

Theratechnologies Reports Data Showing High Expression of Sortilin (SORT1) in Multiple Solid Tumors from Tissue Microarrays

October 26, 2022

- Poster for presentation at the <u>34th EORTC-NCI-AACR Symposium</u> on molecular targets and cancer therapeutics enhances understanding of SORT1 expression in healthy and tumor tissues
- Extensive dataset underscores potential of SORT1 as a new anticancer therapeutic target

MONTREAL, Oct. 26, 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 reports data from a tissue microarrays (TMAs) study demonstrating high expression of sortilin 1 (SORT1) in several solid tumors when compared to normal tissues, to be presented as a poster at the 34th European Organisation for Research and Treatment of Cancer (EORTC), the National Cancer Institute (NCI), and the American Association for Cancer Research (AACR) Symposium on molecular targets and cancer therapeutics being held October 26-28, 2022, in Barcelona, Spain. The data highlight the potential of SORT1 as a new target for internalization of anticancer therapy and will be used to support the ongoing preclinical and clinical programs of Theratechnologies' SORT1+ Technology™ platform.

SORT1 is a receptor protein that binds to circulating proteins and peptides prior to their intracellular internalization. It is involved in the rapid transport of molecules across the cell membrane. SORT1 internalization function can be exploited to internalize a peptide-drug conjugate (PDC) to which docetaxel is attached and potentially inhibit the proliferation of cancer cells. Up to now, the pattern and prevalence of SORT1 expression in different healthy tissues have not been well understood, but SORT1 has been shown to be highly expressed in certain malignancies such as breast and ovarian cancers.

"Our study, the first to assess SORT1 expression across a variety of tissue microarrays representing several malignancies, shows that this receptor is highly expressed in cancer compared to normal tissues," said Christian Marsolais, Ph.D., Senior Vice President and Chief Medical Officer, Theratechnologies. "To our knowledge, no other group has conducted such an extensive screening of tumor or normal tissue biopsies to evaluate the level of SORT1 expression, which is elevated in multiple tumor types and maintained in stages 1 to 4. That makes SORT1 an attractive receptor for targeted delivery and rapid internalization of cancer therapeutic agents."

Researchers reported data on a total of 1,446 cancer cores, using the same immunohistochemistry (IHC) method and scored them using an H-score (an accurate method of describing reactivity in homogeneous tissue such as cancer) ranging from 0 to 300, whereby 0 corresponds to no cell stained for SORT1 and 300 corresponds to strong SORT1 staining in all cells.

The investigators observed high SORT1 expression in multiple solid tumors, as illustrated in the following table:

Tumor Type	Evaluable Cases (n)	% of Indication with H-score ≥100	Average H-score
Non-triple-negative breast cancer (TNBC)	195	88	159
TNBC	171	70	135
Ovarian cancer	249	75	142
Endometrial cancer	101	85	169
Melanoma	162	88	166
Colorectal cancer	201	54	98
Pancreatic cancer	178	26	54

Interestingly, across 257 normal or adjacent tissue evaluable cores, SORT1 staining was either negative (null) or low for most healthy tissues including lung, stomach, liver, ovary, prostate, lymph node, esophagus, small intestine, cervix, skin, spleen, bone marrow, and thymus. Some healthy tissues had moderate or strong staining in >10% of cells, including the colonic mucosa, rectal epithelium, pancreatic islets and vessels, breast lobules, testicular spermatids and Sertoli cells, kidney tubules, and cerebral neuronal cells and astrocytes. The full poster can be found on Theratechnologies' website.

"These findings further strengthen the evidence to support the development of our SORT1+ Technology™ platform, including our ongoing firstin-human study of TH1902, a SORT1-targeted PDC, currently in eight solid tumor types," added Dr. Marsolais. "They could also lay the groundwork for additional PDCs that are in early development."

The Company intends to further evaluate additional tissue microarrays to increase the biopsy sample size and to broaden the range of tumor types and sub-types that may be susceptible to SORT1, such as in prostate, small-cell lung carcinoma and thyroid cancers.

About TH1902 and SORT1+ Technology™

Theratechnologies is currently developing a platform of proprietary peptides called SORT1+ TechnologyTM for cancer drug development targeting SORT1 receptors. The SORT1 receptor plays a significant role in protein internalization, sorting and trafficking. It is highly expressed in cancer cells compared to healthy tissue, which makes SORT1 an attractive target for cancer drug development. Expression of SORT1 is associated with aggressive disease, poor prognosis and decreased survival. It is estimated that the SORT1 receptor is expressed in 40% to 90% of cases of endometrial, ovarian, colorectal, triple-negative breast and pancreatic cancers.

TH1902 is currently Theratechnologies' lead investigational PDC candidate for the treatment of cancer derived from its SORT1+ Technology™. It is

the Company's proprietary peptide linked to docetaxel – a commonly used cytotoxic agent used to treat many cancers. The U.S. FDA granted fast track designation to TH1902 as a single agent for the treatment of all sortilin-positive recurrent advanced solid tumors that are refractory to standard therapy.

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 SORT1 protein as a new target for internalization of anticancer therapy, the development of our SORT1+ TechnologyTM platform, the conduct of our clinical trial using TH1902 and our intent to evaluate additional tissue microarrays. 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, SORT1 is a receptor to target to deliver cancer therapeutics agents, TH1902 will prove safe and effective into humans and we will continue evaluating tissue microarrays. 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, the risk that SORT1 is not the appropriate target to deliver cancer therapeutic agents, we see no sign of efficacy using TH1902 in our Phase 1 clinical trial, and serious adverse side effects are associated with the administration of TH1902. 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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