



Theratechnologies Reports Financial Results for First Quarter Fiscal 2022 and Provides Business Update

April 13, 2022

- Q1 2022 consolidated sales grew 20%, supported by 35% growth in EGRIFTA SV[®] sales

- TH1902 Phase 1/Part A enrollment at 300 mg/m² dose nearing completion, potentially enabling recruitment of larger Phase 1/Part B expansion (basket trial) in the near term

- Three poster presentations at AACR including new in vivo TH1902 Preclinical Data on its effect on Cancer Stem-like Cells (CD-133+)

- Onboarding of commercial field force ongoing and to be fully completed by the end of April, 2022

MONTREAL, April 13, 2022 (GLOBE NEWSWIRE) -- **Theratechnologies Inc. (Theratechnologies, or 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 first quarter of fiscal year 2022 ended February 28, 2022 (Q1 2022).

"Building on the strong momentum of the second half of 2021, our performance continues through to the new year, said Paul Lévesque, President and Chief Executive Officer. "To this end, we are making good headway across our execution goals as evidenced by the strong sales growth in Q1 2022, our historically weakest quarter. In EGRIFTA SV[®], we achieved 35% sales growth, while overall blended commercial sales grew in the double digits by 20%."

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

	Three- months ended February 28		% change
	2022	2021	
EGRIFTA [®] , EGRIFTA SV [®] net sales	11,704	8,688	34.7 %
Trogarzo [®] net sales	6,853	6,742	1.6 %
Revenue	18,557	15,430	20.3 %

"The development of TH1902, our lead investigational peptide drug conjugate linked to docetaxel, a well-established and well-characterized cytotoxic agent used in the treatment of cancer, is also progressing well. We anticipate completing the 300mg/m² dosing regimen for 6 patients with TH1902 before the end of April 2022, and we are now nearing the conclusion of this stage of the trial and establishing the recommended Phase 2 dose (RP2D). This is the last step prior to initiating the program's larger basket study trial. Additionally, we recently presented new TH1902 in vivo preclinical data at the AACR Annual Meeting. Theratechnologies also continues its partner out-licensing discussions for TH1902's development rights in Greater China," concluded, Mr. Lévesque.

Recent Business Highlights

Pipeline Updates

- **TH1902 Study Update:** Enrollment in the Phase 1 trial of TH1902 has picked up momentum in the past few weeks, and we now anticipate that all 6 patients required for the 300mg/m² dosing level will be enrolled before the end of April. This dose is the equivalent to approximately 1.5 times the indicated therapeutic dose of docetaxel. The targeted delivery of TH1902, along with the rapid internalization of the drug in cancer cells could enable the accumulation of 7.5 to 10 times more cytotoxic agent in cancer cells than when administered alone. If the absence of dose limiting toxicities (DLT) is confirmed, this dose will become the recommended Phase 2 dose (RP2D). As previously discussed, once the RP2D is established, initiation of enrollment of the larger open label basket trial will begin immediately. The basket trial will further assess the safety and tolerability of TH1902. The preliminary anti-tumor activity of TH1902 will be evaluated for all patients as per the response evaluation criteria in solid tumors.

Enrollment for the larger trial is expected to begin in this first half of 2022. An amendment to the Phase 1 protocol was submitted to the FDA to include the following solid tumor types: HR+ Breast Cancer, Triple Negative Breast Cancer, Ovarian Cancer, Endometrial Cancer, Melanoma (10 patients per arm) was submitted. In addition, one arm will be added to include Thyroid, Small Cell Lung, Prostate and potential other high Sortilin expressing cancers (15 patients in total). The original trial design consisted of 40 patients across a selection of solid tumors, including colorectal and pancreatic cancers. The plan is now to enroll a total of approximately 70 patients in the basket trial to evaluate the potential anti-tumor activity of TH1902.

To date, the Company has received and responded to the questions raised by the FDA and the Company does not expect to receive any additional questions before the April 15, 2022 deadline date by which time the amendments to the protocol will be deemed accepted and ready to be implemented.

- **TH1902 China Out-licensing and Partnership Strategy:** Out-licensing development and commercialization rights for TH1902 in Greater China continues and are ongoing with a number of different pharmaceutical and biotech companies.
- **Scientific Poster Presentations:** The Company presented three posters at the recently attended **AACR annual meeting**, including new in vivo TH1902 preclinical data demonstrating tumor growth inhibition of human cancer stem-like cells (CD133+) in both triple-negative breast and ovarian cancers.
- **F8 sBLA filing:** As previously announced, our intention was to file a supplemental Biologic License Application (“sBLA”) for the F8 formulation (“F8”) by the end of the first quarter of calendar 2022. In contrast to *EGRIFTA SV*[®] which is reconstituted daily with sterile water for injection, the F8 formulation requires bacteriostatic water for injection (“BWF”), since the reconstituted product is used for seven daily injections. We were recently informed by the sole global supplier of BWF that its plant was recently inspected by the FDA, and that it was required to make modifications before being able to resume manufacturing and shipment of its BWF. Although we believe a return to supply is planned for the fourth quarter of 2022, there is currently no firm timeline for reinitiating shipments, and, as such, this will cause a delay in the potential launch of the F8 formulation. Consequently, we have decided to delay the filing of the sBLA for the F8 formulation until we have greater clarity on the supply issues. As a result of this uncertainty related to the availability of the F8 formulation of tesamorelin, and since the dosing of patients in Phase 3 trial in non-alcoholic steatohepatitis (“NASH”) is dependant on the availability of the F8, we have also decided to pause any external activities related to the planning of the trial until there is more clarity on the availability of BWF. We plan on keeping investors informed as the supply of BWF becomes more certain.

This does not affect the supply of *EGRIFTA SV*[®] since this formulation does not require BWF for reconstitution.

Commercial and Medical Affairs Updates

- **Strengthening of US Commercial and Medical Affairs Capabilities:** In March 2022, Theratechnologies initiated the full deployment of its own internal field force as pandemic restrictions continue to abate, enabling increased physician engagement. Strong momentum created in the second half of 2021 provided the major impetus for this decision, which should increase employee engagement, reduce turnover, and allow recruitment of top-tier talent for our field force. Onboarding of all internal commercial and medical field force will be fully completed by the end of April, 2022.
- **Trogarzo[®] Lifecycle Management:** A sBLA was filed with the U.S. Food and Drug Administration (“FDA”) in the fourth quarter of 2021 for the Company’s Intravenous (“IV”) Push mode of administration of Trogarzo[®] for the treatment of human immunodeficiency virus type 1 (HIV-1). We are pleased to announce that the FDA has accepted our filing and has provided a target action date of October 3, 2022 in accordance with the Prescription Drug User Fee Act (PDUFA). Theratechnologies and TaiMed are also evaluating an intramuscular (IM) mode of administration for Trogarzo[®] within the TMB-302 study. Patient enrollment is progressing well, and we expect full enrollment to be achieved in the coming weeks, enabling completion of the study in the second half of 2022.

2022 Revenue Guidance

Theratechnologies affirms fiscal 2022 revenue to be in the range of \$79 million and \$84 million for full fiscal 2022, or growth of the commercial portfolio to be in the range of 13% and 20% as compared to the 2021 fiscal year.

First 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 interim consolidated financial statements (Interim Financial Statements) for the three-month period ended February 28, 2022 (First Quarter Fiscal 2022) 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 Interim Financial Statements can be found at www.sedar.com, on EDGAR at www.sec.gov and at www.theratech.com. Unless specified otherwise, all amounts in this press release are in U.S. dollars and all capitalized terms have the meaning ascribed thereto in our MD&A.

Revenue

Consolidated revenue for the three-month period ended February 28, 2022 was \$18,557,000 compared to \$15,430,000 for the same period ended February 28, 2021.

For the first quarter of fiscal 2022, net sales of *EGRIFTA SV*[®] reached \$11,704,000 compared to \$8,688,000 in the first quarter of the prior year, representing an increase of 34.7% over the first quarter of 2021, due to the combined effect of a higher number of units sold and higher net selling price.

In the first quarter of fiscal 2022, Trogarzo[®] net sales amounted to \$6,853,000 compared to \$6,742,000 for the same quarter of 2021, representing an increase of 1.6%. While unit sales were higher in both North America and Europe, revenue growth was impacted by greater rebates in Europe.

Cost of Sales

For the three months ended February 28, 2022, cost of sales increased to \$6,099,000 from \$5,411,000 in the same quarter in fiscal 2021, primarily due to the higher cost of goods sold. Cost of goods sold was \$4,878,000 in the first quarter of 2022 compared to \$4,190,000 for the same quarter the previous year. The increase in cost of goods sold was mainly due to higher sales. Cost of sales also included the amortization of the other asset of \$1,221,000 in both Q1 fiscal 2022 and Q1 fiscal 2021.

R&D Expenses

R&D expenses amounted to \$8,003,000 in the three-month period ended February 28, 2022 compared to \$4,883,000 for the same period in 2021. The increase was largely due to higher spending in our oncology programs, increased spending in medical and patient education, as well as increased medical affairs spending in Europe.

Selling Expenses

Selling expenses amounted to \$7,807,000 for the first quarter of 2022 compared to \$6,158,000 for the same three-month period last year, reflecting the addition of key hires in North America and Europe, greater commercialization activities in both territories.

The amortization of the intangible asset value for the EGRIFTA[®] and Trogarzo[®] commercialization rights is also included in selling and market development expenses. As such, we recorded an expense of \$795,000 for both the first quarter of fiscal 2022 and 2021.

General and Administrative Expenses

General and administrative expenses amounted to \$4,368,000 for the three months ended February 28, 2022 compared to \$3,562,000 for the first quarter of 2021. The increase in general and administrative expenses was mainly associated with an overall increase in business activities and increased activity in Europe.

Net Finance Costs

Net finance costs for the three months ended February 28, 2022 were \$1,285,000 compared to \$1,332,000 for the comparable period of 2021. Net finance costs in the first quarter of 2022 and 2021 included interest of \$802,000 on the senior convertible notes issued in June 2018.

Net finance costs also included accretion expense of \$517,000 in the first quarter of 2022, compared to \$581,000 for the comparable period in 2021.

Net Loss

Given the increase in revenue and the increased expenses for the three months ended February 28, 2022, net loss for the period was \$9,032,000, compared to \$5,922,000 for the same period last year.

Liquidity and Financial Position

We ended the first quarter of fiscal 2022 with \$34,283,000 in cash, bonds and money market funds.

During the first quarter of fiscal 2021, the Company completed a public offering for the sale and issuance of 16,727,900 units of the Company for a gross cash consideration of \$46,002,000 including the full exercise of the over-allotment option. Share issue costs amounted to \$3,385,000 resulting in net proceeds of \$42,617,000.

Our current cash, bond and money market funds will be sufficient to fund the Company's operations for the next twelve months. We are currently exploring alternatives to redeem the senior convertible notes issued in June 2018, which become due in June 2023.

For the three-month period ended February 28, 2022, operating activities used cash of \$4,174,000 compared to \$1,896,000 in the comparable period of fiscal 2021, primarily due to the increased loss in 2022.

In the first quarter of fiscal 2022, changes in operating assets and liabilities had a positive impact on cash flow of \$69,000 (2021-negative impact of \$3,332,000). These changes included a negative impact from higher accounts receivable, a decrease in accounts payables and accrued liabilities, and were offset by positive impacts from lower inventories and lower prepaid expenses and deposits.

Conference Call Details

A conference call and webcast will be held on April 13, 2022 at 8:30 a.m. (ET) to discuss the first quarter fiscal 2022 results and recent business highlights. The call will be hosted by Paul Lévesque, President and Chief Executive Officer of Theratechnologies, and other members of the management team.

The conference call can be accessed by dialing 1-844-400-1697 (toll free) or 1-703-736-7400 (International). The conference call will also be accessible via webcast [here](#). An audio replay of the conference call will be available on the same day starting at 11:30 a.m. (ET) until April 20, 2022, by dialing 1-855-859-2056 (North America) or 1-404-537-3406 (International) and by entering the access code: 7843697. An archived webcast will also be available on the Company's Investor Relations website under '[Past Events](#)'.

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 the our forecasted revenues for the 2022 full fiscal year, the conduct of our clinical trials with TH1902, the timelines associated with the initiation of our basket trial using TH1902, the timelines associated with the

onboarding of our commercial and medical field force in the U.S. and the timelines associated with the enrollment and completion of the IM study for 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: the current COVID-19 pandemic will have limited adverse effect on the Company's operations; sales of *EGRIFTA SV*® and Trogarzo® in the United States will increase over time; the Company's commercial practices in the United States and the countries of the European Union 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 countries where such products are commercialized; 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 FDA will approve the IV Push mode of administration of Trogarzo®; the Company will succeed in finding a commercial partner in Greater China for its SORT1+ Technology™ platform; the timelines associated with the completion of the Phase 1a trial using TH1902 and the initiation of the basket trial will be met and the timelines related to the completion of the enrollment of the patients and completion of the study related to the IM mode of administration of Trogarzo® will also be met; 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 adverse impact of the COVID-19 pandemic on (a) the Company's sales efforts and sales initiatives, (b) the capacity of the Company's suppliers to meet their obligations vis-à-vis the Company, (c) the Company's research and development activities, , as well as (d) global trade; the Company's ability and capacity to grow the sales of *EGRIFTA SV*® and Trogarzo® successfully in the United States and Trogarzo® in Europe; the Company's capacity to meet supply and demand for its products; the market acceptance of *EGRIFTA SV*® and Trogarzo® in the United States and of Trogarzo® in Europe; 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; the Company's success in obtaining satisfactory pricing and reimbursement conditions for Trogarzo® in key European countries; the Company's ability and capacity to commercialize Trogarzo® in key countries in the EU; the Company's ability to successfully conduct its Phase 1 clinical trial using TH1902 in various types of cancer and delays that may occur in the timelines to complete such trials; the discovery of a cure for HIV; 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.

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