



## Theratechnologies Initiates Increased Dose Level in Phase 1 Clinical Trial of Sudocetaxel Zendusortide in Advanced Ovarian Cancer

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- *Medical Review Committee approved initiation of recruitment of next cohort of patients, in alignment with dose optimization protocol*
- *First patient out of six already enrolled and treated with initial dose of 2.50 mg/kg/dose*

MONTREAL, March 21, 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 moving to the next dose level in Part 3 of its Phase 1 clinical trial of sudocetaxel zendusortide in patients with advanced ovarian cancer. The study's Medical Review Committee (MRC) has deemed the dose level in the first cohort of patients safe and has approved initiation of the next cohort with an increased dose, in accordance with the updated dose optimization protocol. Study centers are now actively recruiting patients for the second cohort, with one patient already enrolled and treated with the higher dose.

"We are encouraged by the safety and tolerability of the sudocetaxel zendusortide regimen in the first cohort of six patients in Part 3 of the Phase 1 trial," said trial investigator Ira Winer, M.D., Ph.D., FACOG, a member of the Gynecologic Oncology and Phase 1 Clinical Trials Multidisciplinary Teams at Karmanos Cancer Center and Associate Professor of Oncology at Wayne State University. "We will continue to enroll and monitor patients as we further investigate this novel peptide-drug conjugate in individuals with advanced, platinum-resistant ovarian cancer, a population with high unmet medical need."

Part 3 of the Phase 1 study is intended to assess the optimal dose and schedule of sudocetaxel zendusortide, which is being administered on three consecutive weeks followed by one week of rest on Days 1, 8, and 15 of each 28-day cycle. The dose for the initial six patients was 1.75 mg/kg/dose and the dose for the next cohort of patients is 2.50 mg/kg/dose. The MRC approved initiation of the second cohort following attainment of the threshold of one or less dose-limiting toxicities in the first cohort. The study's updated protocol defines DLTs as any Grade 3 or greater toxicity, within the first cycle and any worsening of peripheral neuropathy to Grade 3 or 4 within a three-month period.

"Initiation of treatment at the next dose level is an important milestone for Part 3 of the Phase 1 study and will allow us to further characterize sudocetaxel zendusortide as a potentially viable therapy for individuals with advanced ovarian cancer," commented Christian Marsolais, Ph.D., Senior Vice President and Chief Medical Officer at Theratechnologies. "We welcome discussions with potential partners interested in helping to advance development of this novel peptide-drug conjugate."

Theratechnologies completed enrollment of the first cohort of six patients in Part 3 of the Phase 1 trial in February 2024, and dosed the first patient in October 2023. The U.S. Food and Drug Administration (FDA) approved the amended trial protocol in June 2023. Further 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 peptide-drug conjugate, 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, and the development of the Company's SORT1+ Technology™ platform, including the further development of sudocetaxel

zendusortide. 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 increased 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 conducted by third parties using PDC. We refer current and potential investors to the "Risk Factors" section (Item 3.D) of our Form 20-F dated February 21, 2024 available on SEDAR+ at [www.sedarplus.ca](http://www.sedarplus.ca) and on EDGAR at [www.sec.gov](http://www.sec.gov) 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.

**Contacts:**

Media inquiries:

Julie Schneiderman

Senior Director, Communications & Corporate Affairs

[communications@theratech.com](mailto:communications@theratech.com)

1-514-336-7800

Investor inquiries:

Philippe Dubuc

Senior Vice President and Chief Financial Officer

[ir@theratech.com](mailto:ir@theratech.com)

1-438-315-6608