Theratechnologies Receives January 2024 PDUFA Goal Date for Tesamorelin F8 Formulation sBLA

Oct 04, 2023

This news release constitutes a "designated news release" for the purposes of the Company's prospectus supplement dated December 16, 2021 to its short form base shelf prospectus dated December 14, 2021.

MONTREAL, Oct. 04, 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 U.S. Food and Drug Administration (FDA) has assigned a Prescription Drug User Fee Act (PDUFA) goal date of January 22, 2024 to the Company's supplemental Biologics License Application (sBLA) of the F8 formulation of tesamorelin.

Tesamorelin is the only medication approved in the U.S. for the reduction of excess abdominal fat in adults with HIV who have lipodystrophy. Once approved, the F8 formulation is set to replace the current F4 formulation, which is sold in the U.S. under the trade name *EGRIFTA SV*®. The proposed proprietary name for the F8 formulation of tesamorelin, EGRIFTA MDV™, is already under review by the FDA.

In accordance with the FDA's standard review practices, unless the Company is notified before November 21, 2023, that the application is not sufficiently complete to permit a substantive review, the FDA will file the sBLA for the F8 formulation of tesamorelin.

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 approval and filing of the F8 formulation by the FDA and its proposed trade name, EGRIFTA MDV™, and the exact user fee goal date. 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 file the F8 formulation the user fee goal date will remain on January 22, 2024. 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 filing of the sBLA for the F8 formulation, the postponement of the user fee goal 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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