



Theratechnologies' Lead Peptide Drug Conjugate TH1902 Receives FDA Fast Track Designation for the Treatment of Sortilin-expressing Cancers

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MONTREAL, Feb. 04, 2021 (GLOBE NEWSWIRE) -- Theratechnologies Inc. (Theratechnologies) (TSX: TH) (NASDAQ: THTX), a biopharmaceutical company focused on the development and commercialization of innovative therapies, is pleased to announce that the United States Food and Drug Administration (FDA) has granted fast track designation to TH1902 as a single agent for the treatment of patients with sortilin positive recurrent advanced solid tumors that are refractory to standard therapy.

"Receiving fast track designation for TH1902 at this early stage of development is a significant recognition for our SORT1+ Technology™ and further supports the future development of TH1902. The designation, which applies to all solid tumours expressing sortilin, also highlights the broad applicability and immense medical need for innovative, targeted, and potentially more effective and better-tolerated therapies for cancer," said Dr. Christian Marsolais, Senior Vice President and Chief Medical Officer, Theratechnologies.

Phase 1 clinical trial of TH1902

Theratechnologies announced on January 7, 2021 that it had received a "Study May Proceed" letter from the FDA for the Phase 1 clinical trial of TH1902.

The proposed Phase 1 trial design includes a dose escalation study to evaluate the safety, pharmacokinetics, maximum tolerated dose (MTD) and preliminary anti-tumor activity of TH1902 administered once every three weeks in patients with advanced solid tumors refractory to available anti-cancer therapies. Once the MTD is determined, it is planned that a total of 40 additional patients will be enrolled to evaluate the potential anti-tumor activity of TH1902 in patients with endometrial, ovarian, colorectal, pancreatic and triple negative breast cancers where it has been estimated that the sortilin receptor is expressed in 40 to 90% of cases. The Phase 1 trial is expected to be initiated in the second quarter of calendar year 2021 and is designed to identify a recommended dose for Phase 2 development.

Funda Meric-Bernstam, M.D., Chair of the Department of Investigational Cancer Therapeutics at The University of Texas MD Anderson Cancer Center is the Lead Principal Investigator of the Phase 1 trial for TH1902. The detailed study protocol is available at [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04706962) under the identifier number: NCT04706962.

About Fast Track Designation

The FDA's fast track designation is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose of fast track designation is to bring important new drugs to patients earlier.

A drug that receives fast track designation is eligible for some or all of the following:

- More frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval
- More frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers
- Eligibility for *Accelerated Approval and Priority Review*, if relevant criteria are met
- *Rolling Review*, which means that a drug company can submit completed sections of its Biologic License Application (BLA) or New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed. BLA or NDA review usually does not begin until the drug company has submitted the entire application to the FDA

About TH1902

TH1902 combines Theratechnologies' proprietary peptide to docetaxel. This peptide-drug conjugate (PDC) is the lead candidate stemming from Theratechnologies' SORT1+ Technology™ in oncology.

The Canadian Cancer Society and the Government of Quebec, through the *Consortium Québécois sur la découverte du médicament* (CQDM), will contribute a total of 1.4 million dollars towards some of the research currently being conducted for the development of Theratechnologies' targeted oncology platform.

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 peptide to specifically target sortilin receptors. This could potentially improve the efficacy and safety of those agents.

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, or, 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 TH1902 for the potential treatment of various types of cancer, the timelines to initiate the Phase 1 trial, the determination of the MTD and the enrollment of patients in such Phase 1 trial.

Forward-looking statements are based upon a number of assumptions and include, but are not limited to, the following: pre-clinical in vivo results will be replicated in humans during the Phase 1 trial, we will be able to determine the MTD, the timelines to initiate the Phase 1 trial is accurate, we will be able to enroll patients for the Phase 1 trial, treatment with TH1902 will be efficacious and safe in various types of cancer and no serious adverse side effects will be discovered from the administration of TH1902 to patients.

Forward-looking statements are subject to a variety of risks and uncertainties, many of which are beyond our control that could cause our actual results to differ materially from those that are disclosed in or implied by the forward-looking statements contained in this press release. These risks and uncertainties include, among others, the risk that the Covid-19 pandemic materially adversely affect the conduct of our Phase 1 trial, we are unable to determine the MTD, results obtained from the administration of TH1902 do not allow the pursuit of additional clinical trials, patients die and such death is related to the administration of TH1902 resulting in the abandonment of our Phase 1 trial, discovery of serious adverse side effects also leading to the abandonment of the Phase 1 trial, difficulty in recruiting patients leading to delays in initiating or completing the Phase 1 trial and non-performance by our third-party contract suppliers of their covenants, obligations or undertakings under the terms of our agreements with them.

We refer potential investors to the "Risk Factors" section of our annual information form dated February 24, 2020 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 25, 2020 under Theratechnologies' public filings for additional risks regarding the conduct of our business and Theratechnologies. 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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