
**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): **September 14, 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)

Not Applicable
(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 numbers, 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:

Title of each class:	Trading Symbol(s)	Name of each exchange on which registered:
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.

Members of the Theravance Biopharma, Inc. management team will be participating in presentations at (i) the Morgan Stanley 18th Annual Global Healthcare Conference 2020 on September 14, 2020 and (ii) the H.C. Wainwright 22nd Annual Global Investment Conference on September 15, 2020. A copy of the Company’s corporate overview 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](#) [Slide deck entitled Corporate Overview - dated September 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, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

THERAVANCE BIOPHARMA, INC.

Date: September 14, 2020

By: /s/ Andrew Hindman

Andrew Hindman

Senior Vice President and Chief Financial Officer



Medicines That Make a Difference®

Corporate Overview

September 2020

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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, the Company's expectations regarding its allocation of resources, 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 2020 operating loss, excluding share-based compensation and other financial results.

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 the impacts on the COVID-19 global pandemic on our business, 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, current and 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.

Other risks affecting Theravance Biopharma are in the company's Form 10-Q filed with the SEC on August 10, 2020, and other periodic reports filed with the SEC.

Creating transformational value for stakeholders



Innovative and productive **research engine** feeding **pipeline of organ-selective molecules designed to optimize therapeutic index**



Proven **development expertise** and established **commercial infrastructure** with strong history in respiratory



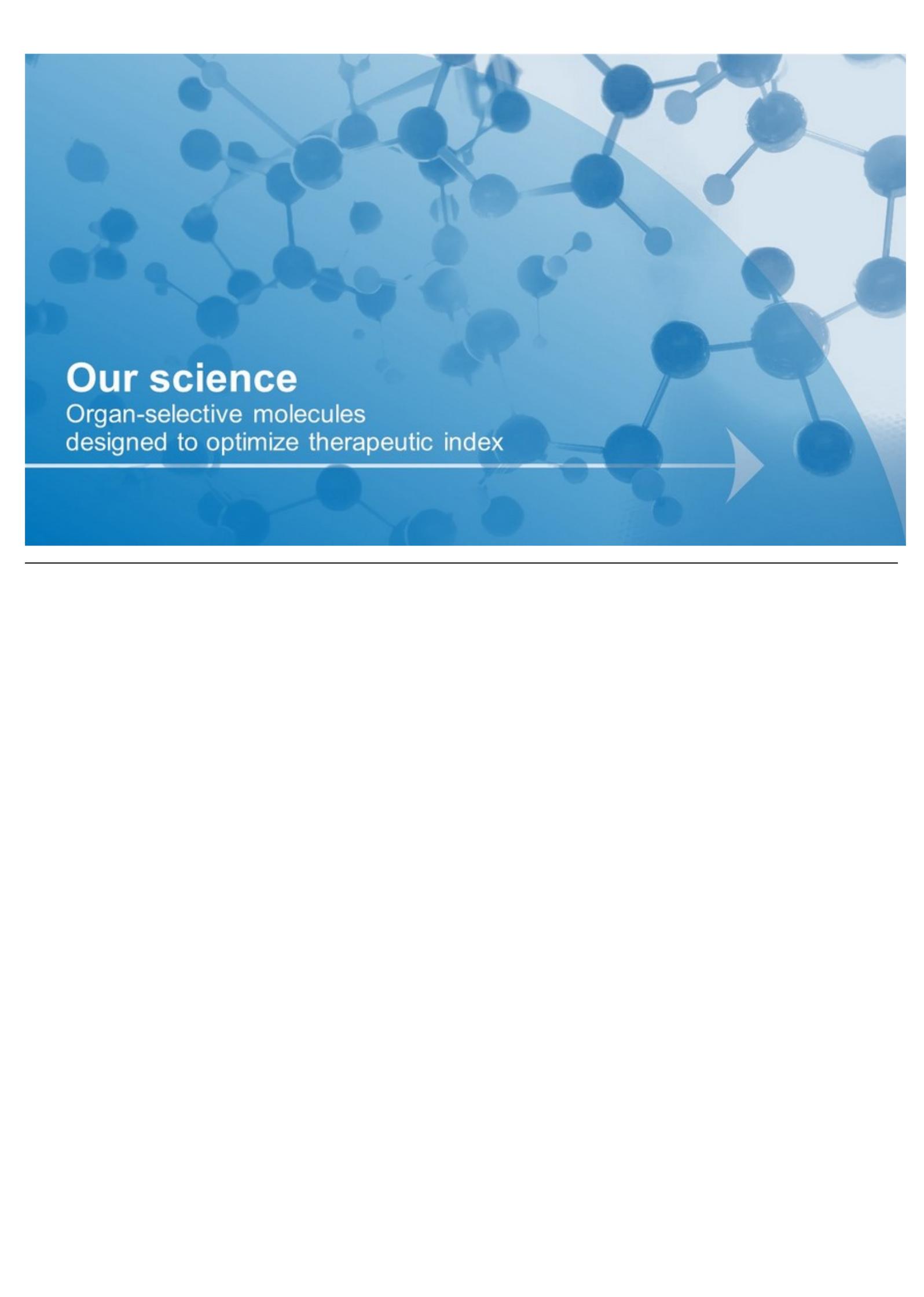
Strategic partnerships complement internal capabilities and balance technical, execution and financial risks



Strong capital position of \$438.3m in cash¹ augmented by TRELEGY ELLIPTA² royalties and YUPELRI[®] launch



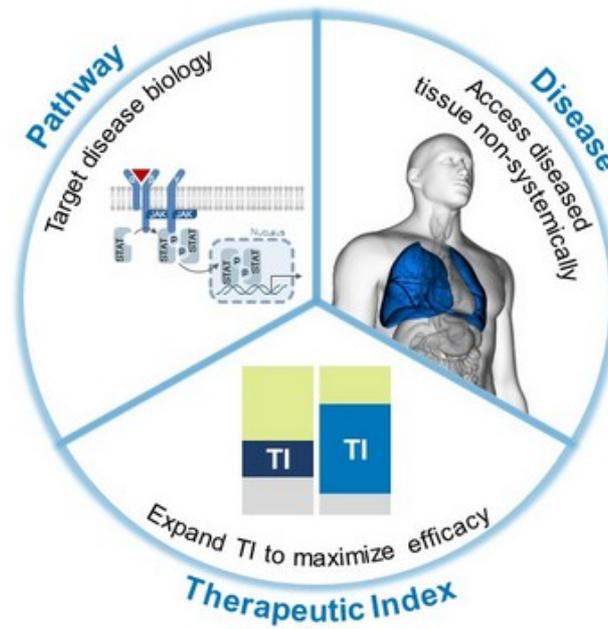
Multiple milestones and **value driving catalysts** in 2020, 2021 and beyond

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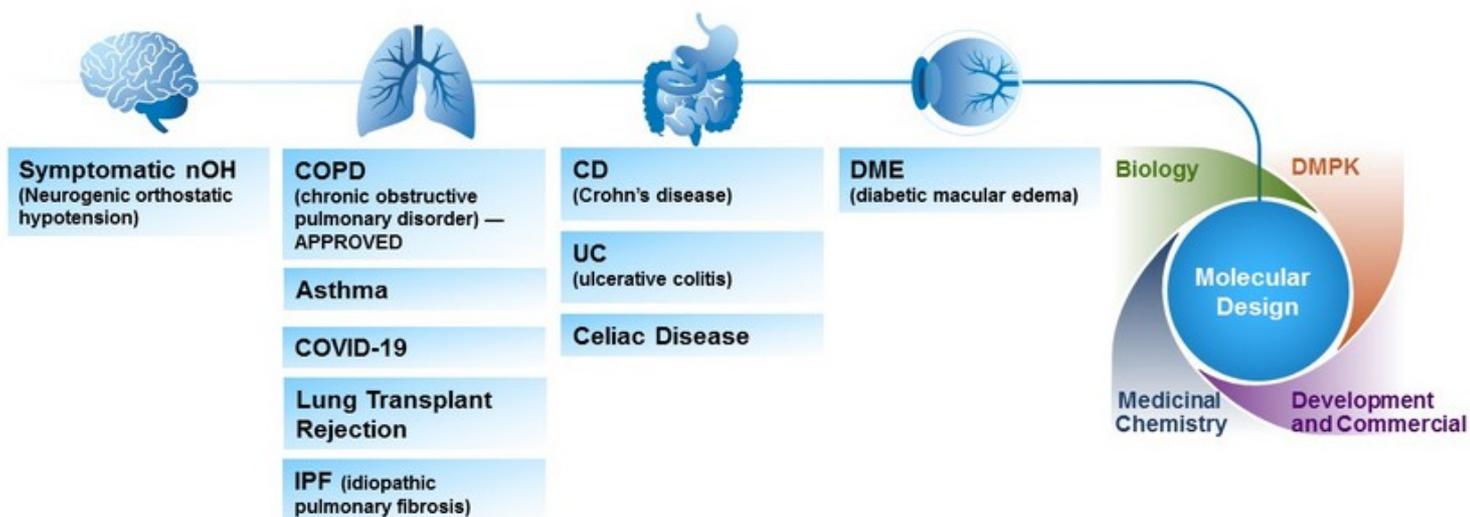
Our science

Organ-selective molecules
designed to optimize therapeutic index

Theravance Biopharma difference: Targeting the right disease with the right molecular design



Research and development portfolio of designed molecules: brain, lung, GI and eye



Key programs supported by proven development and commercial expertise

	Program	Indication	Research	Phase 1	Phase 2	Phase 3	Filed	Marketed	Collaborator
	Ampreloxetine (TD-9855) NRI	Symptomatic nOH	Phase 3						Wholly-owned
Organ-Selective	TD-1473 GI JAKi	UC	Phase 2b/3					Janssen	
		CD	Phase 2						
	TD-5202 Irreversible JAK3i	Inflammatory intestinal diseases	Phase 1						
	YUPELRI® (revefenacin) LAMA	COPD	Marketed					Mylan	
	TD-8236 Inhaled JAKi	Asthma	Phase 2					Wholly-owned	
TD-0903 Inhaled JAKi	COVID-19	Phase 2							
Economic Interests	TRELEGY ELLIPTA¹ FF/UMEC/VI	COPD	Marketed					GSK & Innoviva, Inc.	
		Asthma	Marketed						
	Skin-selective JAKi	Dermatological diseases	Research					Pfizer	



YUPELRI® (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



Once-daily LAMAs are first-line therapy for moderate-to-severe COPD¹

9% of COPD patients (~800,000) use nebulizers for ongoing maintenance therapy; 41% use nebulizers at least occasionally for bronchodilator therapy²

Nebulized therapy associated with reduced hospital readmissions in low PIFR patients³

Theravance
Biopharma



Mylan



TBPH and MYL worldwide strategic collaboration to develop and commercialize nebulized YUPELRI® (revefenacin)



Companies copromote under US profit/loss share

YUPELRI® launch metrics

Strong customer acceptance and market uptake

✓ FORMULARY¹

- 181 wins
(equates to 329 accounts)
- ~86 reviews scheduled
(>456 potential accounts)
- 100% medical support requests fulfilled <30 days

✓ PATIENT

- Field force productivity goals exceeded
- ~44,000 patients² prescribed
(through Q2 2020)

✓ ACCESS

- 100% Medicare Part B³
- 72% of commercial payer lives covered
(comprises ~8% of the YUPELRI® business)

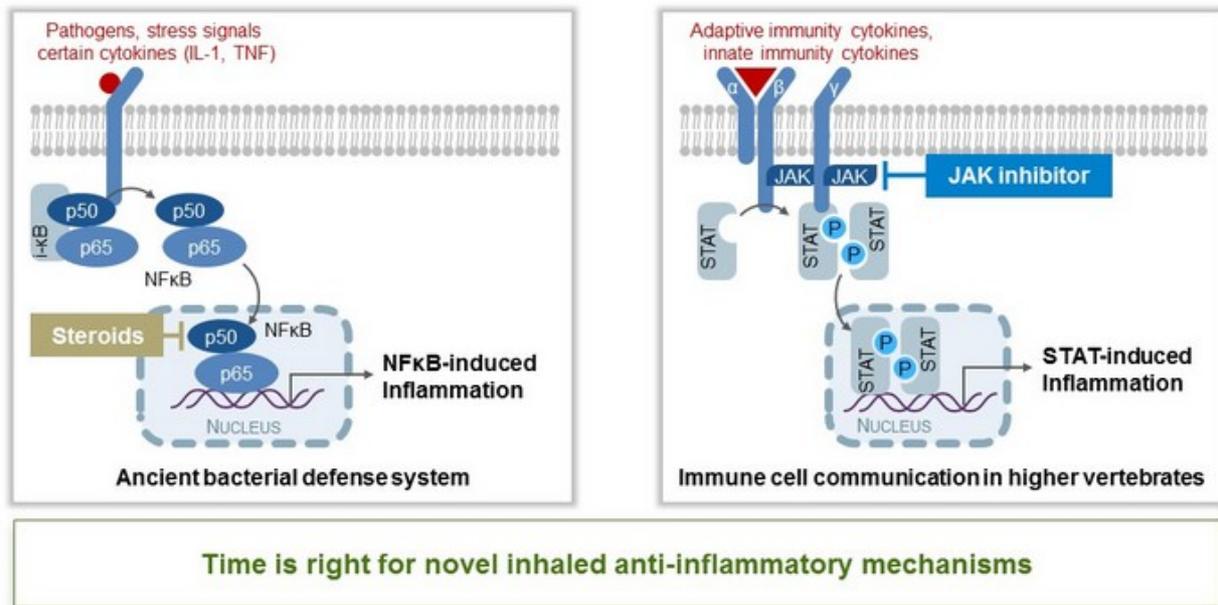


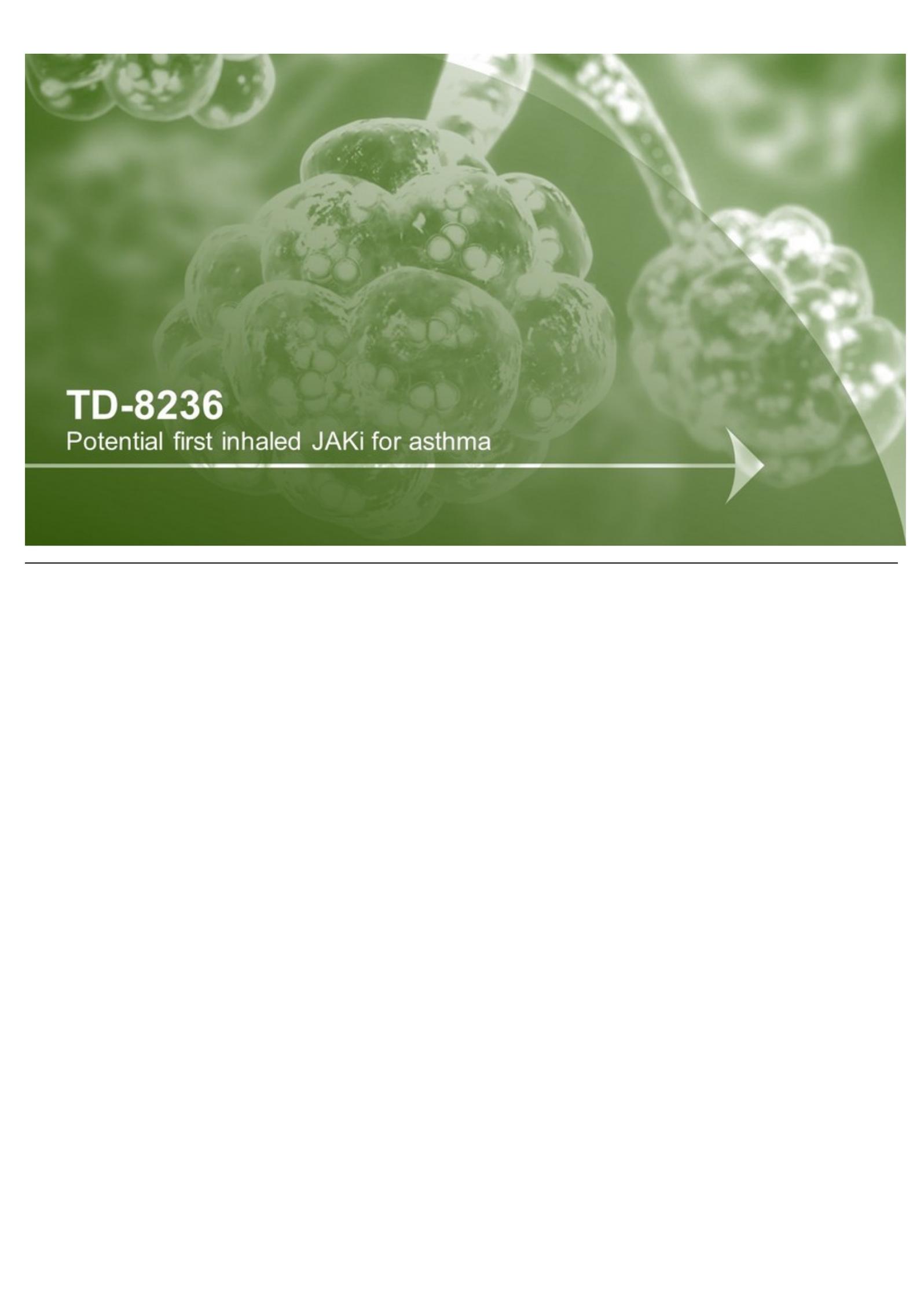
Inhaled JAK inhibitor Portfolio

Potential to transform treatment of respiratory inflammation



Inhaled JAK inhibitors can transform treatment of inflammation-induced respiratory diseases





TD-8236

Potential first inhaled JAKi for asthma

High medical and economic burden in uncontrolled asthma



339M
cases worldwide¹

25M
US cases
8% of adults
8% of children²



Healthcare utilization³

~\$58B US medical costs
~\$15B US asthma market (May 2020)



ICS + LABA (often fail to control disease)
Approved biologics (affect subsets of patients)

- XOLAIR (omalizumab)
- NUCALA (mepolizumab)
- CINQAIR (reslizumab)
- FASENRA (benralizumab)
- DUPIXENT (dupilumab)

Step-up for severe asthma: LTRAs, tiotropium, OCS, biologics

JAK/STAT cytokines implicated in moderate-to-severe asthma

T2-high	T2-low
IL-4	IL-23/IL-12
IL-13	IL-6
IL-5	IL-27
TSLP	IFN-γ

Bold: biologics in development or approved.

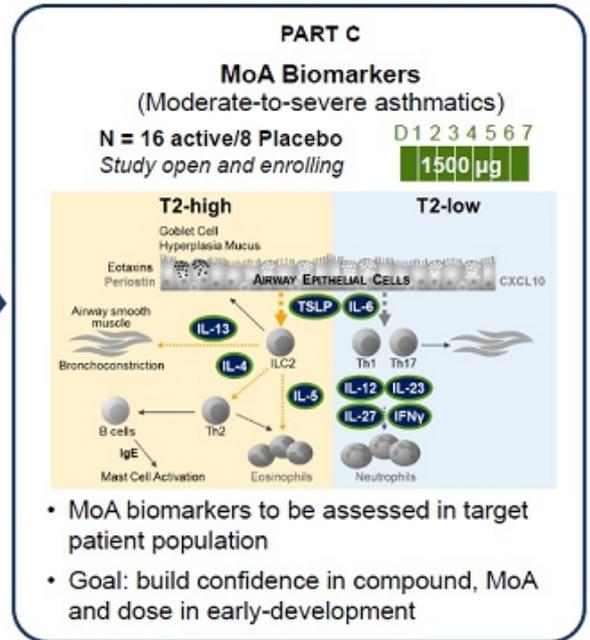


TD-8236

Potential to transform the treatment of respiratory inflammation by treating moderate-to-severe asthma regardless of T2 phenotype, including patients who remain symptomatic despite compliance on high-dose ICS

TD-8236: Phase 1 clinical trial design

Parts A & B completed September 2019; Part C data expected 4Q 2020



TD-8236: Lung-selective pan-JAK inhibitor

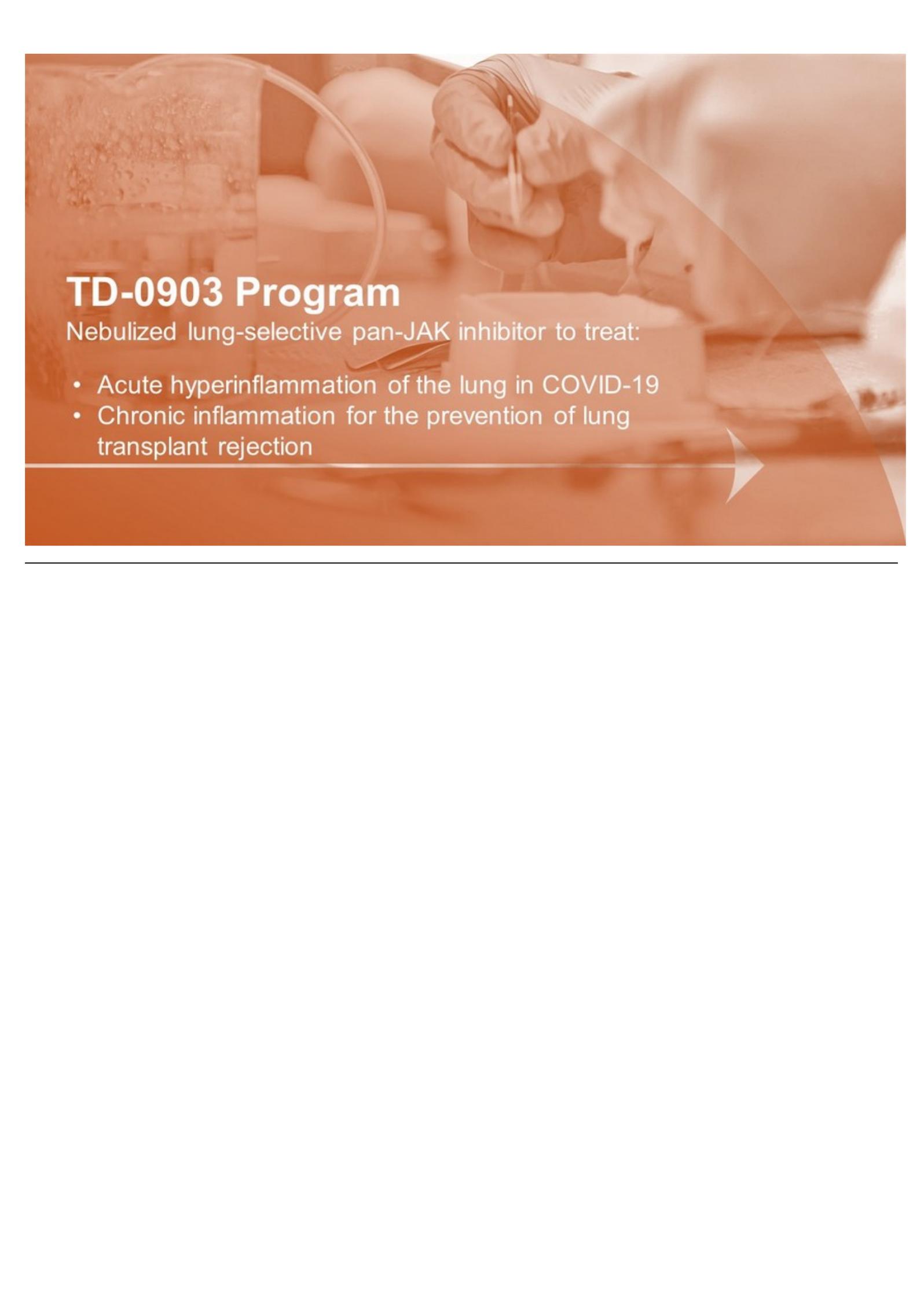
Phase 2 allergen challenge study

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 4th Q 2020



TD-0903 Program

Nebulized lung-selective pan-JAK inhibitor to treat:

- Acute hyperinflammation of the lung in COVID-19
- Chronic inflammation for the prevention of lung transplant rejection

Leveraging respiratory expertise for potential acute treatment in response to a global pandemic



>27.8M
patients worldwide¹

>6M
US patients¹

~2.4%
patients become
hospitalized²



No vaccine available
Current treatment: Supportive therapy

As of July 1, 2020:

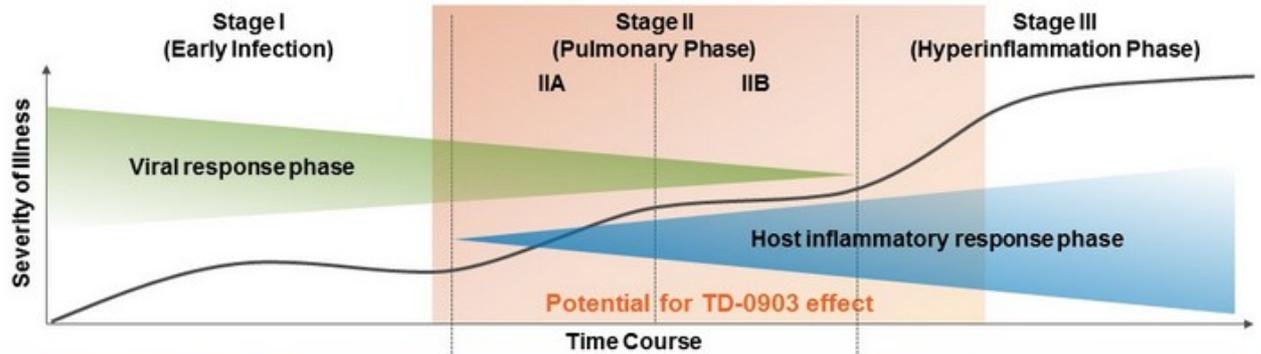
439 drugs in **2327** trials worldwide



TD-0903

Inhaled lung-specific therapeutic: potential to be used in combination with other treatment modalities (e.g., antivirals) to provide additional therapeutic benefit without risk of systemic immunosuppressive issues that may occur with systemic anti-inflammatories

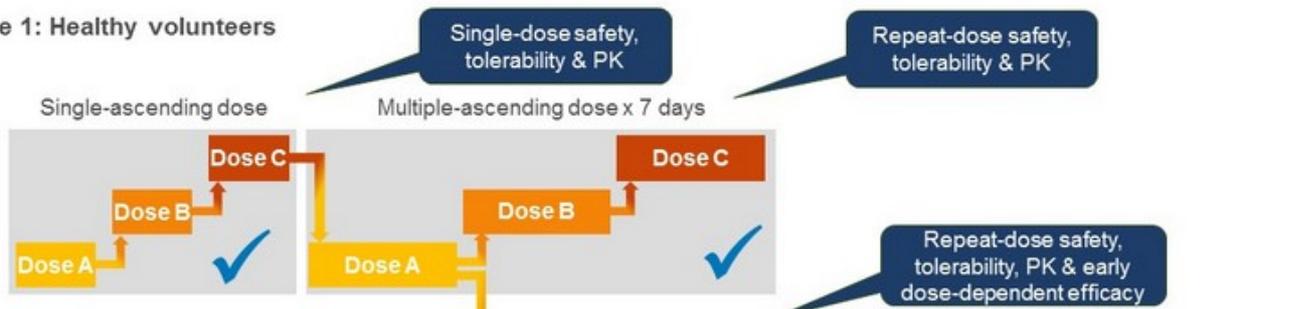
Host inflammatory response to COVID-19 drives ALI and ARDS



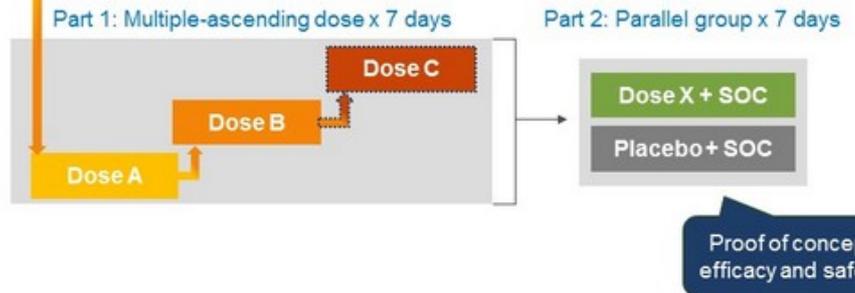
	Stage I (Early Infection)	Stage II (Pulmonary Phase) IIA IIB	Stage III (Hyperinflammation Phase)
Clinical symptoms	Mild constitutional symptoms Fever >99.6°F Dry cough, diarrhea, headache	Shortness of breath Hypoxia (PaO ₂ /FiO ₂ ≤300 mmHg)	ARDS SIRS/shock Cardiac failure
Clinical signs	Lymphopenia, increased prothrombin time, increased D-Dimer and LDH (mild)	Abnormal chest imaging Transaminitis Low normal procalcitonin	Elevated inflammatory markers (CRP, LDH, IL-6, D-dimer, ferritin) Troponin, NT-proBNP elevation
Potential therapies	Remdesivir, chloroquine, hydroxychloroquine, convalescent plasma transfusions		
	Reduce immunosuppression	Corticosteroids, human immunoglobulin, Anti-IL-6; other single pathway inhibitors, JAK inhibitors	

TD-0903: Development plan designed to progress rapidly

Phase 1: Healthy volunteers



Phase 2: Hospitalized COVID-19 patients



First-in-disease opportunity for the prevention of lung transplant rejection



Lung transplants have the poorest prognosis of all solid organ transplants
COPD, IPF, and CF top 3 diagnoses driving need for lung transplantation

6,240

lung transplants worldwide, 2019¹

2,714

lung transplants per year in US²

15%

CAGR since 1988

~50%

mortality at 6 years post transplant³

\$3.5B

medical/productivity costs (2015–2025)



No FDA-approved therapies to prevent lung transplant rejection or CLAD

Current standard of care: triple immunosuppression therapy

- Calcineurin inhibitors (tacrolimus)
- Corticosteroids
- Anti-proliferative agents (MMF)
- IL-2 mAb induction therapy (basiliximab)



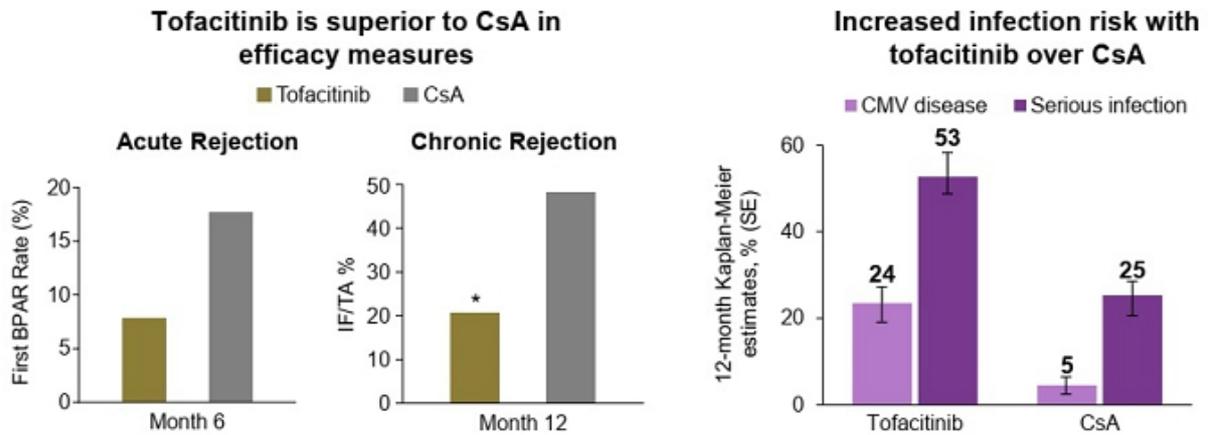
TD-0903

Potential first approved therapy specifically to prevent acute lung transplant rejection and development of CLAD

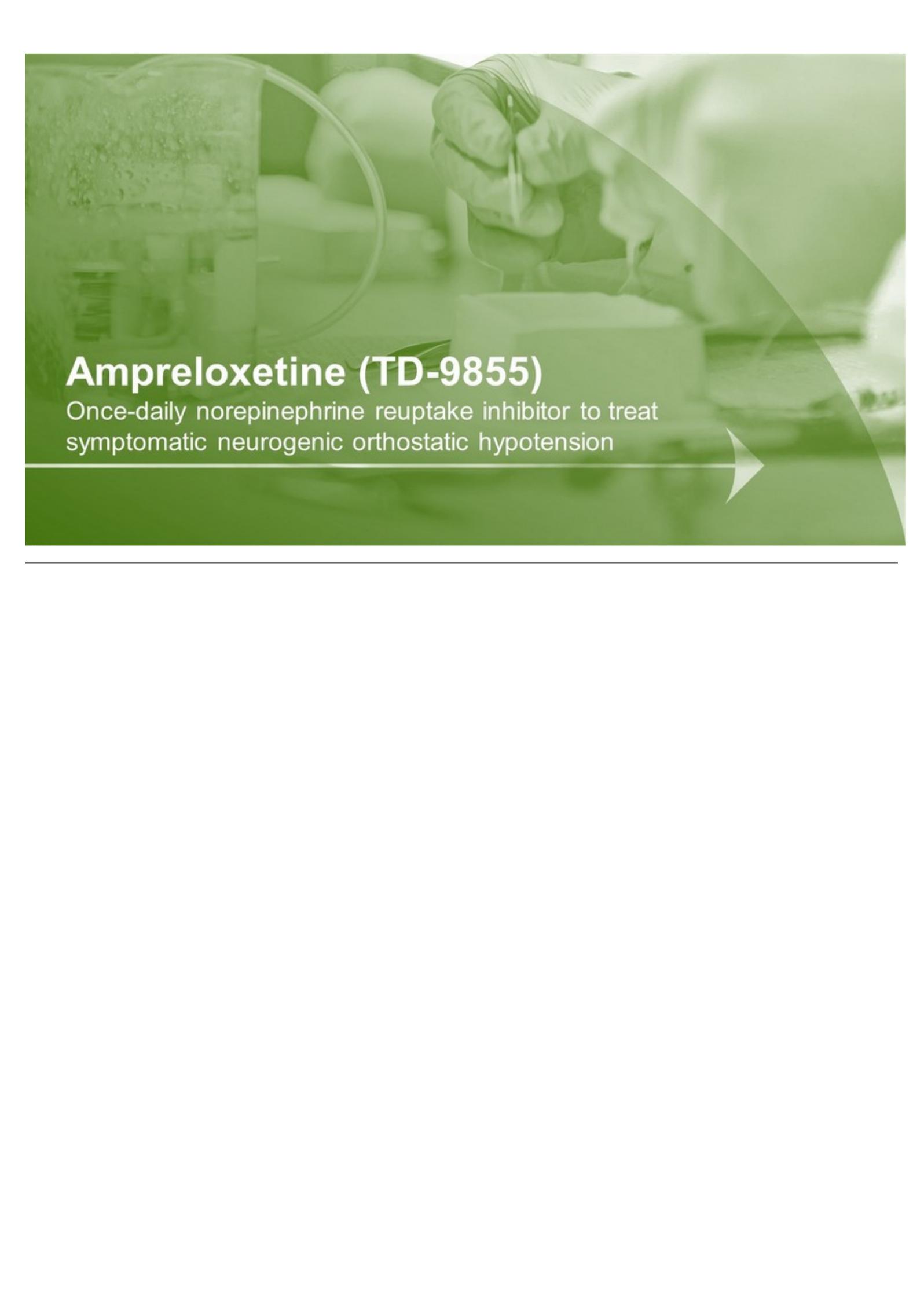
Use following lung transplantation could improve patient morbidity and mortality risk, and reduce need for re-transplantation

Pan-JAK inhibitors can prevent transplant rejections

Noninferiority trial of tofacitinib vs cyclosporine (CsA) in kidney transplant recipients¹



- ▶ JAK inhibition was superior to cyclosporine in prevention of acute and chronic rejections
- ▶ Serious infections increased with systemic JAK inhibitors including CMV



Ampreloxetine (TD-9855)

Once-daily norepinephrine reuptake inhibitor to treat symptomatic neurogenic orthostatic hypotension

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



~350K
US patients

nOH is a symptom of MSA, PAF and PD
70–80% of MSA patients¹, and
30–50% of PD patients² have nOH³



Current treatments (midodrine, fludrocortisone, droxidopa) have significant limitations

Subset of patients do not respond

None demonstrate durable effect

Safety profiles that limit use

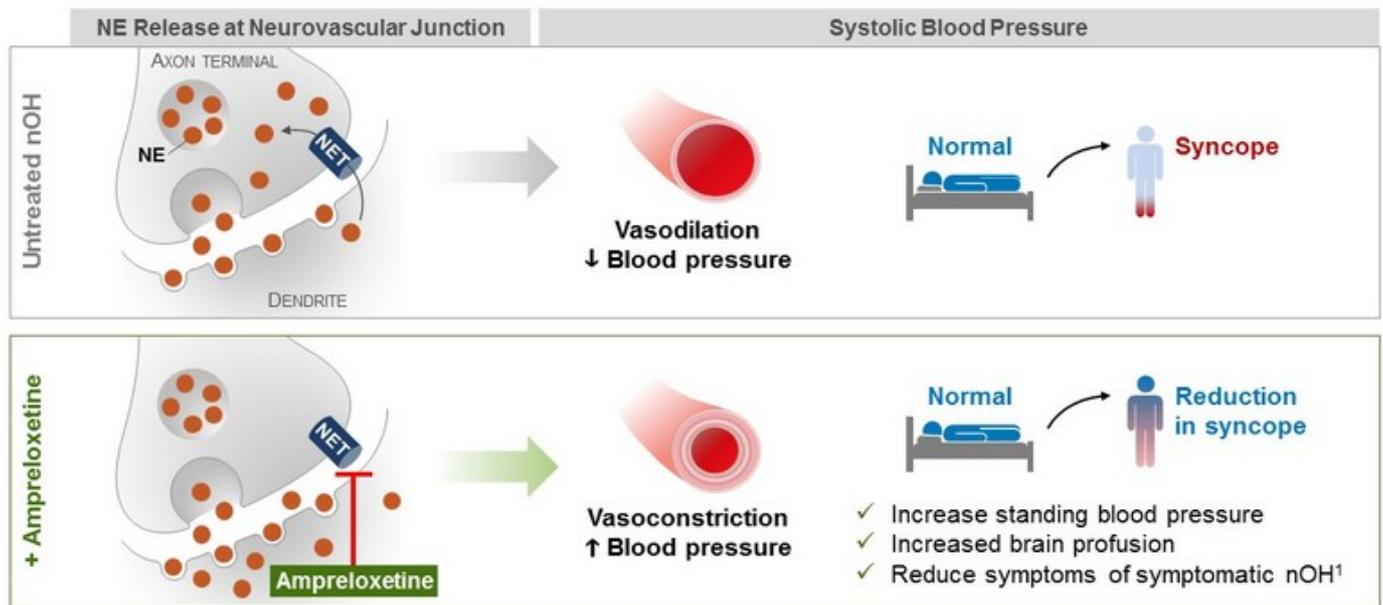
Require multiple daily dosing



Ampreloxetine

Designed to reduce symptoms of nOH by prolonging the effect of endogenous norepinephrine with the potential to provide a meaningful and durable symptom improvement to underserved patients

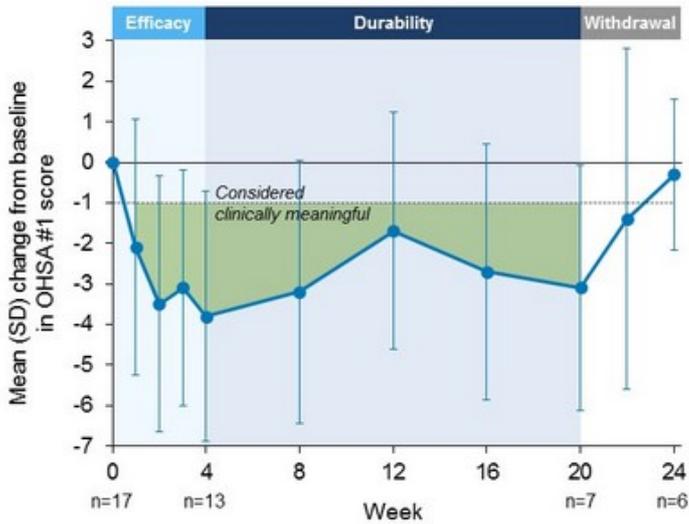
Designed to reduce symptoms of nOH by prolonging the effect of endogenous norepinephrine



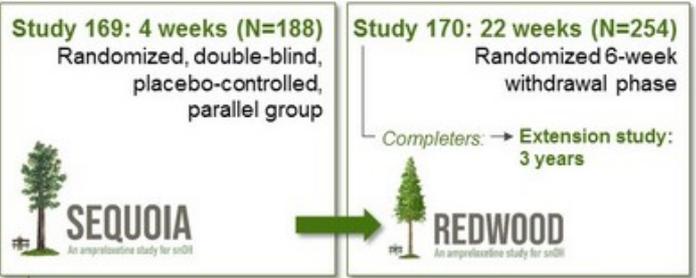
Amprelosetine: Potential to provide meaningful and durable symptom improvement to underserved patients

Amprelosetine

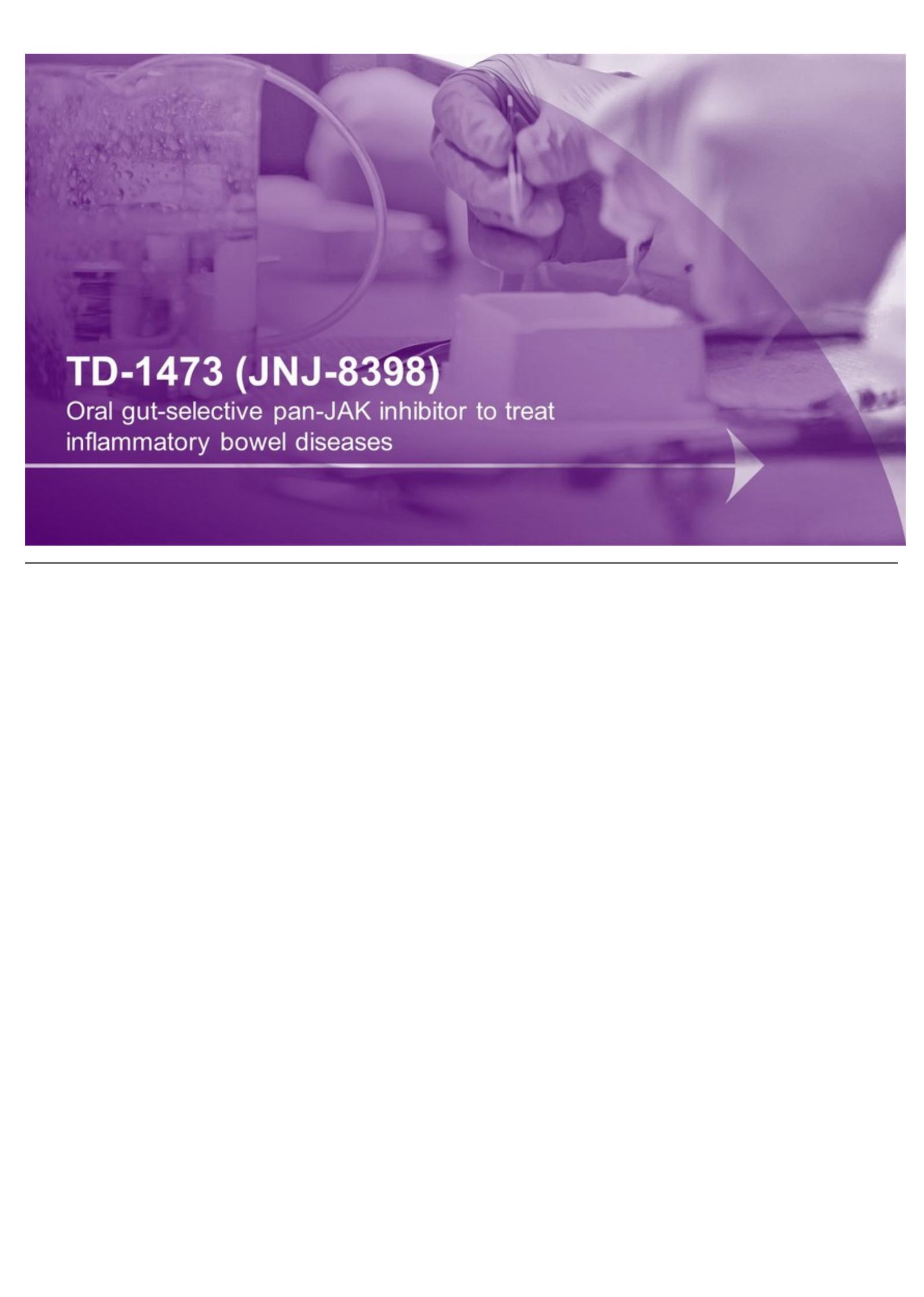
Phase 2 data in nOH; 20 weeks of treatment



Phase 3 Registrational Program



✓ Phase 3 registrational program ongoing; 4-week efficacy data expected 2021



TD-1473 (JNJ-8398)

Oral gut-selective pan-JAK inhibitor to treat
inflammatory bowel diseases

Need for new medicines to treat Inflammatory Bowel Disease



6.8M global cases, 2017¹

1.6M current US patients²

Current US patients **780K** CD cases
907K UC cases

\$16B global IBD treatment market, 2018

\$31B US disease burden²

~4.4% CAGR 2018–2026



Standard of care:
Biologics have become the mainstay of treatment in moderate-to-severe patients

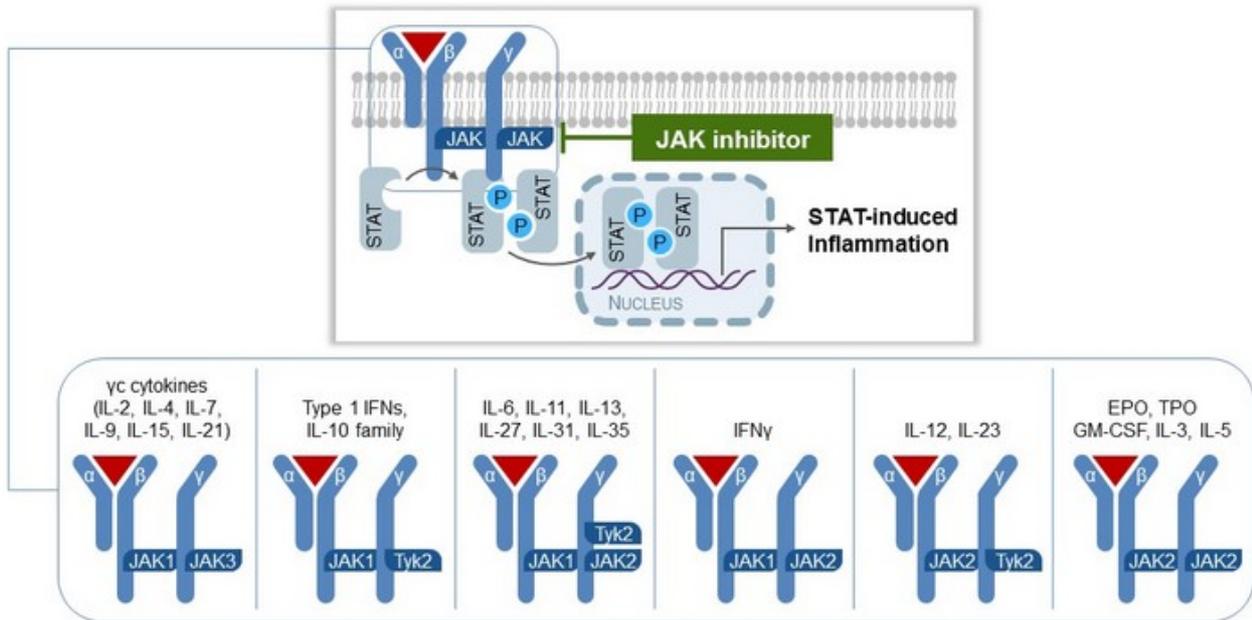
Steroids, immunosuppressants, and TNF inhibitors associated with side effects that further decrease HRQoL



TD-1473

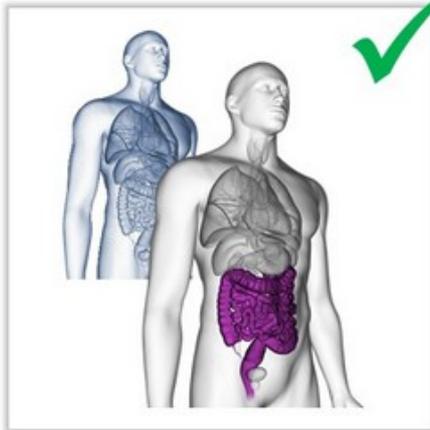
Gut-selective agent: if used earlier in the course of disease, has potential to be a new cost-effective therapy option that reduces associated disease management costs and improves patient HRQoL

JAK-STAT pathway: orchestrating signaling of multiple pro-inflammatory cytokines

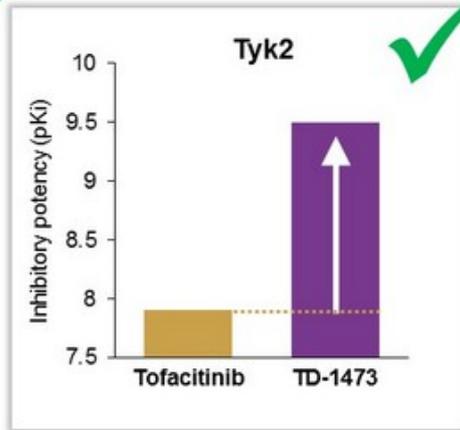


TD-1473 is an oral, gut-selective pan-JAK inhibitor

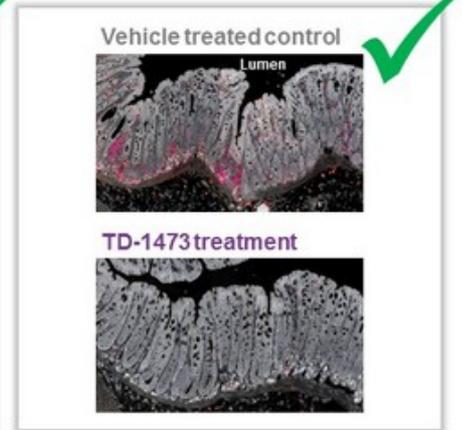
Preclinical data package for TD-1473 represents a potential breakthrough approach to the treatment of IBD



Gut selectivity

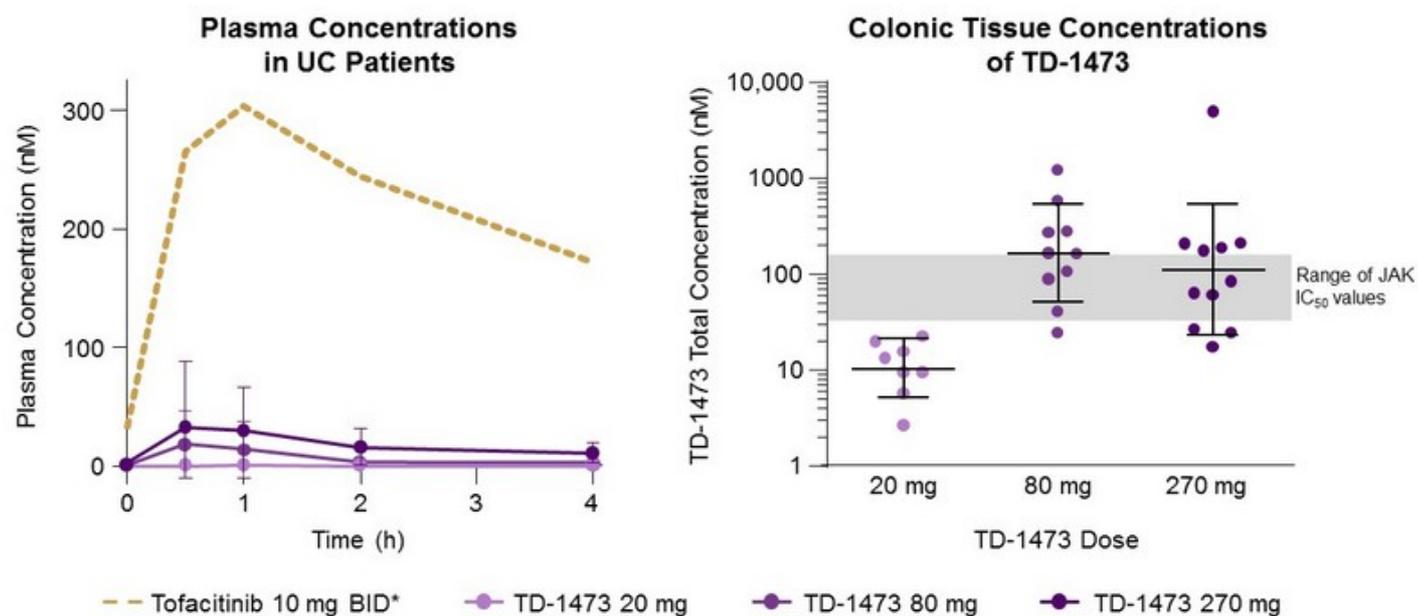


Potent inhibition of Tyk2



Anti-inflammatory activity in disease model

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



TD-1473: Gut-selective pan-JAK inhibitor

Late-stage studies in Crohn's disease and ulcerative colitis



- ✓ Phase 2 Crohn's and Phase 2b/3 ulcerative colitis studies ongoing
- ✓ Phase 2 Crohn's and Phase 2b ulcerative colitis data expected 2021
- ✓ Global collaboration with **Janssen** leverages joint development expertise and provides significant economics to **TBPH²**



TD-5202

Organ-gut selective irreversible JAK3 inhibitor
to treat inflammatory intestinal diseases



Celiac disease has no current treatments and serious health consequences



1%
Global prevalence

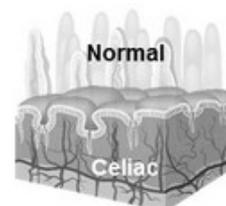
3.3M
US patients^{1,2}

4–4.5x
increase in US
over past 50 y

>2x
higher healthcare
costs than controls

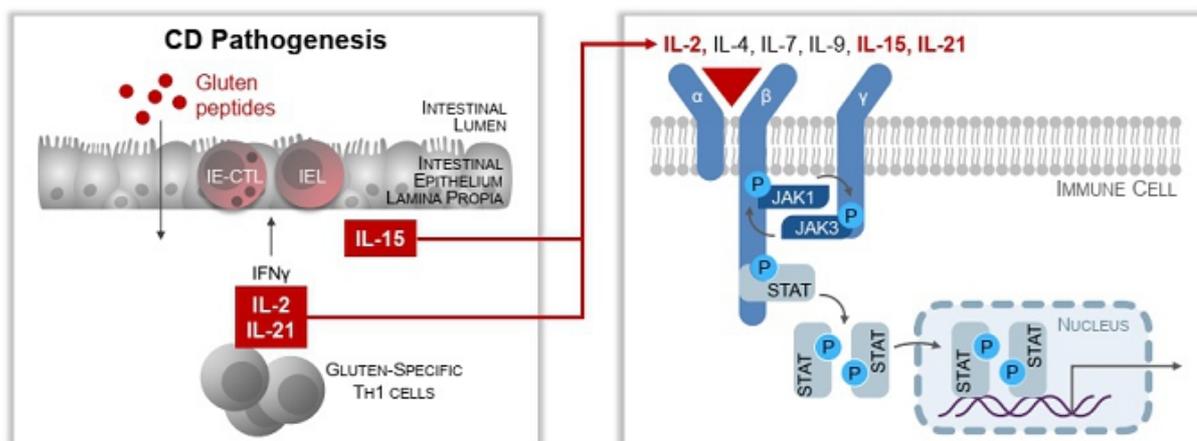


No approved treatment
Only available intervention is strict life-long gluten-free diet
30% of diagnosed patients are poorly controlled despite best dietary efforts³



TD-5202 Organ-gut selective irreversible JAK3 inhibitor:
potential to deliver significant value for both patients and payers

JAK3-dependent cytokines play central role in pathogenesis of celiac disease



- ▶ Proof-of-relevance from recent positive Phase 2 data with systemic JAK3 inhibitor in alopecia areata, another T-cell mediated disease
- ▶ Localized JAK3 inhibition important to avoid systemic immunosuppression (genetic JAK3 deficiency leads to severe immunodeficiency)

TD-5202 FIH Overall Results Summary

TD-5202: generally well-tolerated (single dose ≤ 2000 mg, multiple doses ≤ 1000 mg BID) for 10 consecutive days in healthy subjects



- ▶ No serious or severe AEs were reported
- ▶ All treatment-emergent AEs in TD-5202-treated subjects were mild in severity



- ▶ No clinically significant changes from baseline in vital signs and ECG assessments
- ▶ No clinically significant changes in chemistry or hematology parameters
 - No changes in NK cell count



- ▶ Systemic exposures were dose proportional from 100 to 1000 mg BID
- ▶ Low steady-state systemic exposures: mean $C_{max,ss}$ ~11-fold below the protein-adjusted JAK IC_{50} at the highest tested dose (1000 mg BID), consistent with a gut-selective approach

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Economic interest

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

Economic interest in GSK's TRELEGY

Upward-tiering royalties of ~5.5–8.5% of worldwide net sales¹



TRELEGY

- ✓ Q2 net sales of £194m (or \$241M)
- ✓ Grew market share with sales up 58% year-over-year
- ✓ Asthma sNDA approved September 9, 2020



The Theravance Biopharma Difference

Multiple potential milestones and value-driving catalysts expected in 2020, 2021 and beyond

TD-5202

- ▶ Phase 1 topline data

TD-0903

- ▶ Phase 1 study in healthy volunteers in the UK
- ▶ Phase 2 study in hospitalized patients with COVID-19 in the UK
 - Part 2: multi-center study conducted at hospital-based clinical sites globally, including the U.S.

TD-8236

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

GSK's TRELEGY ELLIPTA¹

- ▶ Asthma sNDA approved September 9, 2020

Ampreloxetine

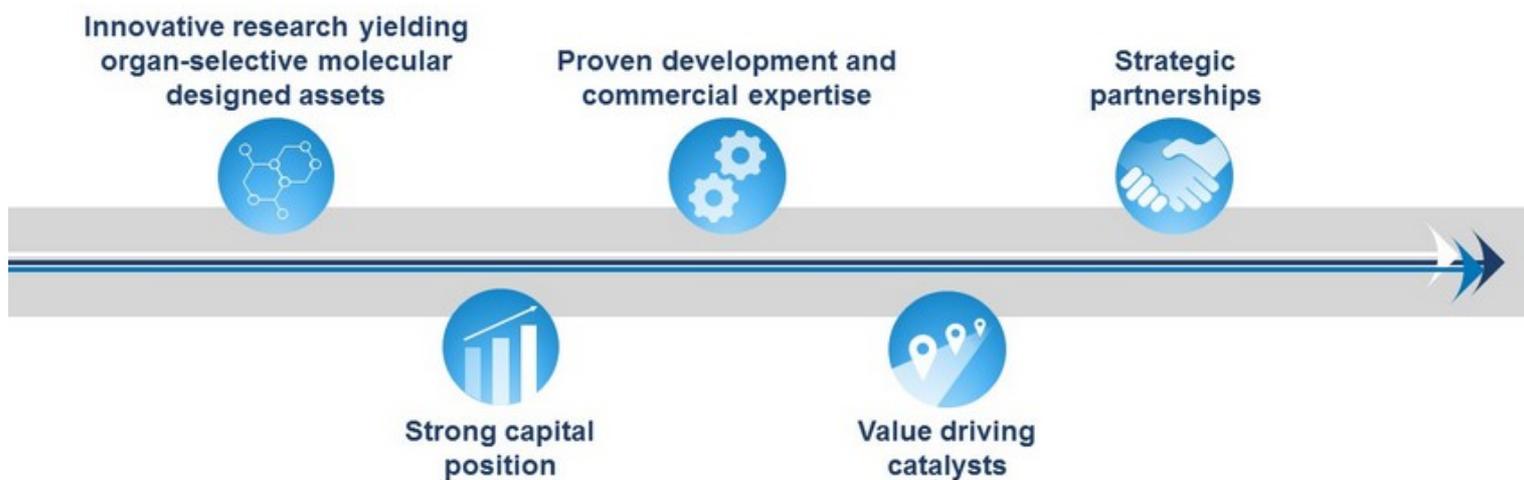
- ▶ Phase 3 4-week efficacy data

TD-1473

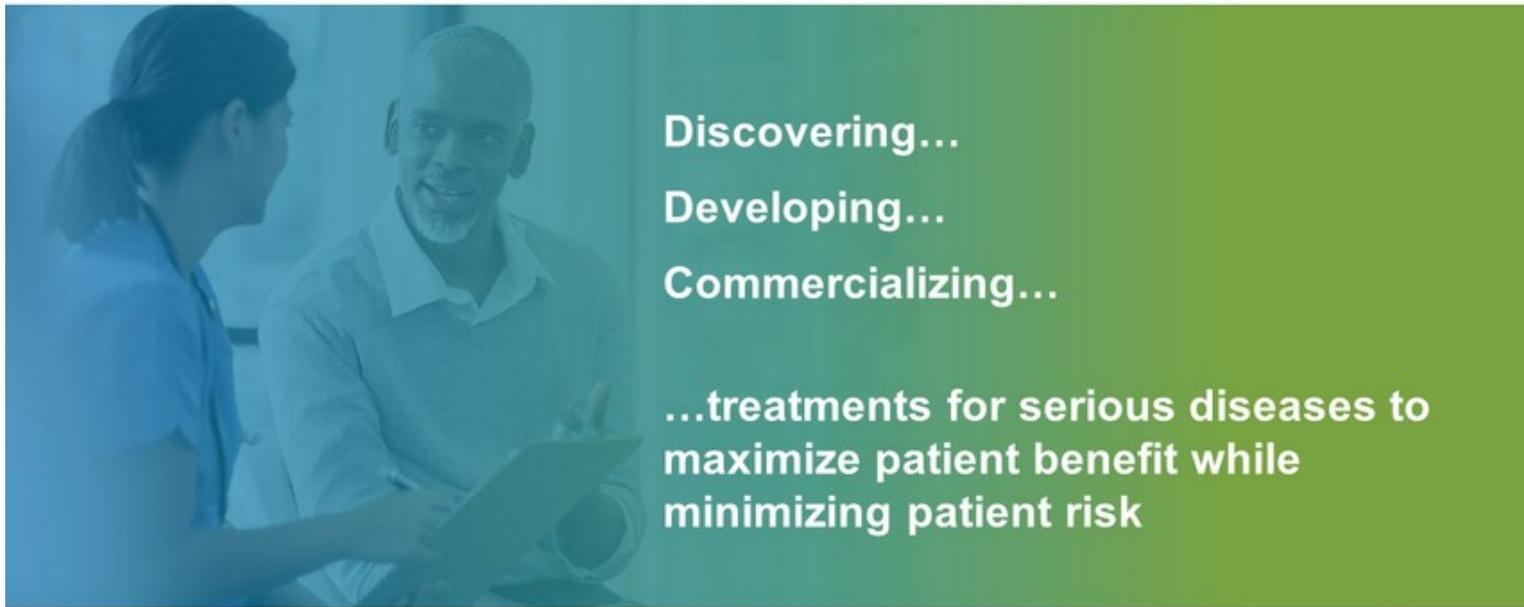
- ▶ Phase 2b/3 ulcerative colitis topline data
- ▶ Phase 2 Crohn's topline data

Commercial progression of YUPELRI[®] and GSK's TRELEGY ELLIPTA

Creating transformational value for stakeholders



Holding steadfast to our mission



About YUPELRI® (revefenacin) inhalation solution

YUPELRI® (revefenacin) inhalation solution is a 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.¹ 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.