Theratechnologies Reports Financial Results for the Third Quarter of Fiscal 2022 and Provides Business Update

October 13, 2022

- Q3 2022 Consolidated Revenue Growth of 17% to $20.8 million

- Q3 2022 North American Revenue Growth of 19%

- TH1902 Phase 1 basket trial proceeding as planned

- On track to meet FY2022 Revenue Guidance $79 - $82 million

MONTREAL, Oct. 13, 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 reported business highlights and financial results for the third quarter of fiscal year 2022, ended August 31, 2022. All figures are in U.S. dollars unless otherwise stated.

“We kicked off the third quarter with many exciting developments and spent the remaining period focusing on strategic growth, corporate alignment and shareholder outreach. As our top line results show, our efforts are making a difference,” said Paul Lévesque, President and Chief Executive Officer.

"In mid-July, we provided an update on the dose escalation portion of the TH1902 Phase 1 study and announced signs of efficacy observed in three heavily pre-treated patients. Our work with the SORT1+ Technology™ is getting noticed in the industry and was featured in the journal *Pharmaceutics*. We continue to believe that our program’s unique mechanism of action gives it a distinct position as a potential cancer therapy.

“Our decision to internalize our field force and strengthen our commercial operations in the United States is starting to deliver results, as evidenced by 19% sales growth in this territory compared to the third quarter of last year; we remain confident we will meet our Fiscal 2022 guidance. Despite the challenging biotech capital markets, and as a testament to our business model, we also announced that we successfully extended the financial runway through a term loan of up to $100 million from Marathon Asset Management. In July, we received the first $40 million tranche of the term loan, which allowed us to rapidly retire more than half of the Company’s convertible notes due in 2023 and strengthened our balance sheet,” concluded Mr. Lévesque.

Revenue Summary for Third Quarter of Fiscal 2022
(in thousands of U.S. dollars)

	Three months ended August 31		% change	Nine months ended August 31		% change
	2022	**2021**		**2022**	**2021**	
EGRIFTA®, EGRIFTA SV® net sales	12,876	11,224	14.7%	35,996	30,256	19.0%
Trogarzo® net sales	7,935	6,628	19.7%	22,640	20,813	8.8%
Revenue	**20,811**	**17,852**	**16.6%**	**58,636**	**51,069**	**14.8%**

RECENT HIGHLIGHTS AND PROGRAM UPDATES

Pipeline Updates

TH1902 Phase 1 Trial Update: On July 14, the Company issued an update on the dose escalation portion of the TH1902 Phase 1 clinical safety study. TH1902 is Theratechnologies’ first-in-human study of its investigational lead peptide drug conjugate (“PDC”) for the treatment of sortilin-expressing cancers. It has received Fast Track designation from the United States Food and Drug Administration (“FDA”).

In this update, we announced that 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. 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 pre-treated 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 (*Prostate-specific Antigen*) 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, the patient received a total of 11 cycles. The 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 currently enrolled six active trial sites across the United States. The plan is to enroll additional sites in the United States, the European Union and Canada.

TH1902 Study in Pharmaceutics Journal

Subsequent to the end of the third quarter, the Company announced the publication of a preclinical study demonstrating the *in vitro* and *in vivo* efficacy of TH1902, an investigational sortilin (SORT1)-targeted peptide-drug conjugate, in inhibiting ovarian cancer and triple-negative breast cancer ("TNBC") stem-like cells' ("CSCs") tumor growth. The study, published as part of the special issue of *Pharmaceutics* "Targeting Drug Resistance and Metastatic Pathways for Cancer Therapy", reports that TH1902 appears to exert anticancer activity that is superior to unconjugated docetaxel in preclinical models, in part by circumventing the chemoresistance phenotype that is often responsible for treatment failure and cancer recurrence.

In the *Pharmaceutics* paper, researchers at Theratechnologies and the Molecular Oncology Laboratory at Université du Québec à Montréal ("UQAM") described the activity of TH1902 against CSCs and its ability to circumvent some of the known resistance phenotypes associated with CSCs. Their findings suggest that TH1902 targets cancer cells overexpressing the sortilin receptor – an effect that is absent in healthy cells. Additionally, at doses equivalent to docetaxel, single-agent TH1902 exhibited superior efficacy against breast and ovarian CSCs, compared to docetaxel alone. Finally, when combined with carboplatin in an ovarian tumor model, the efficacy of TH1902 was also superior to that of paclitaxel- or docetaxel-carboplatin combinations. In TNBC and ovarian CSCs animal models, TH1902 decreased tumor growth by 80%, compared to roughly 35% in docetaxel-treated mouse models.

Trogarzo® Lifecycle Management

On October 3, the Company received notice of approval from the FDA for the 30-Second Intravenous ("IV") Push method of administration of Trogarzo®.

The FDA originally approved Trogarzo® a novel, long-acting monoclonal antibody, in March 2018 to be administered intravenously as a single loading dose followed by a 15-minute maintenance dose, every two weeks. Following this approval, the maintenance dose can be administered as an undiluted IV push over 30 seconds.

The Company believes this simplified method of administration will improve patient compliance and will provide a broader number of access points for patients.

The Company is also conducting a study assessing an intramuscular method of administration of Trogarzo®. This study is now fully enrolled, with the last patient visit scheduled for November 2022. If approved, we believe that this new method of administration will give patients an even more convenient form of administration, and further potentially improving access and compliance to the regimen.

Trogarzo® Data at AIDS 2022 Shows Potential for Improved Treatment Regimens

On July 28, Theratechnologies announced data from two poster presentations at the 24th International AIDS Conference ("AIDS 2022") held in Montreal that provided key understandings on the potential of Trogarzo® to evolve treatment paradigms for heavily treatment-experienced HIV populations on complex regimens.

In summary, the poster presentation entitled *"**Ibalizumab long-term efficacy is not impacted by partially active antiretrovirals"*** demonstrated that in clinical trial patients, long-term viral suppression is not influenced by partially active agents; and the poster presentation entitled ***"Pharmacokinetic modeling and simulation of intramuscular and subcutaneous ibalizumab delivery"*** revealed that Predictive pharmacokinetic modelling shows that new methods of administration, intramuscular and subcutaneous, could be maintained through concentrations greater than 0.3 µg/mL, which has been previously correlated with efficacy with the intravenous infusion.

The two AIDS 2022 scientific presentations followed on data presented at the Italian Conference on AIDS and Antiviral Research (ICAR) entitled ***Evaluation of the in vitro combinatorial activity of Ibalizumab and HIV-1 antivirals***, which was supported by an independent grant. In vitro combination activity between Trogarzo® and nine other ARVs, seven commercially available and two investigational, demonstrated the additive or synergistic effects seen between each pairing. Of note, synergistic activities were seen with dolutegravir, etravirine, tenofovir alafenamide and lenacapavir, a long-acting investigational ARV.

TH1902 China Out-licensing and Partnership Strategy

Discussions around out-licensing the development and commercialization rights for TH1902 in Greater China continue. The Company is optimistic about the prospects as the TH1902 basket trial continues to enroll patients.

EGRIFTA SV® Human Factors Study

As previously announced, the FDA requested that the Company carry out a Human Factors Study ("HFS") to ensure that patients are administering *EGRIFTA SV®* in the appropriate manner. The study has been initiated and is progressing as planned.

F8 sBLA Filing

The Company had planned on filing a supplemental biologic licence application ("sBLA") for its F8 formulation of tesamorelin by the end of the first quarter of calendar 2022. As the FDA asked us to do a HFS for *EGRIFTA SV®*, we have proactively decided to do one also for the F8 formulation. This study has been initiated and will be completed shortly after the *EGRIFTA SV®* HFS study.

Furthermore, given the current uncertainty around the supply of Bacteriostatic Water For Injection ("BWFI"), we have signed an agreement with a contract manufacturer to produce our own supply. We believe this proactive step will ensure we have access to BWFI upon launch of the F8

formulation, if approved. With these decisions made, we are currently on track to deliver the filing of this new formulation in the fourth quarter of 2023, with an approval and launch expected around the first quarter of 2024.

NASH

We continue to have discussions with potential NASH partners and are encouraged to see renewed NASH interest with recent industry announcements. However, our NASH program is still on pause pending resolution on the F8 formulation and finding of a partner with resources and capabilities.

Corporate and Commercial Updates

$100 million Credit Agreement with Marathon Asset Management and Closing of first tranche of $40 million

On July 13, 2022, the Company announced it received a binding commitment with respect to a credit agreement (the “Credit Agreement”) for a non-dilutive term loan with an affiliate of Marathon Asset Management for up to $100 million.

On July 27, 2022, the Company announced that it received funding of $40 million under the terms of this Credit Agreement. A portion of the net proceeds from this amount was used to buy back and cancel $30 million principal amount of convertible notes due June 30, 2023, through private agreements with certain noteholders, while the remainder was allocated to working capital. All amounts drawn under the Credit Agreement bear interest at SOFR plus 9.5%.

2022 Revenue Guidance

Fiscal year 2022 revenue guidance is on track to be in the range of $79 million - $82 million, or growth of the commercial portfolio to be in the range of 13% and 17%, as compared to the 2021 fiscal year.

Third Quarter Fiscal 2022 Financial Results

The financial results presented in this press release are taken from the Company’s Management's Discussion and Analysis (MD&A) and our unaudited consolidated financial statements as at August 31, 2022 (Unaudited Financial Statements) which have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB). The MD&A and the Unaudited Financial Statements can be found at www.sedar.com, on EDGAR at www.sec.gov and at www.theratech.com. Unless specified otherwise and all capitalized terms have the meaning ascribed thereto in our MD&A.

Revenue

For the three- and nine-month periods ended August 31, 2022, consolidated revenue was $20,811,000 and $58,636,000, compared to $17,852,000 and $51,069,000 for the same periods ended August 31, 2021, representing a year-over-year increase of 16.6% and 14.8%, respectively.

For the third quarter of fiscal 2022, net sales of *EGRIFTA SV*® were $12,876,000 compared to $11,224,000 in the third quarter of fiscal 2021, representing an increase of 14.7% year-over-year. Net sales for the nine-month period ended August 31, 2022, were $35,996,000 compared to $30,256,000 in the same period in 2021. Higher *EGRIFTA SV*® sales are the result of increased unit sales and a higher net selling price per unit.

Trogarzo® net sales in the third quarter of fiscal 2022 amounted to $7,935,000 compared to $6,628,000 for the same quarter of 2021, representing an increase of 19.7% year-over-year. For the nine-month period ended August 31, 2022, Trogarzo® net sales were $22,640,000 compared to $20,813,000 in the same period in 2021. Higher sales of Trogarzo® were a result of a stronger performance in the United States, where we recorded 26.0% growth compared to the same quarter of last year, and were hampered by lower sales in Europe, as a result of a weaker overall pricing environment.

Cost of Sales

For the three-month period ended August 31, 2022, cost of sales decreased to $5,292,000 from $5,504,000 in the same period in fiscal 2021. The decrease is mostly related to the end of the amortization of the Other Asset.

For the nine-months ended August 31, 2022, cost of sales increased to $20,370,000 from $16,849,000, this increase is mostly related to the increase in revenues. The increase is also due to a charge, in the second quarter of 2022, arising from the non-production of scheduled batches of *EGRIFTA SV*® that were cancelled due to the planned transition to the F8 formulation of tesamorelin.

Cost of goods sold was $5,292,000 and $17,929,000 in the three- and nine-month periods of 2022 compared to $4,283,000 and $13,187,000 for the same periods in 2021. The increase in cost of goods sold was mainly due to higher unit sales of both *EGRIFTA SV*® and Trogarzo®.

R&D Expenses

R&D expenses in the three- and nine-month periods ended August 31, 2022, amounted to $8,425,000 and $27,484,000 compared to $8,296,000 and $19,596,000 in the comparable periods of fiscal 2021.

The increases in both periods were largely due to higher spending related to the ongoing Phase 1 trial of TH1902. In 2022, we have also initiated important studies related to medical education and follow-up studies in the HIV field. Increased spending in R&D is also related to the on-going trial evaluating the intra-muscular form of administration of Trogarzo®. The increase is also explained by severance costs related to our decision to exit the European market for Trogarzo®.

Selling Expenses

Selling expenses increased to $8,404,000 and $31,582,000 for the three- and nine-month periods ended August 31, 2022, compared to $7,657,000 and $20,716,000 for the same periods last year. The increase is due in part to one-time costs related to setting up of our internal field force in the

United States, as well as spending on new initiatives implemented in 2022 to increase awareness of our products on the North American market. The increase is also explained by severance costs related to our decision to exit the European market for Trogarzo®.

The amortization of the intangible asset value for the *EGRIFTA SV®* and Trogarzo® commercialization rights is also included in selling expenses. As such, we recorded expenses of $642,000 and $8,539,000 for the three- and nine-month periods ended August 31, 2022, compared to $795,000 and $2,745,000 in 2021. The increase in the nine-month period ended August 31, 2022, is related to the accelerated amortization of the Trogarzo® commercialization rights for the European territory following our decision in the second quarter of 2022 to cease commercialization activities in that territory.

General and Administrative Expenses

General and administrative expenses in the three- and nine-month periods ended August 31, 2022, amounted to $4,209,000 and $13,400,000 compared to $3,633,000 and $11,079,000 reported in the comparable periods of fiscal 2021. The increase in General and Administrative expenses is largely due to increased overall business activities in 2022 compared to 2021, as well as key hires in North America to support the implementation and management of our internal field force in the United States. General and administrative expenses for Q3 of 2022 also include severance costs and fees associated to our realignment in Europe.

Net Finance Costs

Net finance costs for the three- and nine-month periods ended August 31, 2022, were $1,879,000 and $4,808,000 compared to $2,254,000 and $4,609,000 for the comparable periods of 2021. Net finance costs in the third quarter of 2022 and 2021 included interest of $554,000 and $847,000 respectively ($2,189,000 and $2,482,000 in the corresponding nine-months periods, respectively) on the senior convertible notes issued in June 2018, as well $490,000 interest on our new term loan. (Please refer to note 7 of the Interim Consolidated Financial Statements).

Net finance costs for the three- and nine-month periods ended August 31, 2022, also included accretion expense of $456,000 and $1,517,000, compared to $612,000 and $1,801,000 for the comparable periods in 2021.

Net Loss

Given the increase in revenue and the smaller increase in expenses in the third quarter of 2022, net loss improved to $7,549,000 from $9,510,000 in the third quarter of 2021. During the nine-month period ended August 31, 2022, net loss increased to $39,308,000 from $21,824,000 in the corresponding period of 2021, mostly due to the accelerated amortization of the Trogarzo® commercialization rights for the European Territory in the second quarter of 2022 of $6,356,000. Net loss in the third quarter of 2022 was also impacted by severance costs and fees related to our decision to exit the European market for Trogarzo® of approximately $900,000. Net loss for the nine-month period ended August 31, 2022 was further impacted by a charge, in the second quarter of 2022, arising from the non-production of scheduled batches of *EGRIFTA SV®* that were cancelled due to the planned transition to the F8 formulation of tesamorelin.

Liquidity and Financial Position

We ended the third quarter of fiscal 2022 with $36,462,000 in cash, bonds and money market funds. The Company believes that its cash position and future operating cash flows will be sufficient to finance its operations for at least the next 12-months from the consolidated statement of financial position date. (See Note 1c) to the Interim Financial Statements).

For the three-month period ended August 31, 2022, cash flows used by operating activities were $4,372,000 compared to $4,554,000 in the same period of fiscal 2021.

In the third quarter of fiscal 2022, changes in operating assets and liabilities had a positive impact on cash flow of $3,176,000, as compared to $1,500,000 in 2021. These changes were mostly attributable to positive impacts from lower accounts receivable ($1,059,000), inventories ($1,536,000) and prepaid expenses ($1,135,000) and were offset by lower accounts payables and accrued liabilities ($1,333,000).

Our financial position was also positively impacted by the net proceeds from the first tranche of the term loan facility ($36,892,000, including deferred financing costs), which were offset by funds used to repurchase $30,000,000 principal amount of convertible notes outstanding ($28,746,000), as well as by the interest paid on the convertible notes.

Conference Call Details

The conference call will be held at 8:30 a.m. (ET) on October 13, 2022 to discuss the results and recent business updates. The call will be hosted by Paul Lévesque, President and Chief Executive Officer. Joining Mr. Lévesque on the call will be other members of the management team, including Chief Financial Officer Philippe Dubuc and Chief Medical Officer Christian Marsolais, who will be available to answer questions from participants following prepared remarks.

Participants are encouraged to join the call at least ten minutes in advance to secure access.

Conference call dial-in and replay information is below:

CONFERENCE CALL INFORMATION	
Conference Call Date:	October 13, 2022
Conference Call Time:	8:30 AM ET
North America Dial-in:	1- 877-513-4119
International Dial-in:	1- 412-902-6615
Access Code:	0675980
CONFERENCE CALL REPLAY	
North America Dial-in:	1- 877-344-7529

International Dial-in:	1- 412-317-0088
Replay Access Code:	1261932
Replay End Date	October 20, 2022

The live conference call will be accessible via webcast at:
https://edge.media-server.com/mmc/p/69eduxxu

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", "promising", "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 forecasted revenues for the 2022 full fiscal year, the conduct of our clinical trials with TH1902, the availability to us of the whole amount of $100 million under the terms of the Credit Agreement, our ability to successfully complete the HFS for both *EGRIFTA SV*® and the F8 formulation, the timelines associated with the filing of an sBLA with the FDA for the F8 formulation and the launch thereof, our discussions with potential partners in NASH and in Greater China for our oncology platform, and the benefits to be derived from the approval of the IV push method of administration of Trogarzo®.

Although the forward-looking information contained in this press release is based upon what the Company believes are reasonable assumptions in light of the information currently available, investors are cautioned against placing undue reliance on this information since actual results may vary from the forward-looking information. Certain assumptions made in preparing the forward-looking statements include that: sales of *EGRIFTA SV*® and Trogarzo® in the United States will increase over time; the Company's commercial practices in the United States will not be found to be in violation of applicable laws; the long-term use of *EGRIFTA SV*® and Trogarzo® will not change their respective current safety profile; no recall or market withdrawal of *EGRIFTA SV*® and Trogarzo® will occur; no laws, regulation, order, decree or judgment will be passed or issued by a governmental body negatively affecting the marketing, promotion or sale of *EGRIFTA SV*® and Trogarzo® in the United States; continuous supply of *EGRIFTA SV*® and Trogarzo® will be available; the Company's relations with third-party suppliers of *EGRIFTA SV*® and Trogarzo® will be conflict-free and such third-party suppliers will have the capacity to manufacture and supply *EGRIFTA SV*® and Trogarzo® to meet market demand on a timely basis; no biosimilar version of *EGRIFTA SV*® will be approved by the FDA; the Company's intellectual property will prevent companies from commercializing biosimilar versions of *EGRIFTA SV*® in the United States; the Company will meet all conditions under the Credit Agreement to draw down all amounts thereunder; the Company will succeed in finding a commercial partner in Greater China for its oncology platform and for its NASH program; the timelines associated with the filing of an sBLA with the FDA for the F8 formulation and the launch thereof will be met; the Company will be able to recruit patients for its clinical trial using TH1902; no material manufacturing issues will be encountered in connection with the manufacture of TH1902; results observed and obtained from the Phase 1 clinical trial using TH1902 will be at least as good as those observed in preclinical studies and will allow the pursuit of this clinical study; the market will accept the new method of administration of Trogarzo®; and the Company's business plan will not be substantially modified.

Forward-looking information 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 information. These risks and uncertainties include, but are not limited to, those related to or arising from: the Company's ability and capacity to grow the sales of *EGRIFTA SV*® and Trogarzo® successfully in the United States; the Company's capacity to meet supply and demand for its products; the market acceptance of *EGRIFTA SV*® and Trogarzo® in the United States, including the IV push method of administration of Trogarzo®; the continuation of the Company's collaborations and other significant agreements with its existing commercial partners and third-party suppliers and its ability to establish and maintain additional collaboration agreements; the Company's success in continuing to seek and maintain reimbursements for *EGRIFTA SV*® and Trogarzo® by third-party payors in the United States; the success and pricing of other competing drugs or therapies that are or may become available in the marketplace; the Company's ability to protect and maintain its intellectual property rights in *EGRIFTA SV*® and tesamorelin; events that could disrupt the Company's ability to successfully meet the timelines set forth herein; the discovery of a cure for HIV; the Company's failure to meet the terms and conditions set forth in the Credit Agreement resulting in an event of default and preventing the Company from accessing the full amount of the term loan; inconclusive results from the conduct of the Company's Phase 1 clinical trial using TH1902; the inability of the Company to enter into a partnership agreement with a third party for its NASH program or for its oncology program in the territory of Greater China; the Company's expectations regarding its financial performance, including revenues, expenses, gross margins, profitability, liquidity, capital expenditures and income taxes; and the Company's estimates regarding its capital requirements.

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. 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.

Investor inquiries:
Elif McDonald

Senior Director, Investor Relations
ir@theratech.com
1-438-315-8563

Media inquiries:
Julie Schneiderman
Senior Director, Communications & Corporate Affairs
communications@theratech.com
1-514-336-7800