

# ANNUAL REPORT PREPARED IN ACCORDANCE WITH THE FIGHTING AGAINST FORCED LABOUR AND CHILD LABOUR IN SUPPLY CHAINS ACT

FOR THE FISCAL YEAR ENDING NOVEMBER 30, 2023

THERATECHNOLOGIES INC.



In this annual report ("Report") made in accordance with the *Fighting Against Forced Labour and Child Labour in Supply Chains Act*, S.C. 2023, c.-9 ("Act"), references to "Theratechnologies", the "Company", the "Corporation", "we", "our" and "us" or similar terms refer to Theratechnologies Inc.

# 1. Introduction

Our legal name and commercial name is Theratechnologies Inc. Our head office and principal place of business is located at 2015 Peel Street, 11<sup>th</sup> Floor, Montreal, Québec, Canada H3A 1T8. Our corporate website is <u>www.theratech.com</u>. The Corporation's subsidiaries do not meet the criteria of entity under section 2 of the Act and as such this Report shall not be considered a joint report. All information provided in this Report is provided for the financial year ending November 30, 2023.

We were incorporated under Part IA of the *Companies Act* (Québec) ("CAQ"), on October 19, 1993, under the name Theratechnologies Inc. On February 14, 2011, the CAQ was abrogated and replaced by the *Quebec Business Corporation Act* ("QBCA"), and companies governed by Part IA of the CAQ such as us became business corporations governed by the QBCA. Our Quebec Enterprise Number is 1142237016.

Our common shares are listed on the TSX under the symbol "TH", and on the U.S. Nasdaq under the symbol "THTX". As a publicly traded corporation listed on a Canadian stock exchange, the Company meets the definition of "Entity" under the Act. Additionally, through the production and distribution of goods within the United States, Theratechnologies satisfies the criteria for classification as a reporting entity under section 9 of the Act. The Corporation is not subject to reporting obligations under supply chain legislation in other jurisdictions.

### 2. <u>Steps taken to prevent and reduce risks of forced labour and child labour</u>

Theratechnologies embraces values of diversity, inclusion and respect and submits itself to the highest standards of ethics. We are involved in the community and support activities to make a positive impact on people's lives, as such we place great emphasis on respecting human rights in all of our business activities.

Generally speaking, we took the following steps during the preceding fiscal year to prevent and reduce the risk of forced labour or child labour in our supply chains:

- the Corporation undertook the mapping of the supply chain of its product EGRIFTA SV<sup>®</sup>. One of the goals of this mapping was to enhance our visibility into all manufacturing and supply operation's location to assess the risk of child and/or forced labour being used; and
- we have pursued the qualification and auditing of all our service providers involved in Good Manufacturing Practices ("GMP") activities.

As further detailed in subsequent section of this Report, the Company is not responsible for the production of Trogarzo<sup>®</sup>. Consequently, the aforementioned actions only apply to the EGRIFTA SV<sup>®</sup> supply chain.



# 3. <u>Structure, Activities and Supply Chains</u>

#### Structure

Theratechnologies is a corporation governed by the QBCA, and as of November 30, 2023, we had the following five wholly owned subsidiaries with Theratechnologies U.S., Inc. being the only material subsidiary among Theratechnologies' affiliates:

- Theratechnologies U.S., Inc., a company governed by the *Delaware General Corporation Law*. Theratechnologies U.S., Inc. assists Theratechnologies Inc. with its commercial activities in the United States. The headquarter of Theratechnologies U.S., Inc. is located at 101 Hudson Street, 21<sup>st</sup> Floor, Jersey City, New Jersey, 07302;
- Theratechnologies Europe Limited, a company governed by the *Companies Act 2014* (Ireland). Theratechnologies Europe Limited assists Theratechnologies Inc. with its commercial activities in the United States. The headquarter of Theratechnologies Europe Limited is located at 12 Duke Lane, 1<sup>st</sup> Floor, Royal Hibernian Way, Dublin 2, Ireland D02 DX07;
- Theratechnologies Intercontinental Inc., a company governed by the QBCA. Theratechnologies Intercontinental Inc., formerly Theratechnologies ME Inc., used to control the worldwide rights to commercialize *EGRIFTA®*, except in the United States, Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries, and Canada. Theratechnologies Intercontinental Inc. is no longer an active subsidiary;
- Theratechnologies Europe Inc., a company governed by the QBCA. Theratechnologies Europe Inc., formerly 9176-5057 Québec Inc., used to control the rights to commercialize *EGRIFTA*<sup>®</sup> in Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries. Theratechnologies Europe Inc. is no longer an active subsidiary; and
- **Pharma-G Inc.**, a company governed by the QBCA. Pharma-G Inc. is no longer an active subsidiary.

As at November 30, 2023, we had a total of 58 employees in Canada, 42 employees in the United States and 3 employees in Ireland. All of our employees were engaged in the following activities: (i) 31 in administration, (ii) 20 in regulatory and medical, (iii) 39 in commercialization, including marketing, and (iv) 13 in research and development functions.

#### Activities and Supply Chain

We are a biopharmaceutical company focused on the development and commercialization of innovative therapies. Our mission is to provide hope to healthcare practitioners and patients by developing and commercializing cutting-edge treatments that address unmet medical needs. We currently commercialize two approved products in the United States for people living with HIV, namely: *EGRIFTA SV*<sup>®</sup> and Trogarzo<sup>®</sup>. In addition to the sale of



our products, we are conducting research and development activities, and we have a pipeline of investigational medicines in the areas of oncology and non alcoholic steatohepatitis.

### EGRIFTA SV®

*EGRIFTA SV*<sup>®</sup> (tesamorelin for injection) is a new formulation of *EGRIFTA*<sup>®</sup> which was originally approved by the Food Drug Administration ("FDA") in November 2010 and was launched in the United States in January 2011. EGRIFTA SV<sup>®</sup> was approved by the FDA in November 2018, was launched in 2019 and has now replaced *EGRIFTA*<sup>®</sup> in such country. *EGRIFTA SV*<sup>®</sup> is currently the only approved therapy in the United States and is indicated for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy. We have been commercializing this product in the United States since May 2014.

We do not own or operate manufacturing facilities for the production of *EGRIFTA SV*<sup>®</sup> or its active pharmaceutical ingredient ("API"), tesamorelin, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently rely on third-party service providers, i.e. Bachem Americas Inc. ("Bachem") and Jubilant HollisterStier, General Partnership ("Jubilant") to manufacture and supply all of our required raw materials, drug substance and drug product for sales of *EGRIFTA SV*<sup>®</sup>.

We have a manufacturing and supply agreement with Bachem relating to the manufacture and supply of the API for *EGRIFTA SV*<sup>®</sup>. The production of the API takes place at Bachem's manufacturing site located in Torrance, California, in the United States. We have an agreement with Jubilant providing for the manufacture and supply of the finished form of EGRIFTA SV<sup>®</sup> for commercial sale in the United States and for tesamorelin in connection with clinical trials ("Jubilant Agreement"). Under the Jubilant Agreement, Jubilant must fill vials with tesamorelin, lyophilize it, label and package those vials and deliver them to locations in accordance with our instructions. The activities provided under the Jubilant Agreement take place at the manufacturing site located in Kirkland, Quebec in Canada.

The Corporation also provides patients with the necessary supplies to administer *EGRIFTA SV*<sup>®</sup>. These supplies are comprised of alcohol swabs, syringes, needles and water for injection. The packaging of these supplies for *EGRIFTA SV*<sup>®</sup> is done through Sharp Packaging Services, LLC ("Sharp"). The services provided by Sharp take place in Allentown, Pennsylvania in the United States.

The finalization of the supply chain mapping process for *EGRIFTA SV*<sup>®</sup> enabled the Corporation to verify that each subcontractor engaged in either the manufacture of the drug product or the administration supplies were situated within Canada (specifically Ontario and Quebec) and the United States (specifically Massachusetts, North Carolina, Pennsylvania, and Tennessee).



# Trogarzo®

Trogarzo<sup>®</sup> (ibalizumab-uiyk) was approved by the FDA in March 2018 and, in combination with other antiretroviral(s), is indicated for the treatment of HIV type 1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen. We have an exclusive license from TaiMed Biologics Inc. ("TaiMed") granting us the rights to commercialize this product in the United States and Canada.

TaiMed serves as our exclusive supplier of Trogarzo<sup>®</sup>. Currently, TaiMed does not own or operate any manufacturing facilities dedicated to the production of Trogarzo<sup>®</sup>. We understand that TaiMed is relying on WuXi Apptec Biologics, Inc., situated in MaShan Binhu District, WuXi 214092, China, and Samsung Biologics Laboratories, located in Yeonsu-gu, Incheon 21987, South Korea, as its suppliers. Additionally, TaiMed bears responsibility for the packaging of the finished product, entrusting this task to Sharp and their manufacturing facility in Allentown, Pennsylvania.

# Distribution of EGRFITA SV<sup>®</sup> and Trogarzo<sup>®</sup>

Both *EGRIFTA SV*<sup>®</sup> and Trogarzo<sup>®</sup> are being provided in the United States through our exclusive third-party logistics service provider, McKesson Specialty Care Distribution, LLC with the sole distribution center being located in Louisville, Kentucky in the United States.

#### Research & Development

In addition to the sale of our products, we are conducting research and development activities. We have a pipeline of investigational medicines in the areas of hepatology and oncology. The oncology pipeline notably includes sudocetaxel zendusortide, a peptidedrug conjugate ("PDC") derived from our licensed platform SORT1+Technology<sup>™</sup> that incorporates docetaxel, that is designed to specifically target sortilin receptors expressed in cancer cells of various types of cancer. Sudocetaxel zendusortide is currently being studied in a Phase 1 clinical trial. We are also working on the development of other PDCs and the potential combination of additional anti-cancer agents with our existing PDCs and with any newly developed ones.

We do not possess or operate manufacturing facilities for the production of sudocetaxel zendusortide, nor do we have immediate plans to establish our own manufacturing operations. Presently, our agreement with STA Pharmaceutical Hong Kong Limited ("STA") encompasses the manufacturing of our peptide ("TH19P01") as well as sudocetaxel zendusortide. Theratechnologies has qualified two STA facilities, located in Shanghai and Jiangsu, China, for the production of TH19P01 and sudocetaxel zendusortide.

For the manufacturing of the finished form of sudocetaxel zendusortide in vials of sterile solution for injection, we rely on Piramal Pharma Solutions, Inc. ("Piramal"). Piramal conducts these services in two facilities, both situated in Kentucky, United States. Subsequently, the vials are forwarded to Sharp Clinical Services, LLC. for labeling and packaging to be used in clinical trials. These activities are conducted in Pennsylvania, United States.



### 4. Policies and Due Diligence Processes

#### Code of Business Conduct and Ethics ("Code")

The Code applies to all directors, officers, and employees of Theratechnologies and those of our subsidiaries. The purpose of the Code is to promote, among other things, honest and ethical conduct and compliance with applicable laws and regulations. Theratechnologies is committed to conducting its business with integrity and believes in encouraging ethical behavior and fostering the right values.

#### Standard Operating Procedures on Supplier Selection ("Supplier SOP")

The Supplier SOP applies to all suppliers involved in GMP activities including without limitation, the manufacturing, packaging, testing and storing of our products. This comprehensive qualification process encompasses the administration of a Supplier Audit Questionnaire ("Questionnaire") containing targeted inquiries concerning the supplier's personnel and their training. This approach ensures that all personnel engaged in the provision of services is adequately trained and qualified. The Questionnaire is an excellent tool for the Company to first identify any instances of child labour within the supply chain.

#### 5. Forced Labour and Child Labour Risks

The Company has initiated the process of identifying the risk of forced labour and child labour within our supply chain; however, we are currently in the preliminary stages of this endeavor.

There are a few reasons the pharmaceutical industry could potentially contribute to, or indirectly cause, forced labour or child labour. The first one being the intricate nature of pharmaceutical supply chains, often spanning multiple countries and involving numerous intermediaries which can make it challenging for companies to monitor the labour practices of third parties efficiently. More precisely, with respect to Theratechnologies, we acknowledge that the presence of certain supply chain activities situated in Shanghai, Jiangsu, Wuxi, and South Korea poses elevated risk due to their remote locations, rendering it more challenging for the Corporation to perform on-site audits.

Furthermore, the involvement of subcontractors from our direct supplier TaiMed (tier two suppliers and potentially tier three) in the supply chain of Trogarzo<sup>®</sup> complicates the task of maintaining control and visibility over the manufacturing activities, thereby posing a heightened risk of forced labour or child labour.

However, it is imperative to acknowledge that the pharmaceutical industry, including Theratechnologies, operates within a very stringent regulatory framework aimed at ensuring the safety and quality of pharmaceutical products. As Theratechnologies commercialize its products in the United States, it is obligated to adhere rigorously to various regulations, including, without limitation, the *Federal Food, Drug, and Cosmetic Act*, the *Drug Supply Chain Security Act*, and all relevant GxP standards, which uphold elevated ethical and professional standards.



We maintain confidence that our strict adherence to the aforementioned laws and standards significantly mitigates the risk of child labour or forced labour within our manufacturing and supply chain activities.

# 6. <u>Remediation Measures</u>

In the last fiscal year, we did not identify any instances of child labor or forced labor within our manufacturing and supply activities. Consequently, the Corporation did not implement any remediation measures for such issues in the preceding fiscal year.

Should the Corporation identify instances of forced labor in our operations or supply chains, we are committed to developing and implementing appropriate remedial actions to address the situation.

### 7. <u>Remediation of loss of income</u>

Since the Corporation did not take any measures to remediate forced labour or child labour, we consequently did not take any measures to remediate the loss of income to the most vulnerable families that could have been affected by our measures taken to eliminate the use of forced labour or child labour in our manufacturing and supply chain activities.

### 8. Training Provided to Employees

Each director, officer, and employee of Theratechnologies receives a yearly training on the content and the importance of the Code. In the last fiscal year, there was no specific training on forced labour or child labour.

### 9. Assessing Effectiveness

We have implemented certain measures in the last fiscal year aiming to reduce the risk of forced labour or child labour in our manufacturing and supply chain activities. Presently, the Corporation doesn't have any policy or procedure in place to assess the effectiveness of such measures in preventing and reducing the risks of forced labour or child labour in our manufacturing and supply chain activities.



#### CERTIFICATION PURSUANT TO THE FIGHTING AGAINST FORCED LABOUR AND CHILD LABOUR IN SUPPLY CHAINS ACT, S.C. 2023, C.-9

This Report was approved by the Board of Directors of Theratechnologies Inc.

In accordance with the requirements of the Act, and in particular subparagraph 11(4)(a) thereof, I attest that I have reviewed the information contained in the Report for the entity or entities listed above. Based on my knowledge, and having exercised reasonable diligence, I attest that the information in the Report is true, accurate and complete in all material respects for the purposes of the Act, for the reporting year listed above.

Signed on May 27, 2024

Paul Lévesque President and Chief Executive Officer

I have the authority to bind Theratechnologies Inc.