Theratechnologies Receives Complete Response Letter (CRL) from the FDA for the F8 Formulation of Tesamorelin sBLA

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- *FDA requesting clarifications around chemistry, manufacturing and controls and additional information related to immunogenicity*
- *CRL does not impact commercial availability of EGRIFTA SV®, the F4 formulation of tesamorelin, the only medication approved in the U.S. for the reduction of excess abdominal fat in adults with HIV and lipodystrophy*

MONTREAL, Jan. 24, 2024 (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 issued a Complete Response Letter (CRL) in response to the Company’s supplemental Biologics License Application (sBLA) for the F8 formulation of tesamorelin. The Company will address the FDA’s request and intends to pursue approval of this newer formulation of tesamorelin.

The questions outlined in the CRL are largely related to chemistry, manufacturing and controls (CMC) concerning the microbiology, assays, impurities and stability for both the lyophilized product and the final reconstituted drug product. In addition, the FDA requested further information to understand the potential impact of the proposed formulation on immunogenicity risk.

“While we are disappointed to receive a Complete Response Letter from the FDA for the F8 formulation of tesamorelin containing questions that were not raised during the review process, we plan to address these new comments as swiftly as possible,” said Christian Marsolais, Ph.D., Senior Vice President and Chief Medical Officer at Theratechnologies. “We remain focused on bringing this new formulation of tesamorelin to market as part of our commitment to innovate and simplify treatments for people with HIV.”

The Company will continue to commercialize *EGRIFTA SV®*, which is the only approved treatment in the U.S. for the reduction of excess abdominal fat in adults with HIV who have lipodystrophy.

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 to *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 X (formerly 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 management's beliefs and assumptions and on information currently available to it. 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 pursuit of the approval of the F8 formulation and the timelines associated with addressing the questions received 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 these statements since actual results may vary from the Forward-Looking Statements contained in this press release. These assumptions include, without limitation, that the Company will be able to satisfactorily address the questions raised by the FDA, resubmit the file to the FDA for approval and obtaining approval of the F8 formulation of tesamorelin. Forward-Looking Statements assumptions are subject to a number of risks and uncertainties, many of which are beyond the Company's 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, the inability of the Company to properly address the concerns of the FDA, and, even if the concerns are addressed, the non-approval of the F8 formulation by the FDA because the Company's responses are not to the satisfaction of the FDA. 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. 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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