Theratechnologies Receives FDA Agreement to Amended Trial Protocol for its Lead PDC Candidate Sudocetaxel Zendusortide

June 2, 2023

- *Phase 1 trial to resume with weekly dosing, a focus on patients with ovarian cancer and refined patient selection*
- *June 13 call for investors and analysts with trial investigators to provide insights on safety and efficacy data presented at ASCO 2023 that informed protocol update*

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, June 02, 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 that the U.S. Food and Drug Administration (FDA) has agreed to the Company's amended protocol for the Phase 1 clinical trial of sudocetaxel zendusortide, an investigational, first-in-class peptide-drug conjugate (PDC) that targets the sortilin (SORT1) receptor and expedites the internalization and delivery of a cytotoxic payload directly into cancer cells. Today's announcement also marks the lifting of the FDA's partial clinical hold on the Phase 1 trial, following the Company's voluntary pause of patient recruitment in December 2022.

In May 2023, Theratechnologies filed the amended trial protocol, which is designed to improve the therapeutic window of sudocetaxel zendusortide and extend its duration of therapy. The updates include a change in the frequency of administration to weekly dosing and a narrowing of the patient population to focus on those with high-grade serous ovarian cancer, including high-grade peritoneal or fallopian tube cancer, or high-grade endometrioid cancer - a population in which preliminary efficacy has been observed thus far. Patient selection has also been refined to focus on those who are less heavily pretreated, with no more than one taxane failure and a maximum of eight prior cancer treatment regimens.

"We are very pleased that the FDA has agreed to our plans to optimize the dosing regimen for sudocetaxel zendusortide, and to other proposed changes to the protocol so that we can now restart this important Phase 1 clinical trial," said Christian Marsolais, Ph.D., Senior Vice President and Chief Medical Officer at Theratechnologies. "We have been working closely with our scientific advisory committee and the FDA to align on this updated protocol, which we believe will expedite development of this novel peptide-drug conjugate and ultimately deliver effective targeted therapy to people with advanced cancers, while minimizing toxicity."

The amended study will be a modified 6+6 design with two different dosing regimens that are within the efficacious range for sudocetaxel zendusortide: 1.75 mg/kg on days 1, 8, and 15 of a 28-day cycle (similar to 210 mg/m^2 every 3 weeks) and 2.5 mg/kg on the same schedule (similar to 300 mg/m^2 every 3 weeks). A minimum of six patients will be enrolled at the 1.75 mg/kg dose followed by an observational period of three months to assess dose-limiting toxicity (DLT). If deemed safe (0 or 1 DLT), the trial will enroll an additional six patients at the 2.5 mg/kg dose. Following a second three-month observational period, four more patients will be enrolled at the higher dose, for a total of 16 patients in Part 3 of the trial. The amendments also include an option for a basket expansion stage that will comprise patients with selected, difficult-to-treat tumor types in which sudocetaxel zendusortide has shown activity.

"Based on our pharmacokinetic and pharmacodynamic analyses, we decided to switch from body surface area dosing to an equivalent weight-based dosing so we could provide a more precise dose and minimize toxicity for each trial participant," added Dr. Marsolais.

"By exploring lower doses administered more frequently, the Company has put sudocetaxel zendusortide in the best position to characterize its full therapeutic potential and tolerability," said Mace Rothenberg, M.D., scientific advisor to Theratechnologies. "The early stages of the trial have already yielded preliminary data on safety and antitumor activity, and the protocol amendment should build upon that encouraging start. Given the limited treatment options for patients affected by high-grade serous ovarian cancer, I look forward to further results from this trial."

Researchers are presenting early results from Part 1 (dose escalation) and Part 2 (dose expansion) of the multicenter, open-label, Phase 1 trial of sudocetaxel zendusortide at a poster session at the 2023 annual meeting of the American Society of Clinical Oncology (ASCO) on Saturday June 3, in Chicago. Those preliminary safety and efficacy data, which can be found here, informed the FDA-approved amended protocol.

On June 13 the Company will host a video conference call for investors and analysts at 10:00 am EDT, during which investigators from the sudocetaxel zendusortide Phase 1 trial will provide insights on the data presented at ASCO 2023 and the amended trial protocol. Registration information can be found here.

About SORT1+ Technology™ and Sudocetaxel Zendusortide (TH1902)

Theratechnologies has established its SORT1+ Technology™ platform as an engine for the development of proprietary peptide-drug conjugates (PDCs) that target the sortilin (SORT1) receptor, which is expressed in multiple tumor types. SORT1 is a "scavenger" receptor that plays a significant role in protein internalization, sorting, and trafficking. Expression of SORT1 is associated with aggressive disease, poor prognosis, and decreased survival. It is estimated that SORT1 is expressed in 40% to 90% of endometrial, ovarian, colorectal, triple-negative breast (TNBC), and pancreatic cancers, making this receptor an attractive target for anticancer drug development.

Sudocetaxel zendusortide is a first-of-its-kind SORT1-targeting PDC, and the first compound to emerge from the SORT1+ Technology™ platform. A new chemical entity, sudocetaxel zendusortide employs a cleavable linker to conjugate (attach) a proprietary peptide to docetaxel, a well-established

cytotoxic chemotherapeutic agent used to treat many cancers. The FDA granted Fast Track designation to sudocetaxel zendusortide as a single agent for the treatment of all sortilin-positive recurrent advanced solid tumors that are refractory to standard therapy. Sudocetaxel zendusortide is currently being evaluated in a Phase 1 clinical trial.

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”, "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 development of sudocetaxel zendusortide and other PDCs stemming from the SORT1+ Technology™ platform, the resumption of the Phase 1 clinical trial using sudocetaxel zendusortide and the recruitment of patients, the optimization of the dosing of sudocetaxel zendusortide, and potential efficacy and safety results to be derived from the use of sudocetaxel zendusortide for the treatment of cancer. 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 Company will be able to recruit patients meeting the selection criteria in a number sufficient to conduct the Phase 1 clinical trial, the proposed dosing regimen will result in strong efficacy data with no safety concerns, research and development activities will generate new PDCs and no unplanned event will cause the Phase 1 clinical trial to be halted or cancelled. Forward-Looking Statements 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 impossibility of demonstrating the safe and effective use of sudocetaxel zendusortide in our clinical trials, the incapacity of the Company to recruit a sufficient number of patients to resume the Phase 1 clinical trial, and the incapacity of the Company to obtain positive results from the continuous development of its SORT1+ Technology™ platform. We refer current and potential investors to the “Risk Factors” section of our Annual Information Form dated February 27, 2023, 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 28, 2023, 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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