Theratechnologies Submits Tesamorelin F8 Formulation sBLA for FDA Review

Sep 25, 2023

- *F8 formulation intended to replace EGRIFTA SV® with simplified dosing for the treatment of excess abdominal fat in adults with HIV and lipodystrophy*

MONTREAL, Sept. 25, 2023 (GLOBE NEWSWIRE) -- Theratechnologies Inc. (“Theratechnologies” or the “Company”) (TSX: TH) (NASDAQ: THTX), a biopharmaceutical company focused on the development and commercialization of innovative therapies, today announced that the Company has filed a supplemental Biologics License Application (sBLA) for the F8 formulation of tesamorelin to the U.S. Food and Drug Administration (FDA) for review. Tesamorelin is the only medication approved in the U.S. for the reduction of excess abdominal fat in adults with HIV who have lipodystrophy.

Pharmacokinetic studies have shown bioequivalence of the F8 formulation to the original F1 formulation of tesamorelin (previously sold under the trade name *EGRIFTA®*). The F8 formulation is eight times more concentrated than *EGRIFTA®* and two times more concentrated than the F4 formulation sold in the U.S. under the trade name *EGRIFTA SV®*, enabling a smaller volume of administration as well as a new product presentation in a multiple-dose vial (MDV) that is reconstituted only once per week. The new formulation is patent protected in the U.S. until 2033.

“In our interactions with HIV healthcare providers, we have seen their growing concern with the clinical challenges of excess abdominal fat, a condition that can cause a myriad of negative health consequences for their patients,” said Christian Marsolais, Ph.D., Senior Vice President and Chief Medical Officer at Theratechnologies. “We developed the F8 formulation of tesamorelin to better address this medical need, as we continue to demonstrate our commitment to the HIV community and healthy aging for people with HIV.”

In accordance with the FDA’s filing review period, Theratechnologies expects to receive an acknowledgment letter of the sBLA application within 30 days along with a Prescription Drug User Fee Act (PDUFA) goal date. The proposed proprietary name for the F8 formulation, EGRIFTA MDV™, is already under review by the FDA.

About *EGRIFTA SV®* (tesamorelin for injection)

EGRIFTA SV® is approved in the U.S. for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy*. *EGRIFTA SV®* is a growth hormone releasing factor (GHRF) analog that acts on pituitary cells in the brain to stimulate the production and release of endogenous growth hormone.

* Limitations of Use:

- Long-term cardiovascular safety of *EGRIFTA SV®* has not been established. Consider risk/benefit of continuation of treatment in patients who have not had a reduction in visceral adipose tissue.
- *EGRIFTA SV®* is not indicated for weight loss management as it has a weight neutral effect.
- There are no data to support improved compliance with anti-retroviral therapies in HIV-positive patients taking *EGRIFTA SV®*.

Do not use *EGRIFTA SV®* if a patient:

- Has a pituitary gland tumor, has had pituitary gland surgery, has other problems related to their pituitary gland, or has had radiation treatment to their head or head trauma.
- Has active cancer.
- Is allergic to tesamorelin or any of the ingredients in *EGRIFTA SV®*.
- Is pregnant or planning to become pregnant.

The most commonly reported adverse reactions of *EGRIFTA SV®* include: hypersensitivity reactions, hyperglycemia, injection site reactions, arthralgia, pain in extremity, myalgia and peripheral edema.

Refer to www.egriftasv.com for the full prescribing information, patient information and instructions for use for further details about this product.

About Theratechnologies

Theratechnologies (TSX: TH) (NASDAQ: THTX) is a biopharmaceutical company focused on the development and commercialization of innovative therapies addressing unmet medical needs. Further information about Theratechnologies is available on the Company's website at www.theratech.com, on SEDAR at www.sedarplus.ca and on EDGAR at www.sec.gov. Follow Theratechnologies on Linkedin and Twitter.

Forward-Looking Information

This press release contains forward-looking statements and forward-looking information (collectively, the “Forward-Looking Statements”), within the meaning of applicable securities laws, that are based on our management's beliefs and assumptions and on information currently available to our management. You can identify Forward-Looking Statements by terms such as "may", "will", "should", "could", “promising”, “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, statements regarding the bioequivalence of the F8 formulation to the original F1 formulation, the approval of the F8 formulation by the FDA and its proposed trade name, EGRIFTA MDV™, and the timelines to receive the acknowledgement letter from the FDA. Although the Forward-Looking Statements contained in this press release are based upon what the Company believes are reasonable assumptions in light of the information currently available, investors are cautioned against placing undue reliance on this information since actual results may vary from the Forward-Looking Statements. Certain assumptions made in preparing the Forward-Looking Statements include that: the FDA will determine that the F8 formulation is bioequivalent to the original F1 formulation, the FDA will approve the F8 formulation and its proposed trade name EGRIFTA MDV™ and the timelines set forth in this press release are accurate. Forward-Looking Statements 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 Statements. These risks and uncertainties include, but are not limited to, those related to or arising from: a delay in the receipt of the acknowledgement letter from the FDA and the PDUFA date, a rejection of the sBLA by the FDA because it deems that the submission does not contain all of the prescribed information, and the non-approval of the F8 formulation by the FDA preventing its commercial launch in the United States. We refer current and potential investors to the "Risk Factors" section of our Annual Information Form dated February 27, 2023, available on SEDAR at www.sedarplus.ca and on EDGAR at www.sec.gov as an exhibit to our report on Form 40-F dated February 28, 2023, under Theratechnologies' public filings for additional risks involved in our business. 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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