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 4, 2019**

THERAVANCE BIOPHARMA, INC.

(Exact Name of Registrant as Specified in its Charter)

Cayman Islands	**001-36033**	**98-1226628**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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))

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. ☐

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

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.

On September 4, 2019, members of the Theravance Biopharma, Inc. management team will be participating in a fireside chat and one-on-one meetings with analysts and investors hosted by Wells Fargo Securities in Boston. A copy of the slide presentation 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 September 4, 2019
104	Cover Page Interactive Data File (cover page XBRL tags embedded within the Inline XBRL document)

SIGNATURE

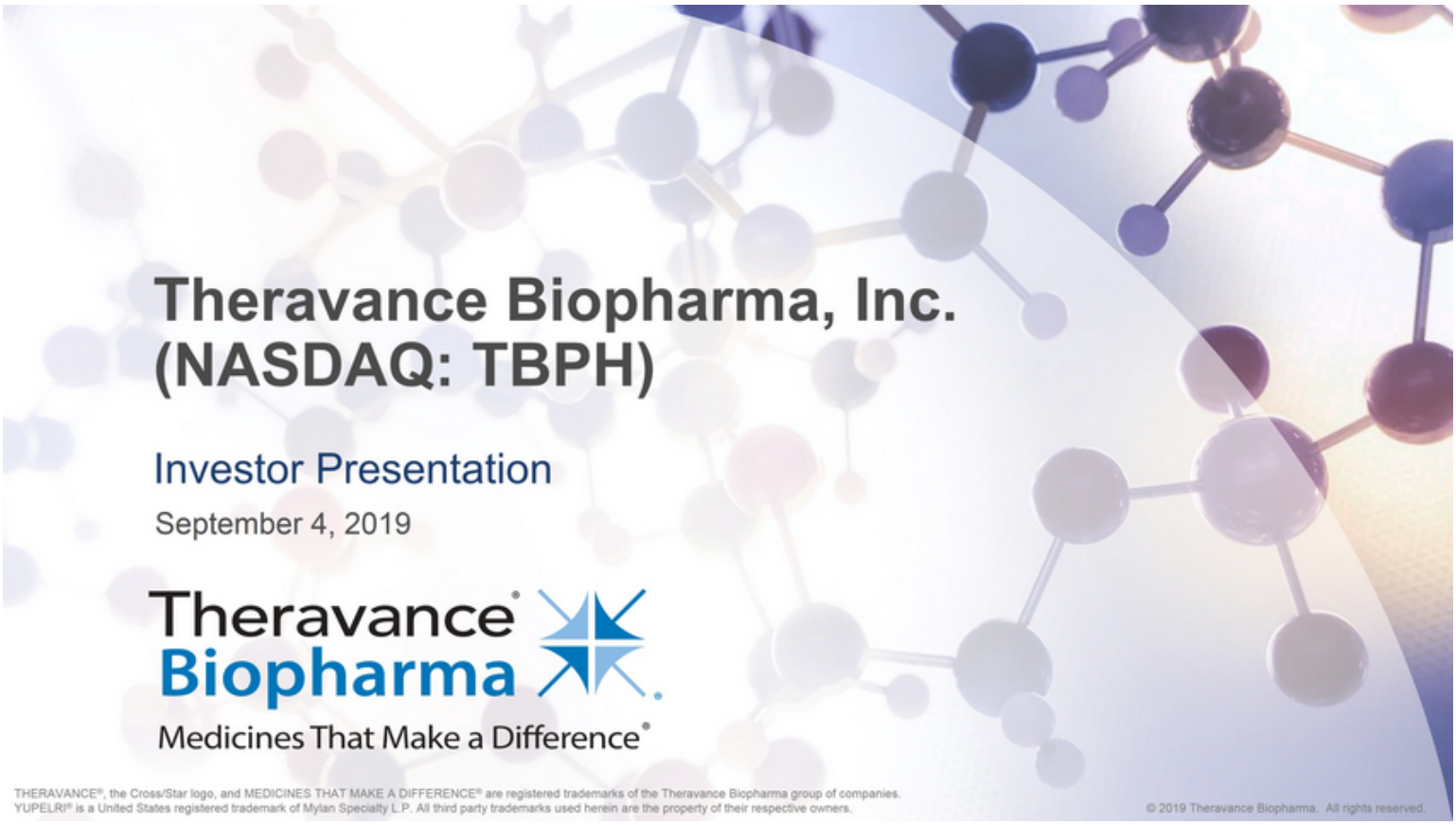
Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

THERAVANCE BIOPHARMA, INC.

Date: September 4, 2019

By: /s/ Andrew Hindman
Andrew Hindman
Senior Vice President and Chief Financial Officer

Exhibit 99.1


Theravance Biopharma, Inc.
(NASDAQ: TBPH)
Investor Presentation
September 4, 2019
Theravance Biopharma
Medicines That Make a Difference®
THERAVANCE®, the Cross/Star logo, and MEDICINES THAT MAKE A DIFFERENCE® are registered trademarks of the Theravance Biopharma group of companies.
YUPELRI® is a United States registered trademark of Mylan Specialty L.P. All third party trademarks used herein are the property of their respective owners.
© 2019 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 current dispute with Innoviva, Inc. and TRC LLC, statements relating to 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 the nature of the current dispute with Innoviva and TRC LLC, the uncertainty of arbitration and litigation and the possibility that an arbitration award or litigation result involving the current dispute could be adverse to the company, delays or difficulties in commencing or completing clinical studies, the potential that results from clinical or non-clinical studies indicate product candidates are unsafe or ineffective (including when our product candidates are studied in combination with other compounds), delays or failure to achieve and maintain regulatory approvals for product candidates, risks of collaborating with third parties to discover, develop and commercialize products, risks associated with establishing and maintaining sales, marketing and distribution capabilities.

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 August 5, 2019, and other periodic reports filed with the SEC.

Insight and Innovation in Novel Organ-selective Medicine

TRANSFORMING TREATMENT OF SINGLE ORGAN DISEASES

Application of organ-selective expertise to biologically compelling targets

- Medicines designed to act locally at site of disease, with minimal systemic exposure, to expand therapeutic index
  - Improved efficacy and safety to offer transformational value to payers, patients and HCP's
  - Difficult-to-replicate design characteristics to provide sustainable competitive advantage

Proven development expertise to deliver innovation

- Integrated R&D approach accelerates time to pivotal studies (TD-1473, ampreloxetine)
- Partnerships to complement and expand existing expertise (TD-1473, YUPELRI®)
- Established commercial infrastructure surrounds value proposition (YUPELRI®)

Strong capital position

- Cash of $396M as of June 30, 2019[1]
- Royalties for GSK's TRELEGY ELLIPTA, the first and only once-daily single inhaler triple therapy[2]
- Commercial launch of YUPELRI®, the first and only once-daily nebulized LAMA for treatment of COPD

[1] Cash, cash equivalents, and marketable securities
[2] TBPH holds 85% economic interest in upward-tiering royalty stream of 6.5% – 10% payable by GSK (net of TRC LLC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters).
YUPELRI® (revefenacin) inhalation solution. Approved for the maintenance treatment of patients with COPD. LAMA: long-acting muscarinic antagonist. COPD: chronic obstructive pulmonary disease

Organ-selective Approach

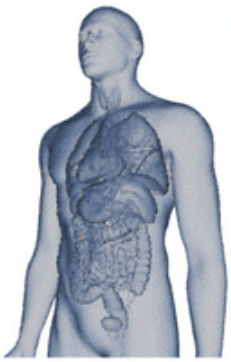
COMPOUNDS DESIGNED TO FULLY HARNESS INTENDED BIOLOGY

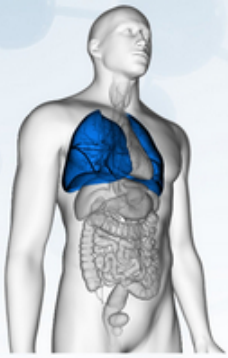
Conventional Systemic Compound

- Often unable to achieve maximal efficacy due to dose limiting safety
- Narrow therapeutic index

Theravance Biopharma Organ-selective Compound

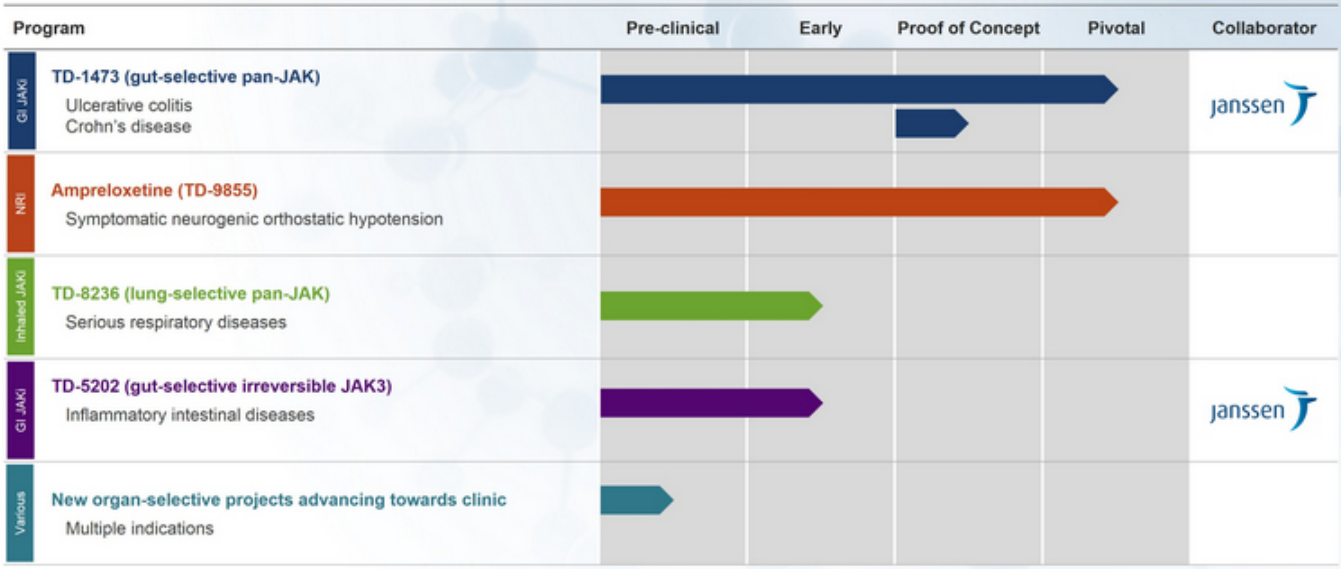
- Opportunity to increase dose for improved efficacy, without cost of systemic safety risk
- Expanded therapeutic index





Illustrated example: lung selectivity

Differentiated Pipeline to Drive Future Growth



Clinical opportunities underpinned by economic interest in TRELEGY ELLIPTA, potential Janssen milestones and YUPELRI® launch

TBPH holds 85% economic interest in upward-tiering royalty stream of 6.5% – 10% payable by GSK (net of TRC LLC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters).
JAKi: Janus kinase inhibitor. NRI: norepinephrine reuptake inhibitor.


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

GSK's TRELEGY ELLIPTA

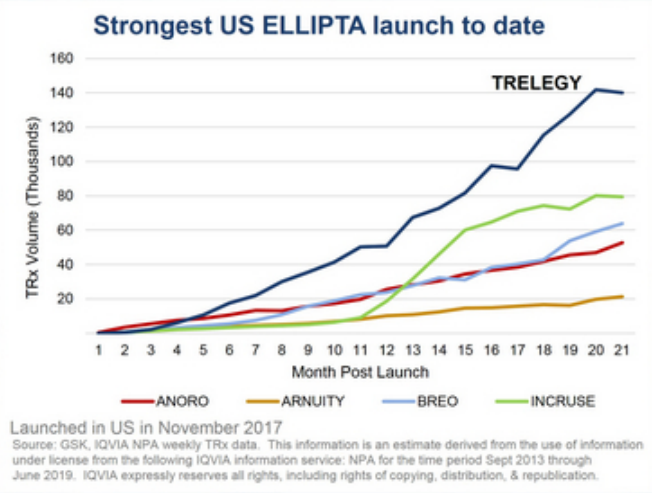
FIRST AND ONLY ONCE-DAILY SINGLE INHALER TRIPLE THERAPY

Economic interest in TRELEGY ELLIPTA

- Upward-tiering royalty of ~5.5% - 8.5% of worldwide net sales[1]
- Passive economic interest; no product cost obligations

Growth continues after first full year on market

- Available in 36 countries, including Japan
- Additional geographies expected 2H19; potential for China approval and launch 4Q19
- sNDA submitted to FDA supporting revised labelling on reduction in risk of all-cause mortality compared with ANORO in patients with COPD
- Phase 3 CAPTAIN study in asthma met primary endpoint; regulatory submissions expected 2H 2019

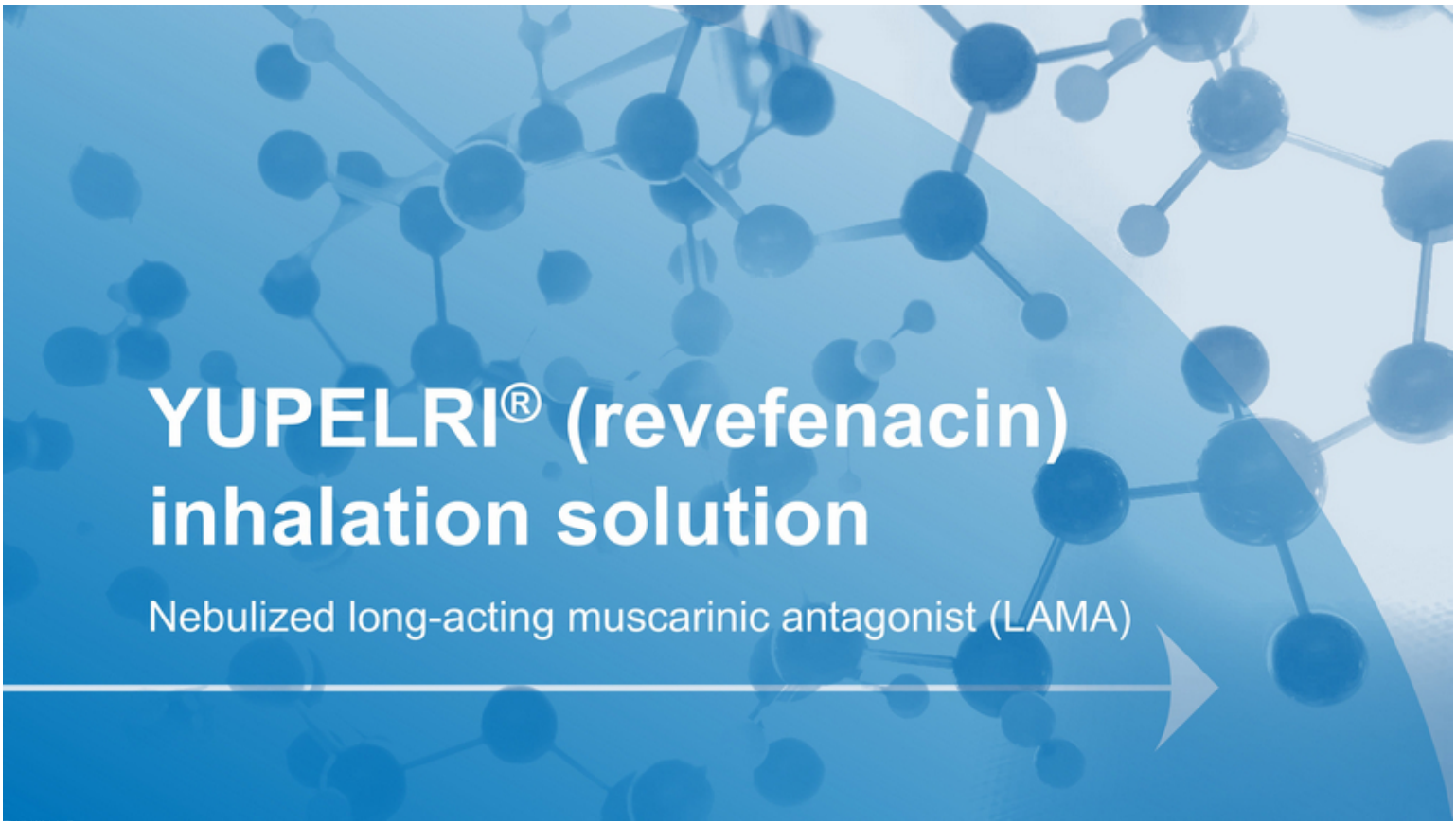


Launched in US in November 2017

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 Sept 2013 through June 2019. IQVIA expressly reserves all rights, including rights of copying, distribution, & republication.

Theravance Biopharma
Medicines That Make a Difference

TRELEGY ELLIPTA is FF/UMEC/VI or fluticasone furoate/umeclidinium/vilanterol; comprised of ICS, LAMA, and LABA, active components of Anoro (UMEC/VI).
[1] TBPH holds 85% economic interest in upward-tiering royalty stream of 6.5% – 10% payable by GSK (net of TRC LLC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters). All statements based on publicly available information.
sNDA: supplemental new drug application


YUPELRI® (revefenacin)
inhalation solution
Nebulized long-acting muscarinic antagonist (LAMA)

YUPELRI®: Formal Commercial Launch Underway

FDA-APPROVED FOR THE MAINTENANCE TREATMENT OF COPD

- *First and only once-daily bronchodilator delivered in a nebulizer*
- *Higher of two doses approved: 175 mcg once daily, for use with any standard jet nebulizer*

Unmet need for nebulized LAMA therapy

- Once-daily LAMAs are first-line therapy for moderate to severe COPD [1]
- No once-daily nebulized LAMAs available previously; only available in handheld devices
- Nebulized therapy associated with reduced hospital readmissions in low PIFR patients [2]

YUPELRI® (revefenacin) inhalation solution. Approved for the maintenance treatment of patients with COPD. COPD = Chronic Obstructive Pulmonary Disease.
[1] Global Strategy for Diagnosis, Management, and Prevention of COPD. [2] Suboptimal Inspiratory Flow Rates Are Associated with COPD and All Cause Readmissions. Loh et al., Annals of ATS 2017.

Compelling Need for Once-Daily Nebulized LAMA

ENDURING PATIENT NICHE AND SIGNIFICANT MARKET OPPORTUNITY

Enduring patient niche

- 9% of COPD patients currently use nebulizers for ongoing maintenance therapy [1]
- >100M patient treatment days in nebulized COPD segment [2]
- 41% of COPD patients use nebulizers at least occasionally for bronchodilator therapy [1]
- Pricing in branded LA nebulized segment ~ 2x handheld Spiriva [2]

Significant market opportunity

- YUPELRI® may be complementary to existing nebulized LABA treatments
- Mylan partnership brings commercial strength in nebulized segment

Theravance Biopharma
Medicines That Make a Difference

[1] TBPH market research (N = 160 physicians); Refers to US COPD patients. [2] IMS Health information service: NSP for period MAT May, 2015. Excludes nebulized SABAs.

Partnership with Mylan Brings Commercial Strength in Nebulized Opportunity

Combined sales infrastructures cover
Hospital, Hospital Discharge and Home Health settings

Targeting HCPs at key intersections in the patient's disease management process

- Hospital is an important site of care for patients with worsening of COPD symptoms
- Theravance Biopharma's established hospital-focused sales force is targeting the inpatient setting
- Theravance Biopharma partners with institutions to transition appropriate patients from hospital to home on YUPELRI®
- Mylan's role is to ensure patients remain on YUPELRI® for maintenance therapy in the outpatient setting

Theravance Biopharma
Medicines That Make a Difference

HD = hospital discharge
HCPs = health care providers

YUPELRI® Launch Update

ENCOURAGING INITIAL MARKET RESPONSE

FORMULARY

42 Wins
(equates to 136 accounts)

~93 Reviews Scheduled
(~405 potential accounts)

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

PATIENT

Field force productivity goals exceeded

~7,000 patients prescribed
(thru 2Q19)

ACCESS

100% Medicare Part B [1]

~46% Commercial

Permanent J-CODE issued
(effective July 1, 2019)

- Majority of YUPELRI® volume flows through durable medical equipment (DME) channel [2]; remaining volume flows through hospitals, retail and long-term care pharmacies
- WAC: $1,030 per month (or ~$34 per day)

Theravance Biopharma
Medicines That Make a Difference

[1] For patients with supplemental insurance
[2] Approximately 3 month lag in data capture

Opportunity for YUPELRI® (revefenacin) in China

POTENTIAL TO ADDRESS LARGE AND UNDERSERVED COPD PATIENT POPULATION

Expansion of development and commercialization agreement

- Mylan granted exclusive development and commercialization rights to nebulized revefenacin in China and adjacent territories
- Theravance Biopharma eligible to receive:
  - $18.5 million upfront payment
  - Up to $54 million in additional potential development and sales milestones
  - Tiered royalties on net sales, if approved
- Mylan responsible for all aspects of development and commercialization in partnered regions

Significant market opportunity

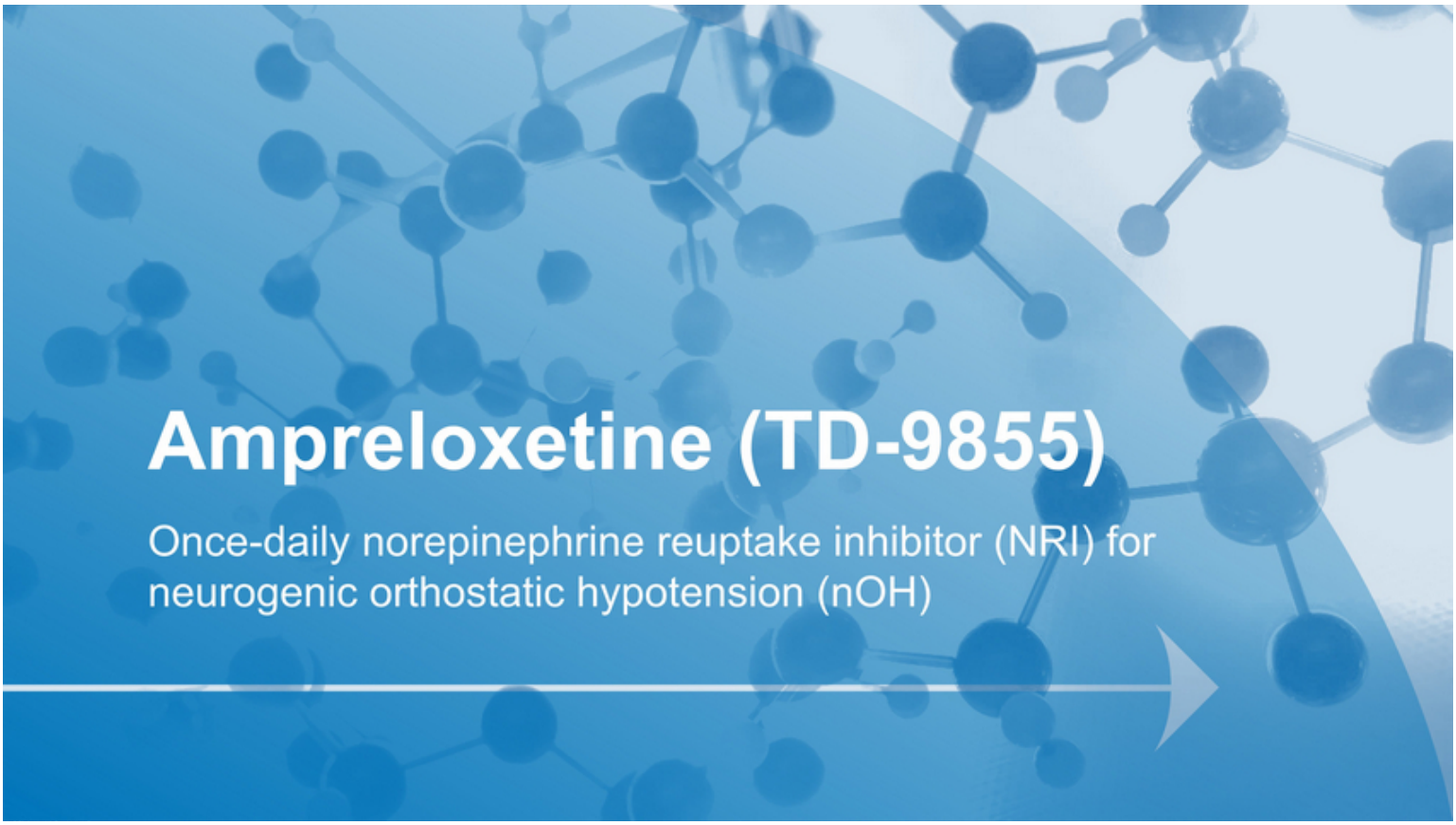
- COPD affects ~100 million individuals in China[1]
- ~43% of COPD patients suffer from moderate to very severe forms of disease[2]
- COPD is one of the top three causes of death in China[3] and presents significant financial burden to healthcare system[2]

Theravance Biopharma and Mylan strategic collaboration

- In 2015, the companies established a strategic collaboration to develop and commercialize nebulized revefenacin products for COPD and other respiratory diseases
  - Theravance Biopharma eligible to receive up to $259 million in potential development and sales milestone payments, as well as profit-sharing arrangement with Mylan on US sales and tiered royalties on ex-US sales
  - Theravance Biopharma retains worldwide rights delivered through other dosage forms, including metered dose inhaler and dry powder inhaler (MDI/PDI)

Theravance Biopharma
Medicines That Make a Difference

[1]C. Wang, J. Xu, L. Yang et al., "Prevalence and risk factors of chronic obstructive pulmonary disease in China (the China Pulmonary Health [CPH] study): a national cross-sectional study," The Lancet, vol. 391, no. 10131, pp. 1706–1717, 2018. [2] Fang L, Gao P, Bao H, et al., "Chronic obstructive pulmonary disease in China: a nationwide prevalence study," Lancet Respir Med 2018; 6: 421–430. [3] Yin P, Wang H, Vos T, et al., "A subnational analysis of mortality and prevalence of COPD in China From 1990 to 2013: Findings from the global burden of disease study 2013," Chest. 2016;150:1269–1280.


Ampreloxetine (TD-9855)
Once-daily norepinephrine reuptake inhibitor (NRI) for neurogenic orthostatic hypotension (nOH)

Symptomatic nOH Represents a Significant Unmet Need

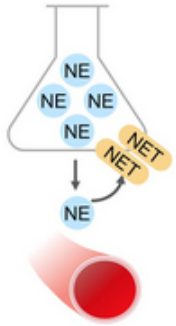
nOH characterized by a sustained drop in blood pressure upon standing, due to body producing insufficient levels of norepinephrine (NE)

- Associated with several autonomic disorders: MSA, PD, PAF
- Symptoms include dizziness, fainting, blurred vision and weakness
- Orphan indication with < 200k patients in US

Opportunity exists for safe and effective treatment

- Only droxidopa (Northera) and midodrine FDA-approved for nOH
- Synthetic exogenous NE analogues impact disease by increasing vascular tone
- Limitations of current therapy: Supine hypertension, TID dosing, patients refractory or discontinue, lack of durability[1]
- Ideal therapy would target durable improvement in symptoms and daily function

Blood pressure key biological driver to nOH symptoms



Vasodilation lowers blood pressure

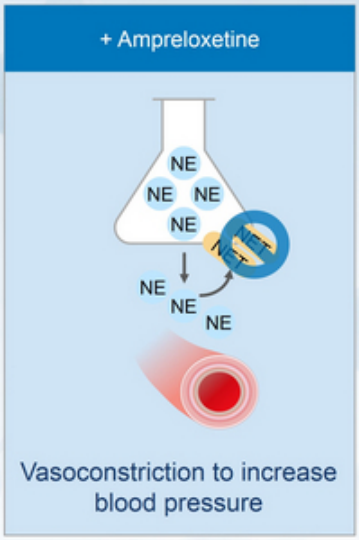
Theravance Biopharma
Medicines That Make a Difference

[1] Existing options associated with one or both therapies noted above; Northera prescribing information.
MSA: multiple system atrophy. PD: Parkinson's disease. PAF: pure autonomic failure. TID: three times per day.

NET Inhibition with Ampreloxetine Offers Potential to Restore Vascular Sympathetic Tone

A path to treating symptomatic nOH without introducing exogenous NE

- Blockade of NET in nOH patients inhibits endogenous neuronal NE uptake
- Increased levels of NE in the synapse cause vasoconstriction and a corresponding increase in blood pressure
- Increase in blood pressure improves symptoms
- Rationale for ampreloxetine in nOH
  - NRI with NE dominance confirmed in humans
  - QD dosing, long half-life, and metabolic profile for potential improved patient outcomes
  - Favorable safety and tolerability profile established in > 500 subjects[1]



Theravance Biopharma
Medicines That Make a Difference

[1] Includes Phase 1 SAD/MAD, elderly, and PET studies in healthy subjects and Phase 2a studies in fibromyalgia and ADHD patients.
NET: norepinephrine transporter. QD: once-daily.

Ampreloxetine: Phase 2 Study in nOH

DESIGNED TO EVALUATE INITIAL AND DURABLE RESPONSE TO THERAPY

Three-part design in patients with nOH:

A
- Single ascending dose portion of ampreloxetine (up to 20 mg)
- Testing blood pressure response to ampreloxetine

B
- Double-blind
- Placebo-controlled
- Single dose (Part A response dose) or placebo

C
- Extension phase
- Open label design
- Up to 24 weeks (20 weeks dosing, 4 week wash out)
- Primary endpoint at 4 weeks

Patients started on Part A, and responders moved to Part B and/or Part C (extension phase)

Purpose: To evaluate the effect of ampreloxetine in improving blood pressure and key nOH symptoms

Part C: Responders in Part A eligible for open-label treatment for up to 5 months

- Designed to assess durability of effect
- Primary assessment at four weeks (Day 29)
- Efficacy evaluations: OHSA[1] #1, standing time duration, standing systolic blood pressure
- Also assessed safety and pharmacokinetics of ampreloxetine

[1] OHSA: Orthostatic Hypotension Symptom Assessment. OHSA #1 measures dizziness (cardinal symptom of nOH), lightheadedness, feeling faint, or feeling of impending black out.

Top-line Phase 2 Results in nOH

PARTS A and B: SINGLE ASCENDING DOSE, AMPRELOXETINE OR PLACEBO

A Initial responses observed

Responses reported in majority of patients treated

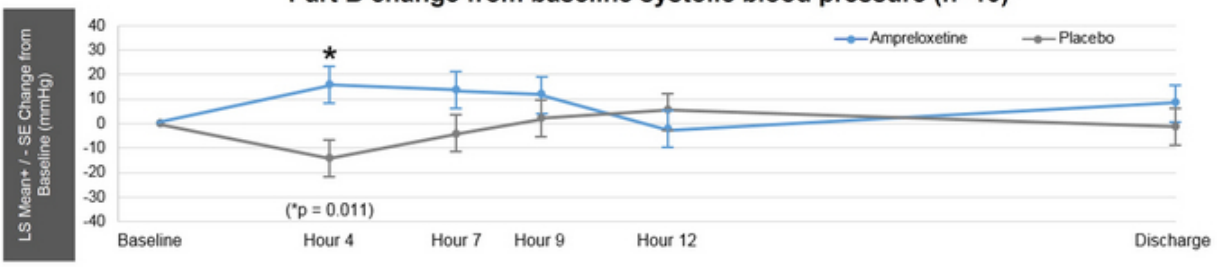
- 27 of 34 patients enrolled in Part A showed improvements in SBP and/or standing time
- Responses observed above 5 mg

B Confirmation vs. placebo

Statistically significant difference of 30 mmHg at 4 hours post-dose (p = 0.011)

- Ampreloxetine increased SBP from a low baseline
- SBP dropped on placebo during day as expected, due to postural changes and eating
- No evidence of supine hypertension with ampreloxetine overnight

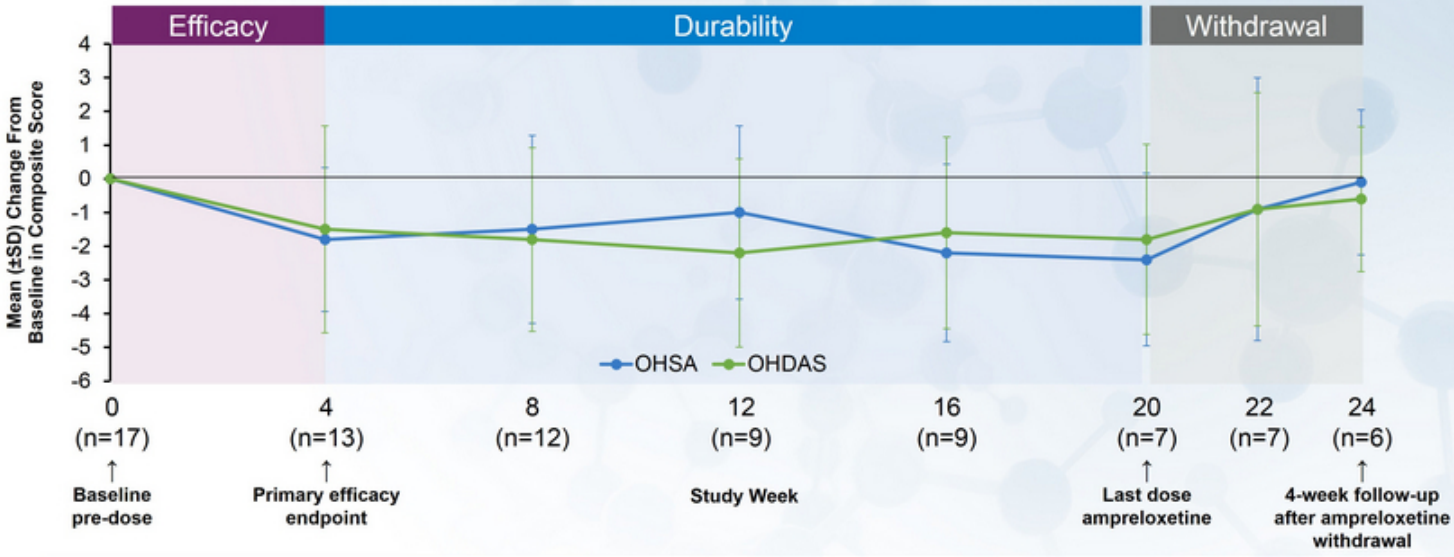
Part B change from baseline systolic blood pressure (n=10)



SBP: systolic blood pressure.

Ampreloxetine: Phase 2 Results in nOH

PART C: MEAN CHANGE FROM BASELINE IN OHSA AND OHDAS COMPOSITE SCORES (SYMPTOMATIC SUBJECTS[1])



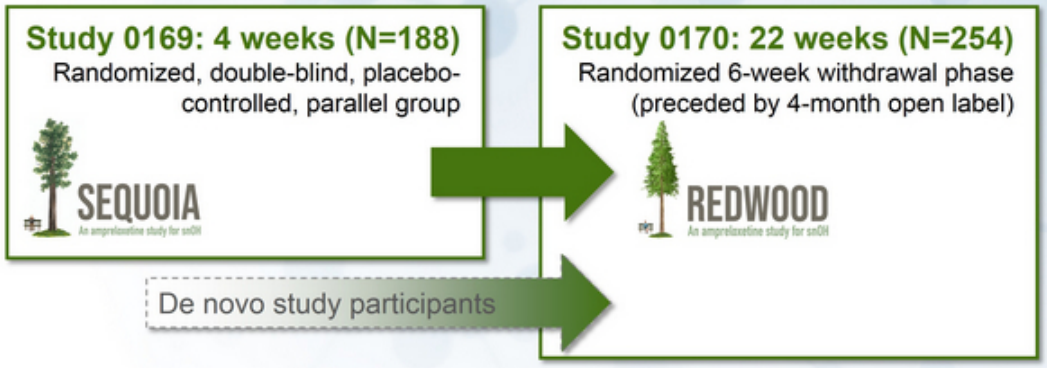
Durable improvements in symptom severity and daily activity sustained out to 20 weeks

Theravance Biopharma
Medicines That Make a Difference

[1]Baseline OHSA #1 >4 points. Kaufman, et. al. ENC. 2019.
Negative change indicates improvement.
OHDAS, Orthostatic Hypotension Daily Activity Scale; OHSA, Orthostatic Hypotension Symptom Assessment.

Ampreloxetine Clinical Program

PHASE 3 REGISTRATIONAL PROGRAM IN SYMPTOMATIC NOH



Phase 2 data supportive of ongoing Phase 3 program; Phase 3 4-week efficacy data expected 2H 2020


TD-1473 JAK Inhibitor Program
Oral gut-selective pan-Janus kinase (JAK) inhibitor for ulcerative colitis and other inflammatory intestinal diseases

Differentiated and Potential Breakthrough Approach

ADVANCING IN COLLABORATION WITH JANSSEN IN UC AND CROHN'S

TD-1473 program objectives: Oral pan-JAK inhibitor that distributes selectively throughout the intestines to treat inflammatory intestinal disease locally, with minimal systemic exposure or corresponding immunosuppressive effects, to enhance safety and efficacy

Encouraging Phase 1b study in UC patients

- Data demonstrated localized biological target engagement with minimal systemic exposure
- Clinical responses after only 4 weeks of therapy

Preclinical models of UC confirmed

- Improvements in diseases scores, local absorption and penetration of TD-1473 throughout intestinal tract

Phase 2 in Crohn's progressing and Phase 2b/3 study in UC underway

- FDA and EMA concur on Phase 2b/3 study design in ulcerative colitis

Encouraging Findings in Phase 1b Study

4-WEEK TREATMENT IN 40 PATIENTS WITH ULCERATIVE COLITIS

Key Findings

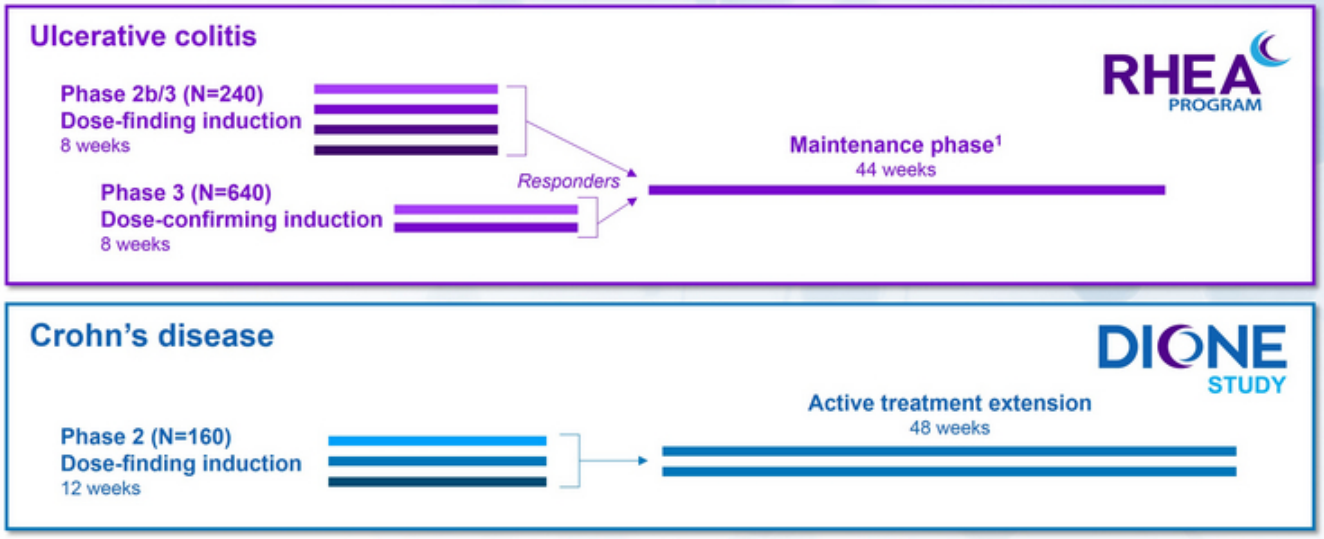
Favorable overall safety and tolerability	No systemic or opportunistic infections (including herpes zoster)
	No evidence of reduce white cell counts
Minimal systemic exposure	Plasma levels of TD-1473 very low
	Consistent in all cohorts with levels observed in healthy volunteers
Biologic activity in GI tract	**Endoscopic improvements and mucosal healing** reported in all active arms; none reported in placebo arm
	Rectal bleeding scores improved above placebo at highest two doses
	Rates of **clinical response** higher for all active doses compared to placebo[1]
	Clinical responses matched by **dose-dependent reductions in surrogate biomarkers**[2]
	Dose-related increases in local GI tissue drug concentrations; higher two doses produced mean concentrations above JAK IC50

Encouraging Phase 1b data and preclinical package including daily dose administration for 6 & 9 months

[1] Clinical response as measured by both partial and full Mayo.
[2] Surrogate biomarkers include C-reactive protein (CRP) and fecal calprotectin.

TD-1473: Gut-selective oral JAK inhibitor

LATE STAGE STUDIES IN ULCERATIVE COLITIS AND CROHN'S DISEASE



Phase 2b/3 study in UC and Phase 2 study in CD progressing; data planned late-2020

[1] Maintenance phase of the study will have induction responder subjects re-randomized to active doses compared to placebo at 44 weeks

Global Collaboration Agreement for TD-1473

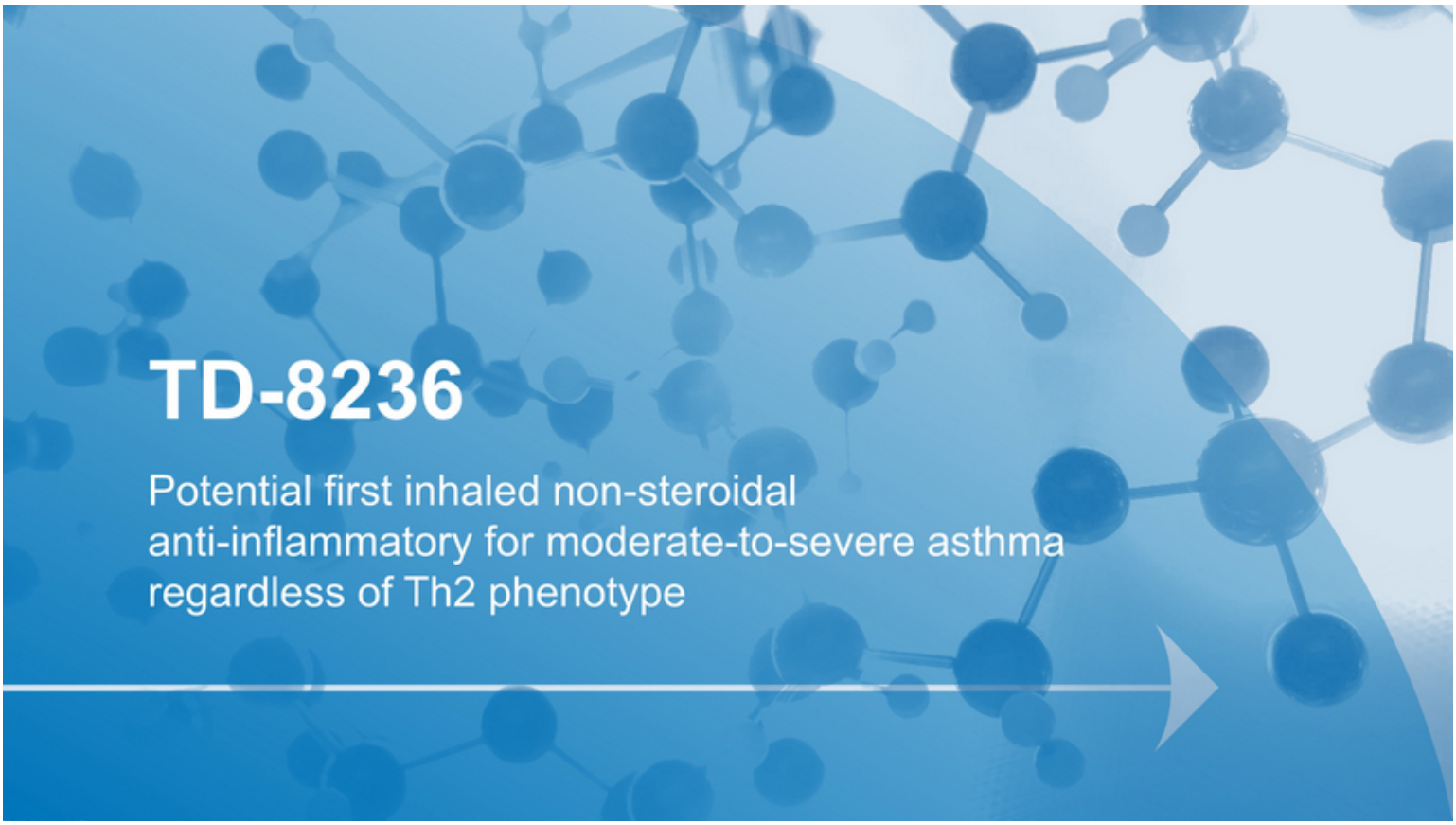
PURPOSED TO MAXIMIZE VALUE OF PROGRAM

Theravance Biopharma
Medicines That Make a Difference®

janssen

- Shared belief in TD-1473 as gut-selective with potential to transform the treatment landscape in inflammatory intestinal disease
- Meaningful program enhancements
  - Accelerate clinical development and advance UC and Crohn's in parallel
  - Apply Janssen expertise in IBD to optimize clinical strategy and execution
  - Maximize worldwide commercial opportunity
- Attractive deal economics reducing overall financial risk
  - Deal value up to $1B milestones, including $100M upfront; additional profit-share in US

Collaboration with global leader in immunology represents milestone for TD-1473, our internally discovered pipeline and strategy to design organ-selective medicines


TD-8236
Potential first inhaled non-steroidal
anti-inflammatory for moderate-to-severe asthma
regardless of Th2 phenotype

High Medical and Economic Burden in Uncontrolled Asthma

Patient population

- 4.9M moderate-to-severe diagnosed patients in US[1]

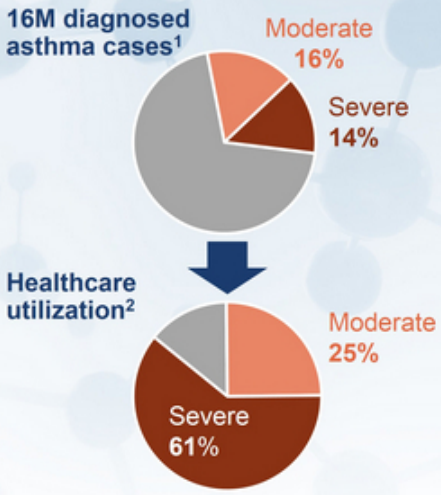
Current treatments

- Inhaled steroids, which often fail to control disease
- Approved biologics affect subsets of patients

Burden of disease

- Acute exacerbations lead to ER visits
- Uncontrolled symptoms interfere with ability to sleep, work and QOL
- US medical costs estimated to be $58B[3]
- Disproportionate healthcare utilization by severe and uncontrolled asthmatics
  - High frequency of hospitalizations and increased use of systemic medications

Small portion of US patients cause high proportion of cost

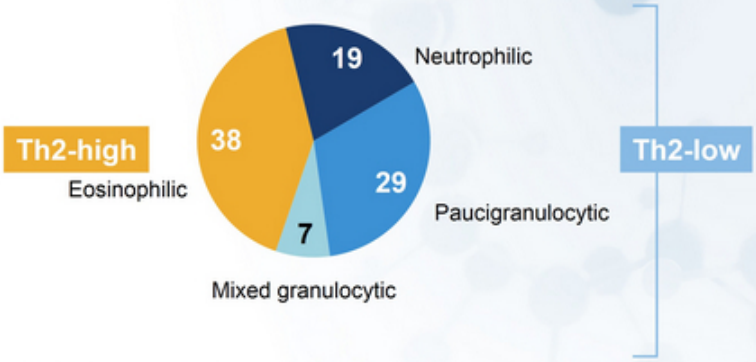


[2] Sadatsafavi, M., et al. Can Respir J, 2010 17(2): 74-80.
[3] Nurmagambetov, T., et al., Ann Am Thorac Soc. 2018 15(3): 348-356.

TD-8236: Lung-selective Inhaled pan-JAK Inhibitor

POTENTIAL TO ADDRESS PATIENTS NEEDS REGARDLESS OF TH2 PHENOTYPE

Patient heterogeneity in severe asthma[1]



JAK/STAT cytokines implicated in severe asthma

Th2-high	Th2-low
IL-4	**IL-23**/IL-12
IL-13	**IL-6**
IL-5	IL-27
TSLP	IFN-γ

Bold denotes biologics in development or approved

TD-8236 shown to potently inhibit targeted mediators of Th2-high and Th2-low asthma in human cells in preclinical studies

- Novel approved biologics address only Th2-high asthma
- Key treatment needs: Prevention of exacerbations and symptom control for patients regardless of Th2 phenotype

Phase 1 data in healthy volunteers and asthmatics (including biomarker measures) expected September 2019

[1] Simpson JL, et al. Resp 2006;11:54-61.

TD-8236: Phase 1 Clinical Trial Design

PART A

SAD (Healthy volunteers)
Safety and PK

PART B

MAD (Mild asthmatics)
Safety, PK, and PD (FeNO)

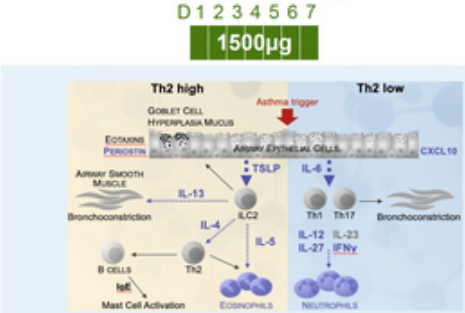
PART C

MoA Biomarkers
(Moderate-to-severe asthmatics)

All cohorts: N = 6 active/2 Placebo

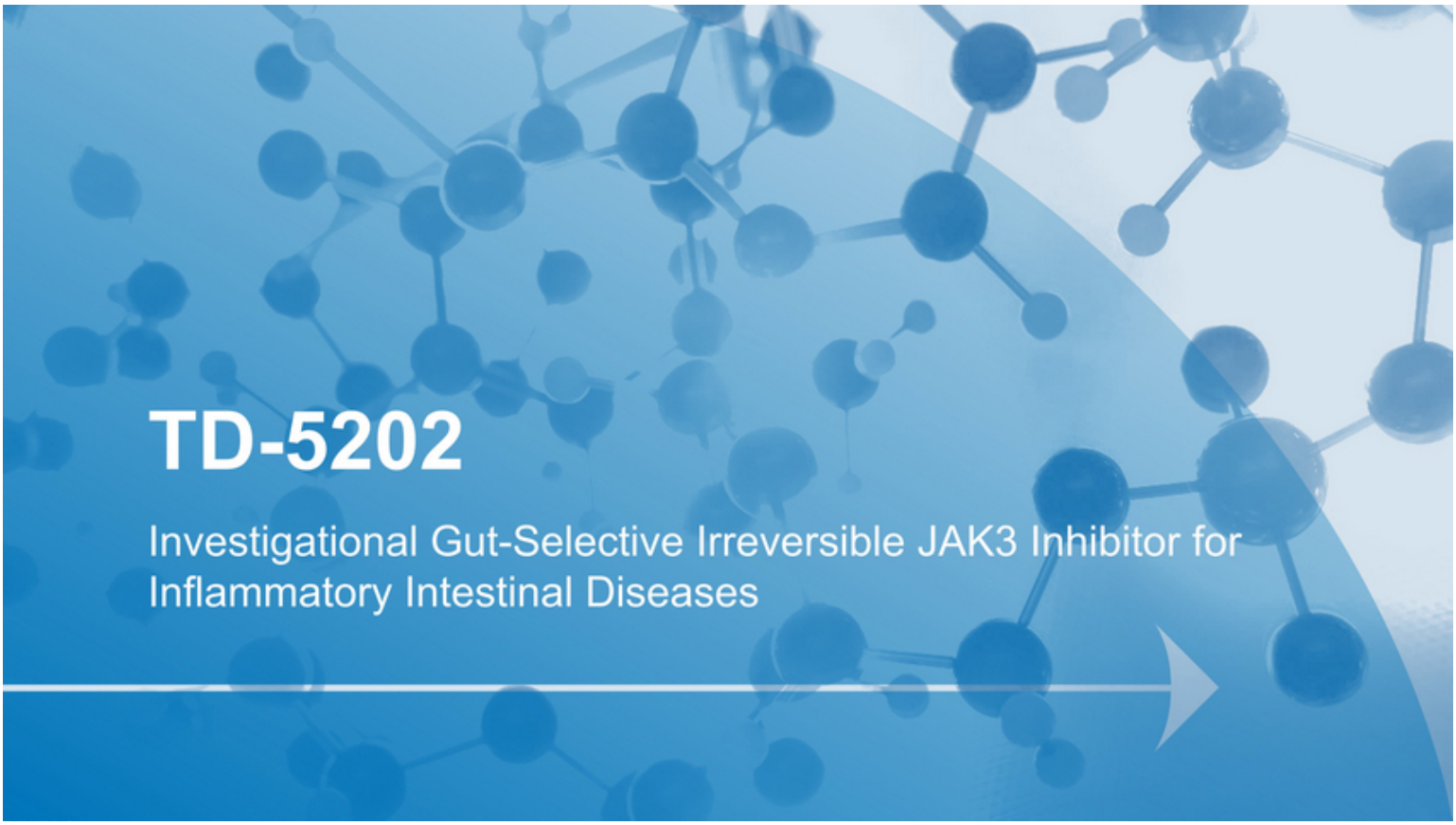
Results September 2019

N = 16 active/8 Placebo
Study open and enrolling

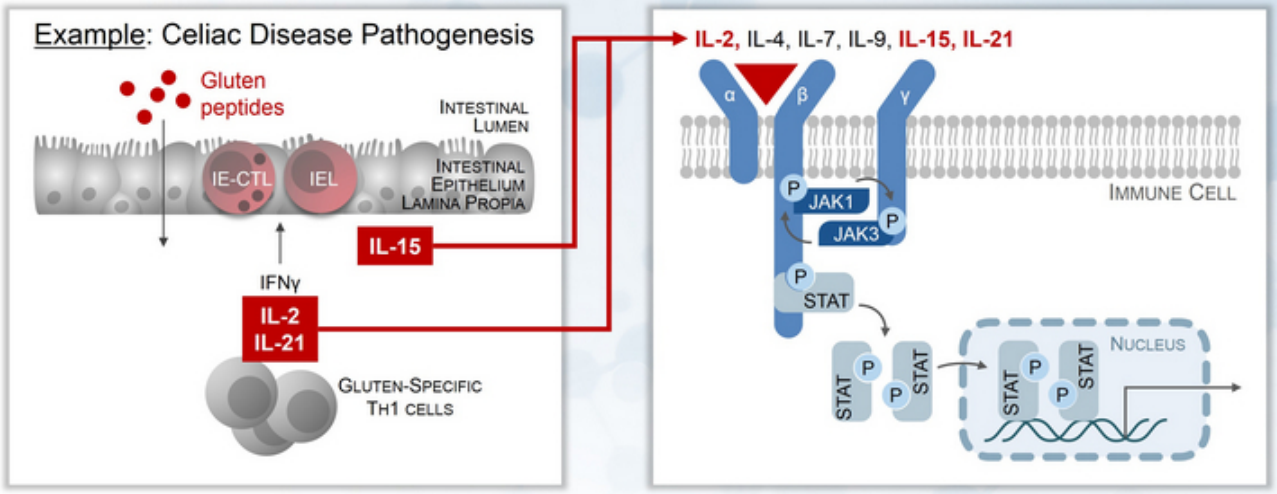


- MoA biomarkers to be assessed in target patient population
- Goal: to build confidence in compound, MoA & dose during early development

FeNO, fractional exhaled nitrous oxide.


TD-5202
Investigational Gut-Selective Irreversible JAK3 Inhibitor for
Inflammatory Intestinal Diseases

JAK3-Dependent Cytokines Play Central Role in Pathogenesis of T-cell Mediated Disease



- Proof-of-relevance from positive Phase 2 data with systemic JAK3 inhibitor in alopecia areata, a T-cell mediated disease[1]
- Localized JAK3 inhibition important to avoid systemic immunosuppression (genetic JAK3 deficiency leads to severe immunodeficiency)

Theravance Biopharma
Medicines That Make a Difference

IE-CTL, intraepithelial cytotoxic lymphocyte; IEL, intraepithelial lymphocyte.
Figure adapted from Jabri B and Sollid L. J Immunol 2017;198:3005-14.
[1] Phase 2a study of PF-06651600.

Unique among JAK family, JAK3 has cysteine residue allowing for JAK3-selective irreversible inhibitor

Allows covalent bond with inhibitor

Potential benefits include:

- Binding specificity
- Irreversible inhibition resulting in longer duration of action

JAK3 Selectivity

	PBMC IC_{50} (nM)	
	IL-2 pSTAT5	IL-10 pSTAT3
JAK Pairing	JAK1/3	JAK1/TYK2
Tofacitinib	25	56
TD-5202	100	>10000

Phase 1 study of TD-5202 in healthy volunteers underway


Opportunities for Value
Creation

Focus on Strategic Priorities

COMMITMENT TO CREATING TRANSFORMATIONAL MEDICINES

Opportunities to Create Transformational Medicines	YUPELRI®	Nebulized LAMA in COPD • U.S. commercial launch underway
	TD-1473	Gut-selective oral JAK inhibitor for inflammatory intestinal diseases • Phase 2b/3 RHEA study in ulcerative colitis ongoing; Phase 2b data planned late-2020 • Phase 2 DIONE study in Crohn's disease ongoing; data planned late-2020
	Ampreloxetine	NRI in symptomatic neurogenic orthostatic hypotension (nOH) • Registrational Phase 3 program progressing; 4-week efficacy data expected 2H 2020
	TD-8236	Lung-selective inhaled pan-JAK inhibitor for serious respiratory diseases • Safety and biomarker data from Phase 1 study in healthy volunteers and asthmatics expected Sep-19
	TD-5202	Gut-selective oral irreversible JAK3 inhibitor for inflammatory intestinal diseases • Phase 1 study in healthy subjects underway
	Research	Organ-selective research platform designed to expand therapeutic index compared to conventional systemic therapies
Economic Interest	TRELEGY ELLIPTA[1]	Single inhaler triple therapy in COPD • Product launched in 36 countries, including Japan; China approval expected 4Q19 • sNDA submitted to FDA supporting revised labelling on reduction in risk of all-cause mortality compared with ANORO ELLIPTA in patients with COPD • Potential sNDA for asthma indication in 2H 2019

Key programs drive near- and long-term value-creating events

TRELEGY ELLIPTA is FF/UMEC/VI or fluticasone furoate/umeclidinium/vilanterol; comprised of ICS, LAMA, and LABA, active components of Anoro (UMEC/VI).
[1] TBPH holds 85% economic interest in upward-tiering royalty stream of 6.5% – 10% payable by GSK (net of TRC LLC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters). All statements based on publicly available information.

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.[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.

[1] TBPH market research (N = 160 physicians); refers to US COPD patients

YUPELRI® (revefenacin) inhalation solution

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.