Theratechnologies to Present Long-Term Efficacy, Safety and Pharmacokinetic Data on Use of TH1902 (sudocetaxel zendusortide) in Solid Tumors at 2024 ASCO Meeting

May 02, 2024

- *First long-term data presentation from Parts 1 and 2 of the Phase 1 clinical trial of sudocetaxel zendusortide in solid tumors*
- *Part 3 of Phase 1 trial in advanced ovarian cancer is ongoing*

MONTREAL, May 02, 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 that it will present long-term efficacy, safety and pharmacokinetic (PK) data on the use of its lead investigational peptide-drug conjugate (PDC) candidate, TH1902 (sudocetaxel zendusortide), in patients with solid tumors. The Company will present the long-term data in a poster session at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting, which takes place May 31-June 4, 2024, in Chicago, IL.

The ASCO poster represents the first presentation of long-term data from Part 1 (dose escalation) and Part 2 (dose expansion) of Theratechnologies’ Phase 1 clinical trial of sudocetaxel zendusortide in individuals with solid tumors, following preliminary evidence of antitumor activity presented at the 2023 ASCO annual meeting. This updated analysis will present further data on long-term efficacy, safety and PK from Parts 1 and 2, focusing specifically on patients receiving sudocetaxel zendusortide at a dose of 300 mg/m^2 every three weeks. Patients in this dosing group have cancers with known high expression of sortilin (SORT1), including ovarian cancer, endometrial cancer, triple-negative breast cancer (TNBC) and melanoma. Part 3 (dose optimization) of the Phase 1 trial, in patients with advanced ovarian cancer, is ongoing.

“We have eagerly awaited the updated analysis from Parts 1 and 2 of the Phase 1 trial, as it will provide our first evidence of the long-term effects of sudocetaxel zendusortide in patients with solid tumors,” said Christian Marsolais, Ph.D., Senior Vice President and Chief Medical Officer at Theratechnologies. “These safety, efficacy and pharmacokinetics data are particularly timely, in that they will provide valuable context as we continue to evaluate this novel peptide-drug conjugate in Part 3 of this ongoing trial.”

Details of the poster presentation are as follows:

June 1, 2024, 9:00 AM-12:00 PM CDT

Presenting Author: Ira Winer, MD, Karmanos Cancer Institute, Detroit, MI

Session Category: Developmental Therapeutics—Molecularly Targeted Agents and Tumor Biology

Session Title: Long-term efficacy, safety and PK data of TH1902 (sudocetaxel zendusortide) in solid tumors: A novel SORT1-targeting peptide-drug-conjugate (PDC)

Location: Hall A, McCormick Place Congress Center, Chicago

Poster Board Number: 226

Abstract Presentation Number: 3081

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 rapid 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 the conduct of Part 3 of the Phase 1 clinical trial using sudocetaxel zendusortide, the data on long-term safety and efficacy of sudocetaxel zendusortide, and the further development of the Company's lead PDC, 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 successfully complete Part 3 of the Phase 1 clinical trial, that signs of long-term efficacy and safety will be observed in such Phase 1 clinical trial whereas no untoward side effects will be reported, and the further development of the Company's lead PDC, sudocetaxel zendusortide, 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, the lack of observation of strong long-term efficacy and safety 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 further development of its lead PDC, sudocetaxel zendusortide. 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 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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