

## THE NEW ENGLAND JOURNAL OF MEDICINE PUBLISHES TWO ARTICLES ON TROGARZO™

*Phase III results and FDA-authored article featured in latest edition of NEJM*

**Montreal, Canada – August 15, 2018** – Theratechnologies Inc. (Theratechnologies) (TSX: TH) is pleased to announce that results from the phase III clinical trial used to obtain FDA approval for Trogarzo™ (ibalizumab-uiyk) injection in the United States were published in the most recent edition of The New England Journal of Medicine (NEJM).<sup>1</sup>

Furthermore, the NEJM published an article, authored by the Office of the Antimicrobial Products of the FDA, giving rationale for the design of the phase III trial of Trogarzo™ that led to its approval.

The phase III, open-label study, enrolled 40 patients with multidrug-resistant (MDR) HIV-1 in whom multiple antiretroviral therapies had failed. All patients at baseline were experiencing viral failure. After a seven-day control period, patients received an intravenous 2000 mg loading dose of Trogarzo™ which was the only change made to their antiretroviral regimen. Through the 24-week treatment period of the study, patients were given a maintenance dose of 800 mg of Trogarzo™ every two weeks along with an optimized background regimen that included at least one additional fully active agent.

The primary endpoint of the study was the proportion of patients with a viral load reduction of at least 0.5 log<sub>10</sub> from baseline, 7 day after the loading dose.

The mean baseline viral load was 4.5 log<sub>10</sub> while the mean CD4 cell count was 150 per microliter. Of the 40 patients, 33 (83%) had a decrease in viral load of at least 0.5 log<sub>10</sub> from baseline. At the end of the 24-week treatment period, 43% of patients had a viral load lower than 50 copies per milliliter (considered below detection level) and 50% had a viral load of less than 200 copies per milliliter.

“The New England Journal of Medicine is among the most highly regarded peer-reviewed medical journals. It lends tremendous credibility to the Trogarzo™ phase III clinical trial results. The medical community, payers and treatment guideline authors will certainly welcome those peer-reviewed articles as it gives perspective and even more reassurance towards the utilisation of Trogarzo™”, said Luc Tanguay, President and CEO, Theratechnologies Inc.

### **About Trogarzo™ (ibalizumab-uiyk) injection**

Trogarzo™ is a CD4-directed post-attachment HIV-1 inhibitor.

Trogarzo™, in combination with other antiretroviral(s), is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen.

Before you receive Trogarzo™, tell your healthcare provider if you are pregnant or plan to become pregnant as it is not known if Trogarzo™ may harm your unborn baby or if you

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<sup>1</sup> n engl j med 379;7, August 16, 2018

are breastfeeding or plan to breastfeed as it is not known if Trogarzo™ passes into breast milk.

Tell your healthcare provider about all the medicines you take, including all prescription and over-the-counter medicines, vitamins, and herbal supplements.

Changes in your immune system (Immune Reconstitution Inflammatory Syndrome) can happen when you start taking HIV-1 medicines. Your immune system might get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your health care provider right away if you start having new symptoms after starting your HIV-1 medicine.

The most common side effects of Trogarzo™ include: diarrhea, dizziness, nausea and rash.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of Trogarzo™. For more information, ask your healthcare provider or pharmacist.

Full prescribing information available at [www.trogarzo.com](http://www.trogarzo.com)

### **About Theratechnologies**

Theratechnologies (TSX: TH) is a specialty pharmaceutical company addressing unmet medical needs to promote healthy living and an improved quality of life among HIV patients. Further information about Theratechnologies is available on the Company's website at [www.theratech.com](http://www.theratech.com) and on SEDAR at [www.sedar.com](http://www.sedar.com).

### **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 belief and assumptions and on information currently available to our management. The forward-looking statements contained in this press release include, but are not limited to statements about the inclusion of Trogarzo™ as a new treatment for MDR HIV-1.

Forward-looking statements 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: physicians and patients will accept Trogarzo™ as a new treatment. These risks and uncertainties include, but are not limited to, the risk that results from the use of Trogarzo™ vary amongst patients taking the drug and that unobserved serious side effects emerge from the use of Trogarzo™.

We refer potential investors to the "Risk Factors" section of our Annual Information Form dated February 6, 2018 available on SEDAR at [www.sedar.com](http://www.sedar.com) for additional risks and uncertainties about Theratechnologies and its business. 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.

**Media inquiries:**

Denis Boucher

Vice President, Communications and Corporate Affairs

Tel.: (514) 336-7800, ext. 236