



Theratechnologies Announces Preliminary Fourth Quarter and Full Fiscal Year 2020 Revenues and Provides Update on R&D Activities

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Expects record Q4 and FY 2020 revenues

Receives 'Study May Proceed' letters from FDA for Phase 3 trial of tesamorelin in NASH and Phase 1 trial of TH1902 in various cancers

MONTREAL, Jan. 07, 2021 (GLOBE NEWSWIRE) -- Theratechnologies Inc. (Theratechnologies or Company) (TSX: TH) (NASDAQ: THTX), a biopharmaceutical company focused on the development and commercialization of innovative therapies, today announced net revenue estimates for its fourth quarter and its full fiscal year ended November 30, 2020 and provided an update on its R&D activities.

Consolidated net revenues for the Company's fourth quarter fiscal year 2020 are expected to be between US\$18.9 million and US\$19.2 million, compared to US\$16.4 million for the same quarter last year, representing an increase of approximately 15% to 17%, and the Company's highest reported quarterly revenues to date.

Consolidated net revenues for the Company's full fiscal year 2020 are expected to be between US\$65.8 million and US\$66.1 million, compared to US\$63.2 million for the fiscal year ended November 30, 2019, representing an increase of approximately 4.1% to 4.6%, and the Company's highest reported annual revenues to date.

"Despite the current pandemic, we delivered record sales in the fourth quarter of our 2020 fiscal year. We believe that the changes we implemented to our sales infrastructure and commercial strategies at the beginning of the fourth quarter have started to positively impact our business. Looking ahead, our goals remain to expand our commercial business and to advance our promising pipeline, further strengthening our foundation for sustained growth," said Paul Lévesque, President and Chief Executive Officer, Theratechnologies.

R&D UPDATE

Tesamorelin for the Treatment of NASH

In November 2020, Theratechnologies filed an Investigational New Drug (IND) application with the United States Food and Drug Administration (FDA) for the Phase 3 development of tesamorelin for the treatment of adults with Nonalcoholic Steatohepatitis (NASH) with liver fibrosis. The Company announced today that it has received a "Study May Proceed" letter from the FDA for the Phase 3 trial with a recommendation that the Company requests a meeting to discuss questions and comments received on certain aspects of the proposed trial design, to ensure alignment with the agency's expectations with NASH trials. The Company intends to follow up on the FDA's recommendation and will formally request a meeting with the agency.

The proposed Phase 3 trial design will enroll participants with liver-biopsy confirmed NASH and stage 2 or 3 fibrosis. Participants will be randomized 1:1 to receive 2 mg of tesamorelin or placebo. A second liver biopsy will be performed after 18 months of treatment for the first 900 participants, approximately. These data will form the basis for filing a supplemental Biologics License Application (sBLA) with the FDA to seek accelerated approval.

The primary endpoint used to seek accelerated approval will be the percentage of participants achieving NASH resolution and no worsening of fibrosis compared to placebo.

Participants will remain in the Phase 3 trial for a total of 60 months. Approximately 2,000 participants in total are expected to be enrolled including a cohort of approximately 75 to 100 participants with HIV.

Theratechnologies' goal is to initiate the Phase 3 trial by the end of the third quarter of calendar year 2021. The final timing of the trial initiation is dependent upon any adjustments to the protocol and trial design as recommended by the FDA and European agencies. Any changes to the trial design or expected timelines based on discussions with the FDA will be disclosed thereafter.

SORT1+ Technology™ in Oncology

In December 2020, the Company filed an IND application with the FDA for the development of TH1902, its lead peptide-drug conjugate (PDC) (docetaxel conjugate) derived from its SORT1+ Technology™ platform, for the treatment of various cancers. The IND application was based on preclinical data obtained in endometrial, ovarian, colorectal, pancreatic, and triple-negative breast (TNBC) cancers.

Theratechnologies announced today that it has received a "Study May Proceed" letter from the FDA for the Phase 1 trial. 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, a total of 40 additional patients will be enrolled to evaluate the potential anti-tumor activity of TH1902 in patients with endometrial, ovarian, colorectal, TNBC and pancreatic cancer. 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. The preclinical evaluation of TH1902 in melanoma is ongoing.

"I am extremely pleased with the efforts of our teams to achieve these two remarkable milestones that will provide tremendous opportunity for the Company. Theratechnologies is in an enviable position with growing sales and a pipeline that has strong potential to address high unmet medical needs," concluded Mr. Lévesque.

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 our fourth quarter and full fiscal year revenues, the timelines to initiate a Phase 3 trial using tesamorelin for the treatment of NASH and the Phase 1 trial using TH1902 for certain types of cancer, revenue growth for 2021, and our positive expectations about the outcome of our clinical trials in NASH and in oncology.

The estimates reported in this press release with respect to the consolidated net revenues for the fourth quarter of 2020 and fiscal year 2020 are preliminary and unaudited. The Corporation's actual results may differ from these estimates due to the completion of the Corporation's financial closing procedures, final adjustments and other developments that may arise between now and the time the financial results for the Corporation's annual and fourth quarter are finalized. These estimates should not be viewed as a substitute for full annual and quarterly financial statements prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Forward-looking statements contained in this press release are based upon a number of assumptions and 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 information. These assumptions include but are not limited to, the following: the current pandemic will not have material adverse consequences on our business plan, the sales of our products, the conduct of our clinical trials and the recruitment related thereto, the health of our employees and the ability of our third party suppliers to perform their obligations under their agreements with us, no undesired side effects derived from the use of our products will lead to warnings or recalls, the absence of a recall on one or all of our products, the capacity of our third-party vendors to manufacture our products to meet demand, the absence of any dispute with our key third-party vendors, the absence of any dispute regarding our intellectual property, obtaining positive results regarding the safety and efficacy of using tesamorelin for the treatment of NASH and of using TH1902 for the treatment of various cancers.

If one or more of the above-mentioned assumptions does not materialize, the results and forecasts contained herein will be materially adversely affected and none of the results and/or forecasts contained herein may materialize. We refer potential investors to the "Risk Factors" section of our annual information form dated February 24, 2020 and to our Form 40-F dated February 25, 2020 filed on EDGAR 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.

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