



## Theratechnologies Completes Enrollment of First Six Patients in Updated Phase 1 Clinical Trial of Sudocetaxel Zendusortide in Advanced Ovarian Cancer

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- *Study milestone further extends momentum for Company's lead PDC candidate and oncology clinical development program*

MONTREAL, Feb. 15, 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 completion of enrollment of the first six participants in Part 3 of its Phase 1 clinical trial of sudocetaxel zendusortide in patients with advanced ovarian cancer. Sudocetaxel zendusortide, also known as TH1902, is an investigational, first-in-class peptide-drug conjugate (PDC) that targets the sortilin receptor (SORT1) and aims to expedite the internalization and delivery of the cytotoxic payload (docetaxel) directly into cancer cells.

"Reaching this important milestone gives fresh momentum to the Phase 1 trial of sudocetaxel zendusortide, and to our overall oncology clinical development program," said Christian Marsolais, Ph.D., Senior Vice President and Chief Medical Officer at Theratechnologies. "As we gear up for the next round of screening, we look forward to adding patients at the next dose level and further characterizing the safety and efficacy of this novel peptide-drug conjugate."

Theratechnologies announced dosing of the first patient in Part 3 of the Phase 1 trial in October 2023. In June 2023, the U.S. Food and Drug Administration (FDA) accepted the Company's [amended protocol for the Phase 1 trial](#), which is designed to optimize the dosing, improve the therapeutic window and extend the duration of therapy of sudocetaxel zendusortide. The amendment, which the Company submitted in May 2023, 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 for a period of three months, the enrollment of the next cohort of six patients at a higher dose will be initiated.

"I am encouraged by the progress made in the Phase 1 trial of sudocetaxel zendusortide, from acceptance of the protocol amendment, to dosing the first patient, to completing enrollment of the first six women in this part of the study," commented Ira Winer, M.D., Ph.D., FACOG, Gynecologic Oncology and Phase I multidisciplinary member at Karmanos Cancer Center and trial investigator. "The ongoing study will yield important information about this agent's utility in treating patients with platinum-resistant ovarian cancer, a population with few effective therapeutic options."

Parts 1 and 2 of the Phase 1 trial provided preliminary evidence of the antitumor activity of sudocetaxel zendusortide, 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 sites 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 receptor (SORT1)-targeting PDC, and the first compound to emerge from the Company's broader licensed oncology 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 the SORT1+ Technology™ platform as an engine for the development of PDCs that target SORT1, 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](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 [X](#) (formerly 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 the conduct of Part 3 of the Phase 1 clinical trial using sudocetaxel zendusortide, the enrolments of additional patients for the next cohort of the trial at the higher dose level, the further characterization of the safety and efficacy of sudocetaxel zendusortide, the establishment of the safety of the initial dose, 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 these statements since actual results may vary

from the Forward-Looking Statements contained in this press release. These assumptions include, without limitation, that the Company will be successful in enrolling the required number of patients for the next cohort of the trial at the higher dose level, signs of efficacy will be observed in such Phase 1 clinical trial whereas no untoward side effects will be reported, the safety of the initial dose will be established, and the development of the Company's SORT1+ Technology™ platform will be successful. 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, difficulties in recruiting patients for the next cohort of the trial at the higher dose level, the lack of observation of strong efficacy results, 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, and competing development programs using PDC 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](http://www.sedarplus.ca) and on EDGAR at [www.sec.gov](http://www.sec.gov) as an exhibit to our report on Form 40-F dated February 28, 2023, 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 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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