR HIV-1 infection and, if approved, that the FDA imposes a significant limitation on its use resulting in a smaller patient population who could benefit from ibalizumab, that additional clinical trials are requested to be conducted prior to approving, or post-approval of, ibalizumab, that sales of *EGRIFTA*® decrease or that untoward side effects become known leading to a recall or the withdrawal of *EGRIFTA*® from the market.

We refer potential investors to the "Risk Factors" section of our Annual Information Form (AIF) dated February 7, 2017 for additional risks and uncertainties about Theratechnologies. The AIF is available on the Company's website at www.theratech.com and on SEDAR at www.sedar.com. 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.

# Contact:

Philippe Dubuc

Senior Vice President and Chief Financial Officer

Tel.: (514) 336-7800, ext. 297