Theratechnologies Announces Path to Resume TH1902 Clinical Development

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MONTREAL, Feb. 16, 2023 (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 an update on the plan to amend and optimize the protocol of its Phase 1 oncology clinical trial with the goal of a timely re-submission to the United States Food and Drug Administration (FDA).

Following a voluntary pause in the study’s enrollment on December 1, 2022, the Company formed a Scientific Advisory Committee (SAC) to help determine the best developmental path forward for TH1902. In addition to the study’s principal investigator, the SAC includes several medical oncologists from across the U.S., who are leading experts in the end-to-end lifecycle of oncology drug development:

- Erika Hamilton, MD, director of Breast Cancer and Gynecologic Cancer Research for Sarah Cannon Research Institute at Tennessee Oncology;
- Daniel Petrylak, MD, professor of medicine in Medical Oncology and Urology and chief, Genitourinary Oncology at Yale School of Medicine; and
- Anthony Tolcher, MD, medical oncologist at Texas Oncology-San Antonio Medical Center.

The Company will continue to seek advice and input from Mace Rothenberg, MD, who is currently a scientific advisor to Theratechnologies.

“We are eager to resume patient enrollment with a revised protocol for TH1902 and have pulled together some of the best scientists in the field of oncology drug development to ensure an optimal amendment,” said Christian Marsolais, Ph.D., Senior Vice President and Chief Medical Officer of Theratechnologies. “Their expert advice will be critical to examining different dosing strategies and patient selection to ultimately improve the chances of success of TH1902.”

Theratechnologies is currently analyzing data and preparing responses to questions received from the FDA. This work is well underway and will be considered by the SAC as part of their meeting, which is scheduled for the latter half of March when the analyses are expected to be ready. Once expert advice is considered, the Company intends to promptly amend the protocol and re-submit to the FDA.

Consistent with the Company’s 2023 objective of generating positive adjusted EBITDA [1] by fiscal year end, any new investments in TH1902 will be stage gated. Once the Phase 1 clinical trial has resumed, Theratechnologies will also evaluate potential partnerships for TH1902.

[1] This is a non-IFRS measure. See “Non-IFRS and Non-U.S. GAAP Measure” below.

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 peptide drug conjugate 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. TH1902 is currently being evaluated in a Phase 1 clinical trial, although patient recruitment has recently been voluntarily paused.

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 timelines to hold the SAC meeting, the expected results stemming from the holding of such SAC meeting, the filing to the FDA of an amendment to the Company’s original Phase 1 clinical trial protocol development of the SORT1+ Technology™ platform, generating positive cash flow from our operations by the 2023 fiscal year end and the finding of a partner for 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: no delay in the SAC meeting will occur; the responses to the FDA questions will be found satisfactory to the SAC and the

SAC will therefore be in a position to advise on amendments to be made to the Phase 1 clinical trial protocol of TH1902; any amendment to the original protocol; the amendments to the Company's protocol will be approved by the FDA and the Company will be able to restart the enrollment of patients; results obtained from resuming our Phase 1 clinical trial using TH1902 will be similar to those observed in the preclinical phase; research and development work on the SORT1+ Technology™ platform will yield positive results leading to the development of one or many peptide-drug conjugates for the treatment of various types of cancer; sales of our products in the United States will continue to grow while our expenses will decrease over time; and the Company will be able to enter into a partnership agreement for the development of the SORT1+ Technology™ platform . 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 occurrence of a delay ion holding the SAC meeting, the absence of conclusive findings by the SAC enabling amendments to the original Phase 1 clinical trial protocol, the non-approval by the FDA of the amended protocol, if and when submitted, difficulties in enrolling patients if we resume the Phase 1 clinical trial using TH1902, negative results obtained from the resumed Phase 1 clinical trial leading to a halt in the development of TH1902, the incapacity of the Company to obtain positive results from the continuous development of its SORT1+ Technology™ platform, no revenue growth from the sale of our products in the United States and/or unexpected important expenses that must be incurred as part of pursuing our business plan, and the incapacity to find a partner for the development of our 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.

Non-IFRS and Non-U.S. GAAP Measure

The information presented in this press release includes a measure that is not determined in accordance with International Financial Reporting Standards ("IFRS") or U.S. generally accepted accounting principles. The financial measure "Adjusted EBITDA" is used by the Company as an indicator of financial performance. "Adjusted EBITDA" is obtained by adding to net profit or loss, finance income and costs, depreciation and amortization, income taxes, share-based compensation from stock options, and certain write-downs (or related reversals) of inventories. "Adjusted EBITDA" excludes the effects of items that primarily reflect the impact of long-term investment and financing decisions rather than the results of day-to-day operations. The Company believes that this measure can be a useful indicator of its operational performance and financial condition from one period to another. The Company uses this non-IFRS measure to make financial, strategic and operating decisions.

Contacts:
Investor inquiries:
Elif McDonald
Senior Director, Investor Relations
ir@theratech.com
1-438-315-8563

Media inquiries:
Julie Schneiderman
Senior Director, Communications & Corporate Affairs
communications@theratech.com
1-514-336-7800