

Theravance Biopharma, Inc. (NASDAQ: TBPH)

Investor Presentation

November 2019



Medicines That Make a Difference®

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.

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

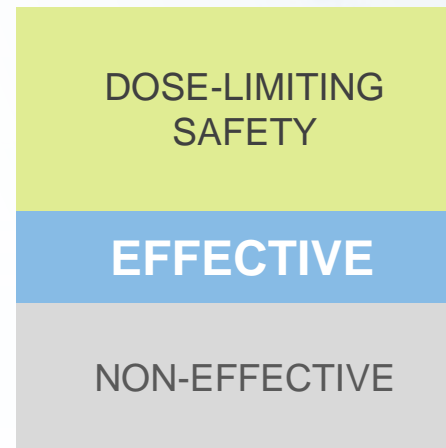
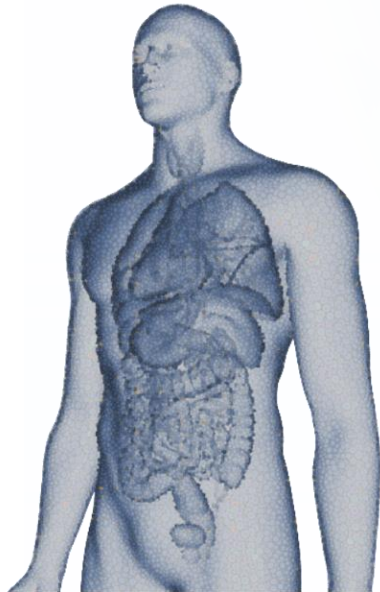
- ▶ Cash of \$353M as of September 30, 2019¹
- ▶ Economic interest in royalties for GSK's TRELEGY ELLIPTA, the first and only once-daily single inhaler triple therapy²
- ▶ Commercial launch of YUPELRI®, the first and only once-daily nebulized LAMA for treatment of COPD

Organ-selective Approach

COMPOUNDS DESIGNED TO FULLY HARNESS INTENDED BIOLOGY

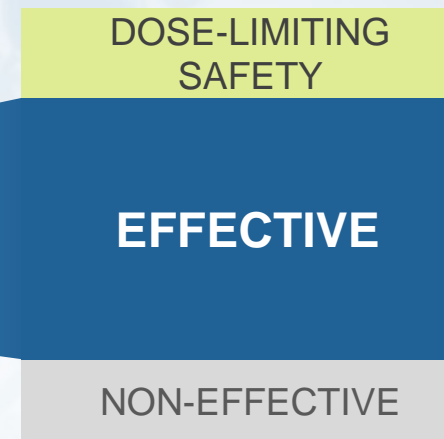
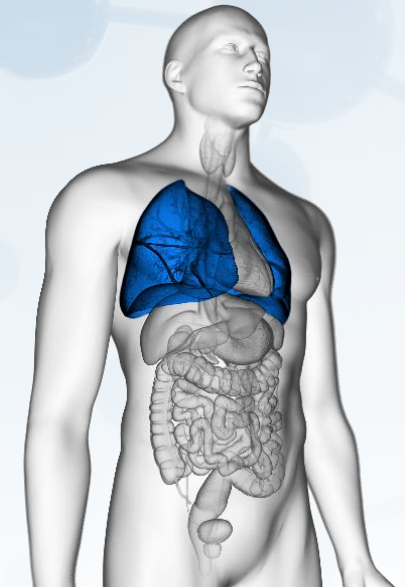
Conventional Systemic Compound

- ▶ 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

Program	Pre-clinical	Early	Proof of Concept	Pivotal	Collaborator
GI JAKI TD-1473 (gut-selective pan-JAK) Ulcerative colitis Crohn's disease					
NRI Ampreloxetine (TD-9855) Symptomatic neurogenic orthostatic hypotension					
Inhaled JAKI TD-8236 (lung-selective pan-JAK) Inflammatory lung diseases					
GI JAKI TD-5202 (gut-selective irreversible JAK3) Inflammatory intestinal diseases					
Various New organ-selective projects advancing towards clinic Multiple indications					

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



Economic Interest

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

GSK's TRELEGY ELLIPTA

FIRST AND ONLY ONCE-DAILY SINGLE INHALER TRIPLE THERAPY

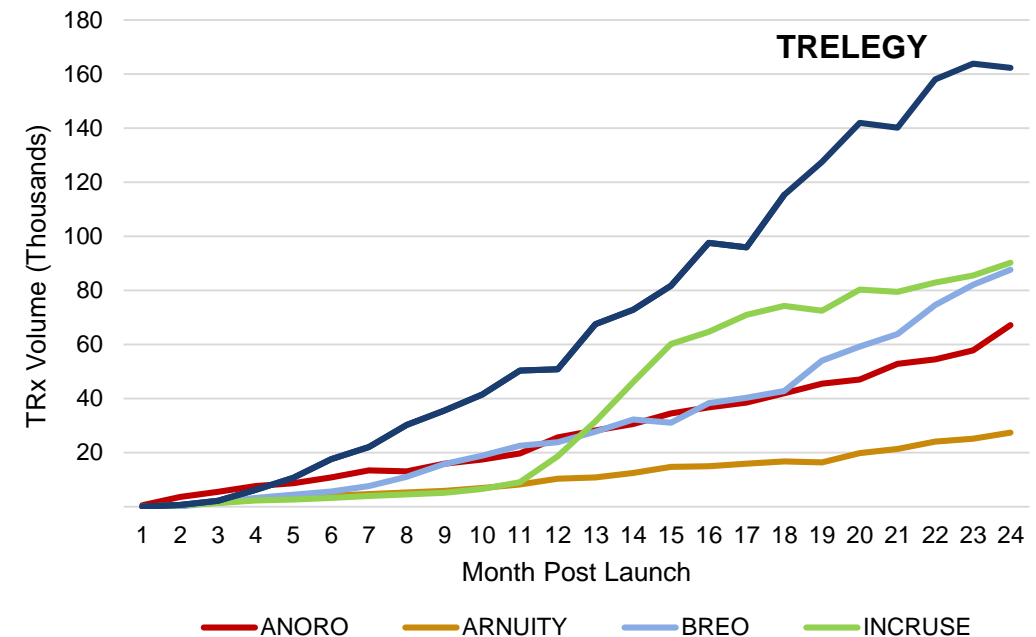
Economic interest in TRELEGY ELLIPTA

- ▶ Upward-tiering royalty payments of approximately 5.5% - 8.5% of worldwide net sales¹
- ▶ Passive economic interest; no product cost obligations

Growth continues after first full year on market

- ✓ Prescriptions achieved ~31% share of COPD market
- ✓ Available in 38 markets, including Japan
- ✓ China launch expected 4Q19
- ✓ sNDA submitted to FDA supporting revised labelling on reduction in risk of all-cause mortality compared with ANORO in patients with COPD
- ✓ sNDA submitted to FDA for use in asthma

Strongest U.S. ELLIPTA Launch to Date



Launched in U.S. 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.



YUPELRI[®] (revefenacin) inhalation solution

Nebulized long-acting muscarinic antagonist (LAMA)



YUPELRI®: Commercial Launch Underway

FDA-APPROVED FOR THE MAINTENANCE TREATMENT OF COPD

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

Enduring patient niche

- ▶ 9% of COPD patients use nebulizers for ongoing maintenance therapy ³
- ▶ >100M patient treatment days in nebulized COPD segment ⁴
- ▶ 41% of COPD patients use nebulizers at least occasionally for bronchodilator therapy ³
- ▶ Pricing in branded LA nebulized segment ~ 2x handheld Spiriva ⁴

Significant market opportunity

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



First and only once-daily nebulized bronchodilator

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

YUPELRI[®] Launch Update

ENCOURAGING INITIAL MARKET RESPONSE

FORMULARY

70 Wins

(equates to 196 accounts)

~60 Reviews Scheduled
(>300 potential accounts)

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

PATIENT

Field force productivity goals
exceeded

~21,000 patients prescribed
(*thru Q3 2019*)

ACCESS

100% Medicare Part B ¹

~50% 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)

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 received \$18.5 million upfront payment and eligible to receive:
 - Up to \$54 million in 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 China¹
- ▶ ~43% of COPD patients suffer from moderate to very severe forms of disease²
- ▶ COPD is one of the top three causes of death in China³ and presents significant financial burden to healthcare system²

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)

The background of the slide features a complex molecular structure, likely representing a chemical compound, rendered in shades of blue and white. The structure consists of numerous interconnected spheres (atoms) and lines (bonds), creating a dense, three-dimensional network. The overall color palette is a gradient of blues, from light to dark, with a prominent diagonal line separating the lighter upper right from the darker lower left.

Ampreloxetine (TD-9855)

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

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Symptomatic nOH Represents a Significant Unmet Need

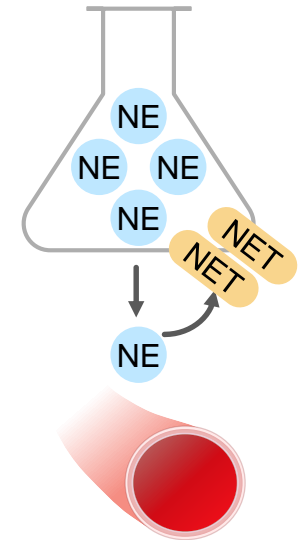
nOH characterized by a sustained drop in blood pressure upon standing, due to body producing insufficient levels of norepinephrine (NE)

- ▶ 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 durability¹
- Ideal therapy would target durable improvement in symptoms and daily function

Blood pressure key biological driver to nOH symptoms

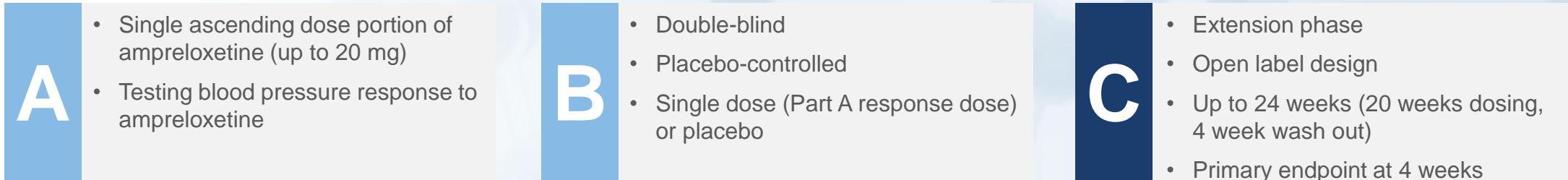


Vasodilation lowers blood pressure

Amprexetine: Phase 2 Study in nOH

DESIGNED TO EVALUATE INITIAL AND DURABLE RESPONSE TO THERAPY

Three-part design in patients with nOH:



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

Purpose: To evaluate the effect of amprexetine 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: OHSA¹ #1, standing time duration, standing systolic blood pressure
- ▶ Also assessed safety and pharmacokinetics of amprexetine

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

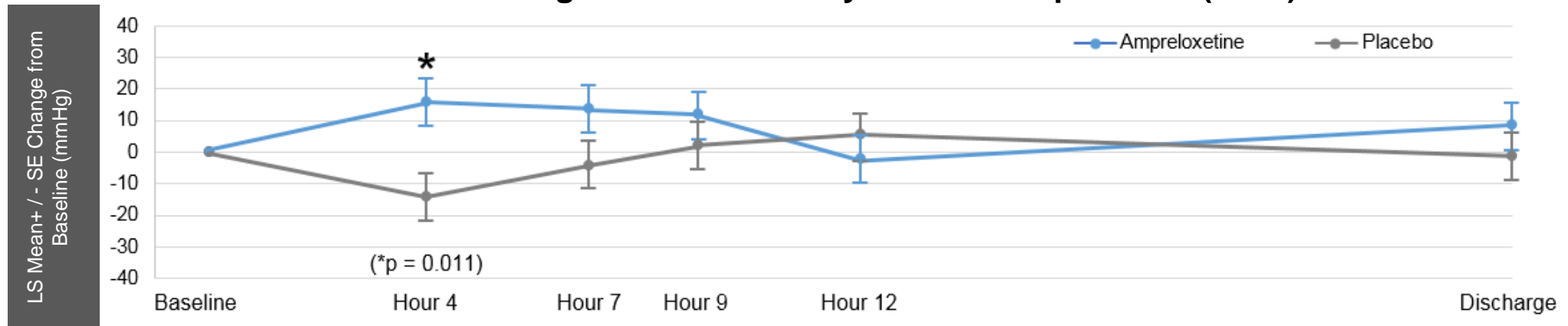
B

Confirmation vs. placebo

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

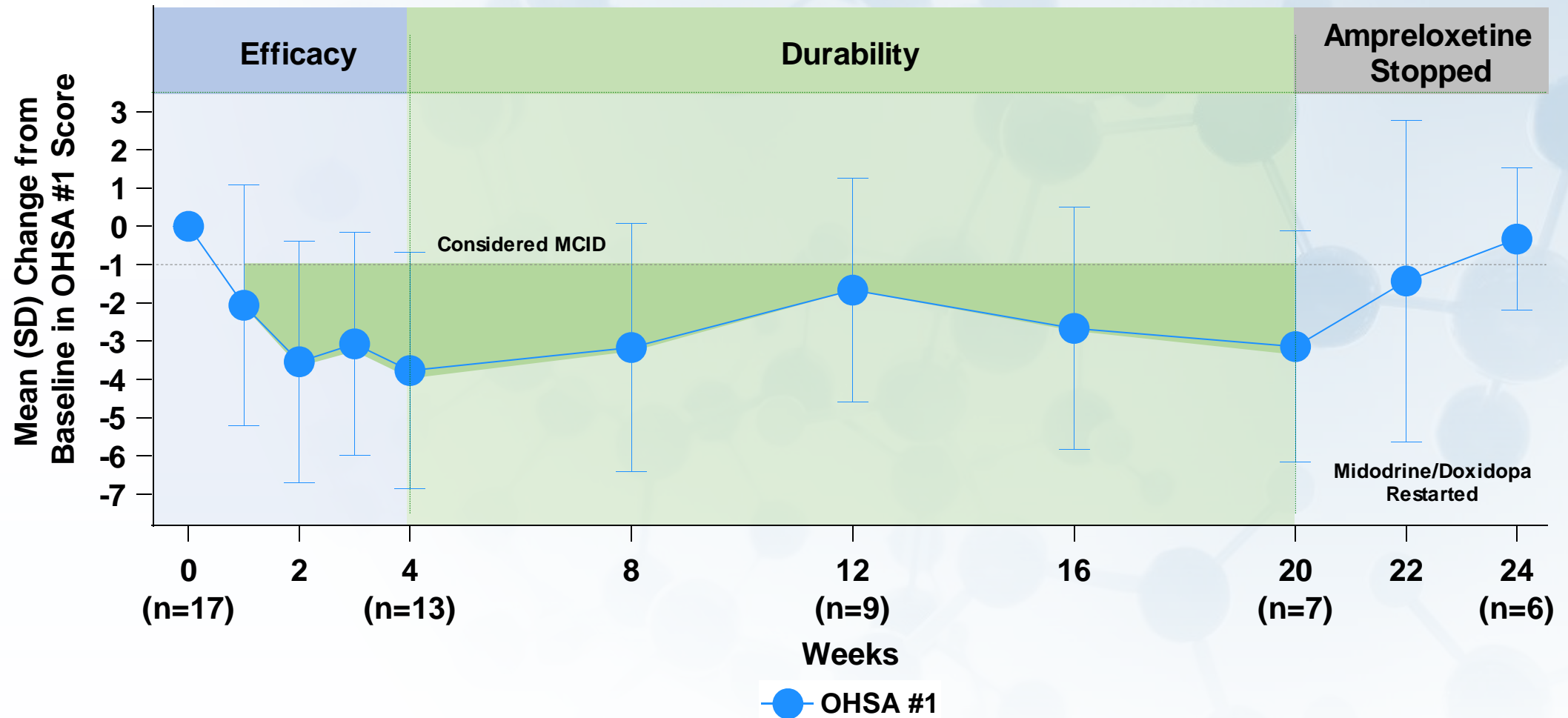
- ▶ Amprexetine increased SBP from a low baseline
- ▶ SBP dropped on placebo during day as expected, due to postural changes and eating
- ▶ No evidence of supine hypertension with amprexetine overnight

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



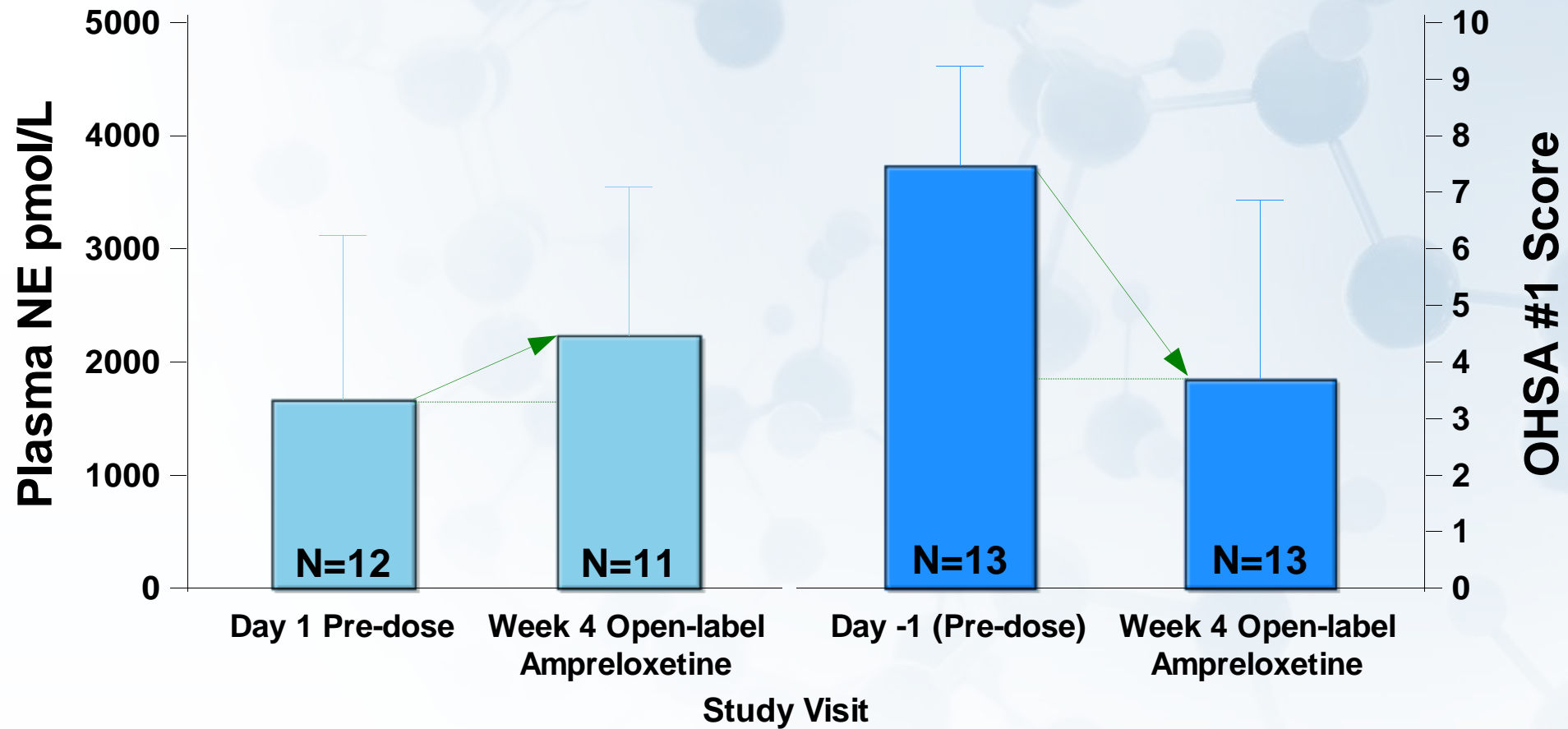
Ampreloxetine: Phase 2 Results in nOH

MEAN CHANGE FROM BASELINE IN OHSA #1 (SYMPTOMATIC SUBJECTS¹)



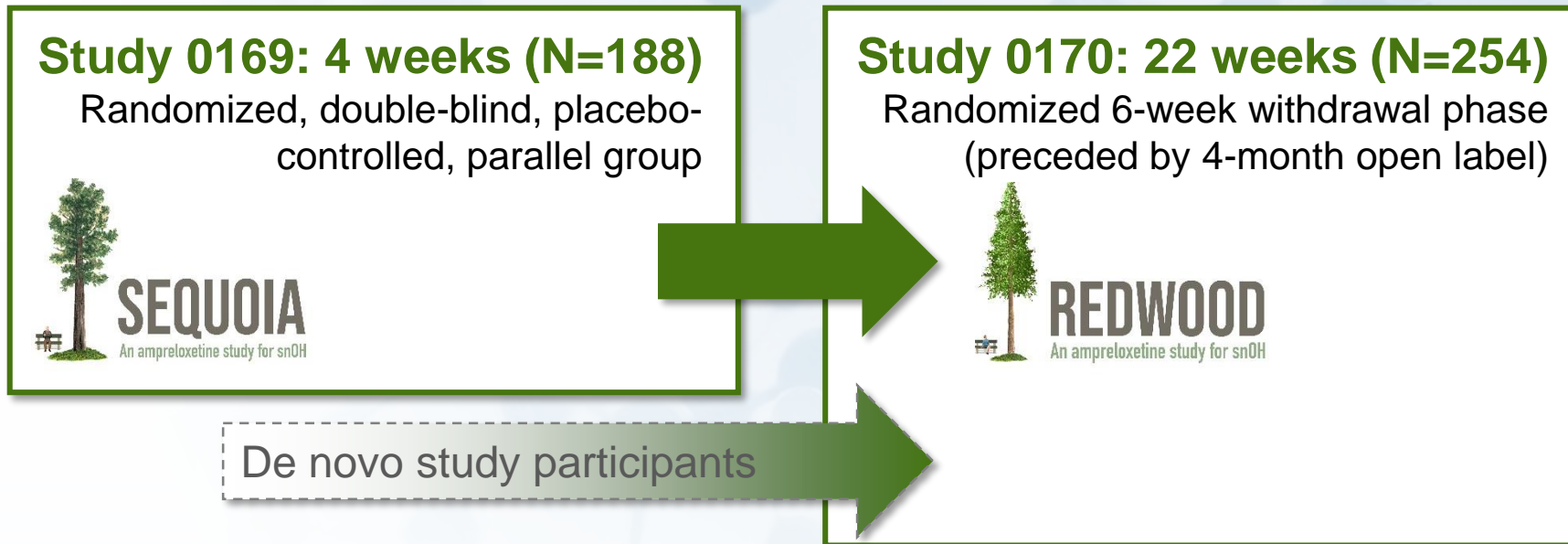
Amprexetine: Phase 2 Results in nOH

NOREPINEPHRINE PLASMA LEVELS & OHSA #1 IN SYMPTOMATIC PATIENTS



Amprexetine: Norepinephrine Reuptake Inhibitor (NRI)

PHASE 3 REGISTRATIONAL PROGRAM IN SYMPTOMATIC NOH



Phase 2 data supportive of ongoing Phase 3 program; Phase 3 4-week efficacy data expected 2H20

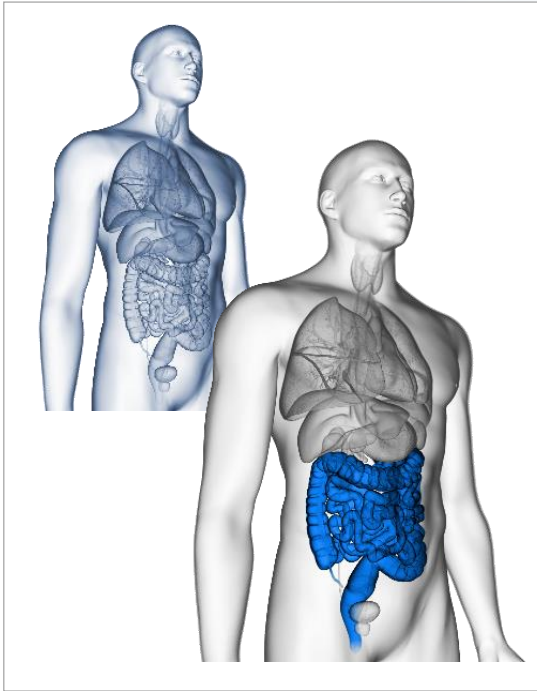
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TD-1473 JAK Inhibitor Program

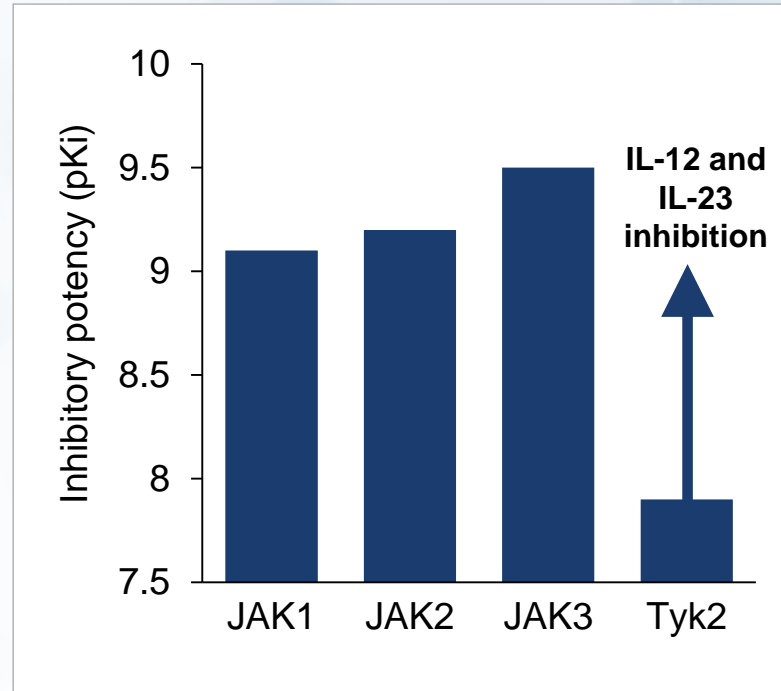
Oral gut-selective pan-Janus kinase (JAK) inhibitor for
ulcerative colitis and other inflammatory intestinal diseases

TD-1473 Research Vision

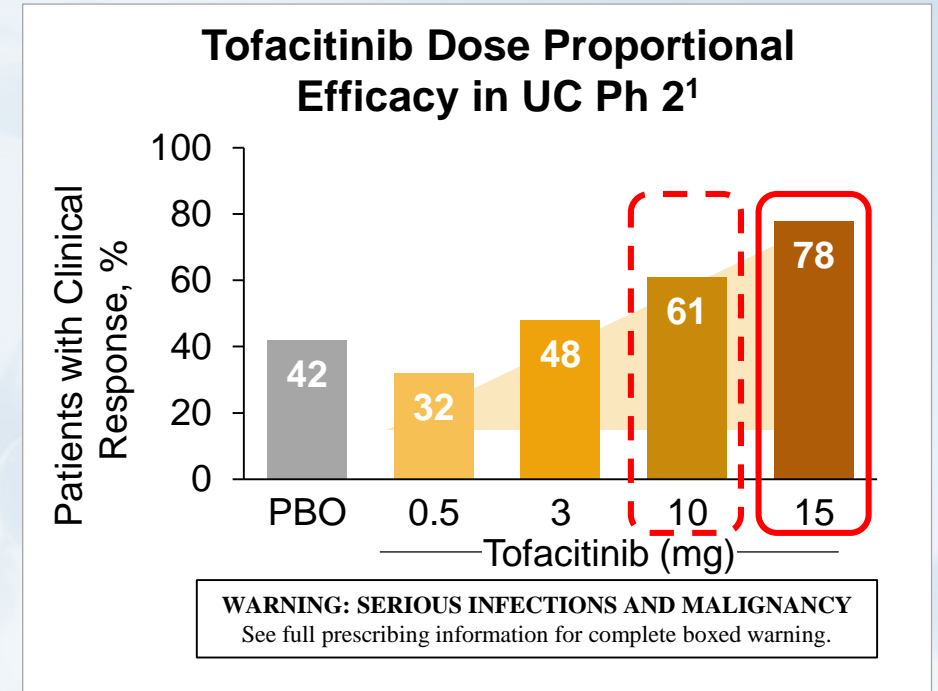
ORGAN-SELECTIVE APPROACH DESIGNED TO EXPAND THERAPEUTIC INDEX



Treat disease at site to maximize efficacy



Optimize pharmacology to include potent inhibition of Tyk2



Improve upon the efficacy of a clinically validated target

Encouraging 4-week exploratory Phase 1b data reported in UC patients;
plus robust preclinical tox package (including daily dose administration for 6 and 9 months)

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

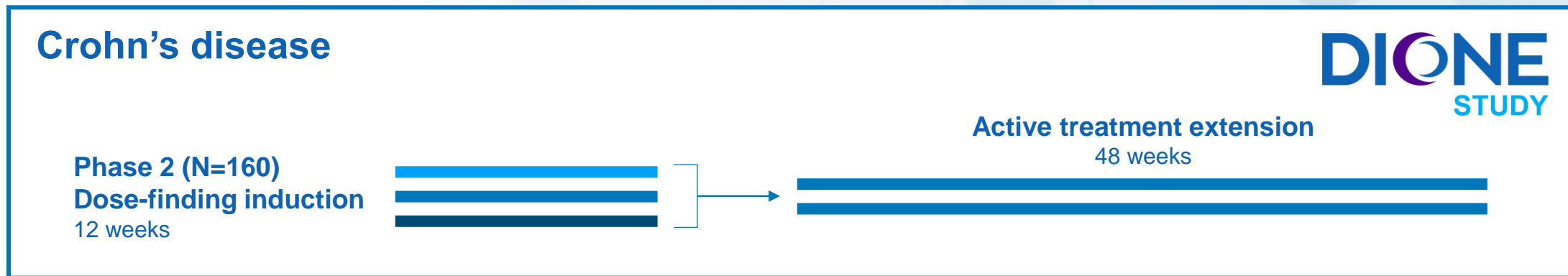
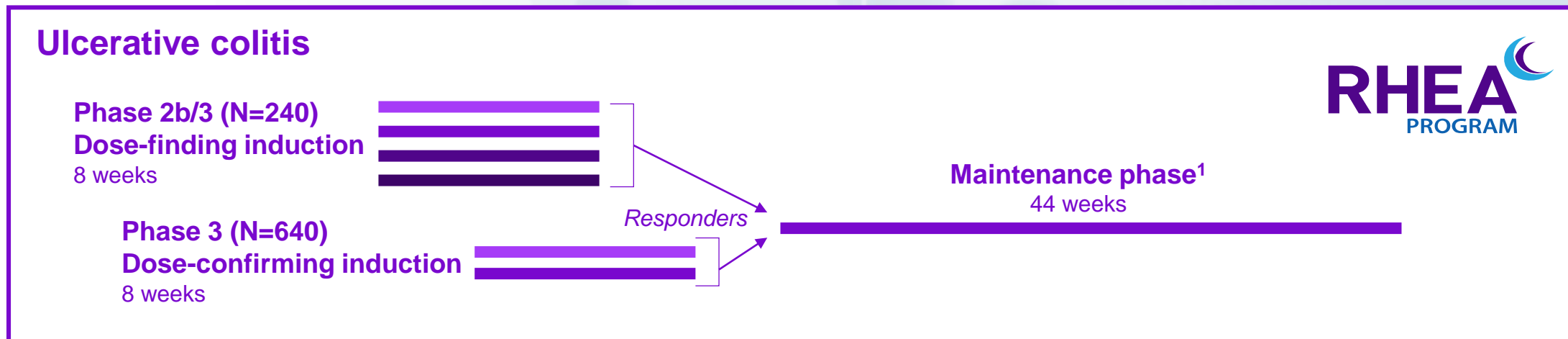
4-WEEK TREATMENT IN 40 PATIENTS WITH ULCERATIVE COLITIS

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

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

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 pan-JAK inhibitor with potential to transform the treatment landscape in inflammatory intestinal diseases
- ▶ 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

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TD-8236

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

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High Medical and Economic Burden in Uncontrolled Asthma

Patient population

- ▶ 4.9M moderate-to-severe diagnosed patients in US¹

Current treatments

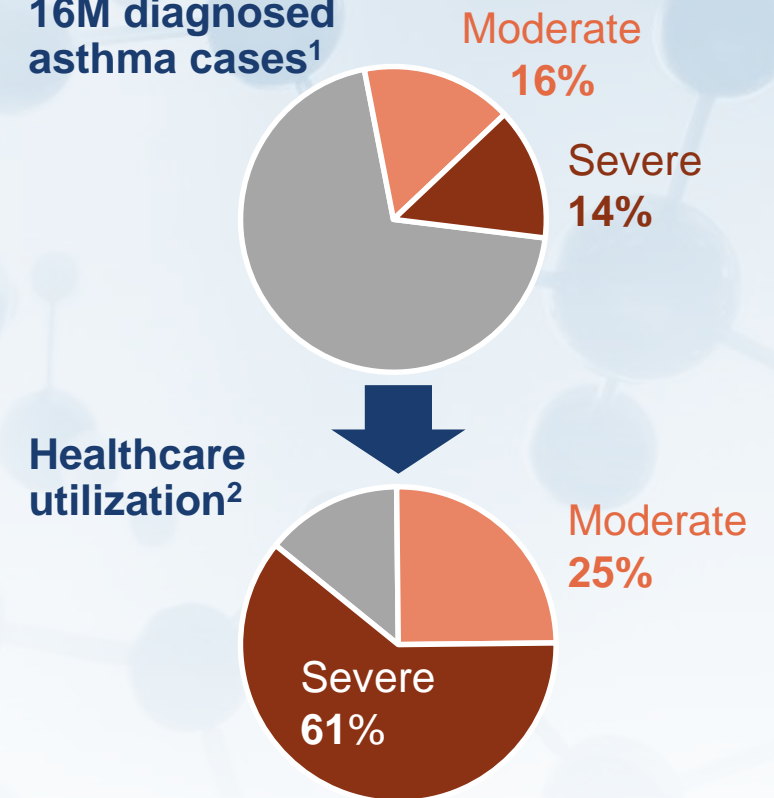
- ▶ Inhaled steroids, which often fail to control disease
- ▶ Approved biologics affect subsets of patients

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 \$58B³
- ▶ 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

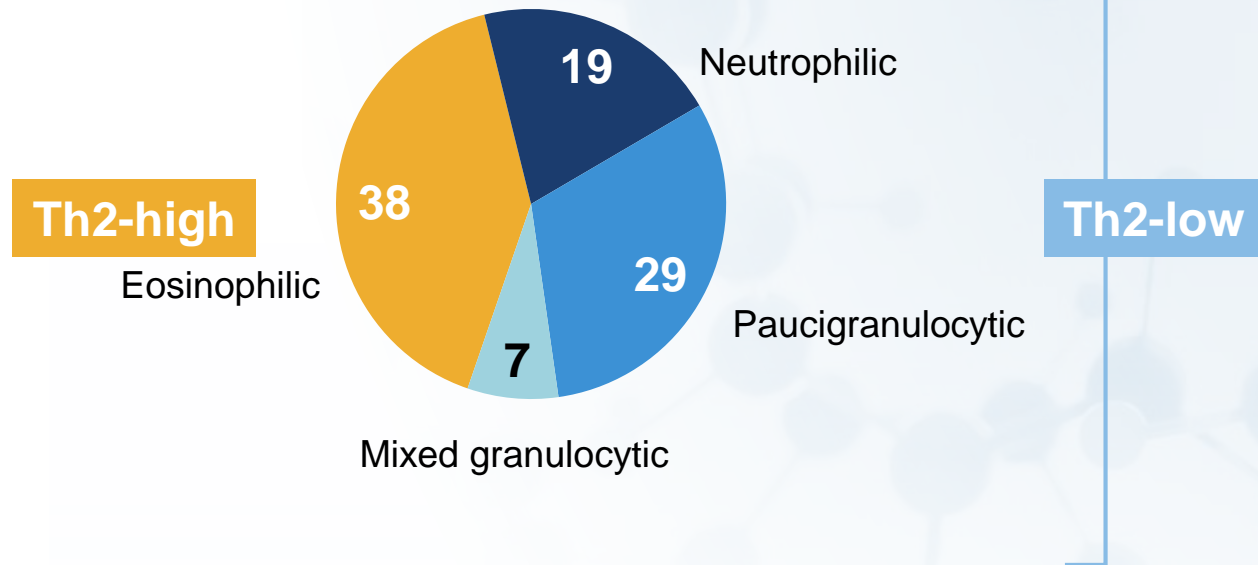
16M diagnosed asthma cases¹



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

POTENTIAL TO ADDRESS PATIENTS NEEDS REGARDLESS OF TH2 PHENOTYPE

Patient heterogeneity in severe asthma¹



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

TD-8236: Phase 1 Clinical Trial Design

PART C ONGOING; DATA PLANNED 1H20

PART A

SAD (Healthy volunteers)
Safety and PK

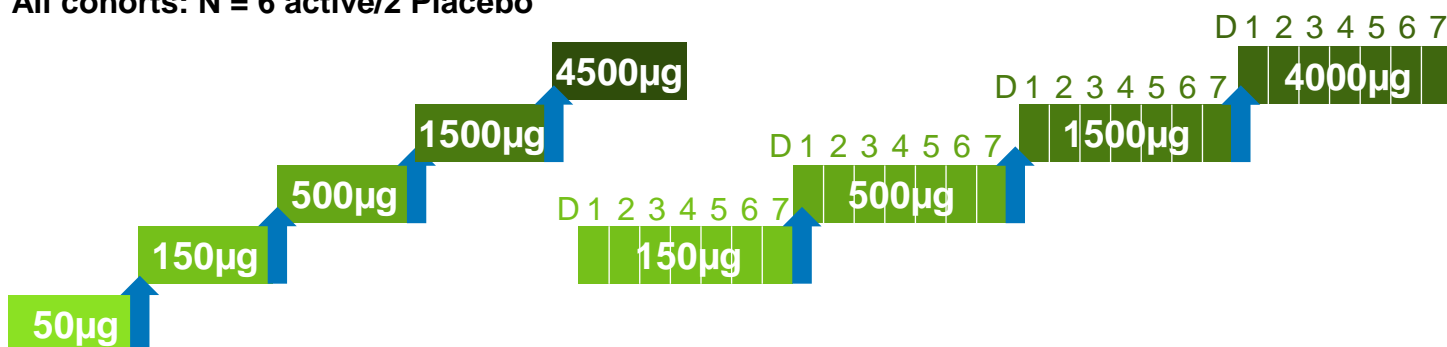
PART B

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

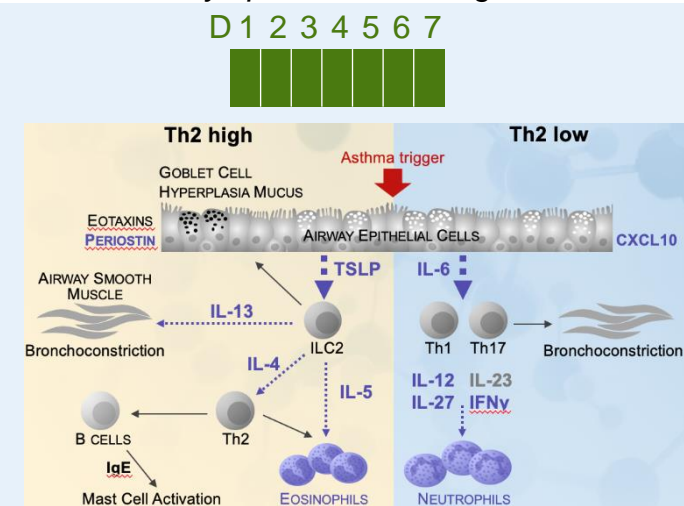
PART C

MoA Biomarkers
(Moderate-to-severe asthmatics)

All cohorts: N = 6 active/2 Placebo



N = 16 active/8 Placebo
Study open and enrolling



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

TD-8236: Positive Phase 1 Clinical Trial in Healthy Subjects and Mild Asthmatics

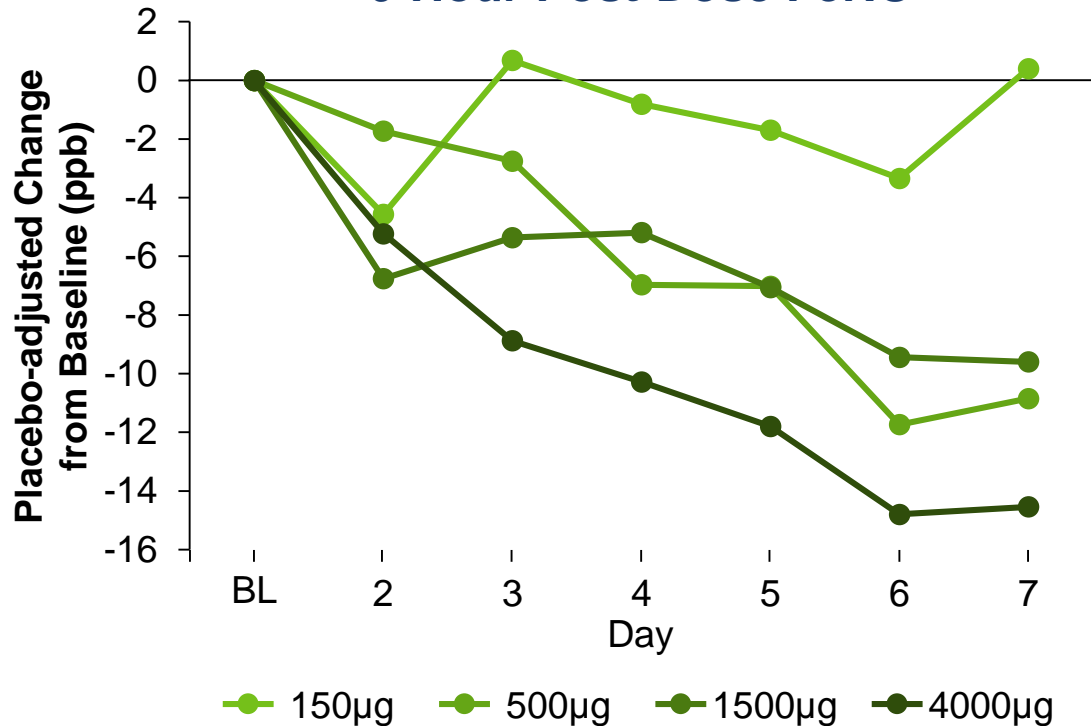
Key Findings

Favorable overall safety and tolerability	No evidence of local irritation or bronchoconstriction
	No severe or serious adverse events reported
	No clinically relevant changes in any safety laboratory measures
Minimal systemic exposure	Low plasma levels after single and 7-consecutive day doses
	Consistent with preclinical data and organ-selective design of compound
Biologic activity in lungs of patients with mild asthma after 7-day treatment	Pre- and 6-hour post-dose FeNO reductions at all doses >150 µg vs placebo
	>10 pbb reduction in pre-dose FeNO on Day 7 for all doses >150 µg
	Data suggest TD-8236 has 24-hour biological activity

Data demonstrated evidence of biological activity in the lung with minimal systemic exposure

Preliminary Positive FeNO Data in Patients with Mild Asthma & Elevated FeNO Levels at Baseline

6-Hour Post-Dose FeNO



- ▶ FeNO is an established disease activity biomarker in asthma
- ▶ Reduction in FeNO associated with a decrease in airway inflammation
- ▶ Evidence of biological activity at 500 µg, 1500 µg, and 4000 µg, distinct from placebo and 150 µg dose groups
- ▶ FeNO data indicate dose response

Plan to initiate lung allergen challenge study 4Q19

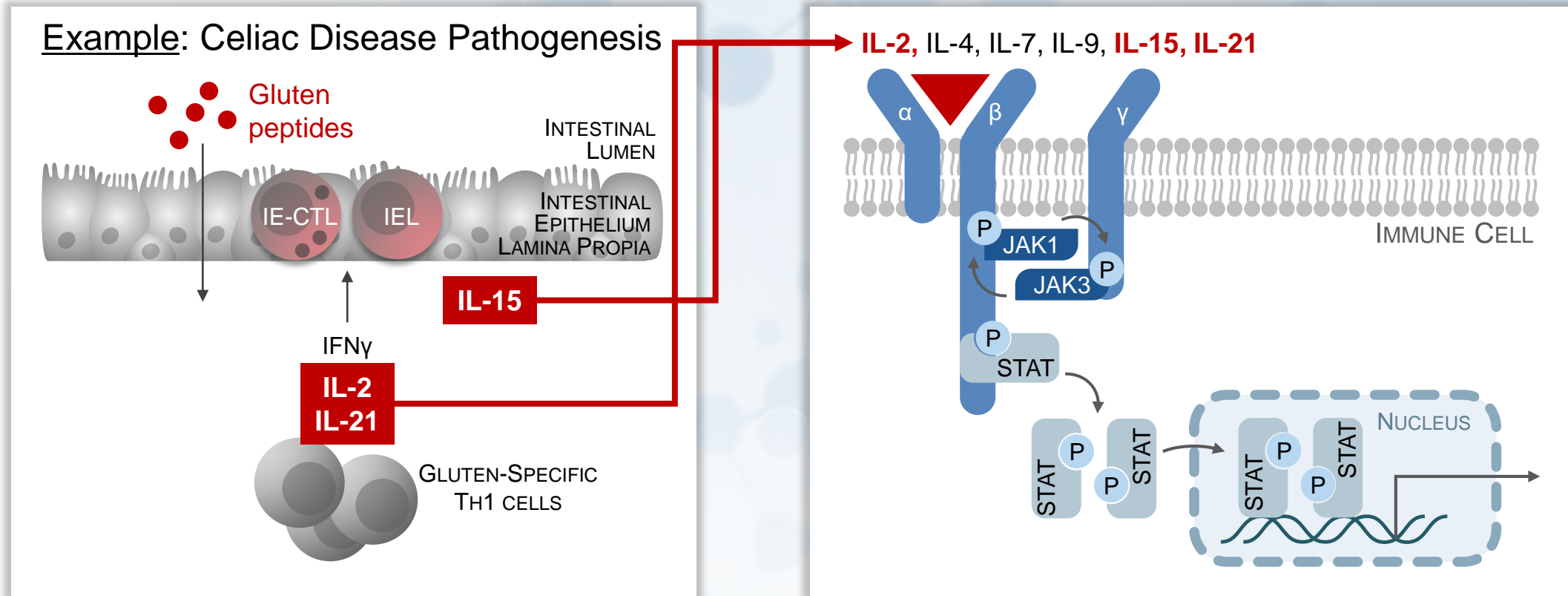
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TD-5202

Investigational Gut-Selective Irreversible JAK3 Inhibitor for
Inflammatory Intestinal Diseases

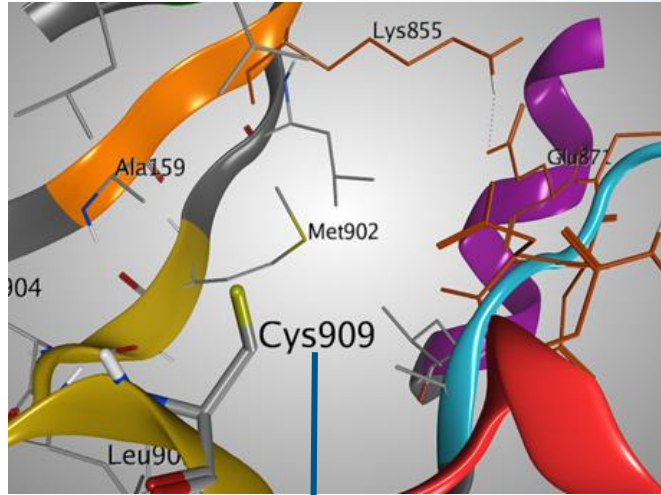
TD-5202: Gut-selective Irreversible JAK3 Inhibitor

JAK3-DEPENDENT CYTOKINES PLAY CENTRAL ROLE IN PATHOGENESIS OF T-CELL MEDIATED DISEASE



- ▶ Proof-of-relevance for T-cell mediated disease from positive Phase 2 data with systemic JAK3 inhibitor in alopecia areata¹
- ▶ Localized JAK3 inhibition important to avoid systemic immunosuppression (genetic JAK3 deficiency leads to severe immunodeficiency)

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

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

Phase 1 study of TD-5202 in healthy volunteers underway; data expected 1H20

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Opportunities for Value Creation

Focus on Strategic Priorities

KEY PROGRAMS DRIVE NEAR AND LONG-TERM VALUE-CREATING EVENTS

Opportunities to Create Transformational Medicines	YUPELRI®	Nebulized LAMA in COPD <ul style="list-style-type: none"> U.S. commercial launch progressing in partnership with Mylan
	TD-1473	Gut-selective oral JAK inhibitor for inflammatory intestinal diseases <ul style="list-style-type: none"> 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
	Amprexetine	NRI in symptomatic neurogenic orthostatic hypotension (nOH) <ul style="list-style-type: none"> Registrational Phase 3 program progressing; 4-week efficacy data planned 2H 2020
	TD-8236	Lung-selective inhaled pan-JAK inhibitor for inflammatory lung diseases <ul style="list-style-type: none"> Positive initial Phase 1 results including biomarker data reported; data from the ongoing biomarker cohort in moderate to severe asthmatics planned 1H 2020 Progressing to allergen challenge study in Q4 2019; data planned 2020
	TD-5202	Gut-selective oral irreversible JAK3 inhibitor for inflammatory intestinal diseases <ul style="list-style-type: none"> Phase 1 study in healthy subjects underway; data planned 1H 2020
	Research	Organ-selective research platform designed to expand therapeutic index compared to conventional systemic therapies
Economic Interest ¹	TRELEGY ELLIPTA ¹	Once-daily single inhaler triple therapy in COPD <ul style="list-style-type: none"> Product launched in 38 markets; China launch expected Q4 2019 sNDA filed supporting revised labelling on reduction in risk of all-cause mortality vs. ANORO in COPD sNDA filed for use in asthma

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.