Theratechnologies Provides Update on the Dose Escalation Portion of Fast Track Designated TH1902 First-in-Human Study in Advanced Resistant Malignancies

July 14, 2022

- Confirmed safety profile at 300 mg/m^2 or 1.5 times the therapeutic dose of docetaxel alone
- *Confirmed low levels of free docetaxel consistent with observations in animal studies*
- *Early signs of efficacy observed in the dose escalation portion of the study*
- *Enrollment of clinical trial sites continue with 6 major cancer centers activated*

MONTREAL, July 14, 2022 (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 provided an update on the dose escalation portion of the TH1902 Phase 1 clinical safety study. This is Theratechnologies' first-in-human study of TH1902, its investigational lead peptide drug conjugate (“PDC”) linked to docetaxel for the treatment of sortilin-expressing cancers. It has received Fast Track designation from the United States Food and Drug Administration (“FDA”).

“We are pleased to provide an update on TH1902’s safety profile and go forward dosage. The pharmacokinetics data observed in humans showed low levels of free docetaxel, consistent with what was observed in the prior animal studies, leading to a better safety profile than cytotoxics alone. We see this as a nod to TH1902’s safety profile,” noted Dr. Christian Marsolais, Chief Medical Officer, Theratechnologies. “In addition, we are excited to see early efficacy signals in heavily pretreated patients in this dose escalation study.”

“We are excited to be a part of the TH1902 Phase I study and to have had the opportunity to be the first in the world to enroll a patient,” said Dr. Satish Shah, Pennsylvania Cancer Specialist and Research Institute. “Our research institute enrolled multiple patients in the dose escalation phase of the study (Part 1), and we are happy to report that two of our advanced prostate cancer patients, who had progressed on standard chemo/hormone therapies, showed signs of efficacy. The first patient achieved a confirmed partial response with the tumor mass reduction of 53%, and the other patient achieved a PSA response with stabilization of disease without any further progression. We also had an endometrial cancer patient with lung metastases achieve a reduction in lung mass. She achieved prolonged stabilization of disease, over a 33-week period, without further progression, and was able to receive 11 cycles of treatment with TH1902. This is a clinically meaningful result in late-stage disease with very limited treatment options.”

A total of 18 heavily pre-treated patients, who received an average of 8 prior cancer treatments, were enrolled in the dose escalation portion of the study. Two of those patients remain on treatment. Following the safety observations at 420 mg/m^2 including grade 3 neuropathy, grade 4 neutropenia, grade 3 ocular changes (visual acuity, keratitis and ocular surface dryness) and grade 2 skin toxicities (rash, pruritis and inflammation), the dose of TH1902 was decreased to 300 mg/m^2 for the next dose level and was expanded to a total of 6 patients. No Dose Limiting Toxicities were observed during the first cycle, therefore, the dose of 300 mg/m^2 was selected for continuation of the basket part of the study. In addition, the levels of free docetaxel are low, at only 11% of those observed at docetaxel treatment dosage of 75 mg/m^2. Thus far 300 mg/m^2 appears to be a well-tolerated dose level, which continues to be evaluated in the larger basket portion of the TH1902 study.

Signs of efficacy have been observed in three heavily pretreated patients in the dose escalation trial, and recorded results include:

- Confirmed partial response in one prostate cancer patient with 53% overall reduction in target lesions after three cycles of TH1902 at 300 mg/m^2, PSA continued to progress.
- Stabilized disease observed in a prostate cancer patient with measurable reduction in target lesion sizes (single digit percentages), including one PSA response. The patient was treated with mixed cycles of TH1902 from 420 mg/m^2 to 300 mg/m^2.
- Stabilized disease observed in an endometrial cancer patient with measurable reduction in target lesion sizes (single digit percentages). Notably, she received a total of 11 cycles. Her dose was escalated from 60 mg/m^2 to 360 mg/m^2.

In an effort to optimize and ensure success of this clinical research program, the Company has enrolled six active trial sites across the United States, including Cedars-Sinai in California, Karmanos Cancer Institute and START Midwest in Michigan, Pennsylvania Cancer Specialists Research Centre, Mary Crowley Cancer Research and University of Texas MD Anderson Cancer Center, both in Texas.

Based on the preclinical results obtained so far, Theratechnologies is optimistic for the continued development of a first-in-class and promising treatment for patients with Sortilin positive solid tumors. The Company continues to advance the development of its SORT1+ Technology™ platform by conjugating the proprietary peptide with other effective anti-cancer agents and by exploring other rational combinations with established anti-cancer drugs.

As noted earlier, the unique mechanism of entry of TH1902 in cancer cells is believed to be a key advantage to improving the therapeutic window of docetaxel. TH1902’s targeted delivery and rapid internationalization in cancer cells via the Sortilin receptor enables the potential to accumulate 7.5 to 10 times more docetaxel in cancer cells as compared to the administration of docetaxel alone. Additionally, as shown in preclinical models, this mechanism reduces the overall exposure of healthy tissue to docetaxel in the body.

About TH1902

TH1902 is Theratechnologies' proprietary peptide drug conjugate ("PDC") linked to docetaxel, a well-established and well-characterized cytotoxic agent. TH1902 is being developed as a single agent for the treatment of all advanced solid tumors expressing sortilin that are refractory to standard therapy. TH1902 is the Company's lead PDC drug candidate stemming from Theratechnologies' SORT1+ Technology™ in oncology.

About SORT1+ Technology™

Theratechnologies has developed a peptide which specifically targets sortilin (SORT1) receptors. SORT1 is expressed in ovarian, endometrial, HR+ and triple negative breast, skin, lung, prostate and thyroid, among other cancers. SORT1 plays a significant role in protein internalization, sorting and trafficking, making it an attractive target for drug development. Commercially available anticancer drugs, like free docetaxel, doxorubicin or tyrosine kinase inhibitors are conjugated to Theratechnologies' investigational novel peptides to specifically target Sortilin receptors with the aim of improving the efficacy and safety of those agents. It has received Fast Track designation from the United States Food and Drug Administration ("FDA").

What is a basket trial? A type of clinical trial that tests how well a new drug or other substance works in patients who have different types of cancer that all have the same mutation or biomarker. In basket trials, patients all receive the same treatment that targets the specific mutation or biomarker found in their cancer. Basket trials may allow new drugs to be tested and approved more quickly than traditional clinical trials. Basket trials may also be useful for studying rare cancers and cancers with rare genetic changes.

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.sedar.com and on EDGAR at 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", "will", "should", "could", "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 development of a treatment for patients with Sortilin positive solid tumors, the development of our SORT1+ Technology™ platform, the conduct and recruitment of patients for the basket trial using TH1902 and the opening of new clinical trial sites. 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 pre-clinical results obtained using TH1902 will be replicated into humans, we will be able to continue recruiting patients to conduct the basket trial using TH1902, no dose limiting toxicities will be observed in patients comprising the basket trial, our manufacturer of TH1902 will be able to supply the required quantity of TH1902 in due time to advance the basket trial, and we will see signs of efficacy of TH1902 in the conduct of the basket trial across all patients forming part of the trial.

Forward-Looking Statements assumptions 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, our inability to recruit patients for the conduct of the basket trial, the observation of adverse safety issues, the lack of demonstration of efficacy in many or in all of the patients forming part of the trial, issues regarding the manufacture and supply of TH1902, and conflicts with third party suppliers in the conduct of our basket trials.

We refer current and potential investors to the "Risk Factors" section of our Annual Information Form dated February 23, 2022 available on SEDAR at www.sedar.com and on EDGAR at www.sec.gov as an exhibit to our report on Form 40-F dated February 24, 2022 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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