

NASDAQ: **THTX** TSX: **TH** 

## Theratechnologies: Clinically Poised for High Growth Opportunities

July 19, 2021

#### **Forward-Looking Information**

The following presentation contains statements that are considered forward-looking information ("FLI") within the meaning of securities regulation.

The FLI in this presentation relates to future events or our future performance. The FLI are based on a number of assumptions and are associated with a number of risks, uncertainties and other unknown factors that may cause our actual results, levels of activity, performance or achievements to be materially different from those implied by the FLI.

Such FLI reflects our current views with respect to future events and is given as of July 19, 2021. We undertake no obligation and do not intend to update or revise the FLI contained in this presentation, except as required by law.

Certain assumptions made in preparing the FLI include, but are not limited to, the following:

- (1) the COVID-19 pandemic will have limited adverse effects on our activities and business plans;
- (2) sales of EGRIFTA SV® and Trogarzo® will continue to grow;
- (3) the known safety and efficacy profile of EGRIFTA SV<sup>®</sup> and Trogarzo<sup>®</sup> will not change as a result of their long-term use;
- (4) the FDA will approve the bioequivalence of the F8 formulation of tesamorelin;
- (5) we will succeed in developing a multi-dose injection pen using the F8 formulation and regulatory agencies will approve same;
- (6) no biosimilar versions of EGRIFTA SV® will be approved by the FDA;
- (7) results obtained from the use of tesamorelin in HIV-infected patients with liver fat will be replicated in the non-HIV NASH population;
- (8) the totality of evidence and data resulting from the conduct of the Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH will demonstrate substantial evidence of efficacy and will be highly persuasive to regulatory agencies in order to gain approval;
- (9) we will be able to secure additional resources to initiate our Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH, including finding a partner;
- (10) we will be able to continue the recruitment of patients to conduct the Phase 1 clinical trial in oncology;
- (11) we will obtain positive results from our Phase 1 clincal trial evaluating TH1902 for the treatment of various cancers;
- (12) we will meet all of the timelines set forth in this presentation; and
- (13) our 2021 business strategies will not change.

The FLI in our presentations may not materialize; accordingly, investors should not place undue reliance on it. We refer you to the "Forward-Looking Information" section of our Management's Discussion and Analysis dated July 13, 2021 and to the "Risk Factors" section of our Annual Information Form dated February 24, 2021. These documents are available at **www.sedar.com**, and on Edgar at **www.sec.gov** for a description of the risks related to the conduct of our business.

Note: EGRIFTA and EGRIFTA SV are registered trademarks of Theratechnologies Inc.; Trogarzo is a registered trademark of TaiMed Biologics, Inc. under license to Theratechnologies Inc.; SORT1+ Technology is a trademark of Theratechnologies Inc.



## **Theratechnologies (NASDAQ:THTX, TSX:TH)**

#### **Corporate Profile**

- Founded in 1993 in Montreal, Canada, Theratechnologies is a biopharmaceutical company focused on the development and commercialization of innovative therapies addressing unmet medical needs
- **Incorporated in Quebec,** with primary offices in Montreal, subsidiary locations in Dublin, Ireland and the United States
- The company has approximately ~**165 employees**\* across Canada, U.S. and Europe
- Dual listed on the Nasdaq Stock Exchange under ticker (NASDAQ:THTX) since 2019 and the Toronto Stock Exchange under ticker (TSX:TH) since 1993

#### **Stock Information**

Stock Price (as of 7/19/21)	\$3.28
<ul> <li>Shares Outstanding (as of 5/31/21)</li> </ul>	~95M
• Market Cap (as of 7/19/21)	~\$310M
Cash, cash equivalents (as of 5/31/21)	~\$57M
<ul> <li>Convertible notes outstanding (5.75% coupon; due 6/30/23; \$14.85 conversion price)</li> </ul>	\$57.5M

Notes: \*Full-time employees and dedicated third parties \$ values in USD



### **Promising R&D Pipeline and Commercial Portfolio**

#### **Promising R&D Pipeline**

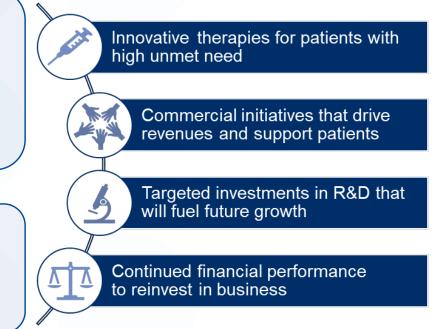
#### Novel therapies in Oncology, NASH, and HIV

- Phase 1 trial initiated in sortilin-expressing cancers
- NASH in non-HIV and HIV populations
- Next-generation administration method for Trogarzo<sup>®</sup> and EGRIFTA SV<sup>®</sup>

#### **Two Commercially Approved Therapies**

#### Improving standard of care for people living with HIV

- Trogarzo<sup>®</sup> for multidrug resistant (MDR) HIV-1 in adults
- EGRIFTA SV® for HIV-associated lipodystrophy



## **Oncology, NASH and HIV R&D Pipeline**

	Draduat	Phase of Development					
	Product	Preclinical	Phase 1	Phase 2	Phase 3	Milestones	
Oncology	<b>TH1902 (PDC)</b> SORT1+ Technology™					Phase 1 trial initiated in March 2021; Interim safety & efficacy readout expected in Q4CY21	
Onco	<b>TH1904 (PDC)</b> SORT1+ Technology™					Toxicity program and manufacturing scale-up	
NASH	Tesamorelin F8 NASH					Completed discussions with regulatory agencies; Seeking potential partnership to launch Phase 3 clinical trial	
	<b>Trogarzo<sup>®</sup> IV Push</b> Multi-drug resistant HIV-1					IV Push expected to be completed in Q3'21	
₽H	<b>Trogarzo<sup>®</sup> Intramuscular</b> Multi-drug resistant HIV-1					Intramuscular study planned with TaiMed Biologics; protoco amendment submitted	
	<b>Tesamorelin F8</b> HIV-associated lipodystrophy					Bioequivalence study completed; sBLA to be filed early 2022	

Notes:

Clinical study for Trogarzo IV Push is being conducted by TaiMed Biologics, Inc.
Clinical study for Trogarzo Intramuscular (IM) will be conducted by Theratechnologies





## Oncology: SORT1+ Technology<sup>™</sup>

## SORT1+ Technology™: First-in-Class Peptide Drug Conjugate (PDC) Platform Targeting Sortilin (SORT1) Receptors for Cancer

**Targets SORT1,** a novel receptor that is highly expressed in many types of cancer and is associated with poor prognosis and decreased survival.

**Rapid internalization leading to high cytotoxic concentration** inside the cancer cells for improved efficacy, safety, and durable response.

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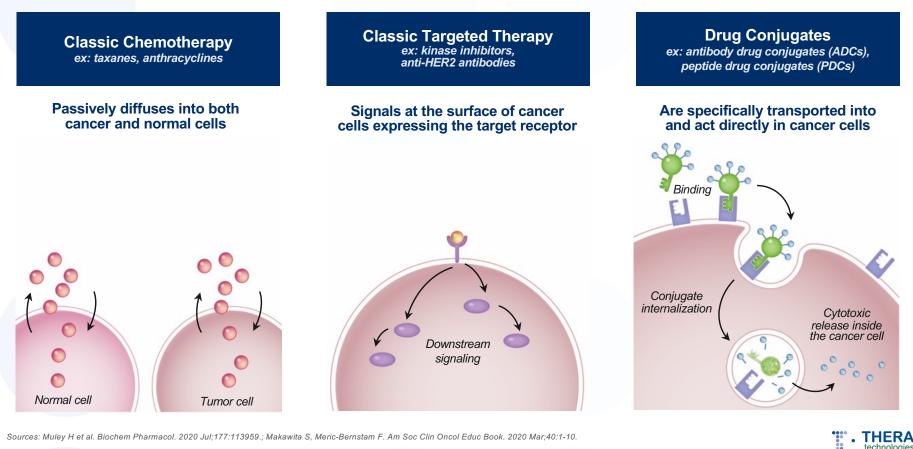
**Overcomes two key resistance mechanisms:** Bypasses the MDR1 efflux pump and inhibits vasculogenic mimicry (VM) formation.

**TH1902** is the lead **PDC** and is currently in Phase 1 clinical development. FDA has granted **fast track designation** for TH1902 to be developed as a **single agent** for treatment of patients with **SORT1+ recurrent advanced solid tumors** that are **refractory to standard therapy** 

Source: Seyfried TN et al. Crit Rev Onc. 2013; 18(1-2):43-73.



#### **Drug Conjugates: A Novel Platform for Optimal Delivery** of Metastatic Cancer Treatment

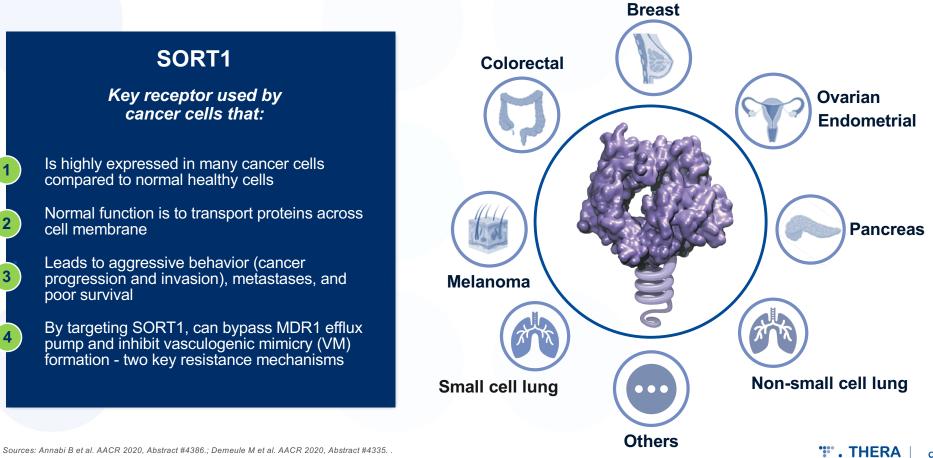


Sources: Muley H et al. Biochem Pharmacol. 2020 Jul;177:113959.; Makawita S, Meric-Bernstam F. Am Soc Clin Oncol Educ Book. 2020 Mar;40:1-10.

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#### The SORT1 Receptor Is an Attractive Novel Target for Cancer Therapy



Sources: Annabi B et al. AACR 2020. Abstract #4386.; Demeule M et al. AACR 2020. Abstract #4335.

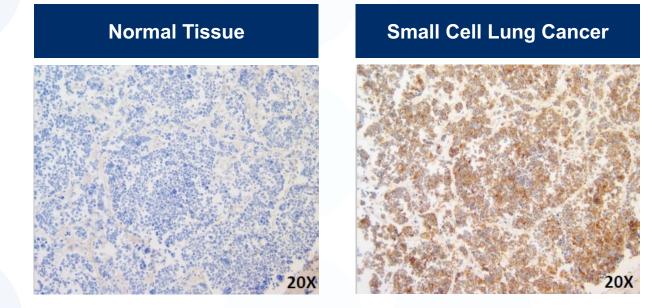
#### SORT1 is Highly Expressed in Cancer Cells Compared to Normal Cells

Attractive target: As cancer aggressiveness increases, SORT1 expression increases<sup>1</sup> Affects outcomes: High SORT1 gene expression is associated with decreased survival<sup>2</sup> Fraction survival in all TNBC patients Metastatic lymph node 1.2 from breast carcinoma (n=161) 1.0 0.8 Low Sortilin Infiltrating ductal 0.6carcinoma of breast **High Sortilin** 0.4 0.2 -50 100 150 200 0 Normal adjacent breast tissue TNBC, triple-negative breast cancer Time (months)

Source: Demeule M et al. AACR 2020, Abstract #4335.2. Currie JC et al. AACR 2020, Abstract #4472. i

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## SORT1 Staining in Small Cell Lung Cancer



STAINING SORT1: brown Nucleus: blue

Source: Theratechnologies, Data on File.



## TH1902: Lead PDC Using Theratechnologies' Proprietary SORT1+ Technology™

#### Peptide<sup>1,2</sup>

- Targets SORT1 receptor, expressed in multiple cancers
- Can be conjugated to variety of anti-cancer agents with consistent number of payload molecules
- Provides rapid internalization and delivery of payload inside the cell, limiting degradation in the circulation and off target toxicity

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#### • Cytotoxic payload<sup>2-4</sup>

- For TH1902 is **docetaxel (2:1 ratio)**, a well-established agent for a variety of cancers with known safety profile
- Increases therapeutic window of docetaxel
  - Use smaller dose to get greater efficacy and less toxicity (neutropenia)

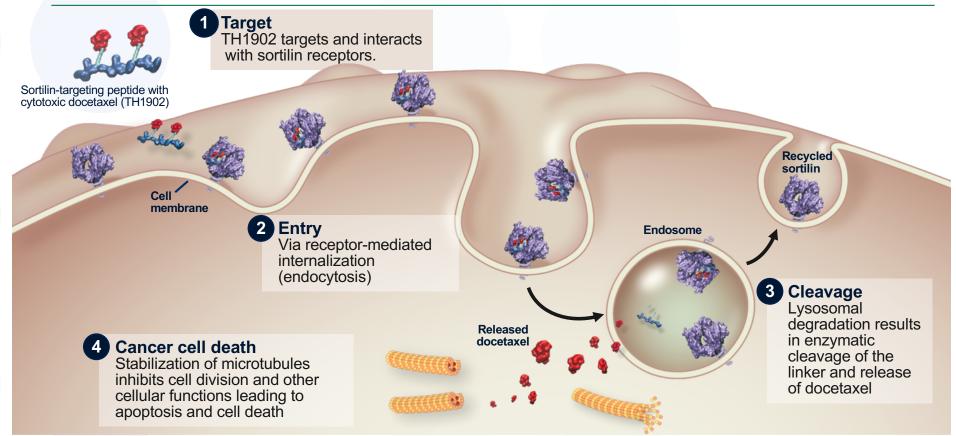
#### ➤ Cleavable linker<sup>2,3</sup>

- Links the SORT1-targeting peptide to the cytotoxic docetaxel
- Increased stability in plasma with improved distribution into targeted cancer cells
- Enables rapid release of docetaxel inside the cancer cell

Notes:

- 1) Annabi B et al. AACR 2020, Abstract #4386.
- 2) Hoppenz P et al. Front Chem. 2020; 8: 571.
- 3) Currie JC et al. AACR 2020, Abstract #4472.
- 4) Zhang E et al. Expert Opin Drug Deliv. 2019 Mar;16(3):301-31.

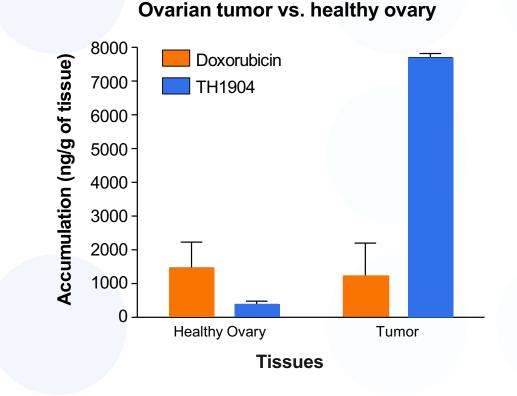
#### TH1902: Delivering Cancer-Killing Docetaxel Directly Into Cancer Cells



Sources: Demeule M et al. AACR 2020, Abstract #4335.; Makawita S, Meric-Bernstam F. Am Soc Clin Oncol Educ Book. 2020 Mar;40:1-10.; Taxotere (docetaxel Prescribing Information. Bridgewater, NJ: Sanofi-Aventis U.S. LLC.; May 2020).



### Theratechnologies' PDC Increases Concentration of Anti-Cancer Payload Inside the Cancer Cell



High accumulation in ovarian tumor

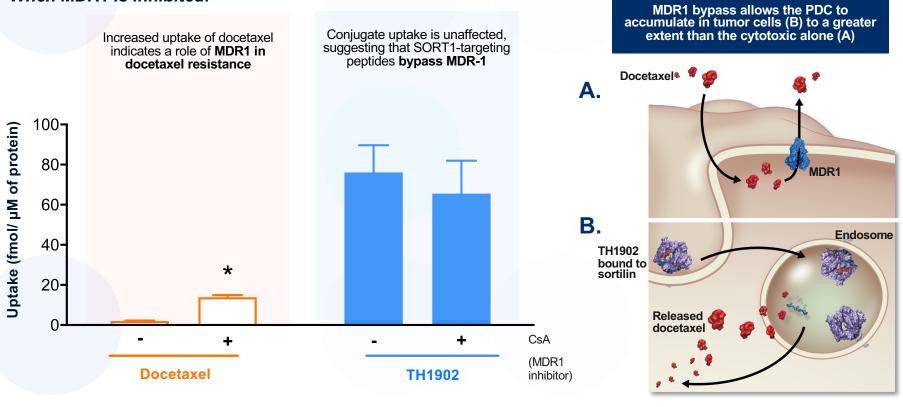
Low accumulation in healthy ovary tissue

TH1904, doxorubicin peptide conjugate Source: Demeule M et al. AACR 2017. Abstract #5146.



## SORT1+ Technology™: Potentially Increased Efficacy in Refractory/Resistant Tumors (bypass of MDR1 pump)

**MDR1 efflux pump** is often used by cancer cells to resist treatment *When MDR1 is inhibited:* 



TH1902, docetaxel peptide conjugate; CsA, cyclosporin A Source: Theratechnologies, Data on File.

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#### Theratechnologies' PDC's Inhibit Vasculogenic Mimicry – A Key Survival Mechanism for Some Tumors

- Cancer cells need blood, nutrients and oxygen to sustain growth and cell division
- This is achieved by either forming new blood vessels (angiogenesis) or by forming new channels lined with cancer cells that extend from the existing vasculature a process called vasculogenic mimicry (VM)
- VM is SORT1-dependent and is associated with cancer resistance and aggressive disease



Preliminary data using SORT1+ Technology<sup>™</sup> suggests it can potentially inhibit the formation of VM structures associated with cancer resistance mechanisms

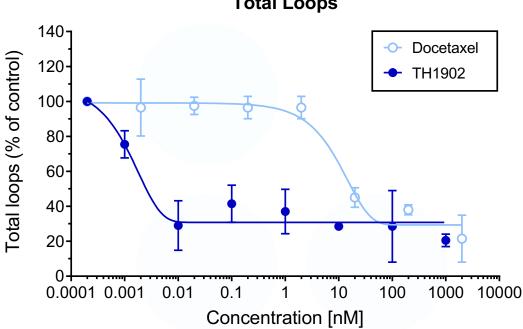
Sources: Demeule M et al. AACR 2020, Abstract #4335.; Gong F-L et al. J Cell Biochem. 2020; 121:4756-4771.; Sun B et al. Oncotarget. 2017;8(18):30502-30510



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### **TH1902: Theratechnologies' Lead Investigational PDC Demonstrates Reduced VM Formation**

TH1902 inhibits VM at lower concentrations than the anti-cancer payload



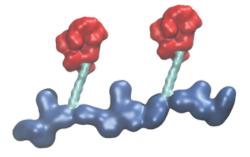
**Total Loops** 

Source: Demeule M et al. AACR 2020, Abstract #4335.



### TH1902: New Chemical Entity with New Mechanism of Entry into Cancer Cells

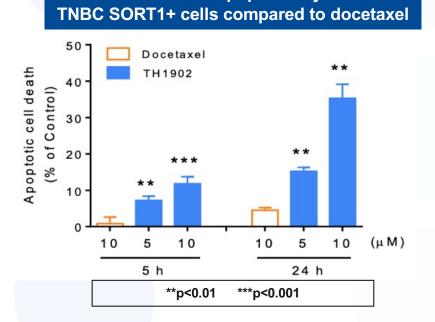
- MoA of TH1902 is unique and different compared to docetaxel
  - ✓ Enters cell via a sortilin-dependent mechanism
  - Increases intracellular concentration of the cytotoxic
  - ✓ Bypasses P-pg efflux pump (MDR1)
  - ✓ Inhibits formation of VM structures
  - ✓ Better inhibition of cancer cell migration
- Different PK profile and better tolerability
- Increases therapeutic window of docetaxel
- Intellectual property protected with composition of matter claims



Source: Theratechnologies, Data on File.

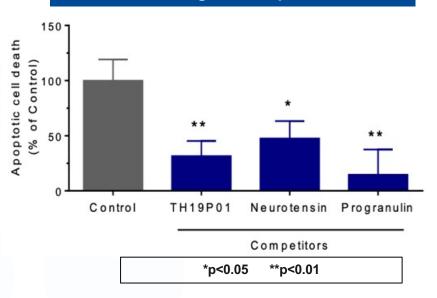


#### **TH1902 Induces Faster Cancer Cell Death than Docetaxel Alone**



Faster induction of apoptosis by TH1902 in

#### Apoptotic induction can be reversed by SORT1 ligand competitors

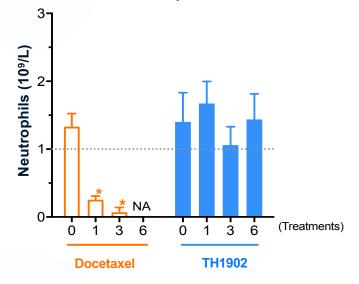




#### **Neutropenia: A Silent Killer in Cancer Treatment**

- Neutropenia is a serious side effect frequently associated with cancer chemotherapy
- Systemic infection resulting in neutropenic sepsis is a leading cause of morbidity and mortality in cancer patients
- Onset of neutropenia causes prolonged periods of hospitalization, blood transfusions, and delay or discontinuation of chemotherapy treatment

## Neutropenia is not seen with TH1902 even after multiple administrations

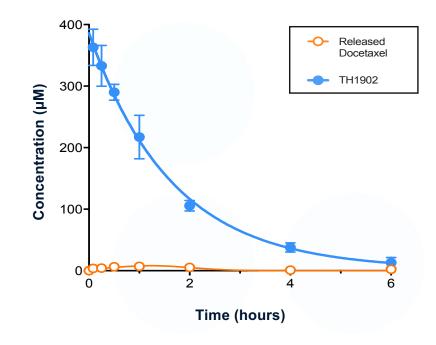


TH1902 did not induce neutropenia in preclinical models; may allow for sustained treatment, better tolerability and increased efficacy



### **TH1902 Demonstrates Improved Tolerability**

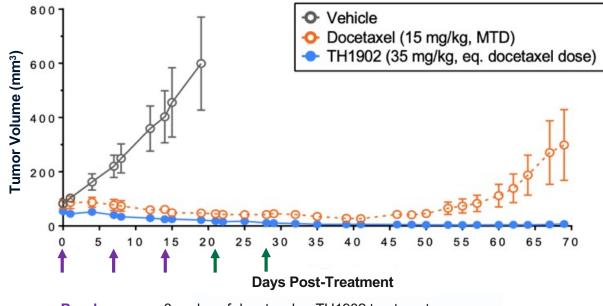
#### Minimal docetaxel released in blood further limiting off-target toxicity



Source: Currie JC et al. AACR 2020, Abstract #4472.



#### TH1902 Sustains Reductions in Breast Cancer Tumor Burden Over Time

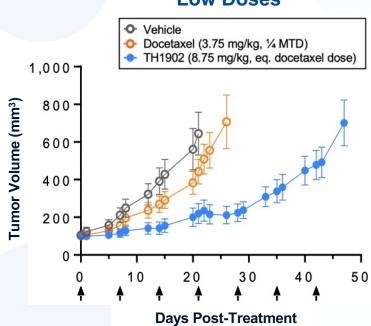


**Purple arrows:** 3 cycles of docetaxel or TH1902 treatment **Green arrows:** 2 additional cycles of TH1902

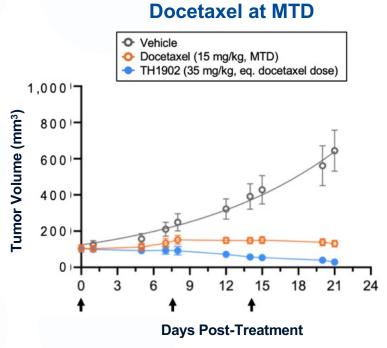
Source: Demeule M et al. AACR 2021, Abstract #1313; TNBC s.c. xenograft tumor models



#### **TH1902: Preclinical Data in Pancreatic Cancer**



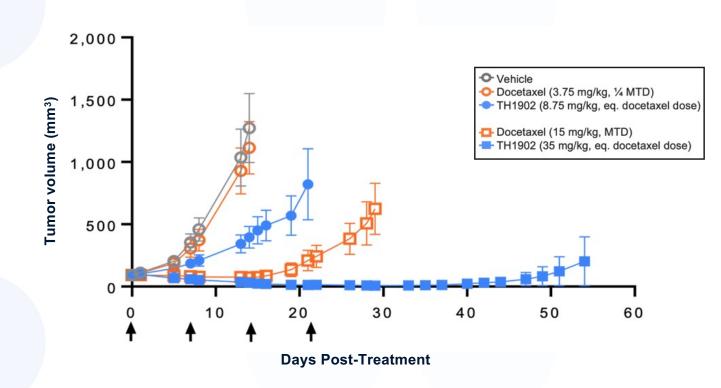
Low Doses



Source: Demeule M et al. AACR 2021, Abstract #1313; Pancreatic (PANC-1) s.c. xenograft tumor model



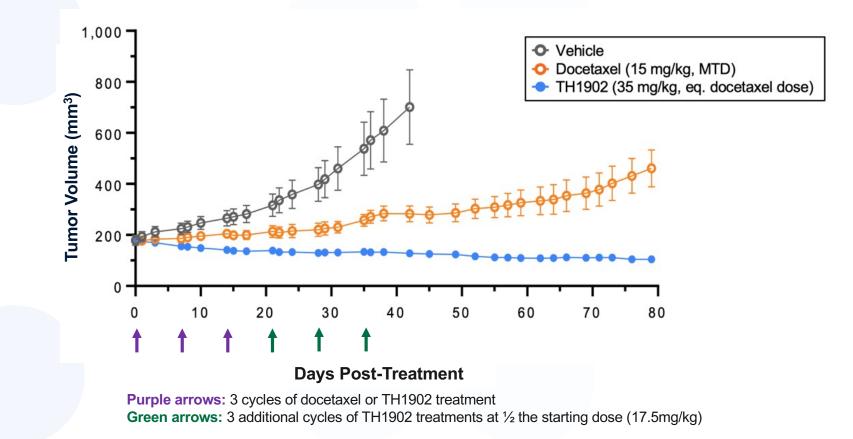
### **TH1902: Preclinical Data in Endometrial Cancer**



Source: Demeule M et al. AACR 2021, Abstract #1313; Endometrial (HT-29) s.c. xenograft tumor model



#### **TH1902: Preclinical Data in Melanoma**

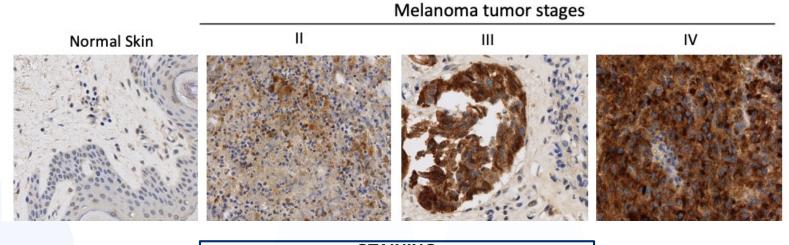


Source: Demeule M et al. AACR 2021, Abstract #1313.;I Melanoma (SK-MEL-28) s.c. xenograft tumor model



## **SORT1 Expression in Melanoma**

Tissue microarray (IHC) shows strong expression of sortilin in human melanomas and is strongly correlated with increasing stage of disease



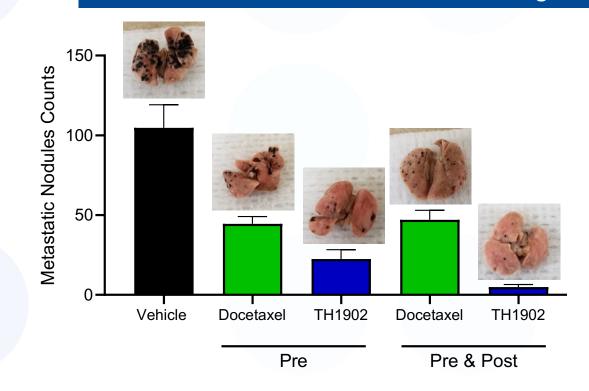
STAINING SORT1: brown Nucleus: blue

Source: Demeule M et al. AACR 2021, Abstract #1313.



### TH1902 Demonstrates Promising Preclinical Results in Metastatic Cancer Model

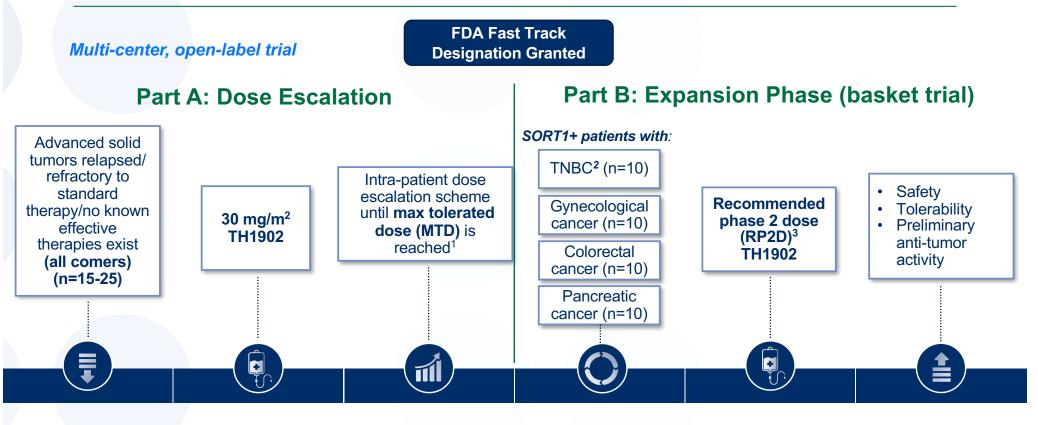
Melanoma metastatic nodules in the lungs



Source: Theratechnologies internal data; B16-F10 melanoma cells of immunocompetent mice



#### Phase 1 Trial of TH1902 Is Underway



Notes:

<sup>1</sup> If ≥2 patients in a dose cohort experience an emergent DLT by Day 21 of the first treatment cycle, dose escalation will stop, and the prior dose level will be declared as the MTD. MTD is defined as highest dose level at which ≤1 of 6 patients in a cohort develop an emergent dose-limiting toxicity;

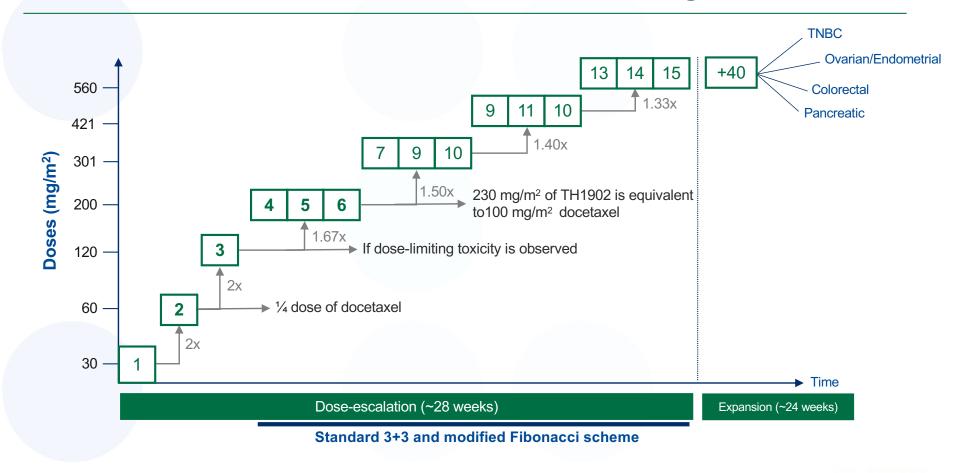
<sup>2</sup>As indicated; TNBC, triple-negative breast cancer;

<sup>3</sup>RP2D is defined as one dose level below the MTD and is the recommended phase 2 dose to further assess TH1902 for safety/tolerability and preliminary anti-tumor activity

Theratechnologies, Inc. Protocol Synposis - TH1902-CTR-0001.



#### **Phase 1 Clinical Trial: Dose Escalation Design**



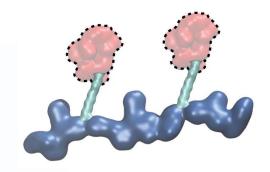
Source: Theratechnologies, Inc. Protocol Synposis - TH1902-CTR-0001.



## SORT1+ Technology™: An Investigational First-in-Class Cancer Treatment Platform

- Small size and specificity for the target (SORT1) allows rapid penetration of the conjugate into the tumor and rapid release of the cytotoxic into the cancer cells, potentiating cell killing effect and minimizing off-target toxicity.
- Contains stable linker with minimal degradation outside of cancer cells, limiting off-target toxicity.
- TH1902, at 1/4 of equivalent dose of docetaxel (MTD), produces significant tumor regression
- Multiple administrations of TH1902, at the equivalent MTD dose of docetaxel, can be given with no neutropenia

- Overcomes two key resistance mechanisms: bypasses the MDR1 efflux pump and inhibits vasculogenic mimicry (VM) formation
- Consistent and easier conjugation techniques allow for potential conjugation with a variety of cytotoxic agents:
  - Docetaxel (TH1902)
  - Doxorubicin (TH1904)
  - Potentially others (e.g., TH2101, with SN38)



Sources: Annabi B et al. AACR 2020, Abstract #4386.; Demeule M et al. AACR 2020, Abstract #4335. MTD = max tolerated dose

## **SORT1+** Technology<sup>™</sup>: Future Opportunities



Explore different **dosing schedules** (weekly, intermittent vs continual) in order to **increase the therapeutic window** in terms of efficacy and safety.



Gain better understanding of the exact MOA, impact on surrounding tissue/tumor microenvironment (TME) and fate of conjugate once it enters the cell and is degraded.

Explore **conjugation with a variety of anti-cancer agents** (cytotoxics, TKIs etc) and potential synergistic new partnerships (proprietary molecules).

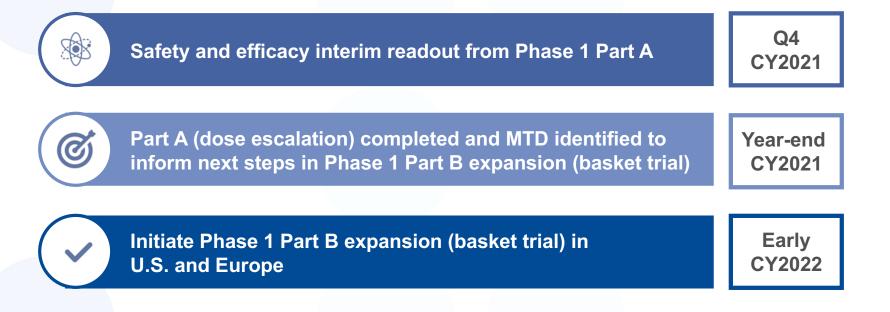


Explore **rational combinations** of SORT1+ Technology<sup>™</sup> with other treatments, especially immunotherapies.



Explore the need for a **companion diagnostic** for SORT1 to determine correlation of sortilin expression with response, improve patient selection, track treatment efficacy and identify early metastases.

### Key Milestones: Accelerate TH1902 through Clinical Development and Rapidly Towards an Approval



Notes: Milestones and timelines subject to change; Please refer to the "Risk Factors" section of our Annual Information Form dated February 24, 2021 available at www.sedar.com, and to Form 40-F dated February 25, 2021 available on Edgar at www.sec.gov for a complete description of the risks related our oncology pipeline program and our Phase 1 clinical trial of TH1902. CY, calendar year



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## **General and HIV-Associated NASH:** Tesamorelin

#### **Tesamorelin for the Treatment of NASH**

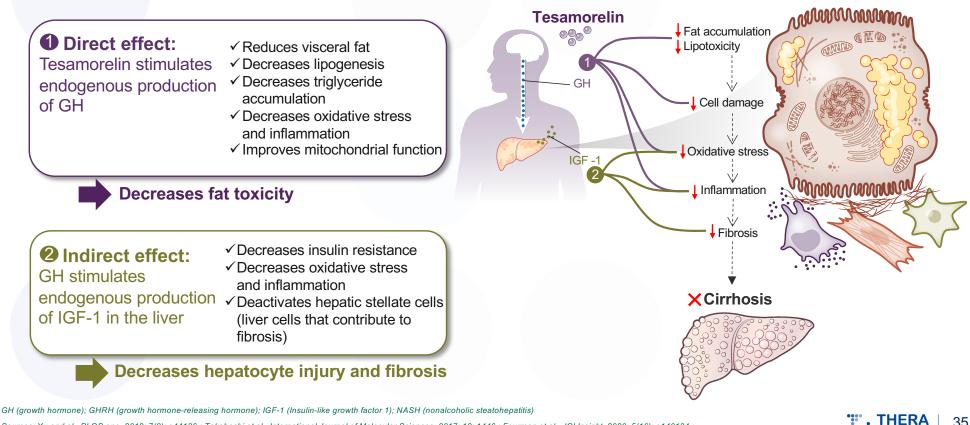
Unique MOA	<ul> <li>✓ Stimulates endogenous release of GH</li> <li>✓ Decreases liver inflammation</li> <li>✓ First-in-class approach targeting underlying cause of NASH</li> </ul>			
Positive Clinical Results in Acute HIV	<ul> <li>✓ 37% relative liver fat reduction</li> <li>✓ Suggests strong efficacy in broader NASH patient population</li> <li>✓ Significant reduction in fibrosis progression</li> </ul>			
Well-Established Safety Profile	<ul> <li>✓ 10+ years of product history in HIV</li> <li>✓ Data suggests tesamorelin could play a significant role in treating NASH</li> <li>✓ Phase 3 trial design aligns with FDA/EMA guidelines*</li> </ul>			
Significant Market Opportunity	<ul> <li>✓ Currently no approved treatment for NASH</li> <li>✓ Over 6 million F2/F3 NASH patients in the U.S. alone</li> </ul>			
Strong IP	✓ Patent runway in the U.S. through 2040			

Sources: Stanley, 2019, Investigator-initiated study; Clemmons DR, Miller S, Mamputu JC (2017) Safety and metabolic effects of tesamorelin, a growth hormone-releasing factor analogue, in patients with type 2 diabetes: A randomized, placebo-controlled trial. PLOS ONE 12(6): e0179538.; Estes C, Razavi H, Loomba R, Younossi Z, Sanyal AJ. Modeling the epidemic of nonalcoholic fatty liver disease demonstrates an exponential increase in burden of disease. Hepatology. 2018;67(1):123-133. doi:10.1002/hep.29466 \* The Phase 3 trial design in NASH remains subject to discussions with the FDA



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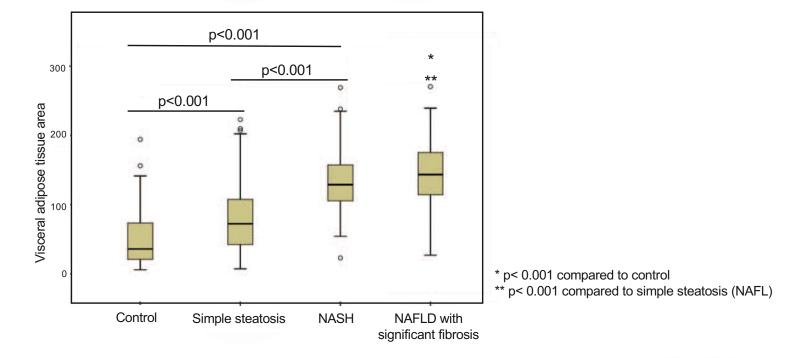
#### **Tesamorelin: A Growth Hormone Releasing Hormone (GHRH) Targeting the Underlying Mechanisms of NASH**



Sources: Xu and al., PLOS one, 2012: 7(8): e44136; Takahashi et al., International Journal of Molecular Sciences, 2017: 18: 1446.; Fourman et al., JCI Insight, 2020: 5(16): e140134.; Connolly, J Clin Transl Hepatol 2018. 5. Liu Z et al. Diabetes. 2016 Dec;65(12):3598-3609

# Visceral Adipose Tissue Predicts Development and Progression of Liver Disease

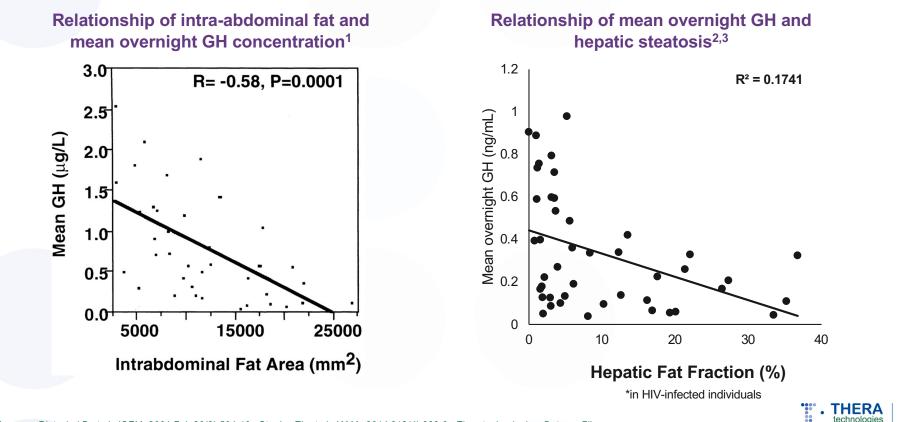
Every 10cm<sup>2</sup> increase of VAT is associated with a 1.18 increase in the risk of developing NASH (P = 0.005)



Source: Yu SJ et al. Medicine 2015;94:e2159.

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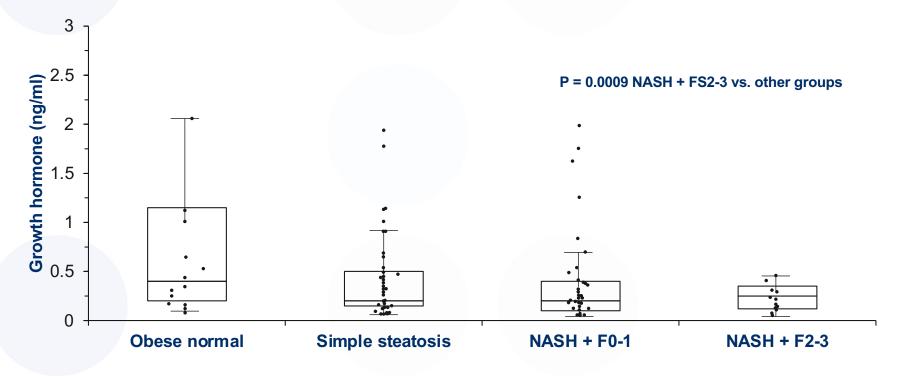
## **Relationship of GH with Visceral Adiposity and Hepatic Steatosis**



Sources: Rietschel P et al, JCEM. 2001 Feb;86(2):504-10.; Stanley TL et al. JAMA. 2014;312(4):380-9.; Theratechnologies, Data on File.

### **Association Between GH and Liver Fibrosis**

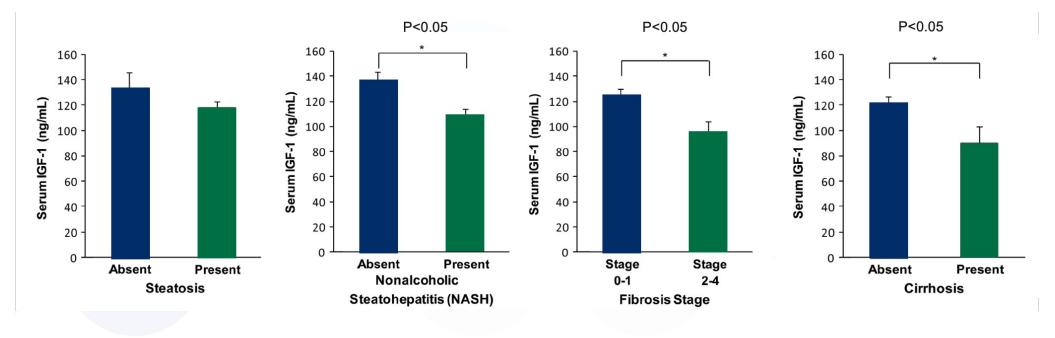
All patients with NASH fibrosis stage 2-3 had circulating levels of GH, which is within criteria for adult GH deficiency (<0.45 ng/mL). P value was calculated using Kruskal-Wallis test: 0.0009



Source: Koehler E et al. Liver Int. 2012 Feb;32(2):279-86.

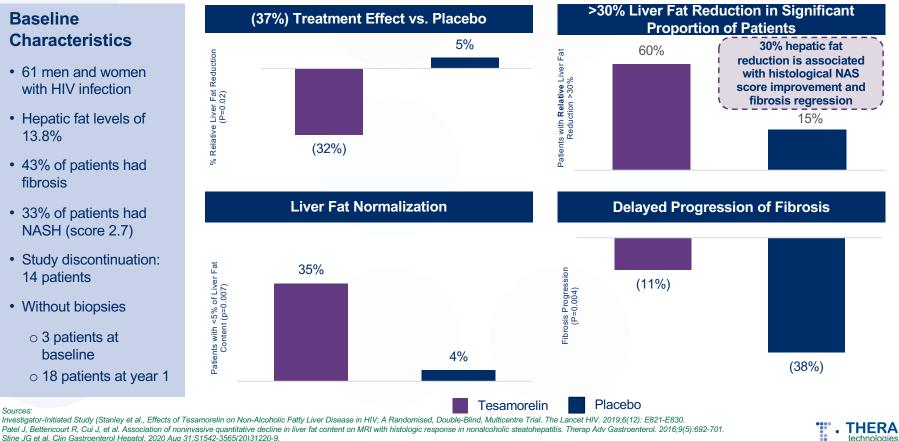
### **Association Between IGF-1 and NAFLD**

Inflammation, hepatocyte ballooning, fibrosis, and cirrhosis, but not steatosis, are associated with low serum IGF-1 levels





## **Effects of Tesamorelin in HIV NAFLD/NASH Patients**



Stine JG et al. Clin Gastroenterol Hepatol. 2020 Aug 31;S1542-3565(20)31220-9. Tamaki et al. Gut. 2021.

### **Improvement in NASH Markers with Tesamorelin**

- HIV NAFLD patients
- 43 patients received biopsy at baseline and at year one
- 12-month study duration

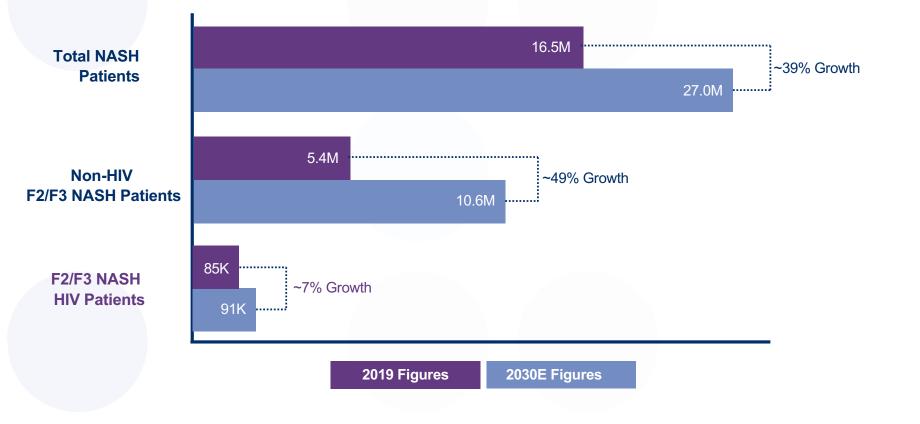
	Inflammation (%)		Balloon	ning (%)	Fibrosis (%)	
	Tesamorelin (n=19)	Placebo (n=24)	Tesamorelin (n=19)	Placebo (n=24)	Tesamorelin (n=19)	Placebo (n=24)
Improvement	26.3	12.5	10.5	8.3	10.5	12.5
Worsening	10.5	16.7	5.3	16.7	10.5	33.3

Source:

Investigator-Initiated Study (Stanley et al., Effects of Tesamorelin on Non-Alcoholic Fatty Liver Disease in HIV; A Randomised, Double-Blind, Multicentre Trial. The Lancet HIV. 2019;6(12): E821-E830)



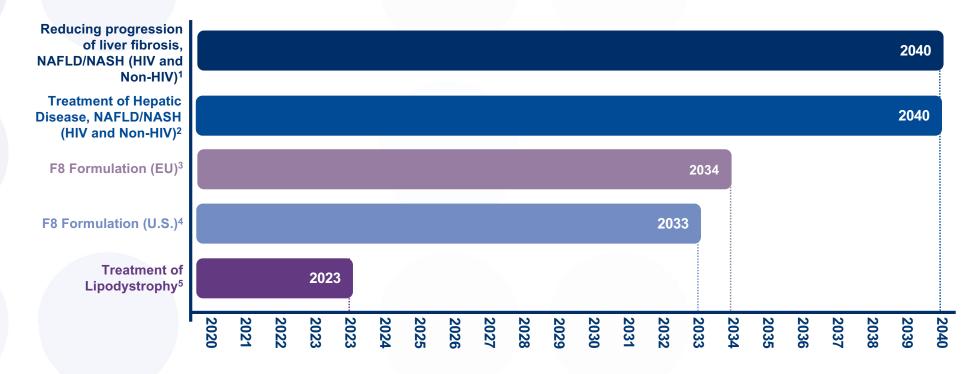
## U.S. Market Represents a Significant and Growing Opportunity in NASH



Sources: Estes C, Razavi H, Loomba R, Younossi Z, Sanyal AJ. Modeling the epidemic of nonalcoholic fatty liver disease demonstrates an exponential increase in burden of disease. Hepatology. 2018;67(1):123-133. doi:10.1002/hep.29466.; Wall Street consensus forecast figures based on Intercept and Madrigal, and company estimates

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### **Tesamorelin's Robust Intellectual Property Portfolio**



1) U.S. patent 10,946,073

2) U.S. patent 10,799,562

3) EP 2,961,432

4) U.S. patent 8,871,713 B2

5) U.S. patent 7,316,997; U.S. patent 8,314,066; U.S. patent 8,435,945

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### **Update on Tesamorelin Development Pathway in NASH**

- Discussions with FDA and EMA are complete
- Phase 3 clinical trial **design finalized**; evaluating options to best optimize NASH development and commercialization opportunity
- External U.S.-based biopharma advisory firm retained to assist in identifying **potential partner**
- Partner identification and negotiations will alter initiation of trial previously expected to begin in Q3 CY2021



## **Final Development Pathway Evaluating Tesamorelin in NASH**

### Ready-to-Proceed Phase 3 Trial Design based on Regulatory Discussions

- Multicenter, double-blind, placebo-controlled two-part study evaluating safety and efficacy of tesamorelin in liver-biopsy confirmed patients with NAS score of at least 4 and stage 2 or 3 fibrosis
  - Tesamorelin F8 (2 mg) compared to placebo
  - o Trial will include participants in the U.S. and Europe
- Futility analysis to be performed after approximately 400 patients have completed 18 months of treatment and have received second liver biopsy
- sBLA expected to be filed after approximately 1,100 patients, including 75 to 100 people living with HIV, have completed 18 months of treatment and have received second liver biopsy
- Primary endpoint: NASH resolution and no worsening of fibrosis compared to placebo after 18 months as per FDA guidelines
- Following potential approval, additional 1,800 patients expected to be enrolled to continue measuring clinical outcomes over period of five years





# HIV Therapies: Trogarzo<sup>®</sup> (ibalizumab-uiyk)/ EGRIFTA SV<sup>®</sup> (tesamorelin for injection)

## **Commercial HIV Portfolio**

	Ducduct	Phase of Development						Milesterre
	Product	Preclinical	Phase 1	Phase 2	Phase 3	Approved	Marketed	Milestones
V	Trogarzo* (ibalizumab-uiyk) Injection 200mg/133mL(I50mg/mL)							Expand commercialization efforts in EU and RoW
エ	tesamorelin for injection							Enhanced patient education and prescriber engagement; leverage KOL community

### **HIV Franchise – Initiatives Launched**

- ✓ Enhance communications of clinical / scientific evidence to close the education gap with providers
- ✓ Develop patient activities to increase understanding of disease progression and benefits of EGRIFTA SV<sup>®</sup>
- ✓ Utilize digital strategies to increase brand awareness among physicians and KOLs

### Next-Generation Administration and Delivery

- Patient / Prescriber Education: Targeted educational initiatives to key KOLs, patients and the HIV community
- ✓ Life Cycle Management: Multi-dose pen injector in development for tesamorelin F8 formulation; Trogarzo<sup>®</sup> IV Push study underway; Trogarzo<sup>®</sup> IM study planned
- Continued Commitment: Providing best-in-class treatments for people living with HIV; HIV patient cohort to be included in Phase 3 NASH trial

## **Trogarzo®** (ibalizumab-uiyk) injection

- Ibalizumab a monoclonal antibody targeting the CD4 receptor
- Indicated for MDR HIV-1 in adults
- Helps people living with HIV to attain an undetectable viral load
  - Potency: novel mechanism of action that is fully active with no expected cross-resistance
  - o Durability: powerful and durable virologic response
  - Long Activity: the first and only long-acting ARV
  - Simplicity: no expected drug-drug interactions and wellestablished safety profile
- Regulatory exclusivity in the U.S. until March 2030; EU regulatory exclusivity until September 2029
- Study evaluating IV push formulation of Trogarzo<sup>®</sup> expected to be completed in Q3'21; Initiation of Trogarzo<sup>®</sup> IM study planned
- In vitro data show ibalizumab is active against HIV-2

#### Notes:

- Most common drug-related adverse reactions include diarrhea, dizziness, nausea and rash

### **Key Highlights**

- First HIV treatment approved with a new mechanism of action in more than 10 years
- Infused every two weeks, the first and only anti-retroviral therapy (ART) that does not require daily dosing
- ✓ No drug-drug interactions with other ARTs

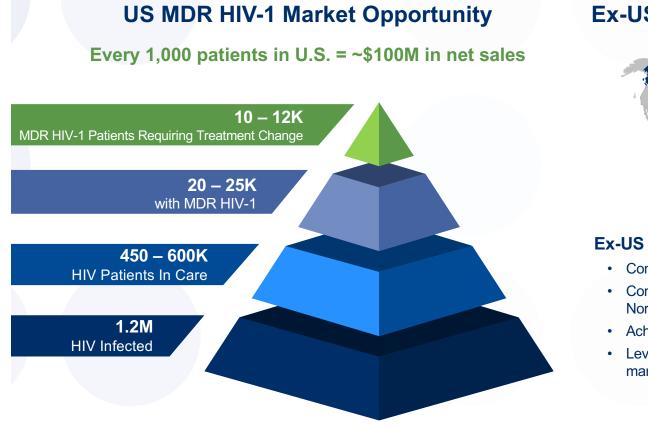


<sup>-</sup> Clinical study for Trogarzo IV Push is being conducted by TaiMed Biologics, Inc.

<sup>-</sup> Clinical study for Trogarzo Intramuscular (IM) will be conducted by Theratechnologies

<sup>-</sup> For more information visit www.trogarzo.com

## **Global Market Opportunity for Trogarzo<sup>®</sup>**



### **Ex-US MDR HIV-1 Market Opportunity**



### **Ex-US Strategy:**

- Commercially available in Germany
- Continued expansion into Top 5 EU geographies in addition to Norway and Israel
- Achieve favorable pricing supported by patient benefit profile
- Leverage existing localized KOL relationships to capture HIV market opportunities, which could scale to parity with the U.S.

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Source: GlobalData, Pharma Point Human Immunodeficiency Virus HIV Global Drug Forecast and Market Analysis to 2025

## **EGRIFTA SV®** (tesamorelin for injection)

### **Key Highlights**

- ✓ Single vial with small volume injection at room temperature
- Unique mechanism of action that regulates growth hormone (GH) secretion
- Tesamorelin's ability to increase endogenous GH secretion is the foundation for development in NASH
- **Tesamorelin** a growth hormone-releasing hormone (GHRH) that stimulates the pituitary gland to release endogenous GH in a pulsatile way
- Only treatment available for adults with HIV and lipodystrophy that reduces excess visceral abdominal fat
  - o Specificity: unique mechanism of action that regulates GH secretion
  - Maintained Efficacy: results shown at week 26 and maintained at week 52 with 27% decrease in visceral abdominal fat
  - Simplicity: a single vial with a small volume of injection storable at room temperature
  - Medical Benefit: left untreated, excess visceral abdominal fat is linked to potential severe health consequences that could lead to an increase risk in mortality
- EGRIFTA SV® is expected to drive increased patient compliance
- Well-established safety profile as evidenced by 10+ years of commercial availability with a high degree of tolerability

#### Notes.

• Most commonly reported adverse reactions (>5%): Arthralgia, injection site erythema, injection site pruritus, pain in extremity, peripheral edema, and myalgia

For more information visit www.egriftasv.com



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## **Financial Strength and Stability**



Note: Values in USD millions except share/warrant/option and conversion price data



## **Highly Experienced Senior Leadership Team**



Paul Lévesque President and CEO

- 35+ years of pharma industry experience and track record for delivering growth
- BSc in biochemistry from Laval University and a Diploma in Management from McGill University





- Philippe Dubuc SVP and CFO
- 25+ years of experience in investment banking
- MBA from McGill University and a B.Comm from Concordia University





### Christian Marsolais SVP and CMO

- 25+ years of experience in research, development, and commercialization of new drugs
- Pivotal in the approval of EGRIFTA<sup>®</sup> by the FDA
- Ph.D. in biochemistry from the Université de Montréal





### Conor Walshe General Manager, EU

- 15+ years of experience in commercial development, strategic expansion and operations in pharmaceutical industry
- Bachelor's and Master's degrees from University College, Dublin







### John Leasure Global Commercial Officer

- 30+ years of experience in sales, marketing, operations and general management in pharmaceutical industry
- Bachelor's from Gettysburg College, Pennsylvania



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