

---

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, DC 20549

---

**FORM 8-K**

---

**Current Report Pursuant  
to Section 13 or 15(d) of the  
Securities Exchange Act of 1934**

Date of Report (Date of earliest event Reported): **January 13, 2020**

---

**THERAVANCE BIOPHARMA, INC.**  
(Exact Name of Registrant as Specified in its Charter)

---

**Cayman Islands**  
(State or Other Jurisdiction of  
Incorporation)

**001-36033**  
(Commission File Number)

**98-1226628**  
(I.R.S. Employer Identification Number)

**PO Box 309  
Ugland House, South Church Street  
George Town, Grand Cayman, Cayman Islands KY1-1104  
(650) 808-6000**

(Addresses, including zip code, and telephone number, including area code, of principal executive offices)

---

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

<b>Title of each class:</b>	<b>Trading Symbol(s)</b>	<b>Name of each exchange on which registered:</b>
Ordinary Share \$0.00001 Par Value	TBPH	NASDAQ Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

---

---

**Item 7.01. Regulation FD Disclosure.**

*The information in this Current Report (including Exhibit 99.1) is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Current Report (including Exhibit 99.1) shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.*

January 13-16, members of the Theravance Biopharma, Inc. management team will be conducting one-on-one meetings with analysts and investors and making a conference presentation in San Francisco, CA using a corporate slide presentation which is being furnished pursuant to Regulation FD as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

[99.1 Theravance Biopharma Investor Presentation dated January 2020](#)

104 Cover Page Interactive Data File (cover page XBRL tags embedded within the Inline XBRL document)

---

**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**THERAVANCE BIOPHARMA, INC.**

Date: January 13, 2020

By: /s/ Andrew Hindman

Andrew Hindman

Senior Vice President and Chief Financial Officer

---



Medicines That Make a Difference®

# Corporate Presentation

January 2020

THERAVANCE®, the Cross/Star logo and MEDICINES THAT MAKE A DIFFERENCE® are registered trademarks of the Theravance Biopharma group of companies. All third party trademarks used herein are the property of their respective owners.

© 2020 Theravance Biopharma. All rights reserved.

# Forward looking statements

Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, the company cautions investors that any forward-looking statements or projections made by the company are subject to risks and uncertainties that may cause actual results to differ materially from the forward-looking statements or projections.

Examples of forward-looking statements in this presentation may include the Company's strategies, plans and objectives, the Company's regulatory strategies and timing of clinical studies (including the data therefrom), the potential characteristics, benefits and mechanisms of action of the Company's product and product candidates, the potential that the Company's research programs will progress product candidates into the clinic, the Company's expectations for product candidates through development, potential regulatory approval and commercialization (including their differentiation from other products or potential products), product sales or profit share revenue and the Company's expectations for its 2019 operating loss, excluding share-based compensation.

The company's forward-looking statements are based on the estimates and assumptions of management as of the date of this presentation and are subject to risks and uncertainties that may cause the actual results to be materially different than those projected, such as risks related to potential future disagreements with Innoviva, Inc. and TRC LLC, the uncertainty of arbitration and litigation and the possibility that an arbitration award or litigation result could be adverse to the Company, delays or difficulties in commencing, enrolling or completing clinical studies, the potential that results from clinical or non-clinical studies indicate the Company's compounds or product candidates are unsafe or ineffective, risks that product candidates do not obtain approval from regulatory authorities, the feasibility of undertaking future clinical trials for our product candidates based on policies and feedback from regulatory authorities, dependence on third parties to conduct clinical studies, delays or failure to achieve and maintain regulatory approvals for product candidates, risks of collaborating with or relying on third parties to discover, develop, manufacture and commercialize products, and risks associated with establishing and maintaining sales, marketing and distribution capabilities with appropriate technical expertise and supporting infrastructure.

Other risks affecting the company are described under the heading "Risk Factors" and elsewhere in the company's Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 8, 2019, and other periodic reports filed with the SEC.

## Strategic objective

Transform the treatment of serious diseases through the discovery, development, and commercialization of ***organ-selective medicines*** designed to maximize patient benefit while minimizing patient risk

# Creating transformational value for stakeholders



Innovative and productive **research engine** feeding **pipeline of organ-selective assets**



Proven **development expertise** and established **commercial infrastructure**



**Strategic partnerships** complement internal capabilities and balance technical, execution and financial risks



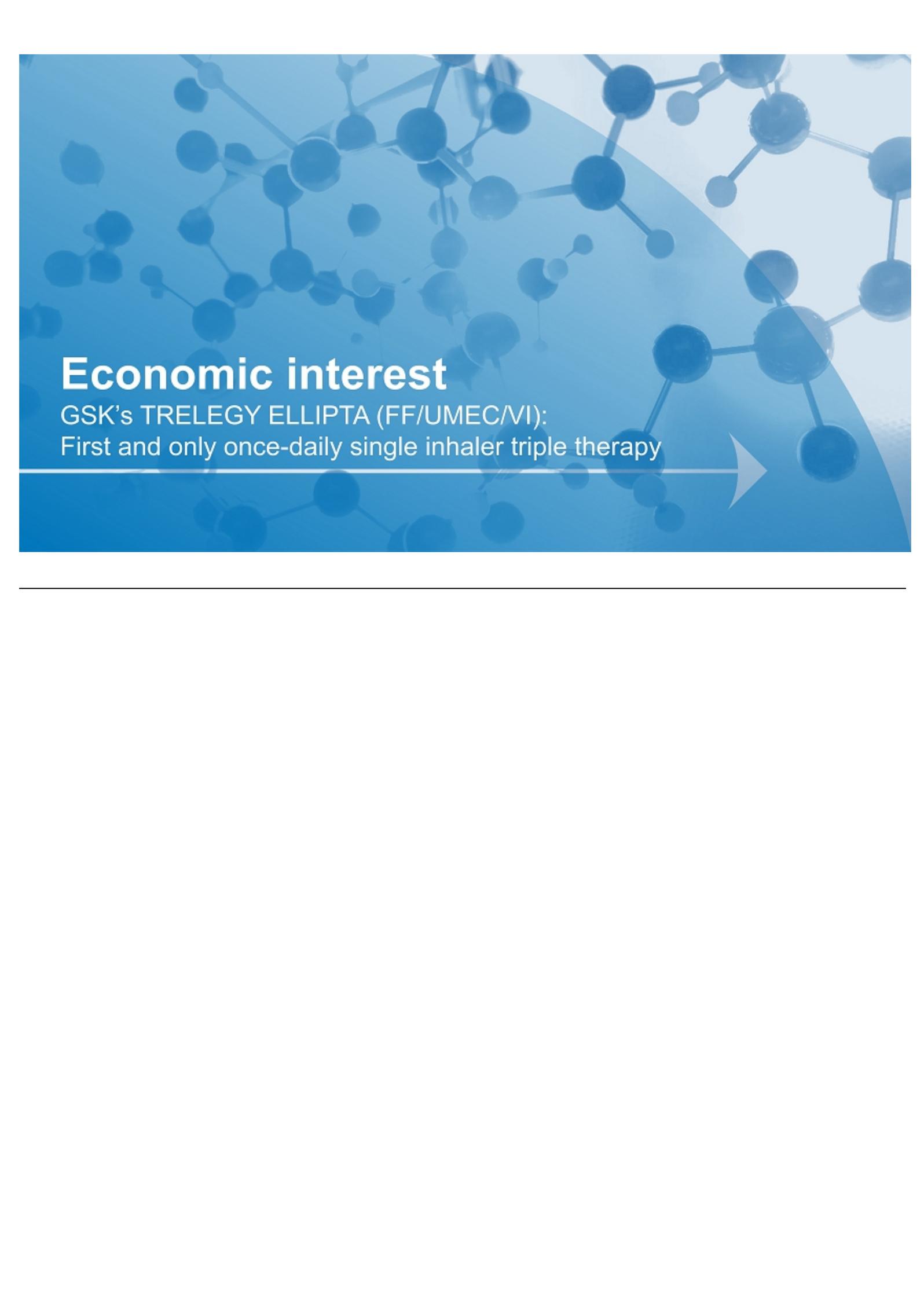
**Strong capital position** augmented by TRELEGY ELLIPTA<sup>1</sup> royalties and YUPELRI<sup>®</sup> launch



Multiple milestones and **value driving catalysts** in 2020 and beyond

# Key programs supported by proven development and commercial expertise

	Program	Indication	Research	Phase 1	Phase 2	Phase 3	Filed	Marketed	Collaborator
Organ-selective	YUPELRI® (revefenacin) LAMA	COPD	[Progress bar]					Marketed	Mylan
	TD-1473 GI JAKi	UC	[Progress bar]			Phase 2b/3			Janssen
		CD	[Progress bar]			Phase 2			
	TD-8236 Inhaled JAKi	Inflammatory lung diseases	[Progress bar]			Phase 2			Wholly-owned
	TD-5202 Irreversible JAK3i	Inflammatory intestinal diseases	[Progress bar]			Phase 1			Janssen
New programs	Multiple	[Progress bar]			Research			Wholly-owned	
	Ampreloxetine (TD-9855) NRI	Symptomatic neurogenic orthostatic hypotension	[Progress bar]			Phase 3			Wholly-owned
Economic Interests	TRELEGY ELLIPTA FF/UMECEVI	COPD	[Progress bar]					Marketed	GSK & Innoviva, Inc.
		Asthma	[Progress bar]					Filed	
	Skin-selective JAKi	Dermatological diseases	[Progress bar]			Research			Pfizer

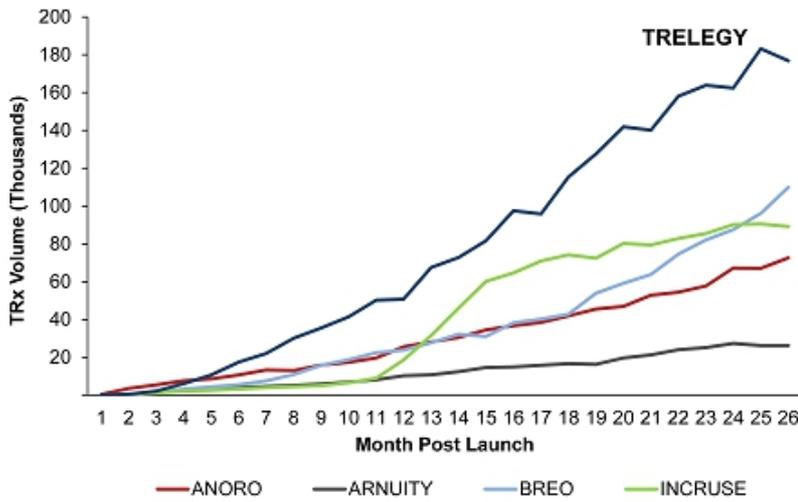
The background of the slide features a blue gradient with a semi-transparent molecular structure overlay. The structure consists of various sized spheres (atoms) connected by lines (bonds), creating a complex network. A large, light blue arrow points from the left towards the right, passing behind the text.

# **Economic interest**

GSK's TRELEGY ELLIPTA (FF/UMEC/VI):  
First and only once-daily single inhaler triple therapy

# Economic interest in GSK's TRELEGY ELLIPTA

UPWARD-TIERING ROYALTIES OF ~5.5% TO 8.5% OF WORLDWIDE NET SALES<sup>1</sup>



- ✓ Strongest US ELLIPTA launch to date
- ✓ ~31% share in class
- ✓ Marketed in >38 countries, including China launched in 4Q19
- ✓ sNDA filed 2Q19 for mortality benefit compared with ANORO in COPD
- ✓ sNDA filed 3Q19 for use in asthma

Launched in US in November 2017

Source: GSK, IQVIA NPA weekly TRx data. This information is an estimate derived from the use of information under license from the following IQVIA information service: NPA for the time period Sep 2013 through Nov 2019. IQVIA expressly reserves all rights, including rights of copying, distribution, and republication.



**YUPELRI<sup>®</sup> (revefenacin)**  
**inhalation solution**

First and only once-daily, nebulized  
maintenance medicine for COPD

---

# YUPELRI® (revefenacin) inhalation solution

FDA-APPROVED FOR THE MAINTENANCE TREATMENT OF COPD



First and only once-daily, nebulized maintenance medicine for COPD

Once-daily LAMAs are first-line therapy for moderate to severe COPD<sup>1</sup>

9% of COPD patients (~800,000) use nebulizers for ongoing maintenance therapy; 41% use nebulizers at least occasionally for bronchodilator therapy<sup>2</sup>

Nebulized therapy associated with reduced hospital readmissions in low PIFR patients<sup>3</sup>

# YUPELRI® commercial strategy

COMBINED SALES INFRASTRUCTURES TARGET HCPS AT KEY INTERSECTIONS



TBPH and MYL worldwide strategic collaboration to develop and commercialize nebulized YUPELRI® (revefenacin)<sup>1</sup>



Companies copromote under US profit share

# YUPELRI® launch metrics

## STRONG CUSTOMER ACCEPTANCE AND MARKET UPTAKE

### ✓ FORMULARY

**85 wins**  
(equates to 220 accounts)

**~70 reviews scheduled**  
(>400 potential accounts)

**100% medical support**  
requests **fulfilled** <30 days

### ✓ PATIENT

Field force productivity goals exceeded

**~30,000 patients<sup>2</sup>** prescribed  
(through Q4 2019)

### ✓ ACCESS

**100% Medicare Part B<sup>1</sup>**

**~50% commercial**

**Permanent J-CODE issued<sup>3</sup>**

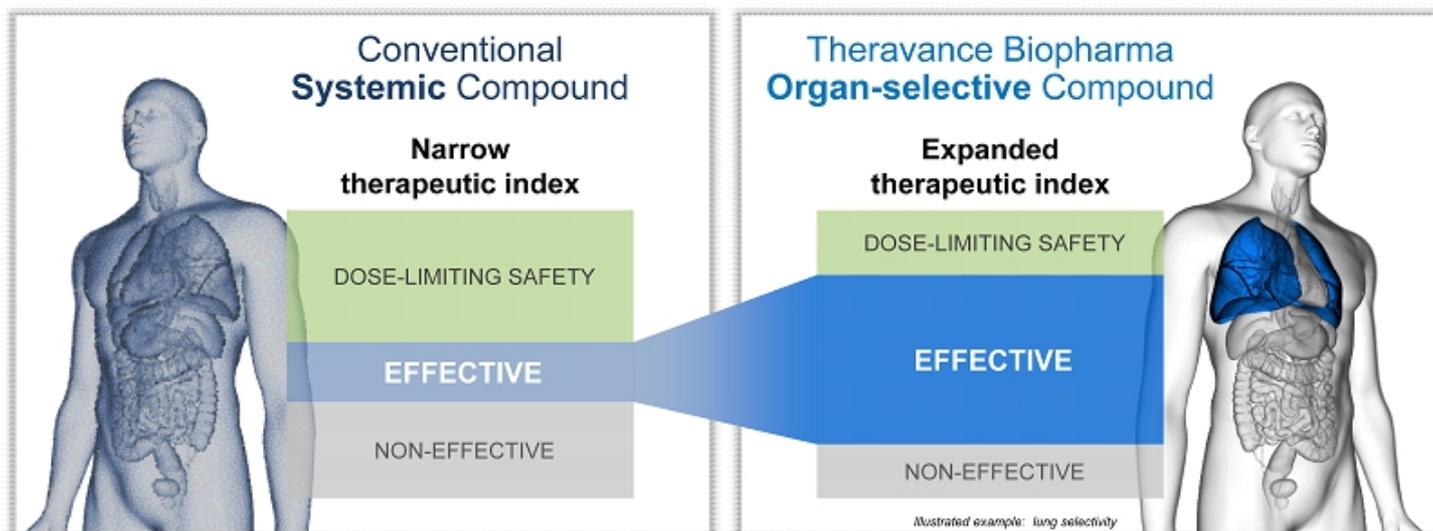


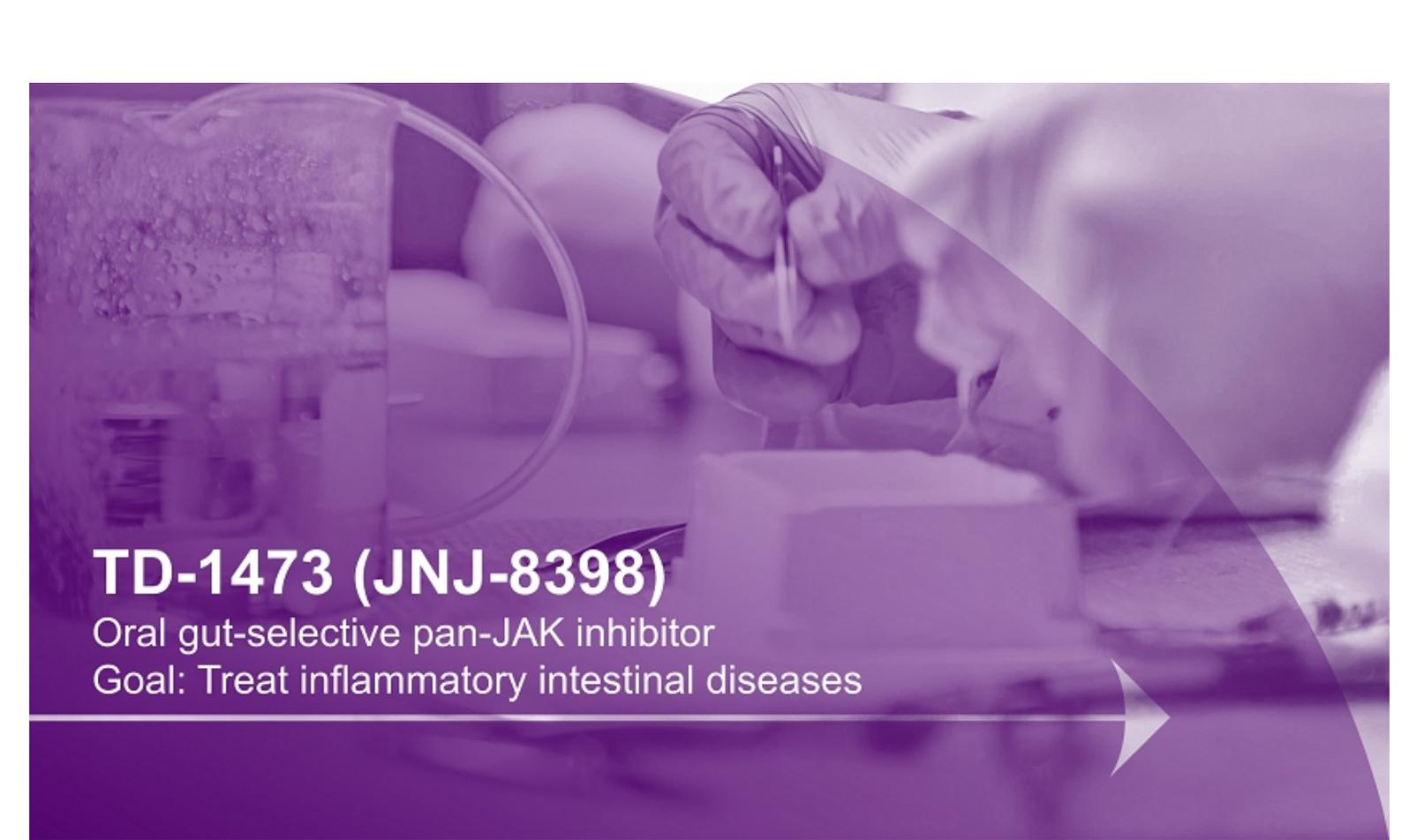
## **Our science**

Organ-selective approach  
designed to optimize therapeutic index



# Organ-selective approach leverages proven and deep expertise in developing lung-selective medicines for respiratory disease





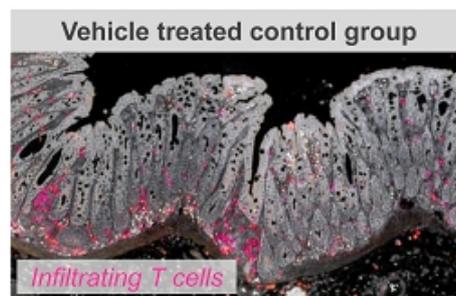
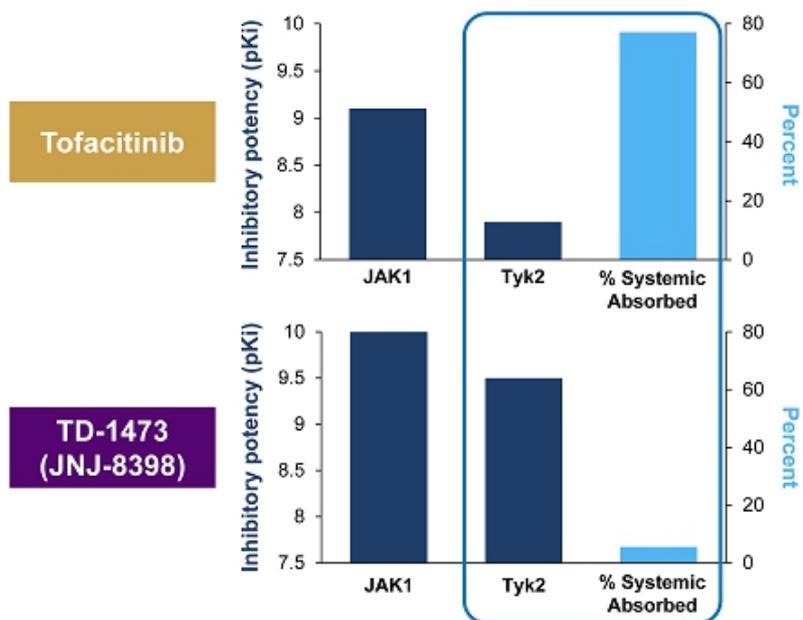
## **TD-1473 (JNJ-8398)**

Oral gut-selective pan-JAK inhibitor

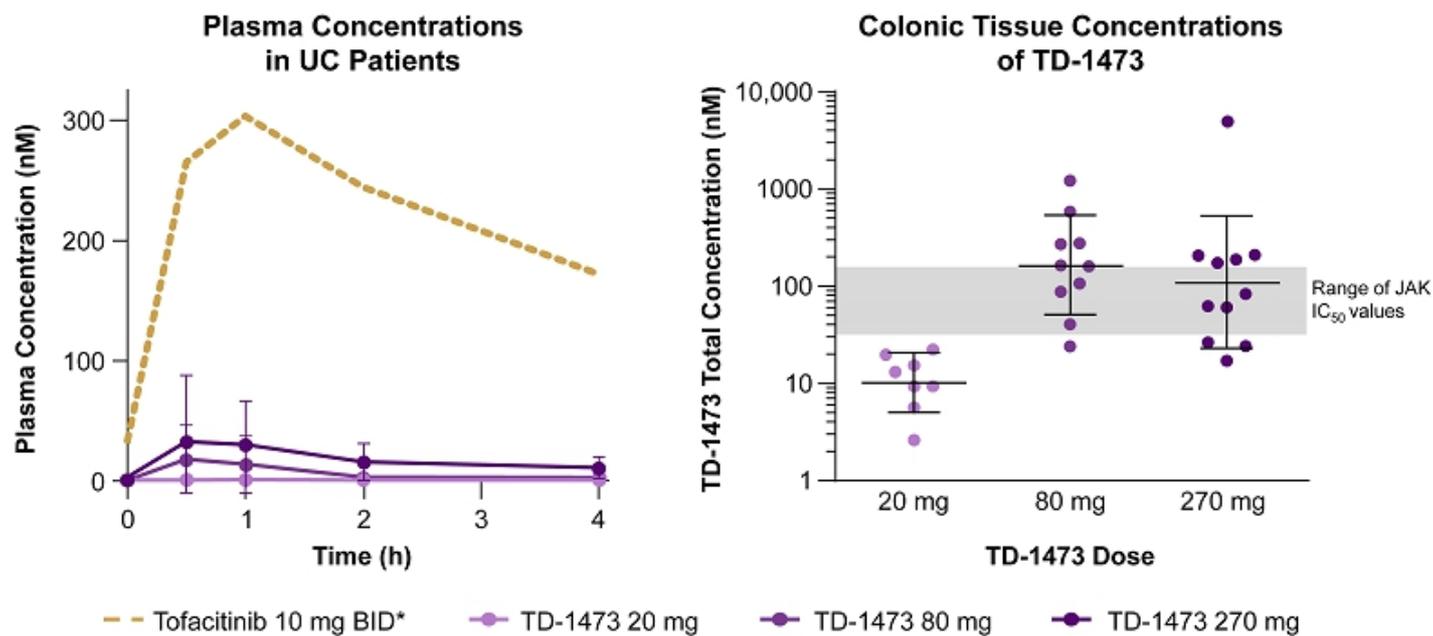
Goal: Treat inflammatory intestinal diseases



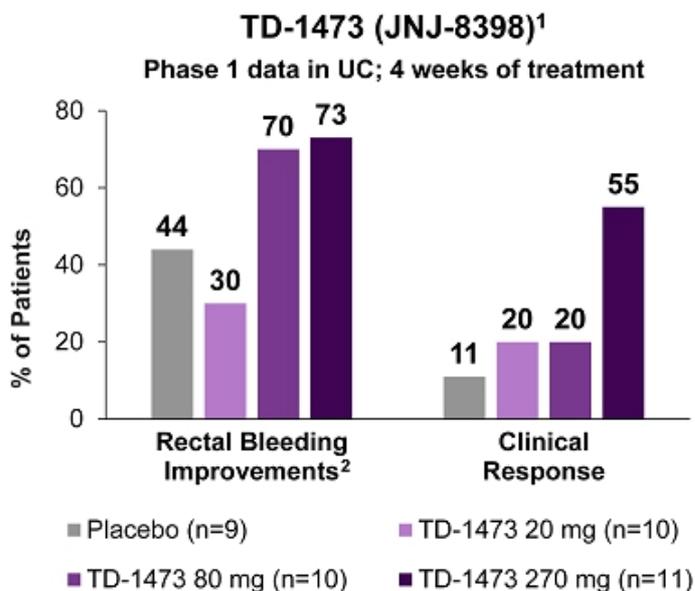
# Improved preclinical profile of a novel, potent, gut-selective pan-JAK inhibitor



# Systemic exposures low; tissue concentrations at or above JAK inhibition levels



# Potential for increased efficacy and safety with gut selectivity



# TD-1473: Gut-selective pan-JAK inhibitor

## LATE-STAGE STUDIES IN ULCERATIVE COLITIS AND CROHN'S DISEASE

**Crohn's disease**  
**Phase 2: 12 weeks (N=160)**  
 Dose-finding induction  
 → **Active treatment extension: 48 weeks**

**DIONE**  
 STUDY

**Ulcerative colitis**  
**Phase 2b/3: 8 weeks (N=240)**  
 Dose-finding induction  
**Phase 3: 8 weeks (N=640)**  
 Dose-confirming induction  
 Responders ▶ **Maintenance phase<sup>3</sup>: 44 weeks**

**RHEA**  
 PROGRAM

- ✓ Phase 2 Crohn's and Phase 2b/3 UC studies ongoing
- ✓ Phase 2 Crohn's and Phase 2b UC data expected late-2020
- ✓ Global collaboration with **JNJ** leverages joint development expertise and provides significant economics to **TBPH<sup>4</sup>**



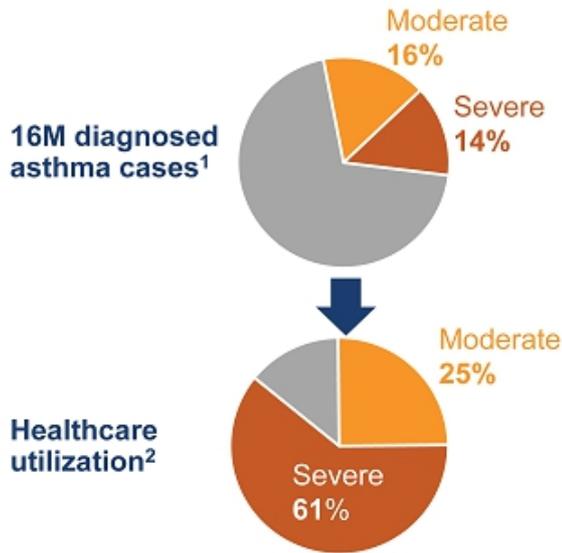
## TD-8236

Inhaled lung-selective pan-JAK inhibitor  
Goal: Treat moderate-to-severe asthma  
regardless of T2 phenotype

---

# High medical and economic burden in uncontrolled asthma

Small portion of US patients cause ~\$58B in medical costs



JAK/STAT cytokines implicated in moderate to severe asthma

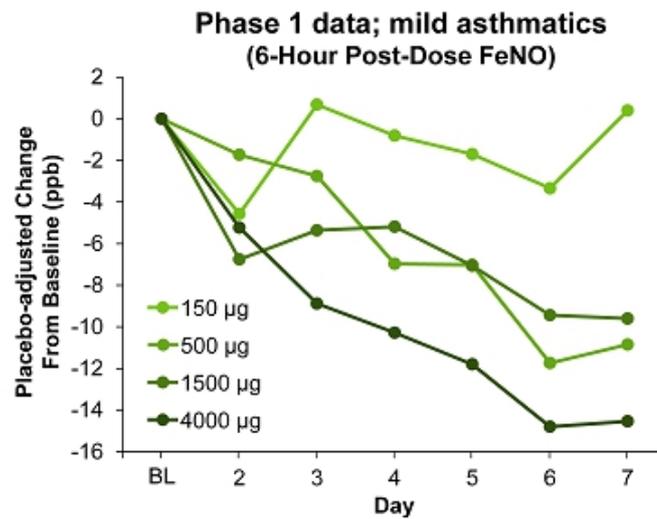
T2-high	T2-low
<b>IL-4</b>	<b>IL-23/IL-12</b>
<b>IL-13</b>	<b>IL-6</b>
<b>IL-5</b>	<b>IL-27</b>
<b>TSLP</b>	<b>IFN-<math>\gamma</math></b>

*Bold denotes biologics in development or approved*

**Inhaled pan-JAK inhibitor has the potential to address patient needs regardless of T2 phenotype**

# TD-8236: Lung-selective pan-JAK inhibitor

## PRELIMINARY POSITIVE FENO DATA IN MILD ASTHMATICS



- ✓ Phase 1 biomarker study in moderate to severe asthmatics ongoing; data expected mid-2020

# TD-8236: Lung-selective pan-JAK inhibitor

## PHASE 2 ALLERGEN CHALLENGE STUDY

### TD-8236 Phase 2 Lung Allergen Challenge 12 weeks (N=21)

Dose characterization  
Randomized, double-blind, placebo-controlled,  
crossover study

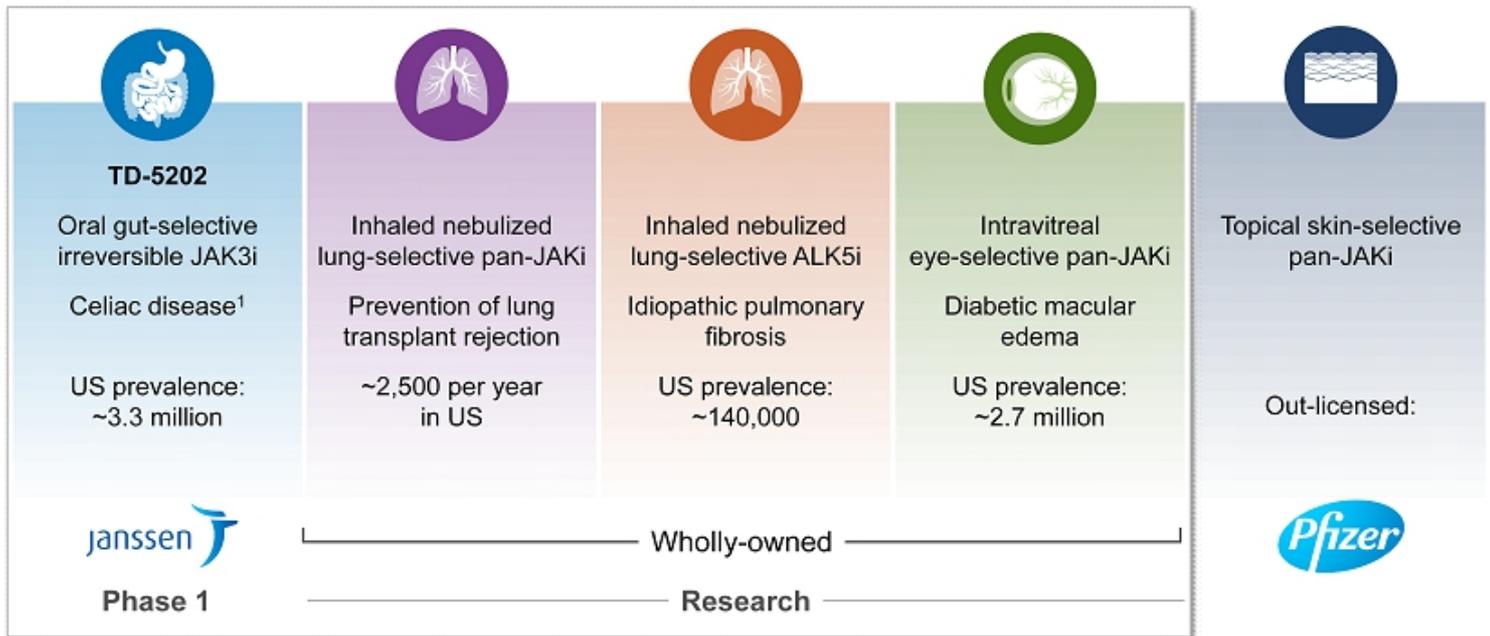
- ✓ Phase 2 allergen challenge study underway
- ✓ Data expected 2020

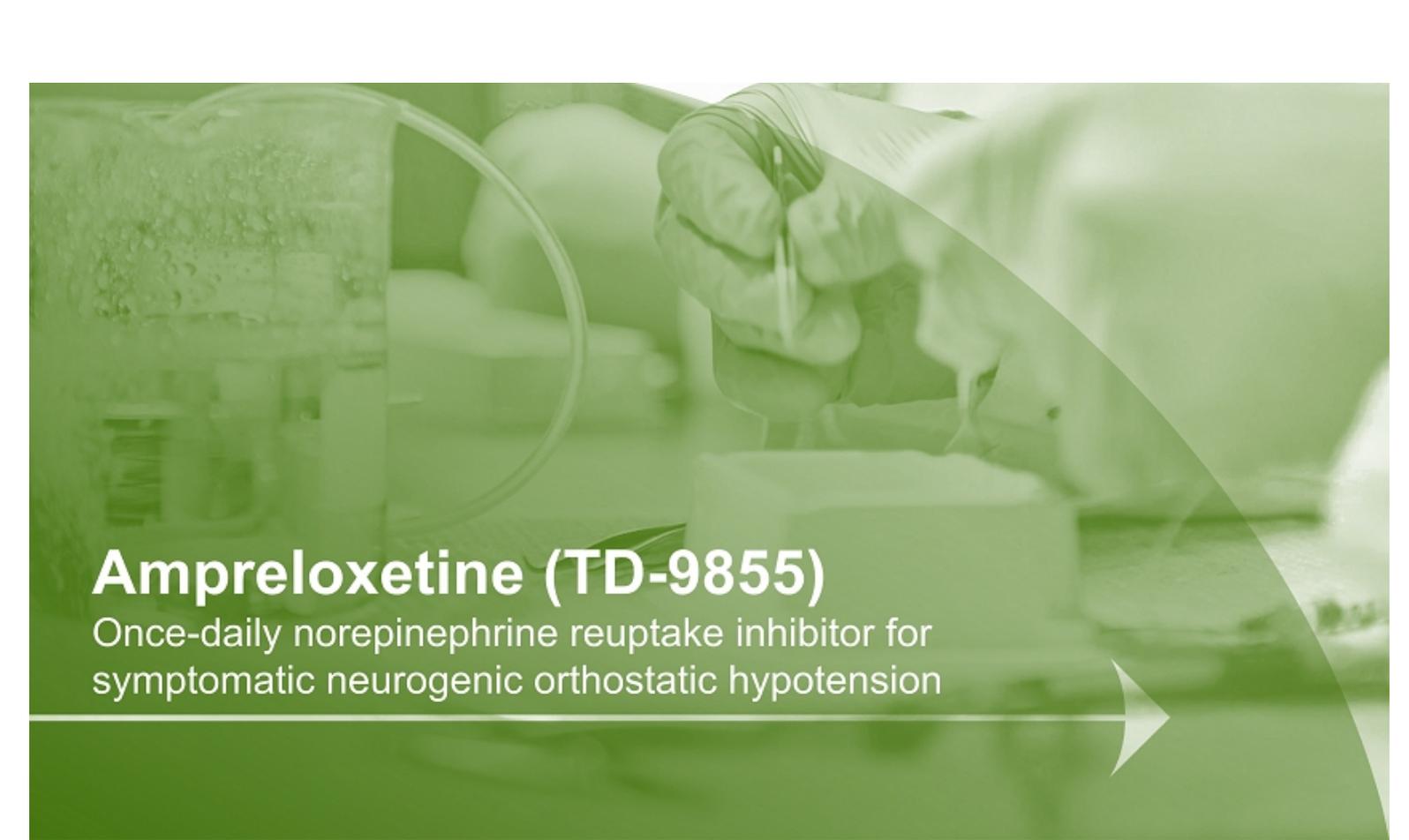


**Early-stage  
organ-selective programs**

---

# Opportunity to address multiple therapeutic areas with novel organ-selective approach





## **Ampreloxetine (TD-9855)**

Once-daily norepinephrine reuptake inhibitor for  
symptomatic neurogenic orthostatic hypotension

---

# Reduced quality of life, significant care-giver burden and limited therapeutic options for symptomatic nOH patients



nOH is a symptom of MSA, PAF and PD

- ▶ 18% of PD<sup>1</sup> and 83% of MSA<sup>2</sup> patients have nOH
- ▶ ~350K patients in the US

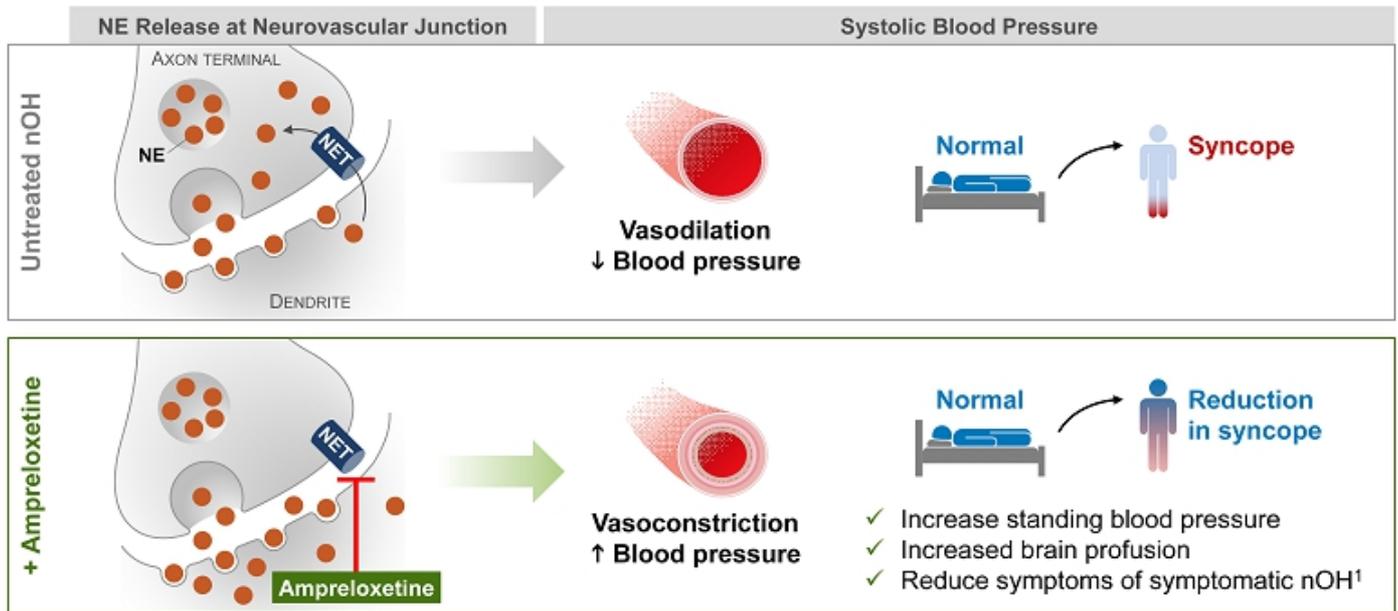
Current treatments have significant limitations

- ▶ Subset of patients do not respond
- ▶ None have demonstrated durable effect
- ▶ Require multiple daily dosing

High burden condition

- ▶ Impact on activities of daily living and quality of life
- ▶ Significant caregiver burden
- ▶ Economic burden to the US healthcare system

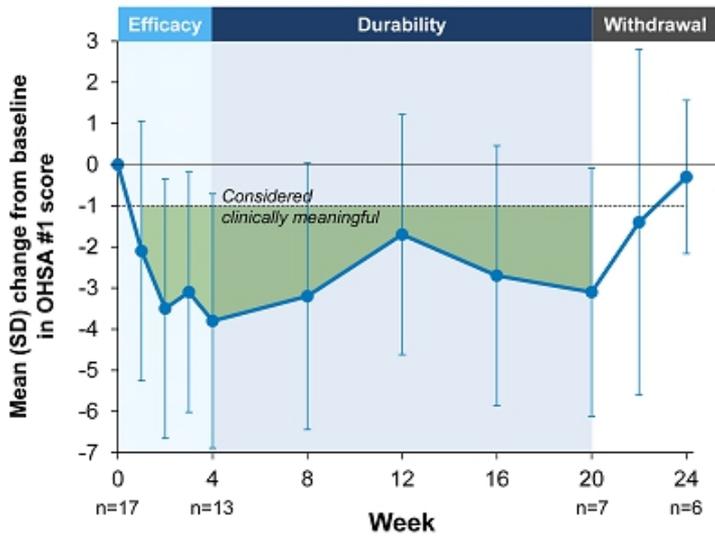
# Designed to reduce symptoms of nOH by prolonging the effect of endogenous norepinephrine



# Potential to provide meaningful and durable symptom improvement to underserved patients

## Amprexetine

Phase 2 data in nOH; 20 weeks of treatment



## Phase 3 Registrational Program

**Study 169: 4 weeks (N=188)**

Randomized, double-blind, placebo-controlled, parallel group



**Study 170: 22 weeks (N=254)**

Randomized 6-week withdrawal phase

Completers: → Extension study: 3 years



- ✓ Phase 3 registrational program ongoing; 4-week efficacy data expected 2H20



# The Theravance Biopharma Difference

# Multiple potential milestones and value driving catalysts in 2020 and beyond

2020

## TD-5202

- ▶ Phase 1 topline data

## TD-8236

- ▶ Phase 1 Part C data in severe asthmatics
- ▶ Phase 2 allergen challenge data

## TRELEGY ELLIPTA<sup>1</sup>

- ▶ FDA approval decision for asthma
- ▶ FDA approval decision for mortality benefit vs. ANORO in COPD

## Ampreloxetine

- ▶ Phase 3 4-week efficacy data

## TD-1473

- ▶ Phase 2b/3 ulcerative colitis topline data
- ▶ Phase 2 Crohn's topline data

Commercial progression of YUPELRI® and TRELEGY ELLIPTA

2021

# Creating transformational value for stakeholders

Innovative research yielding organ-selective assets



Proven development and commercial expertise



Strategic partnerships



Strong capital position



Value driving catalysts

## Strategic objective

Transform the treatment of serious diseases through the discovery, development, and commercialization of **organ-selective medicines** designed to maximize patient benefit while minimizing patient risk

# About YUPELRI® (revefenacin) inhalation solution

YUPELRI® (revefenacin) inhalation solution is a novel once-daily nebulized LAMA approved for the maintenance treatment of COPD in the US.

Market research by Theravance Biopharma indicates approximately 9% of the treated COPD patients in the US use nebulizers for ongoing maintenance therapy.<sup>1</sup> LAMAs are a cornerstone of maintenance therapy for COPD and YUPELRI is positioned as the first once-daily single-agent bronchodilator product for COPD patients who require, or prefer, nebulized therapy. YUPELRI's stability in both metered dose inhaler and dry powder device formulations suggest that this LAMA could also serve as a foundation for novel handheld combination products.

# YUPELRI® (revefenacin) inhalation solution

YUPELRI® inhalation solution is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

## Important Safety Information (US)

YUPELRI is contraindicated in patients with hypersensitivity to revefenacin or any component of this product.

YUPELRI should not be initiated in patients during acutely deteriorating or potentially life-threatening episodes of COPD, or for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm. Acute symptoms should be treated with an inhaled short-acting beta2-agonist.

As with other inhaled medicines, YUPELRI can produce paradoxical bronchospasm that may be life-threatening. If paradoxical bronchospasm occurs following dosing with YUPELRI, it should be treated immediately with an inhaled, short-acting bronchodilator. YUPELRI should be discontinued immediately and alternative therapy should be instituted.

YUPELRI should be used with caution in patients with narrow-angle glaucoma. Patients should be instructed to immediately consult their healthcare provider if they develop any signs and symptoms of acute narrow-angle glaucoma, including eye pain or discomfort, blurred vision, visual halos or colored images in association with red eyes from conjunctival congestion and corneal edema.

Worsening of urinary retention may occur. Use with caution in patients with prostatic hyperplasia or bladder-neck obstruction and instruct patients to contact a healthcare provider immediately if symptoms occur.

Immediate hypersensitivity reactions may occur after administration of YUPELRI. If a reaction occurs, YUPELRI should be stopped at once and alternative treatments considered.

The most common adverse reactions occurring in clinical trials at an incidence greater than or equal to 2% in the YUPELRI group, and higher than placebo, included cough, nasopharyngitis, upper respiratory infection, headache and back pain.

Coadministration of anticholinergic medicines or OATP1B1 and OATP1B3 inhibitors with YUPELRI is not recommended.

YUPELRI is not recommended in patients with any degree of hepatic impairment.