



## Theratechnologies Announces Exclusive Licensing Agreement with Ionis to Commercialize Olezarsen and Donidalorsen in Canada

Dec 04, 2024

*Addition of investigational RNA-targeted medicines build upon Theratechnologies' foundational HIV portfolio*

*Submissions to Health Canada planned for 2025*

MONTREAL, Dec. 04, 2024 (GLOBE NEWSWIRE) -- Theratechnologies Inc. ("Theratechnologies" or the "Company") (TSX: TH) (NASDAQ: THTX), a pharmaceutical company focused on the development and commercialization of innovative therapies, today announced it has entered into an agreement with Ionis Pharmaceuticals, Inc. (Ionis) to license two investigational RNA-targeted medicines developed by Ionis. Under the agreement, Theratechnologies receives exclusive rights in Canada for olezarsen, which is being evaluated for familial chylomicronemia syndrome (FCS) and severe hypertriglyceridemia (sHTG), and for donidalorsen, which is being evaluated for the treatment of hereditary angioedema (HAE). All figures are in U.S. dollars unless otherwise stated.

"Theratechnologies is proud to be the partner of choice for Ionis to bring two innovative treatments for three potential indications to patients with unmet medical needs across Canada, thus expanding upon our foundational HIV portfolio and primary business in the U.S.," said Paul Lévesque, President and Chief Executive Officer of Theratechnologies. "The agreement with Ionis is a testament to our team's capabilities to advance innovation across North America and reaffirms our commitment to be a commercially focused company that delivers sustained top- and bottom-line growth and value for shareholders."

"We are pleased to partner with Theratechnologies, bringing together their deep regional expertise in Canada and our shared goal of delivering innovative new medicines to people living with severe and debilitating diseases," said Brett Monia, Ph.D., Ionis Chief Executive Officer. "Ionis is well-positioned to deliver these medicines to the U.S. market as we rapidly approach our first anticipated independent commercial launches, assuming regulatory approvals of olezarsen in FCS and donidalorsen in HAE. Our new partnership with Theratechnologies supports our commitment to ensure access to our innovative medicines globally."

### *Olezarsen*

Olezarsen is an investigational RNA-targeted medicine designed to lower the body's production of apoC-III, a protein produced in the liver that regulates triglyceride (TG) metabolism in the blood. It is being evaluated for the treatment of both FCS and sHTG.

FCS is characterized by extremely elevated TG levels, chronic, debilitating symptoms and recurrent, potentially life-threatening acute pancreatitis. Generally, the prevalence of FCS in Canada is similar to the broader global population. However, in specific regions like Eastern Québec, the prevalence of FCS is believed to be approximately 100-fold higher (1:10,000) than the global average due to the founder effect.

sHTG is characterized by a severe elevation in TG levels and can result in serious health complications, including potentially life-threatening acute pancreatitis. The disease affects a much larger patient population than FCS, with a total addressable market for sHTG in the U.S. representing up to approximately 3 million patients and a similar prevalence in Canada on a per capita basis.

The U.S. Food and Drug Administration (FDA) has accepted for Priority Review the olezarsen New Drug Application (NDA) for the treatment of adults with FCS. The FDA has designated olezarsen as an Orphan Drug and has set a Prescription Drug User Fee Act (PDUFA) action date of December 19, 2024. Theratechnologies plans to submit olezarsen in FCS to Health Canada for review in 2025. If the Company receives a Notice of Compliance, it will be the first approved treatment for FCS treatment in Canada.

Ionis has completed enrollment of the Phase 3 olezarsen clinical program for patients with sHTG (CORE, CORE2 and ESSENCE), with results from all three trials anticipated in the second half of 2025.

### *Donidalorsen*

Donidalorsen is an investigational RNA-targeted medicine designed to reduce the production of prekallikrein (PKK), a protein that plays an important role in the activation of inflammatory mediators associated with acute attacks of HAE.

HAE is a rare and potentially life-threatening genetic condition that involves recurrent attacks of severe swelling (angioedema) in various parts of the body. HAE (Type 1 and Type 2) has a combined estimated prevalence of approximately one in 50,000 people.

The FDA has recently accepted the donidalorsen NDA for review for the treatment of hereditary angioedema, with a PDUFA action date of August 21, 2025. Regulatory submissions are also progressing in Europe. Donidalorsen received Orphan Drug Designation from the FDA in 2023 and from the European Commission in 2024. Theratechnologies plans to submit donidalorsen for HAE to Health Canada for review in 2025.

### *Transaction Information*

Ionis has granted Theratechnologies an exclusive license to commercialize olezarsen and donidalorsen for use in Canada.

Ionis will receive a \$10 million upfront payment upon execution of the agreement as well as milestone payments up to \$12.75 million based on the achievement of regulatory milestones, public reimbursement, and annual sales targets. Ionis will also be entitled to receive tiered double-digit royalties on annual net sales of each medicine.

Theratechnologies will be responsible for filing, obtaining and maintaining regulatory approval for olezarsen and donidalorsen in Canada. Ionis will be

manufacturing and supplying both products to Theratechnologies and has granted the Company a right to manufacture both products in certain limited circumstances.

The term of the licensing agreement with Ionis will continue until Theratechnologies permanently ceases commercializing all licensed products in Canada, or unless earlier terminated in accordance with customary termination provisions for transactions of this like-nature.

### **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](http://www.theratech.com), on SEDAR+ at [www.sedarplus.ca](http://www.sedarplus.ca) and on EDGAR at [www.sec.gov](http://www.sec.gov). Follow Theratechnologies on [LinkedIn](#) and X ([Twitter](#)).

### **About Ionis Pharmaceuticals, Inc.**

For three decades, Ionis has invented medicines that bring better futures to people with serious diseases. Ionis currently has five marketed medicines and a leading pipeline in neurology, cardiology, and other areas of high patient need. As the pioneer in RNA-targeted medicines, Ionis continues to drive innovation in RNA therapies in addition to advancing new approaches in gene editing. A deep understanding of disease biology and industry-leading technology propels our work, coupled with a passion and urgency to deliver life-changing advances for patients. To learn more about Ionis, visit [ionis.com](http://ionis.com) and follow us on [X \(Twitter\)](#), [LinkedIn](#) and [Instagram](#).

### **Forward-Looking Information**

This press release contains forward-looking statements and forward-looking information (collectively, the "Forward-Looking Statements") within the meaning of applicable securities laws, that are based on management's beliefs and assumptions and on information currently available to it. 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: (i) the top and bottom-line growth of the Company; (ii) the estimates related to the prevalence of sHTG and HAE in Canada; (iii) the time periods related to the filing of the new drug submissions for each of donidalorsen and olezarsen with Health Canada; and (iv) the time period related to the receipt of results from the Phase 3 olezarsen clinical program for patients with sHTG. 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 contained in this press release. Certain assumptions made in preparing the Forward-Looking Statements include that: (i) sales of the products currently sold by the Company will continue to grow; (ii) the donidalorsen and olezarsen compounds, when filed with Health Canada, will be approved by the agency; (iii) both of these compounds, if and when approved, will be reimbursed in Canada and will be accepted by the Canadian marketplace as treatment for which they will be indicated; (iv) sales of these compounds will contribute to the top and bottom-line growth of the Company; (v) we will have all of the information required to file new drug submissions for each of those compounds with Health Canada according to the timelines set forth herein; and (vi) the results from the Phase 3 olezarsen clinical program will be available to us in the second half of 2025. Forward-Looking Statements assumptions are subject to a number of risks and uncertainties, many of which are beyond the Company's 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: (i) a decrease in sales of our commercialized products; (ii) the non-approval by Health Canada of one or both of the compounds; (iii) even if approved by Health Canada, the non-reimbursement in Canada of one or both of these compounds; (iv) the non-acceptance by the marketplace of these new compounds to treat the diseases they will be indicated for; (v) competing treatments from the entry of new drug products; (vi) delays in the filing of new drug submissions for any of those compounds; (vii) unexpected expense increases in connection with our activities, including seeking the approval of, and/or commercially launching, any of those compounds; and (viii) delays in receiving the results from the Phase 3 olezarsen clinical program. The Company refers current and potential investors to the "Risk Factors" section of the Company's Form 20-F dated February 21, 2024, available on SEDAR+ at [www.sedarplus.ca](http://www.sedarplus.ca) and on EDGAR at [www.sec.gov](http://www.sec.gov) 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 the Company's expectations as of that date.

### **Contacts:**

Media inquiries:

Julie Schneiderman

Senior Director, Communications & Corporate Affairs

[communications@theratech.com](mailto:communications@theratech.com)

1-514-336-7800

Investor Inquiries:

Philippe Dubuc

Senior Vice President and Chief Financial Officer

[pdubuc@theratech.com](mailto:pdubuc@theratech.com)

438-315-6608