



## Theratechnologies Announces a Risk of a Temporary Supply Disruption for EGRIFTA SV® in Early 2025

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MONTREAL, Sept. 17, 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 a risk of a temporary supply disruption for *EGRIFTA SV*® (tesamorelin for injection) in early 2025 caused by an unexpected voluntary shutdown of the Company's contract manufacturer's facility following an inspection by the US Food and Drug Administration (FDA), as well as the FDA review timeline to resume distribution of the product.

"We are collaborating closely with our manufacturer and other stakeholders and will continue to work with the FDA to resume production of *EGRIFTA SV*®," said Paul Lévesque President and CEO at Theratechnologies. "We remain confident that we will avoid any impact on patients in 2025."

The Company will implement measures to carefully manage the inventory levels of *EGRIFTA SV*® to meet patient demand until early January 2025, and estimates that these measures will result in a shortfall of approximately US\$1.6 million in revenue from *EGRIFTA SV*® for its fiscal year 2024.

"Although this situation will affect revenues in the fourth quarter of 2024, we remain on track to deliver a strong Adjusted EBITDA in the current fiscal year and will be providing more details as part of the release of our third quarter results in October," concluded Lévesque.

### Background:

Theratechnologies' manufacturer of *EGRIFTA SV*® recently implemented a three-month voluntary shutdown of its facility to address observations by the FDA Office of Compliance, following a plant inspection. The observations issued by the FDA are not related to the manufacturing process of *EGRIFTA SV*®, but rather related to the manufacturing environment of the facility. The manufacturer is finalizing its remediation measures and has confirmed to the Company that it plans to resume activities by mid-October. Based on these timelines, a batch of *EGRIFTA SV*® is currently scheduled to be manufactured on October 21, 2024.

In order to resume distribution of *EGRIFTA SV*®, Theratechnologies was requested by the FDA to file a Prior Approval Supplement (PAS) describing the changes made by its manufacturer. The Company expects to file the PAS on or around the manufacturing date. A PAS is reviewed by the FDA within four months of receipt.

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](http://www.theratech.com), on SEDAR+ at [www.sedarplus.ca](http://www.sedarplus.ca) and on EDGAR at [www.sec.gov](http://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 effectiveness of the measures to be implemented by the Company to manage the inventory level of *EGRIFTA SV*®; (iii) the dates on which the Company's manufacturer will resume its manufacturing activities and the manufacture of a new batch of *EGRIFTA SV*®; and (iv) the monetary impact on the Company's revenue for the fiscal year 2024.

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 be satisfied with the remediation measures implemented by the manufacturer in response to the observations issued by the FDA and the manufacturer will resume its activities by mid-October and will manufacture a new batch of *EGRIFTA SV*® on October 21, 2024; (ii) no delay in the implementation of the remaining remediation measures at the manufacturer's site will occur; (iii) the information allowing the Company to file a PAS will be available to the Company prior to October 21, 2024; (iv) the new batch of *EGRIFTA SV*® to be manufactured will meet the specifications for market release; (v) the FDA will approve the PAS as filed by the Company; (vi) current market demand for *EGRIFTA SV*® will remain unaffected; and (vii) the financial impact assessment made by the Company about the potential revenue shortfall from *EGRIFTA SV*® is accurate.

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 issuance of additional observations by the FDA to the manufacturer following the finalization of their

review of the remediation measures implemented at the manufacturer's site; (ii) a delay by the manufacturer in implementing the final remediation measures at the manufacturer's site; (iii) the receipt of negative results from the implemented remediation measures; (iv) a delay in providing the information from the remediation measures to the Company; (v) a delay by the Company in filing the PAS; (vi) a decrease in demand for *EGRIFTA* SV<sup>®</sup> due to the risk of shortage; (vii) the failure of the new batch of *EGRIFTA* SV<sup>®</sup> to meet the specifications allowing its release to the market; and (viii) the FDA non-approval of the PAS to be filed by the Company.

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](http://www.sedarplus.ca) and on EDGAR at [www.sec.gov](http://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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