



Theratechnologies Announces Reimbursement Agreement in Italy for Trogarzo® for Eligible Patients With Multi-Drug Resistant HIV-1

October 26, 2021

MONTREAL, Oct. 26, 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 it has reached an agreement with the Italian Medicines Agency, AIFA, for the reimbursement of Trogarzo® for eligible people aged 18 and older living with multi-drug resistant (MDR) HIV-1.

"This agreement is an important milestone for Trogarzo® and for HIV-1 patients in Italy," said Conor Walshe, General Manager, Europe. "Italy is the first country with a universal healthcare plan that has approved the formal reimbursement of Trogarzo® for all patients in need. We expect to launch Trogarzo® in Italy during the current quarter and look forward to its wider commercial availability in Europe over the coming months."

Trogarzo® was first approved by the U.S. Food and Drug Administration (FDA) in March 2018 and was the first long-acting agent approved for the treatment of HIV-1 infection in heavily treatment-experienced adults with MDR HIV-1 infection failing their current antiretroviral regimen. Trogarzo® was approved by the European Medical Agency (EMA) in September 2019 for the treatment of adults infected with MDR HIV-1 for whom it is otherwise not possible to construct a suppressive antiviral regimen and is also commercially available in Germany. A number of patients are also being treated with Trogarzo® in other European countries through early access programs. Theratechnologies plans to launch Trogarzo® on a country-by-country basis across Europe as it gains reimbursement in each individual country. In addition, the Company received regulatory approval in Israel for Trogarzo® and is working to secure pricing and reimbursement.

About Trogarzo®¹

Trogarzo® a humanized monoclonal antibody of immunoglobulin G type 4 (IgG4), is a CD4 domain 2-directed HIV-1 inhibitor.

Trogarzo® blocks HIV-1 from infecting CD4+ T cells by binding to domain 2 of CD4 and interfering with the post-attachment steps required for the entry of HIV-1 virus particles into host cells and preventing the viral transmission that occurs via cell-cell fusion. Trogarzo® is administered every 2 weeks via intravenous infusion.

The most frequently reported adverse reactions were rash (9.2%), diarrhea (3.9%), dizziness (3.9%), headache (3.9%), nausea (3.9%), fatigue (2.0%) and vomiting (2.0%).

For more information on Trogarzo®, please contact medinfo.eu@theratech.com.

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 commercialization of Trogarzo® in Italy and other European countries.

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 current pandemic will not adversely affect the launch of Trogarzo® in Italy and the commercial availability of this drug in other European countries, the timelines set forth in this press release will be met, and Trogarzo® will not be subject to any recall.

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, those related to or arising from: the adverse impact of the ongoing COVID-19 pandemic on (a) the Company's sales efforts and sales initiatives, including the launch of Trogarzo® in Italy and the commercial availability of this drug in other European countries, (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, (d) the health of the Company's employees and its capacity to rely on its resources, as well as (e) global trade; 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 24, 2021 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, 2021 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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¹ Trogarzo (ibalizumab) [SMPC] : Theratechnologies Europe Limited; 2021.