Theratechnologies Receives March 2025 PDUFA Goal Date for Updated Tesamorelin F8 Formulation sBLA

Dec 10, 2024

MONTREAL, Dec. 10, 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 United States Food and Drug Administration (FDA) has assigned a Prescription Drug User Fee Act (PDUFA) goal date of March 25, 2025 to the Company’s recently submitted supplemental Biologics License Application for the F8 formulation of tesamorelin.

If approved by the FDA, the F8 formulation is intended to replace the F4 formulation, which is sold in the U.S. under the trade name *EGRIFTA SV*®. The new formulation is patent protected in the U.S. until 2033.

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 time period related to the review of the sBLA by 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. Certain assumptions made in preparing the Forward-Looking Statements include that: (i) the FDA will complete its review within the timelines set forth in the press release; (ii) the Company’s responses to the issues raised by the FDA in its Complete Response Letter (“CRL”) will be satisfactory to the FDA; (iii) the FDA will approve the sBLA for the F8 formulation; and (iv) if approved, health care providers and patients will adopt the F8 formulation. 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: (i) the review period of the sBLA which could be longer than the timelines set forth in this press release ;(ii) the non-approval of the sBLA by the FDA, or the issuance of another CRL; and (iii) the negative reception by the marketplace of the F8 formulation, if approved. The Company refers current and potential investors to the “Risk Factors” section of the Company’s annual information form filed under Form 20-F dated February 21, 2024 available on SEDAR+ at www.sedarplus.ca and on EDGAR at www.sec.gov 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 the Company’s expectations as of that date.

The Company undertakes 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.

Contacts:

Investor Inquiries:
Joanne Choi
Senior Director, Investor Relations
jchoi@theratech.com
1-551-261-0401

Media inquiries:
Julie Schneiderman
Senior Director, Communications & Corporate Affairs
communications@theratech.com
1-514-336-7800