



## Theratechnologies to Present Preliminary Safety and Efficacy Data from Phase 1 Trial of Sudocetaxel Zendusortide in Heavily Pretreated Cancer Patients at ASCO 2023

May 25, 2023

- Preliminary signs of antitumor activity noted in 36% of patients, with two partial responses (PR) and seven patients with prolonged stable disease (SD)
- Efficacy and tolerability data from dose escalation and expansion results inform protocol amendment designed to improve therapeutic window of sudocetaxel zendusortide

MONTREAL, May 25, 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 preliminary efficacy data from a Phase 1 study of its lead investigational peptide-drug conjugate (PDC) candidate, sudocetaxel zendusortide (formerly TH1902), in patients with advanced solid tumors. In a June 3 poster session at the 2023 annual meeting of the American Society of Clinical Oncology (ASCO) in Chicago, researchers will present early results from Part 1 (dose escalation) and Part 2 (dose expansion) of the multicenter, open-label trial of sudocetaxel zendusortide, in which 36% of heavily pretreated participants experienced a clinical benefit, including two patients with partial responses (PR) and seven achieving prolonged stable disease (SD).

Based on the results presented at ASCO, Theratechnologies is engaged with the U.S. Food and Drug Administration (FDA) to amend the protocol of the Phase 1 clinical trial of sudocetaxel zendusortide. The amendments are designed to improve the therapeutic window and allow for more prolonged therapy with sudocetaxel zendusortide, reflecting changes in patient selection and evaluation of alternative dosing regimens.

"The early efficacy data for our lead peptide-drug conjugate, sudocetaxel zendusortide, confirm that it rapidly internalizes and hyper-targets delivery of cytotoxic payload directly into cancer cells," said Christian Marsolais, Ph.D., Senior Vice President and Chief Medical Officer at Theratechnologies. "We look forward to re-initiating our trial with a revised protocol that increases the likelihood of showing the full therapeutic potential of sudocetaxel zendusortide."

"These preliminary data on safety and antitumor activity have informed the proposed changes to the protocol, with the intention of improving the risk-benefit profile of sudocetaxel zendusortide in the next stage of the trial," commented lead investigator Funda Meric-Bernstam, M.D., Chair of the Department of Investigational Cancer Therapeutics at The University of Texas MD Anderson Cancer Center.

### Study details and results

Part 1 of the study enrolled 18 adults with a confirmed diagnosis of a metastatic or advanced-stage solid tumor that is refractory to standard therapies (average of 8 prior lines of therapies). The starting dose of 30 mg/m<sup>2</sup> every 3 weeks (Q3W) was selected based on sudocetaxel zendusortide preclinical data. Among participants in Part 1, one patient with endometrial cancer experienced SD for 233 days (33 weeks), a second patient with prostate cancer had SD that lasted for 119 days (17 weeks), and a third patient with ovarian cancer experienced SD for 295 days (42 weeks).

Eighteen additional patients were enrolled into the 300 mg/m<sup>2</sup> Q3W dose expansion cohort (Part 2). In an interim efficacy and safety analysis of the 300 mg/m<sup>2</sup> dose cohort from Parts 1 and 2 (n=25), five of six patients (83%) with ovarian cancer had a best overall response (BOR) of either PR (n=1) or SD (n=4). In the triple-negative breast cancer (TNBC) population, three of four patients (75%) had a BOR of SD, with one patient experiencing SD for at least four cycles and continued clinical benefit up to at least 24 weeks. In the two patients with prostate cancer, one experienced a PR.

Sudocetaxel zendusortide doses below 300 mg/m<sup>2</sup> were well-tolerated in Part 1 of the trial, which established the maximum tolerated dose (MTD) and dose-limiting toxicities at 360 mg/m<sup>2</sup> and 420 mg/m<sup>2</sup>, respectively. Based on those results, investigators selected a 300-mg/m<sup>2</sup> dose for Part 2 (dose expansion) of the basket trial, to determine the safety and efficacy of sudocetaxel zendusortide in patients with multiple tumor types with high expression of the sortilin (SORT1) receptor. At 300 mg/m<sup>2</sup>, the most common treatment-related adverse events (>20%) were ocular changes, neuropathy, gastrointestinal disturbances, and musculoskeletal complaints, with Grade 3 or greater toxicities at a frequency of ≤12%.

### Poster presentation details:

**Title:** "Sudocetaxel zendusortide (TH1902), a novel sortilin-receptor (SORT1)-targeting peptide-drug-conjugate (PDC) in patients (pts) with advanced solid tumors: Results from part 1 (dose-escalation) of a phase 1, open-label study"

**Lead author:** Funda Meric-Bernstam, M.D., Chair of the Department of Investigational Cancer Therapeutics at The University of Texas MD Anderson Cancer Center

**Abstract number:** 3089

**Session Date and Time:** Saturday June 3, 2023, Developmental Therapeutics - Molecularly Targeted Agents and Tumor Biology, 8:00-11:00 CDT

### 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 the first-of-its-kind SORT1-targeting PDC, and the first 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. Patient recruitment was voluntarily paused on December 1, 2022, and in alignment with this decision, the FDA placed the trial on partial clinical hold. In May 2023, the Company submitted a proposed protocol amendment to the FDA that is currently under review.

### **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.sedar.com](http://www.sedar.com), and on EDGAR at [www.sec.gov](http://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 efficacy data regarding the use of sudocetaxel zendusortide, the development of the SORT1+ Technology™ platform, the resumption of the Phase 1 clinical trial using sudocetaxel zendusortide, the approval of the amended protocol filed with the FDA, and potential efficacy 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 FDA will approve the amended protocol to re-initiate the Phase 1 clinical trial using sudocetaxel zendusortide, the recruitment of patients meeting selection criteria will be enrolled to re-initiate the Phase 1 clinical trial, and safety and efficacy results from our preclinical trial will be replicated in humans during our Phase 1 clinical trial and subsequent trials, if any. 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 impossibility of resuming the Phase 1 clinical trial using sudocetaxel zendusortide, the incapacity of the Company to obtain positive results from the continuous development of its SORT1+ Technology™ platform, 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 27, 2023, available on SEDAR at [www.sedar.com](http://www.sedar.com) 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, 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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