



Theratechnologies Announces Update from Ongoing TH1902 Study

December 1, 2022

This news release constitutes a “designated news release” for the purposes of the Company’s prospectus supplement dated December 16, 2021 to its short form base shelf prospectus dated December 14, 2021.

MONTREAL, Dec. 01, 2022 (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 it has decided to pause the enrollment of patients in its Phase 1 clinical trial of TH1902, the Company’s lead investigational peptide drug conjugate (PDC) for the treatment of sortilin-expressing cancers. The Company plans to submit an amendment to its protocol to the U.S. Food and Drug Administration (FDA) for approval.

Theratechnologies voluntarily made the decision to pause enrollment and revisit the study design after consulting with its investigators. Efficacy results observed thus far were not convincing enough to pursue enrolling patients and did not outweigh the adverse events seen in some patients. As previously reported, these adverse events consist mainly of neuropathy and eye toxicity.

The current intent for the protocol amendment is to modify the dosage regimen to optimize the delivery of TH1902, with lower doses at more frequent intervals. The Company continues to investigate the results obtained thus far in the Phase 1 clinical trial.

“While we are disappointed with these developments, we remain committed to advancing our SORT1+ Technology platform and will continue investigating its potential in the treatment of advanced cancers,” said Christian Marsolais, Ph.D., Senior Vice President and Chief Medical Officer, Theratechnologies.

About SORT1+ Technology™ and TH1902

Theratechnologies is currently developing a platform of proprietary peptides called SORT1+ Technology™ for cancer drug development targeting SORT1 receptors. The SORT1 receptor plays a significant role in protein internalization, sorting and trafficking. It is highly expressed in cancer cells compared to healthy tissue, which makes SORT1 an attractive target for cancer drug development. Expression of SORT1 is associated with aggressive disease, poor prognosis and decreased survival. It is estimated that the SORT1 receptor is expressed in 40% to 90% of cases of endometrial, ovarian, colorectal, triple-negative breast and pancreatic cancers.

TH1902 is currently Theratechnologies’ lead investigational PDC candidate for the treatment of cancer derived from its SORT1+ Technology™. It is the Company’s proprietary peptide linked to docetaxel – a commonly used cytotoxic agent used to treat many cancers. The FDA granted fast track designation to TH1902 as a single agent for the treatment of all sortilin-positive recurrent advanced solid tumors that are refractory to standard therapy.

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.sedar.com and on EDGAR at www.sec.gov.

Forward-Looking Information

This press release contains forward-looking statements and forward-looking information (collectively, “Forward-Looking Statements”), within the meaning of applicable securities laws, that are based on our management’s beliefs and assumptions and on information currently available to our management. You can identify Forward-Looking Statements by terms such as “may”, “will”, “should”, “could”, “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 filing of an amendment to its Phase 1 clinical trial protocol to the FDA, the optimization of the dosage regimen of TH1902 and the advancement of the SORT1+ Technology™ platform. 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. Certain assumptions made in preparing the Forward-Looking Statements include that the amendments to the protocol to be submitted to the FDA will be approved by the FDA allowing the Company to pursue its Phase 1 clinical trial using TH1902, the proposed revised dosage regimen will generate results similar to those observed in preclinical model, research and development work on the SORT1+ Technology™ platform will yield positive results leading to the development of one or many drugs treating various types of cancer. Forward-Looking Statements assumptions are subject to a number of risks and uncertainties, many of which are beyond Theratechnologies’ 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, the non-approval by the FDA of the amendments to the protocol of the Phase 1 clinical trial studying TH1902, the halt of the Phase 1 clinical trial using TH1902, the observation of adverse safety issues and the lack of demonstration of efficacy in many or in all of the patients forming part of the Phase 1 clinical trial, difficulty in recruiting patients if we resume the clinical trial, and lack of resources to further develop the SORT1+ Technology™ platform. We refer current and potential investors to the “Risk Factors” section of our Annual Information Form dated February 23, 2022 available on SEDAR at www.sedar.com and on EDGAR at www.sec.gov as an exhibit to our report on Form 40-F dated February 24, 2022 under Theratechnologies’ public filings for additional risks related to the Company. 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 our expectations as of that date. We undertake 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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