Theratechnologies Initiates Basket Portion of TH1902 First-in-Human Study in Advanced Resistant Malignancies

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- *Phase 1b dose established at 300 mg/m^2 or 1.5 times the therapeutic dose of docetaxel alone*
- *Expansion study will evaluate TH1902 in solid tumors with high expression of Sortilin receptor*

MONTREAL, May 10, 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 initiated enrollment of patients in the basket portion of the first-in-human study of TH1902, Theratechnologies’ investigational lead peptide drug conjugate (PDC) for the treatment of sortilin-expressing cancers.

Dr. Christian Marsolais, Senior Vice President and Chief Medical Officer, Theratechnologies, noted, “We are pleased to move forward to the next stage of development of TH1902, the basket portion of the first-in-human study. We firmly believe that the unique mechanism of entry of TH1902 in cancer cells is a key advantage to improve 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. Based on the pre-clinical results obtained so far, we are optimistic in the development of a first-in-class and promising treatment for patients with Sortilin positive solid tumors. Additionally, we continue to advance the development of our SORT1+ Technology™ platform by conjugating our proprietary peptide with other effective anti-cancer agents.”

Based on the data of the dose escalation part of the study, the dose of TH1902 for the expansion study was established at 300 mg/m^2 or 1.5 times the therapeutic dose of docetaxel alone. No dose limiting toxicities were observed following the completion of the first cycle in the last 6 patients treated at 300 mg/m^2. The basket portion of the first-in-human study is an expansion study designed to assess TH1902 as monotherapy treatment of advanced refractory or resistant solid tumor types expressing high levels of Sortilin, including Hormone Receptor-positive (HR+) Breast Cancer, Triple Negative Breast Cancer, Ovarian Cancer, Endometrial Cancer, and Melanoma with approximately 10 patients per tumor type. One arm will include a mix of tumor types including Thyroid, Small Cell Lung, Prostate and potential other high Sortilin expressing cancers with approximately 15 patients in total. In addition to evaluating the anti-tumor activity of TH1902, the study will continue to evaluate the safety and pharmacokinetics of TH1902. Exploratory pharmacodynamic and biomarker analyses will also be conducted.

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, triple negative breast, skin, lung, colorectal and pancreatic cancers, among others. SORT1 plays a significant role in protein internalization, sorting and trafficking, making it an attractive target for drug development.

Commercially available anticancer drugs, like 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.

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, and the conduct and recruitment of patients for the basket trial.

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 recruit patients to conduct the basket trial, 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, 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 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.

For media inquiries:
Philippe Dubuc
Senior Vice President and Chief Financial Officer
communications@theratech.com
514-336-7800