Theratechnologies Announces Preliminary Tolerability and Efficacy Data from Phase 1b, Dose-Ranging Trial of Sudocetaxel Zendusortide in Patients with Advanced Ovarian Cancer

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No dose-limiting toxicities reported in two different weekly doses in heavily pre-treated patients

Preliminary evidence of dose response includes significant tumor shrinkage and one patient with complete resolution of a liver lesion

MONTREAL, Dec. 09, 2024 (GLOBE NEWSWIRE) -- Theratechnologies Inc. (“Thera technologies” or the “Company”) (TSX: TH) (NASDAQ: THTX), a biopharmaceutical company focused on the development and commercialization of innovative therapies, today announced data from Part 3 (dose optimization, weekly dosing schedule) of its ongoing Phase 1b trial of sudocetaxel zendusortide (TH1902) – the company’s lead investigational peptide drug conjugate (PDC) – in patients with advanced ovarian cancer. Based on results demonstrating favorable tolerability and signals of efficacy, the Medical Review Committee, which includes study investigators and external experts, has unanimously recommended continued evaluation and exploration of higher doses.

“We are encouraged by the tolerability and preliminary efficacy data for sudocetaxel zendusortide seen thus far in this part of the Phase 1 study, which was designed to explore dose optimization utilizing a weekly dosing schedule in a population of heavily pre-treated ovarian cancer patients,” commented Christian Marsolais, Ph.D., Senior Vice President and Chief Medical Officer at Theratechnologies. “These latest results add to the growing body of evidence that our novel PDC technology can deliver a toxic payload into cancer cells with little impact on non-cancerous tissues and we believe there could be further clinical implications at a higher dose.”

A total of 13 patients with advanced ovarian cancer who progressed despite prior platinum-based and taxane chemotherapy were enrolled in two Arms in Part 3 of the Phase 1b trial. Seven patients were enrolled in Arm A and received a 1.75-mg/kg/week dose of sudocetaxel zendusortide on a weekly infusion, three-weeks-on/one-week-off schedule every 28 days. The six patients enrolled in Arm B received a 2.5-mg/kg/week dose on the same schedule.

Investigators observed no dose-limiting toxicities in either arm. Although there were no responses observed in the five Arm A participants that comprised the per-protocol (PP) set, there was encouraging evidence of activity observed in three of the six patients enrolled in the Arm B PP set, including one patient with a complete resolution of a liver lesion. Those three Arm B patients also experienced significant reductions in the CA-125 ovarian tumor marker as well as significant tumor shrinkage, including two patients with more than a 25% reduction in tumor size. Additionally, Arm B participants in the PP set received a mean of 10.25 weeks of treatment compared to a mean of 7.6 weeks of treatment in patients treated on Arm A. All patients in Arm B received at least two cycles of treatment, with some completing up to four cycles (on-treatment range: 4-18 weeks).

The Company received permission from the U.S. Food and Drug Administration (FDA) in 2023 to amend the initial Phase 1b clinical trial protocol based on results from Parts 1 and 2, which utilized every-3-week dosing. For Part 3, the protocol was amended to explore dosing weekly for three weeks, followed by a one-week break and shifted the focus to patients with ovarian cancer. At the 2024 American Society of Clinical Oncology (ASCO) annual meeting earlier this year, Theratechnologies presented an updated analysis from Parts 1 and 2 of the study, in which sudocetaxel zendusortide induced durable disease stabilization (up to 45 weeks) lasting beyond treatment completion in several patients with a variety of solid tumors. The ASCO presentation also highlighted early signals of efficacy observed in female cancers (ovarian cancer, endometrial cancer, triple-negative breast cancer [TNBC]), as well as a manageable safety profile when sudocetaxel zendusortide was dosed at 300mg/m^2 given once every 3 weeks with few Grade 3 adverse events (AEs).

“The latest data from Part 3 of the Phase 1 trial build on a compelling body of preclinical and translational evidence of antitumor activity with sudocetaxel zendusortide,” said 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 Professor of Oncology at Wayne State University School of Medicine in Detroit, MI. “While this is a small sample of patients, it is not often that we see promising signs of efficacy, combined with favorable safety and tolerability data, in this patient population with advanced disease. We therefore recommend and encourage continued investigation with further dose escalation for this agent.”

In addition to the Phase 1b clinical trial results, there is also an extensive body of preclinical data demonstrating the flexibility of the Company’s SORT1+ Technology™ platform when conjugated with different toxic payloads. With a significant portion of the clinical trial data to date now available, Theratechnologies will accelerate its search for a partner to advance its oncology program.

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.

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, on SEDAR+ at www.sedarplus.ca and on EDGAR at 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: (i) the conjugation of different toxic payloads to be directed into cancer cells; (ii) signs of efficacy, combined with safety and tolerability data of sudocetaxel zendusortide; (iii) the further development of the Company's lead PDC, sudocetaxel zendusortide; and (iv) the search for a partner to advance the oncology program. 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: (i) the technology stemming from the oncology platform will allow for the development and conjugation of various PDC and payloads to treat cancer; and (ii) the Company will be able to find a partner to pursue the development of the oncology platform. 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, (i) the lack of observation of signs of efficacy and safety results as sudocetaxel zendusortide may be further studied; (ii) difficulties in developing and conjugating payloads to peptides derived from the oncology platform; and (iii) the inability of the Company to find a partner to pursue the development of the oncology platform. We refer current and potential investors to the "Risk Factors" section of our annual information form filed under a Form 20-F dated February 21, 2024, available on SEDAR+ at www.sedarplus.ca and on EDGAR at 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.

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