Theratechnologies Provides Update on EGRIFTA SV® Supply

Jan 09, 2025

MONTREAL, Jan. 09, 2025 (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 a shortage of *EGRIFTA SV®* (tesamorelin for injection) will occur at the patient level in mid-January 2025, following a voluntary shutdown of the contract manufacturing facility in 2024. While the Company is aware of remaining inventory of *EGRIFTA SV®* in certain pharmacies throughout the United States, several pharmacies have reported stockouts.

Theratechnologies filed a required Prior Approval Supplement (PAS) to the U.S. Food and Drug Administration (FDA) on December 18, 2024. The Company subsequently submitted questions as part of a Type D meeting request concerning the status of two recently manufactured batches of *EGRIFTA SV®*, which are waiting to be released to pharmacies. The FDA confirmed that it would respond to the Company’s questions in writing no later than February 8, 2025.

“We remain committed to people with HIV who rely on *EGRIFTA SV®,* as it is the only FDA-approved medicine of its kind, and we will continue to work with the FDA to expedite the release of the new batches for patients,” said Christian Marsolais, Ph.D., Senior Vice President and Chief Medical Officer at Theratechnologies.

The Company will update the market on any further material developments.

EGRIFTA SV® is distributed in the United States only.

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 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: (i) the time period related to the availability of *EGRIFTA SV®* to patients; (ii) the date by which the FDA will respond to the Company’s questions following its request to have a Type D meeting; and (iii) the timelines related to the potential release of the recently manufactured batches of *EGRIFTA SV®*. 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 provide answers to the questions asked by the Company by February 8, 2025; (ii) the responses to the questions asked by the Company will confirm that the Company is able to release the recently manufactured batches of *EGRIFTA SV®* or will confirm that the review of the PAS will be completed prior to the expiry of a four-month period; (iii) current market demand for *EGRIFTA SV®* will remain unaffected; (iv) the shortage of *EGRIFTA SV®* will not adversely impact the financial conditions of the Company; and (v) the Company will be able to negotiate waivers of defaults with its secured creditors to the extent the drug shortage period results in defaults under its credit agreements. 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) delays in responding to the Company’s questions beyond February 8, 2025; (ii) refusal by the FDA to release the recently manufactured batches of *EGRIFTA SV®* until the PAS review is completed; (iii) FDA’s review of the PAS not being completed before April 18, 2025; (iv) non-approval of the PAS; (v) issuance of questions as part of the PAS review by the FDA resulting in delays in completing the PAS review and resulting in delays beyond April 18, 2025 to release the recently manufactured batches of *EGRIFTA SV®*; (vi) issuance of a complete response letter following the filing of the PAS as a result of the manufacturing site being classified as Official Action Indicated preventing the Company from releasing the recently manufactured batches of *EGRIFTA SV®*; (vii) a decrease in demand for *EGRIFTA SV®* due to its shortage potentially adversely impacting the resumption of the commercialization of *EGRIFTA SV®*; (viii) losses of key employees due to the shortage; and (ix) defaults under the covenants of the credit agreements resulting from the shortage. The Company refers current and potential investors to the “Risk Factors” section of the Company’s 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.

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