Theratechnologies Announces Filing of FDA Prior Approval Supplement for EGRIFTA SV® Manufacturing Environment

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MONTREAL, Dec. 18, 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 Company has submitted a Prior Approval Supplement (PAS) to the U.S. Food and Drug Administration (FDA) describing the changes made to the manufacturing environment of the facility where *EGRIFTA SV®* is produced. A PAS is reviewed by the FDA within four months of receipt and an approval is needed prior to the distribution of the recently manufactured batches of *EGRIFTA SV®*.

Existing inventory levels of *EGRIFTA SV®* are expected to meet patient demand until mid-January 2025. Theratechnologies therefore continues discussions with the relevant FDA divisions in an effort to accelerate the release of *EGRIFTA SV®* and avoid a product shortage at the patient level.

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 review period of the PAS by the FDA, the availability of *EGRIFTA SV®* to patients and the avoidance of an *EGRIFTA SV®* shortage at the patient level. 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 PAS as filed will meet FDA’s regulatory requirements; (ii) the classification of the Company’s third party manufacturing site as official action indicated (OAI) will not result in the issuance of a complete response letter (CRL) following the submission of the PAS; (iii) the Company will be successful in its discussions with the various FDA divisions leading to the release of the recently manufactured batches of *EGRIFTA SV®* in order to avoid a drug shortage at the patient level; (iv) the FDA will review and approve the PAS before mid-January 2025; and (v) market demand for *EGRIFTA SV®* will remain unaffected despite the risk, or the occurrence, of a 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) the occurrence of a drug shortage of *EGRIFTA SV®* due to various factors, including the inability of the Company to convince the FDA to accelerate the review timelines of the PAS or agree to alternative solutions allowing the release of the recently manufactured batches of *EGRIFTA SV®*, the rejection of the PAS for failure to meet regulatory requirements, the issuance of comments by the FDA on the PAS impacting its review timelines, the issuance of a CRL requiring the Company’s manufacturing site to be reinspected prior to any newly-manufactured batch of *EGRIFTA SV®* being released to the market; (ii) reduced revenues in the Company’s first quarter of its fiscal year 2025 in the event the PAS is not reviewed expeditiously or alternative solutions are not implemented allowing the Company to resume sales of *EGRIFTA SV®* before a four-month period; and (iii) patient attrition and lower demand for *EGRIFTA SV®* as a result of a drug 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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