Theratechnologies Announces Resumed Production of EGRIFTA SV®

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MONTREAL, Dec. 03, 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 production of *EGRIFTA SV®* has resumed following a voluntary shutdown of the Company’s contract manufacturer’s facility to address observations from an inspection by the US Food and Drug Administration (FDA).

One newly manufactured batch of *EGRIFTA SV®* has completed standard quality control and will be available for release to the market upon approval from the FDA of a Prior Approval Supplement, which the Company is expected to file around mid-December 2024. The manufacturing of two additional batches of *EGRIFTA SV®* is currently underway. The Company implemented measures to carefully manage existing inventory levels of *EGRIFTA SV®* to meet patient demand until mid-January 2025.

Theratechnologies continues to collaborate closely with the relevant divisions of the FDA and other key stakeholders to avoid a shortage at the patient level in 2025.

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 the release of the newly manufactured batch of *EGRIFTA SV®*, the time period related to the filing of the PAS and the availability of *EGRIFTA SV®* to patients.

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 Company will receive all of the relevant information from its third party manufacturer to file a PAS within the timelines set forth herein; (ii) the FDA will review and approve the PAS before mid-January 2025; (iii) the two additional batches of *EGRIFTA SV®* will be within specifications when manufacturing is completed; and (iv) current market demand for *EGRIFTA SV®* will remain unaffected despite the risk of drug shortage.

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) drug shortage of *EGRIFTA SV®* due to various factors, including delays in filing the PAS, rejection of the PAS for failure to meet regulatory requirements, the issuance of comments by the FDA on the PAS impacting its review timelines; and (ii) a decrease in demand for *EGRIFTA SV®* due to the risk of shortage.

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.

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