Theratechnologies Announces Dosing of First Patient in Updated Clinical Trial of Sudocetaxel Zendusortide in Advanced Ovarian Cancer

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- *Milestone for Company's lead peptide-drug conjugate candidate follows FDA acceptance of protocol amendment for Phase 1 study on June 2, 2023*

MONTREAL, Oct. 12, 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 dosing of the first participant in Part 3 of its Phase 1 clinical trial of sudocetaxel zendusortide in patients with advanced ovarian cancer. Sudocetaxel zendusortide is 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.

"We are excited to dose the first of six patients in Part 3 of the Phase 1 trial of sudocetaxel zendusortide with its modified design and dosing regimen," said Christian Marsolais, Ph.D., Senior Vice President and Chief Medical Officer at Theratechnologies. "We look forward to building on the efficacy we've observed so far, which is mainly long-term disease stabilization in a number of advanced patients. This first-patient-dosed milestone, thus extends the momentum of our oncology clinical development program."

"Patients with chemo-resistant ovarian cancer are in dire need of effective treatment options," said Ira Winer, M.D., Ph.D., FACOG, Gynecologic Oncology and Phase I multidisciplinary member at Karmanos Cancer Center and trial investigator. "Based on promising preliminary data during the first parts of the Phase 1 trial for sudocetaxel zendusortide, I hope to see both improved tolerability and continued benefit in this patient population as the trial moves onto this next phase."

The announcement follows U.S. Food and Drug Administration (FDA) acceptance on June 2, 2023 of the Company's amended protocol for the Phase 1 trial. The revised protocol is designed to improve the therapeutic window of sudocetaxel zendusortide and extend its duration of therapy. It includes weekly administration and also narrows the patient population to focus on individuals with high-grade serous ovarian cancer, including high-grade peritoneal or fallopian tube cancer, or high-grade endometrioid cancer - a population in which sudocetaxel zendusortide has demonstrated preliminary efficacy. After establishing the safety of the initial dose in the first six patients, the study aims to enroll a total of 16 patients in Part 3.

Enrollment of the first patient in Part 3 of the trial follows closely upon demonstration of antitumor activity in Parts 1 and 2, as presented at the 2023 annual meeting of the American Society of Clinical Oncology. Details about the study design, participation criteria and contact information for the five U.S. sites simultaneously enrolling patients can be found at: https://clinicaltrials.gov/study/NCT04706962.

About Sudocetaxel Zendusortide (TH1902) and SORT1+ Technology™

Sudocetaxel zendusortide is a first-of-its-kind sortilin- (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.

Theratechnologies has established its SORT1+ Technology™ platform as an engine for the development of proprietary PDCs that target 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.

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 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", "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 conduct of Part 3 of the Phase 1 clinical trial using sudocetaxel zendusortide, the enrolments of patients in such trial, the observation of signs of efficacy from this Phase 1 clinical trial and the development of the Company's 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 this information 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 successful in enrolling the required number of patients to finalize Part 3 of its Phase 1 clinical trial, signs of efficacy will be observed in such Phase 1 clinical trial whereas no untoward side effects will be reported, and the development of the Company's

SORT1+ Technology™ platform will be successful. 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, those related to or arising from: difficulties in recruiting patients to conduct the Phase 1 clinical trial, the reporting of adverse side effects from the use of sudocetaxel zendusortide leading to a halt on the clinical trial and, eventually, the Company's development of its SORT1+ Technology ™ platform, the lack of observation of strong efficacy results, and competing development programs conducted by third parties. 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.sedarplus.ca 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 involved in our business. 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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