UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 8-K

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

Date of Report (Date of earliest event Reported): **January 11, 2021**

THERAVANCE BIOPHARMA, INC.

(Exact Name of Registrant as Specified in its Charter)

Cayman Islands	**001-36033**	**Not Applicable**
(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 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 Exhibits 99.1 and 99.2) 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 Exhibits 99.1 and 99.2) 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 presenting at the 39th Annual J.P. Morgan Healthcare Conference on January 13, 2021 and from January 11-14, 2021 conducting one-on-one meetings with analysts and investors during the conference using a slide presentation which is being furnished pursuant to Regulation FD as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. Additionally, a copy of an Appendix of additional materials is furnished as Exhibit 99.2 to this Current Report and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1	Slide deck entitled JP Morgan Healthcare Conference
99.2	Slide deck entitled JP Morgan 2021 Appendix
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: January 11, 2021

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

Exhibit 99.1


Theravance Biopharma
Medicines That Make a Difference®
JP Morgan Healthcare Conference
January 13, 2021
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All third party trademarks used herein are the property of their respective owners.
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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.

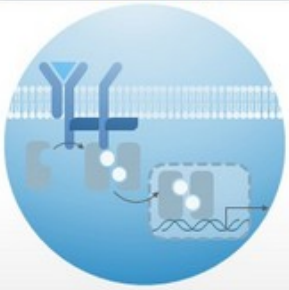
The company's forward-looking statements are based on the estimates and assumptions of management as of the date of this presentation and are subject to risks and uncertainties that may cause the actual results to be materially different than those projected, such as risks related to the impacts on the 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 November 9, 2020, and other periodic reports filed with the SEC.


Our science
Organ-selective molecules
designed to optimize therapeutic index

Theravance Biopharma difference: Targeting disease with organ selective medicines

Pathway



Target disease biology

Disease

Optimize effect in the organ where the disease is active

Therapeutic Index

Expand TI with the goal of maximizing efficacy and limiting systemic side effects

Pioneering a new generation of small molecule drugs designed to better meet patient needs

TI, therapeutic index.

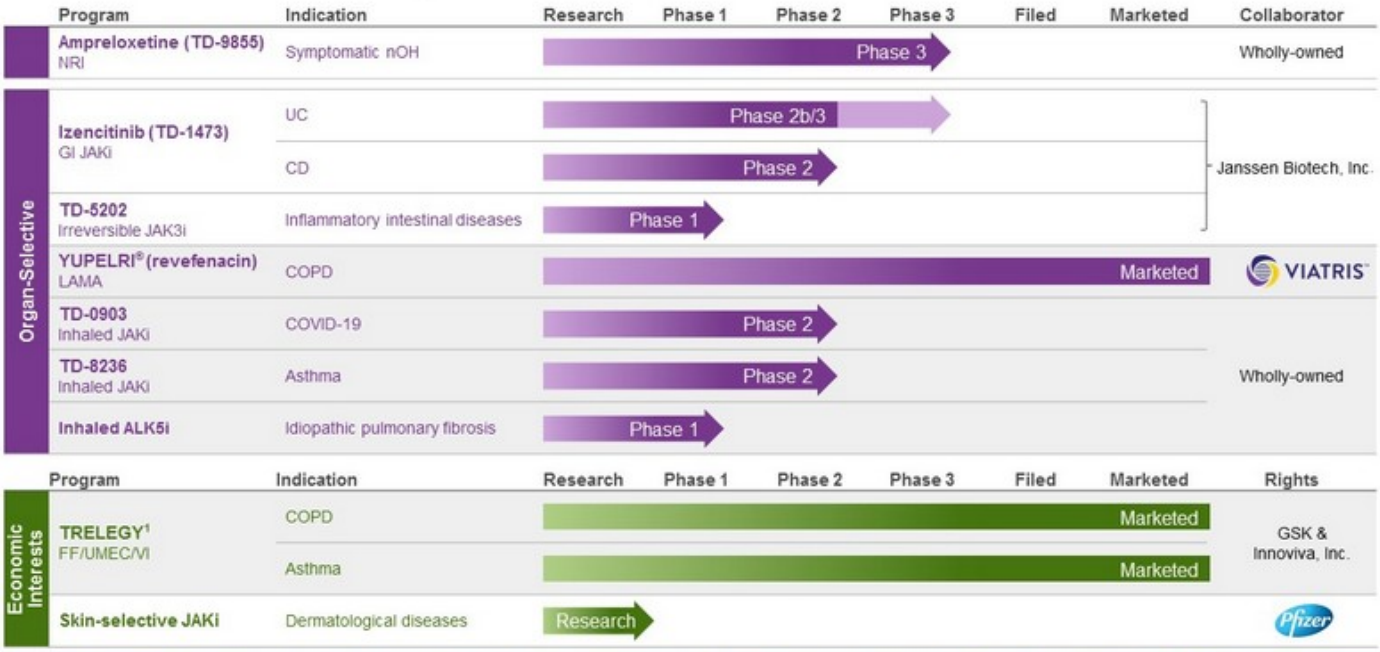
2021: Three Areas for Transformational Impact

Development Pipeline

Ampreloxetine
Izencitinib
TD-0903

Changing Financial Profile

Key programs supported by proven development and commercial expertise



1. TBPH holds 85% economic interest in upward-tiering royalty stream of 6.5% – 10% payable by GSK (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC Agreement over the next four fiscal quarters). 75% of TRC income received is pledged to service outstanding notes, 25% of royalties received retained by TBPH. All statements concerning TRELEGY ELLIPTA based on publicly available information. CD, Crohn's disease; COPD, chronic obstructive pulmonary disease; FF/UMEC/VI, fluticasone furoate/umeclidinium/vilanterol; JAKi, Janus kinase inhibitor; LAMA, long acting muscarinic receptor antagonist; nOH, neurogenic orthostatic hypotension; NRI, norepinephrine reuptake inhibitor; UC, ulcerative colitis.

2021: Three Areas for Transformational Impact

Development Pipeline

Ampreloxetine
Izencitinib
TD-0903

Changing Financial Profile

YUPELRI® (revefenacin) inhalation solution

FDA-approved for the maintenance treatment of COPD
First and only once-daily, nebulized maintenance medicine for COPD

Once-daily LAMAs are first-line therapy for moderate-to-severe COPD[1]

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

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

Theravance Biopharma + VIATRIS™

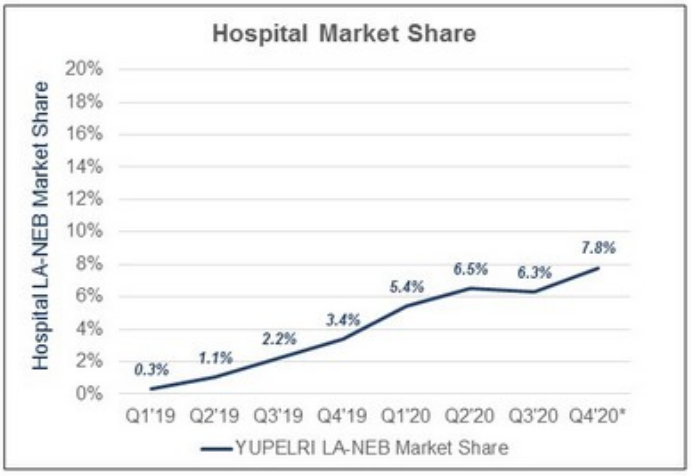
Companies co-promote under US profit/loss share

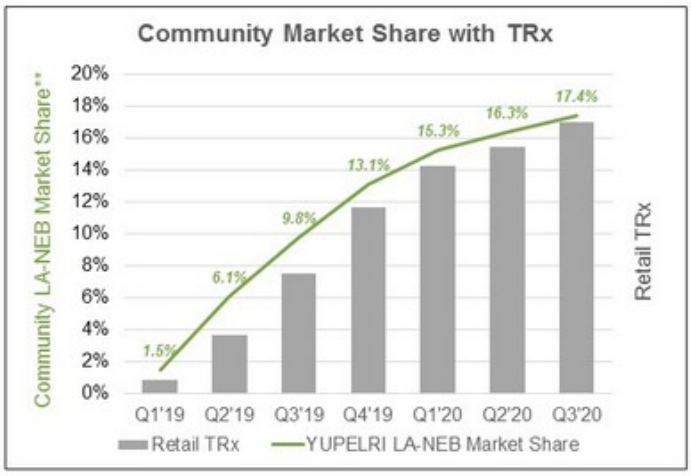
Theravance Biopharma
Medicines That Make a Difference

1. Global Strategy for Diagnosis, Management, and Prevention of COPD, 2018.
2. TBPH market research (N = 160 physicians); refers to US COPD patients.
COPD, chronic obstructive pulmonary disease; LAMA, long acting muscarinic receptor antagonist

YUPELRI® hospital sales and community TRx trends

Continued growth through Q1'20 across both the hospital and retail channels;
Signs of recovery to initial growth trajectory leading into 2021





Most patients that receive YUPELRI® in the hospital are discharged with an Rx[1]

*Q4'20 through 12/18/2020

TRx volume represents retail only which is typically 33% of Retail + DME

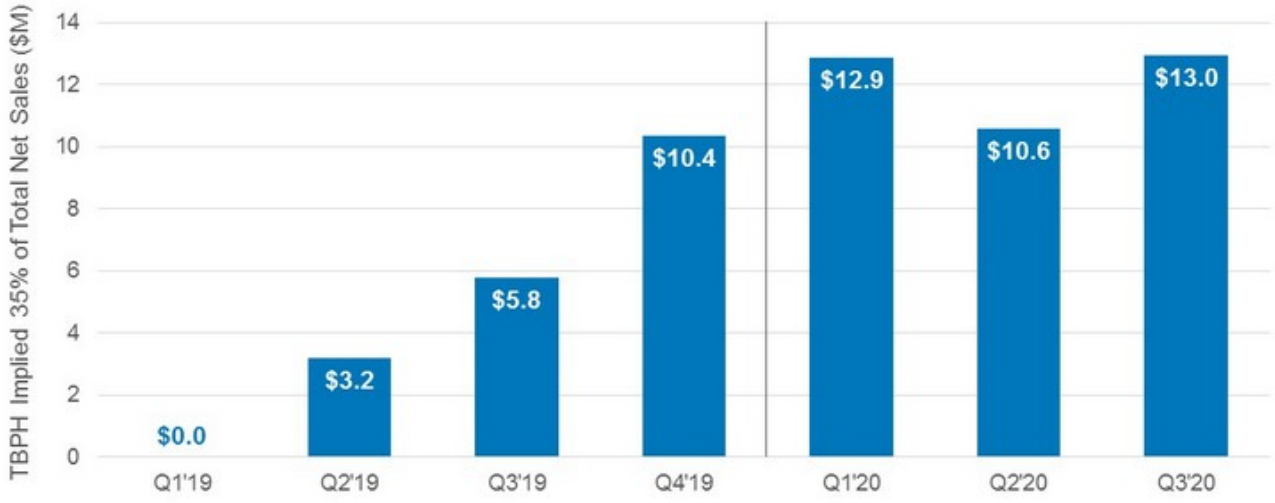
**Community LA-NEB Market Share includes Retail + DME / Med B FFS

Theravance Biopharma
Medicines That Make a Difference

1. Joint VTRS/TBPH Market Research
* Hospital - IQVIA DDD through 12/18/2020.
** Community - IQVIA XPO Excl. LTC (Retail) and SolutionaRx (DME / Med B FFS) through 9/30/2020.
LA-NEB Market: YUPELRI, BROVANA, LONHALA, PERFOROMIST

TBPH implied 35% of YUPELRI® US net sales by quarter

Growth in net sales through Q1'20 and recovery in Q3'20 driven by volume



TBPH implied 35% of YUPELRI US net sales represents TBPH's split of the combined TBPH and VIATRIS net revenue

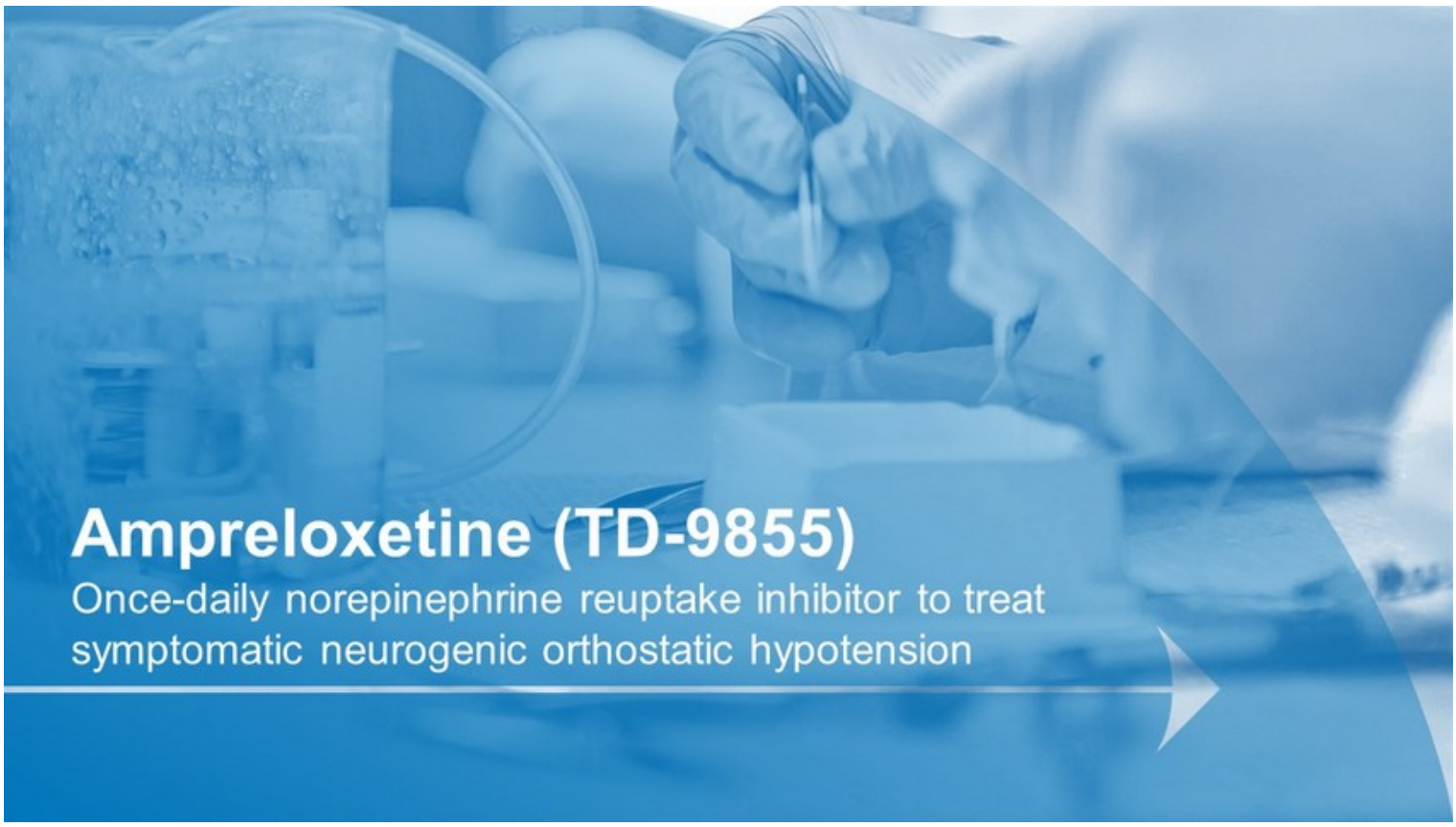
See TBPH 10Q filed Nov 9, 2020 for greater detail re TBPH implied 35%.

2021: Three Areas for Transformational Impact

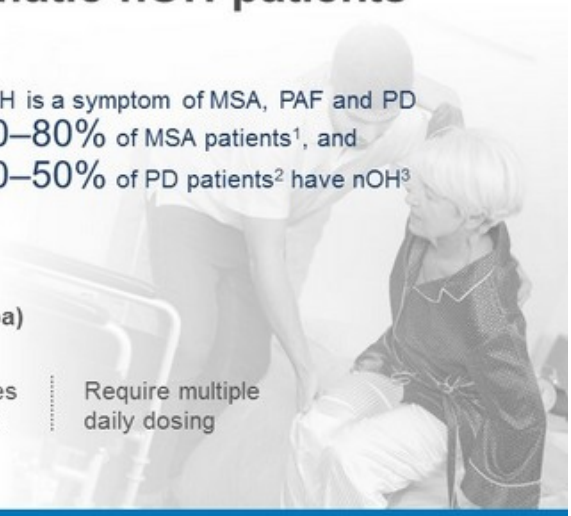
Development Pipeline

Ampreloxetine
Izencitinib
TD-0903

Changing Financial Profile


Ampreloxetine (TD-9855)
Once-daily norepinephrine reuptake inhibitor to treat symptomatic neurogenic orthostatic hypotension

Reduced quality of life, significant caregiver burden and limited therapeutic options for symptomatic nOH patients



PATIENT POPULATION

~350K US patients | **~700K** APAC patients | **~700K** EU patients

nOH is a symptom of MSA, PAF and PD
70–80% of MSA patients[1], and
30–50% of PD patients[2] have nOH[3]

CURRENT TREATMENT LANDSCAPE

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

STRATEGIC OPPORTUNITY

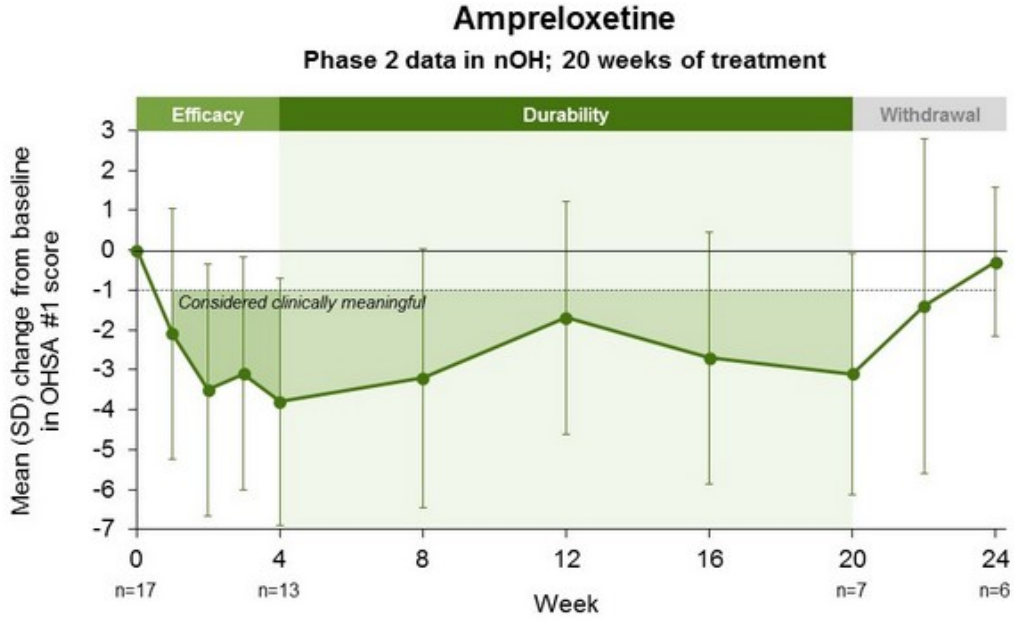
Ampreloxetine

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

Theravance Biopharma
Medicines That Make a Difference

1. Mathias C, et al. J Neurol 1999;246:893-8.
2. Ha AD, et al. Parkinsonism Relat Disord 2011;17:625-8.
3. Not all patients are treated with prescription medication.
APAC, Asian and Pacific; MSA, multiple system atrophy; PAF, pure autonomic failure; PD, Parkinson's Disease; nOH, neurogenic orthostatic hypotension

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

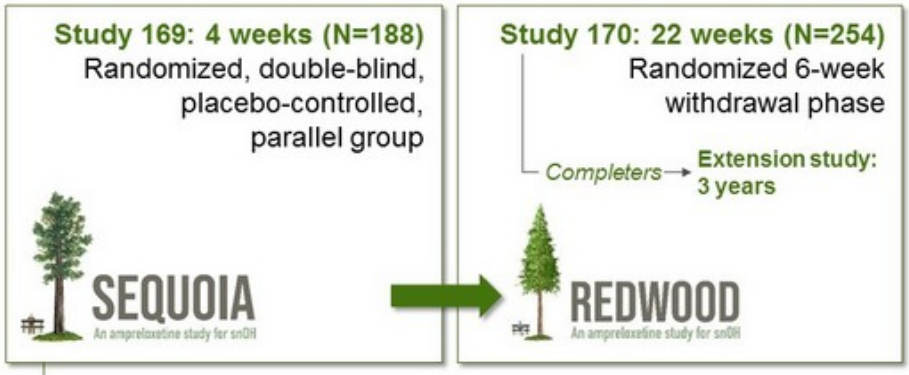


Theravance Biopharma
Medicines That Make a Difference

Baseline OHSA #1 (Orthostatic Hypotension Symptom Assessment Question 1) >4 points.
Negative change indicates improvement in symptoms; improvement of 1 point is defined as the MCID (minimal clinically important difference).
nOH, neurogenic orthostatic hypotension; SD, standard deviation.

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

Phase 3 Registrational Program



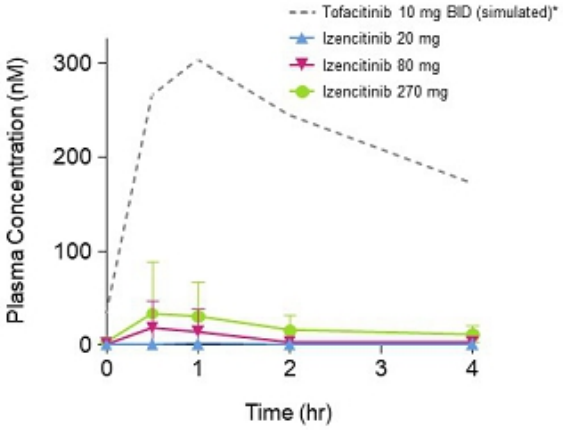
Phase 3 registrational program ongoing; 4-week efficacy data expected Q3 2021

All subjects who complete Study 169 may enroll into 170; all subjects who complete 170 may enroll into extension study/171.
Baseline OHSA #1 (Orthostatic Hypotension Symptom Assessment Question 1) >4 points. Negative change indicates improvement in symptoms; improvement of 1 point is defined as the MCID (minimal clinically important difference).
Discontinuation rates for the Phase 3 trials as of Jan. 2020: 0169 – 5.3 percent; 0170 – 33.3 percent

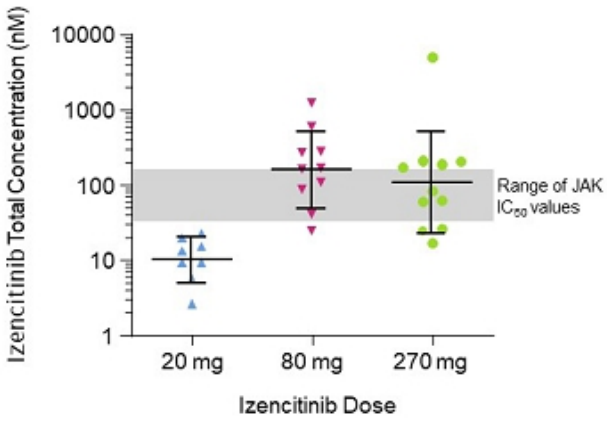

Izencitinib (TD-1473/JNJ-8398)
Oral gut-selective pan-JAK inhibitor to treat
inflammatory bowel diseases

Izencitinib results in low systemic exposures but high colonic concentrations above JAK inhibition levels

Steady State Plasma Izencitinib PK in Patients with UC



Colonic Tissue Izencitinib Concentrations



- >10-fold lower systemic exposure with izencitinib vs 10 mg BID tofacitinib (based upon published data)
- Tissue exposures at 80 and 270 mg of izencitinib within the range of cellular JAK IC_{50} values

Theravance Biopharma
Medicines That Make a Difference

Sandborn et al. J Crohns Colitis;2020;14:1202-13 and Sandborn et al. DDW 2019; oral presentation.
*Simulated tofacitinib concentrations extracted from J Pharmacol Exp Ther 2014;348:165-73.
BID, twice daily; hr, hour; IC_{50}, concentration to produce 50% maximal inhibition; PK, pharmacokinetics.

Pre-clinical and Phase 1b results led to late stage IBD studies with izencitinib

Favorable data from this innovative exploratory Phase 1b study[1]

- Confirmed gut selectivity
  - High colonic concentration with low systemic drug exposures, consistent with pre-clinical data
  - For the goal of maximized therapeutic index
- Demonstrated numerically higher rates of clinical outcomes with reductions in biomarkers after only 4 weeks of treatment
  - Numerical improvements in rectal bleeding and mucosal healing
- Led to decision to proceed with development of izencitinib

Global collaboration with **Janssen Biotech, Inc.** leverages joint development expertise with the potential for up to a total of $1B in milestone payments to **TBPH** plus profit-share in US (33% TBPH, 67% Janssen) and double-digit royalties to TBPH ex-US[2]

Crohn's disease (0173)

DIONE STUDY

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

Ongoing; data expected Q3 2021

Ulcerative colitis (0157)

RHEA PROGRAM

Phase 2b/3: 8 weeks (N=240)
Dose-finding induction

Phase 3: 8 weeks (N=640)
Dose-confirming induction

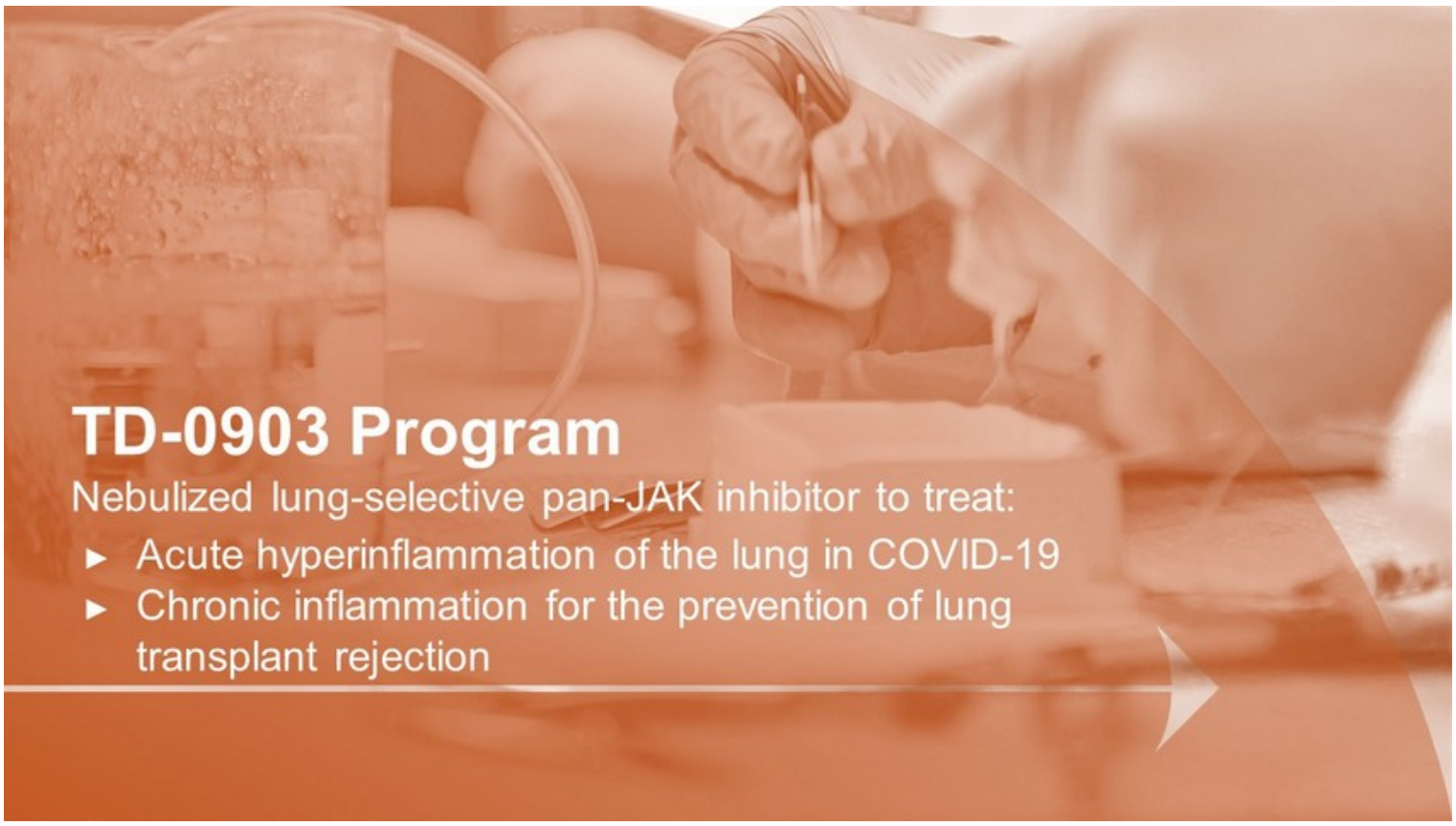
Responders → **Maintenance phase[3]: 44 weeks**

Long-Term Safety Study[4]: 3 years (0164)

Ongoing; Phase 2b data expected Q3 2021

Theravance Biopharma
Medicines That Make a Difference

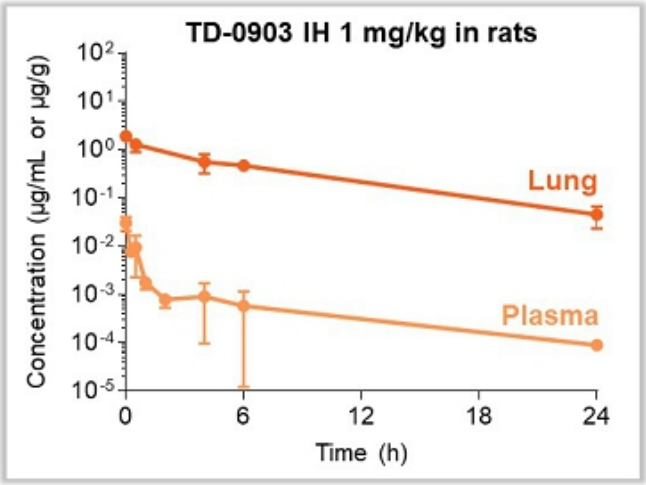
1. Sandborn et al. J Crohns Colitis;2020:14:1202-13.
2. Deal value up to $1B in payments to TBPH, including $100M upfront previously received; subject to Janssen opt-in.
3. Maintenance study will have induction responder patients re-randomized to active doses compared to placebo at 44 weeks.
4. Patients may enter the Long-Term safety study by completing or terminating Maintenance study due to loss of response.


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

TD-0903: Lung-selective inhaled pan-JAKi

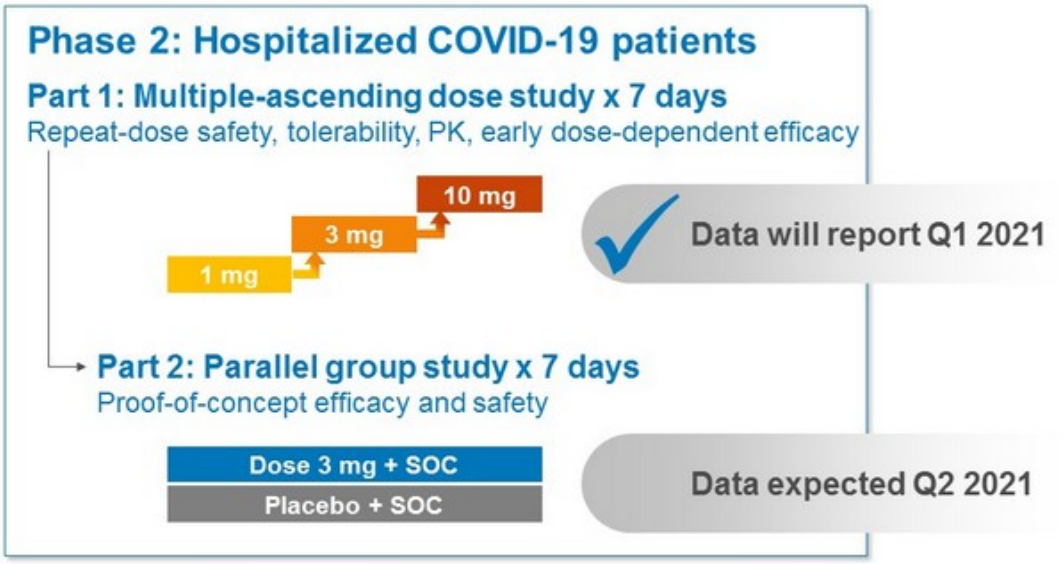
Aiming for maximal anti-inflammatory activity in pulmonary tissue while minimizing systemic exposure

- High affinity for JAK1, JAK2, JAK3, and Tyk2 kinase domains
- High potency for inhibition of cytokine-induced activation of JAK-STAT signaling pathways
  - *In vitro*: human epithelial and immune cells
  - *In vivo*: murine inhalation cytokine-challenge models
- Lung-selective design
  - High lung to plasma ratios
  - Rapid systemic clearance with no evidence of systemic immunosuppression
  - PK/PD modeling supports extended duration of action



BALF lymphocytes and relevant mediators inhibited by OA tool JAK inhibitor TR065925. Based on internal data on file.

TD-0903: Development plan designed to progress rapidly



SOC, standard of care; PK, pharmacokinetic

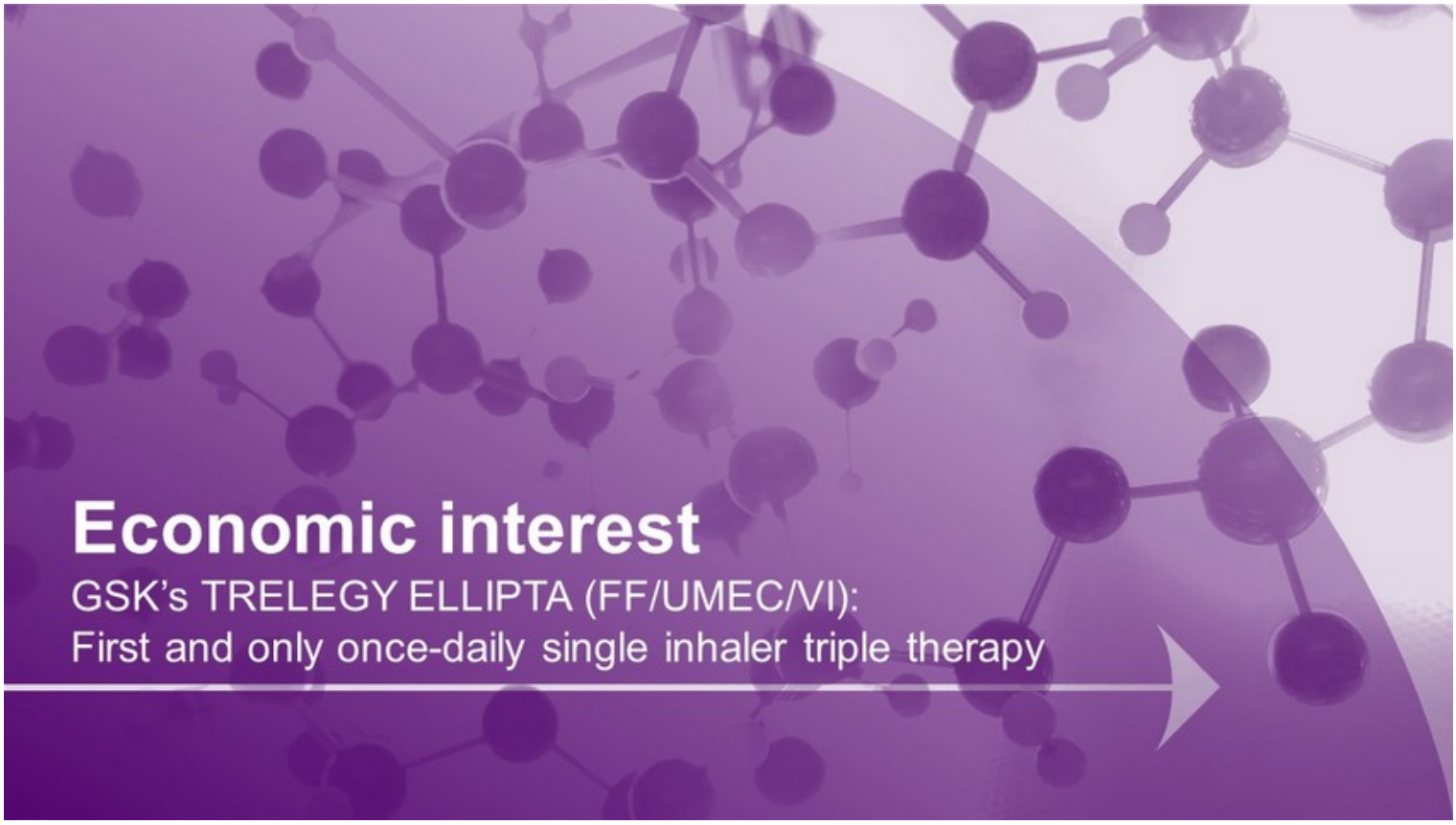
2021: Three Areas for Transformational Impact

YUPELRI® revefenacin inhalation solution

Development Pipeline

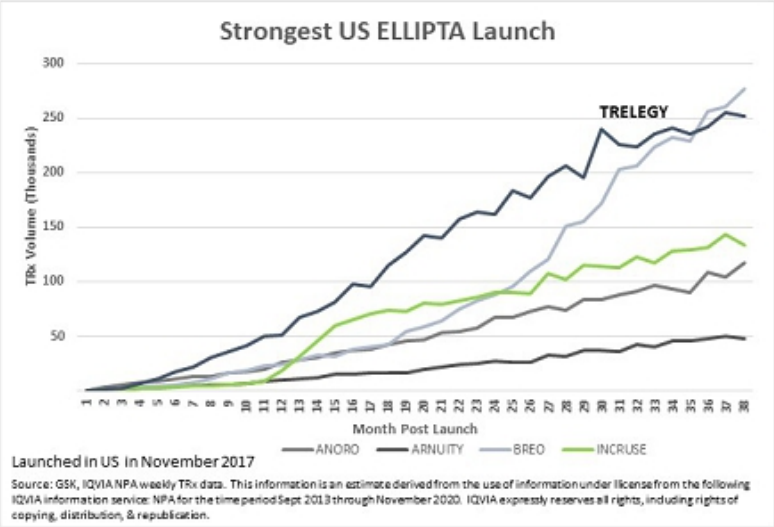
Ampreloxetine
Izencitinib
TD-0903

Changing Financial Profile


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 sales[1]



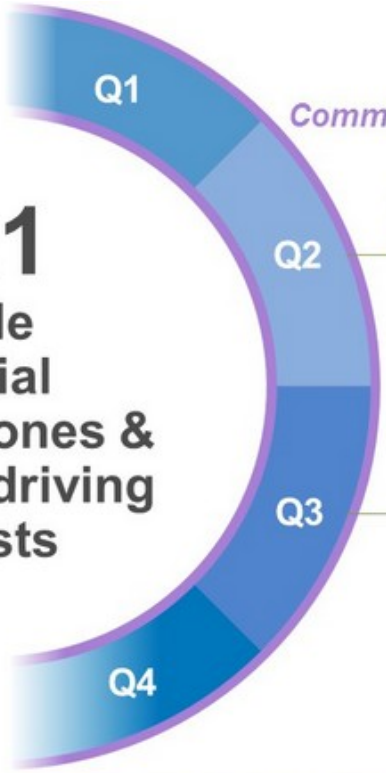
Launched in US in November 2017

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 November 2020. IQVIA expressly reserves all rights, including rights of copying, distribution, & republication.

TRELEGY

- Q3 net sales of £194MM (or $252MM)
- Sales up 45% year-over-year
- US asthma indication approved September 9, 2020, and launched 3rd Q
  - Results from the CAPTAIN study published in *The Lancet Respiratory Medicine*

1. TBPH holds 85% economic interest in upward-tiering royalty stream of 6.5% – 10% payable by GSK (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC Agreement over the next four fiscal quarters). 75% of TRC income received is pledged to service outstanding notes, 25% of royalties retained by TBPH. Our non-recourse Triple II 9.5% Fixed Rate Term Notes are due on or before 2035. All statements concerning TRELEGY based on publicly available information. TRELEGY is FF/UMEC/VI or fluticasone furoate/umeclidinium/vilanterol; comprised of ICS, LAMA, and LABA, active components of Anoro (UMEC/VI).



Commercial progress of YUPELRI® & GSK's TRELEGY

2021

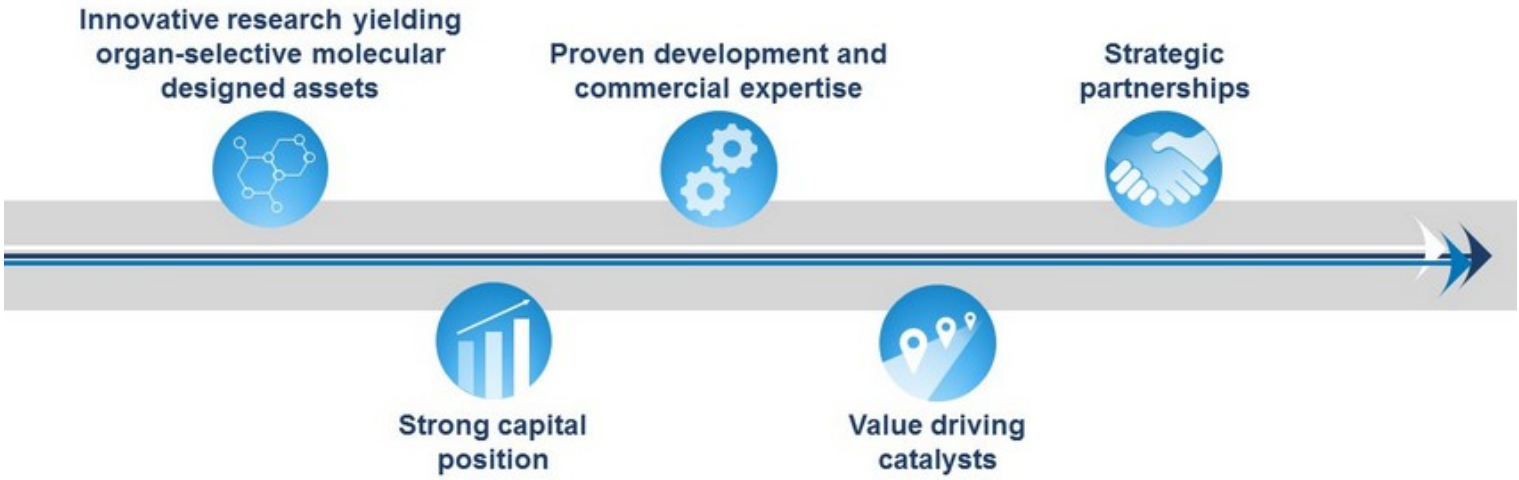
Multiple potential milestones & value-driving catalysts

TOPLINE RESULTS

- **TD-0903**
  Phase 2 COVID-19
- **Ampreloxetine**
  SEQUOIA Phase 3 symptomatic nOH
- **Izencitinib**
  RHEA Phase 2b ulcerative colitis
- **Izencitinib**
  DIONE Phase 2 Crohn's disease

TBPH holds 85% economic interest in upward-tiering royalty stream of 6.5% – 10% payable by GSK (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC Agreement over the next four fiscal quarters). 75% of TRC income received is pledged to service outstanding notes, 25% of royalties retained by TBPH. Our non-recourse Triple II 9.5% Fixed Rate Term Notes due on or before 2035. All statements concerning TRELEGY based on publicly available information. TRELEGY is FF/UMEC/VI or fluticasone furoate/umeclidinium/vilanterol; comprised of ICS, LAMA, and LABA, active components of Anoro (UMEC/VI).")

Creating transformational value for stakeholders



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.

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

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.

OATP, organic anion transporting polypeptide.

Exhibit 99.2

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

Symptomatic nOH
(Neurogenic orthostatic hypotension)

COPD
(chronic obstructive pulmonary disorder) — APPROVED

Asthma

COVID-19

Lung Transplant Rejection

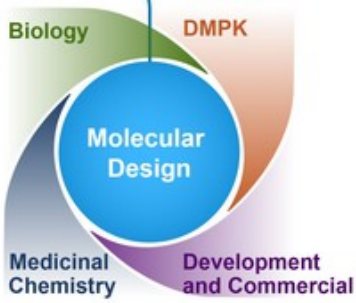
IPF (idiopathic pulmonary fibrosis)

CD
(Crohn's disease)

UC
(ulcerative colitis)

Celiac Disease

DME
(diabetic macular edema)



DMPK, drug metabolism and pharmacokinetics; GI, gastrointestinal.


YUPELRI
(revefenacin) inhalation solution
175 mcg/3 mL
For Oral Inhalation Only
Mylan
30
YUPELRI® (revefenacin) inhalation solution
First and only once-daily, nebulized maintenance medicine for COPD

YUPELRI® launch metrics

Strong customer acceptance and market uptake

FORMULARY[1]

- **191 wins** (equates to 363 accounts)
- **78% of formulary accounts ordering**
- **100% medical support requests fulfilled** <30 days

PATIENT

- **Field force continues hybrid approach to customer interactions (live and virtual)**
- **~50,000 patients[2] prescribed** *(through Q3 2020)*

ACCESS

- **100% Medicare Part B[3]**
- **74% of commercial payer lives covered** (comprises **~8%** of the YUPELRI® business)

- **Theravance Biopharma's implied 35% share of Net Sales during Q3 2020 was $13M**
- **Increased market share and achieved quarter-over-quarter Net Sales growth of 22%**

Majority of YUPELRI® volume flows through durable medical equipment channel (approximately 3-month lag in data capture); remaining volume flows through hospitals, retail and long-term care pharmacies. Wholesale acquisition cost (WAC): $1,103 per month (or ~$37 per day). 1. Launch through October 2, 2020. 2. TBPH estimate derived from integrating multiple data sources. 3. For patients with supplemental insurance; approximately 20% of patients may be responsible for co-pay and/or supplemental insurance. Source: www.CMS.gov.

Key Success Drivers for YUPELRI®

Launch to Date

- Established Nebulized LAMA Market Leader
- Continued growth of hospital accounts with YUPELRI® on formulary
- Successful partnership with VIATRIS leading to continued growth in Community and overall brand
- Strong access with payers / Medicare Part B
- 18% higher refill rate over 12 months vs. Nebulized LABA average[1]

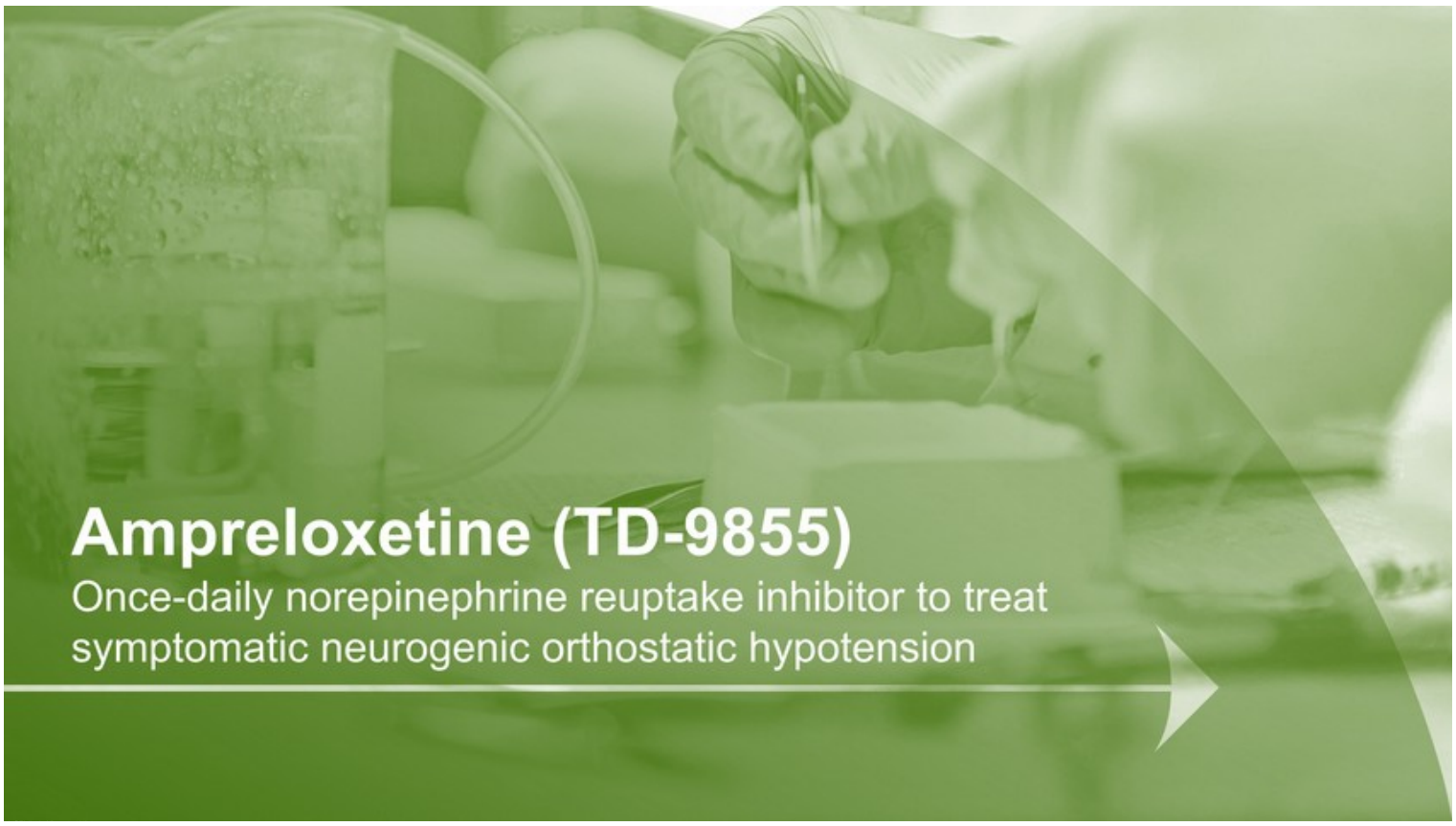
2021 and Beyond

- Expected growth of hospital account formularies as well as overall prescriber base
- Further communication of GOLD guidelines recognizing LAMAs as foundational therapy for the majority of patients with COPD, especially as Nebulized LABAs reach LOE
- Continued momentum with an alternative therapy to handhelds and short-acting agents used for maintenance therapy

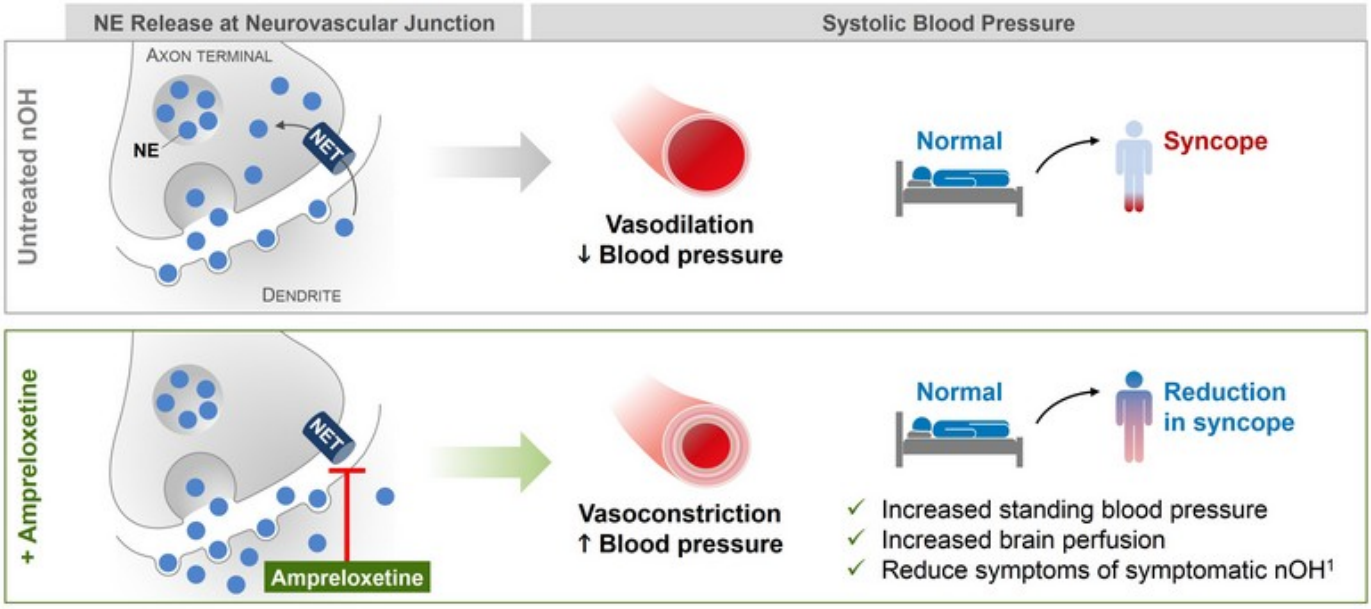
YUPELRI® revefenacin inhalation solution

Theravance Biopharma
Medicines That Make a Difference

1. Symphony Health Patient-Level Claims Data through Q2'20.
LABA, long-acting beta agonist.; LAMA, long-acting muscarinic agonist


Ampreloxetine (TD-9855)
Once-daily norepinephrine reuptake inhibitor to treat
symptomatic neurogenic orthostatic hypotension

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



1. Palma JA, Kaufmann H. Mov Disord Clin Pract 2017;4:298-308.
NE, norepinephrine; NET, norepinephrine transporters.

Decentralized trials move activities from the clinic to home

Global clinical trials are being decentralized along a continuum

Traditional Trial Operations

- Site-centric operating model
- Burden on site resources
- Patient burden

Decentralized Trial

- Patient-centric model
- Leverage technology for remote visits, monitoring and data collection
- Established home health and distribution channels

Theravance Biopharma
Medicines That Make a Difference

Source: Theravance Biopharma Clinical Operations.

Ampreloxetine: has the potential to transform Theravance Biopharma into an independent commercial biopharma

Established disease, targeted market

Established nOH treatment paradigm

nOH is included in medical treatment guidelines for PD and MSA patients; once diagnosed, patients get on drug treatment quickly

Specialist networks in place

A concentrated group of neurologists and cardiologists treat patients with nOH; 'at risk' patients already identified and managed by specialty institutions

An urgency to treat

Physicians report high urgency to treat snOH due to the high impact on patients' QoL, high risk of injury from falls and caregiver burden

A strong value proposition

Manageable opportunity

TBPH's infrastructure capable of commercializing ampreloxetine in the US with limited and targeted additions to current resources

Understanding of current access barriers

Meaningful value proposition will drive patient access; Ampreloxetine has the potential to improve the durability of treatment effect and thereby reduce costly events associated with nOH

Established patient advocacy

Strong message from Parkinson's and MSA advocacy groups that patients need new therapies to better manage nOH

snOH, symptomatic neurogenic orthostatic hypotension

Izencitinib (TD-1473) (JNJ-8398)

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

Need for new medicines to treat Inflammatory Bowel Disease

PATIENT POPULATION

6.8M global cases, 2017[1]

1.6M current US patients[2]

Current US patients **780K** CD cases[3] **907K** UC cases[4]

$16B global IBD treatment market, 2018[5]

$31B US disease burden[2]

CURRENT TREATMENT LANDSCAPE

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

STRATEGIC OPPORTUNITY

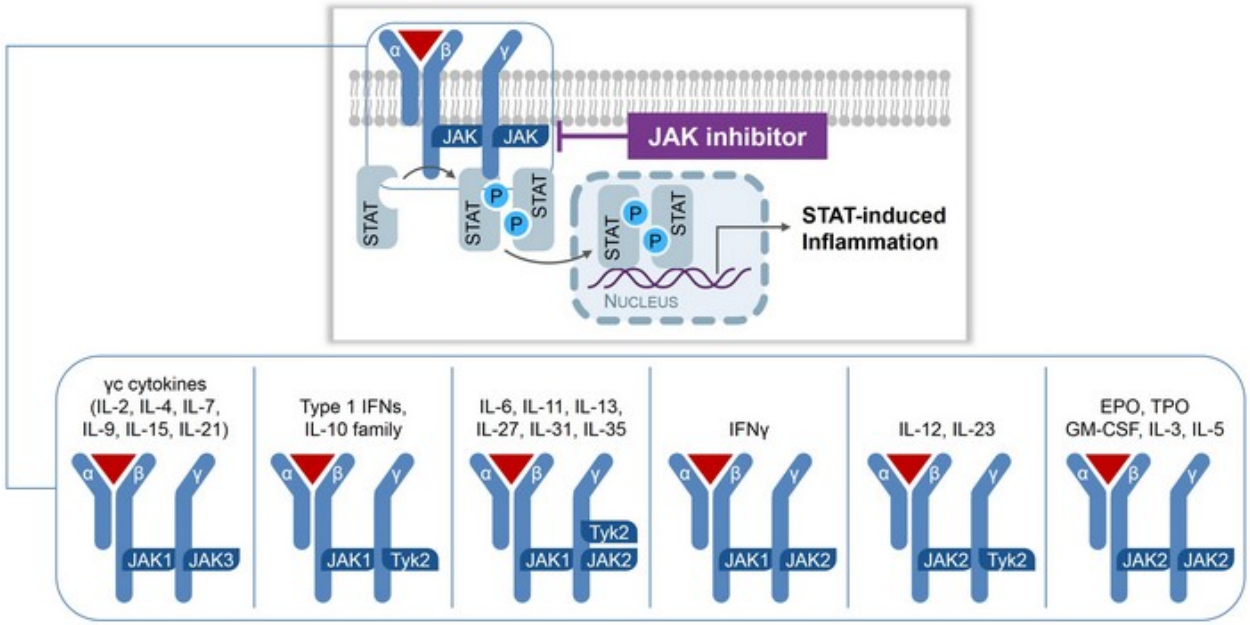
Izencitinib

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

Theravance Biopharma
Medicines That Make a Difference

1. GBD 2017 Inflammatory Bowel Disease Collaborators. Lancet 2020;5:17-30. 2. https://www.crohnscolitisfoundation.org/sites/default/files/2019-02/Updated%20IBD%20Factbook.pdf.
3. https://www.healthline.com/health/crohns-disease/facts-statistics-infographic 4. https://med.stanford.edu/news/all-news/2020/02/stanford-scientists-link-ulcerative-colitis-to-missing-gut-micro.html
5. https://www.transparencymarketresearch.com/inflammatory-bowel-disease.html
HRQoL, health-related quality of life; IBD, inflammatory bowel disease.

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

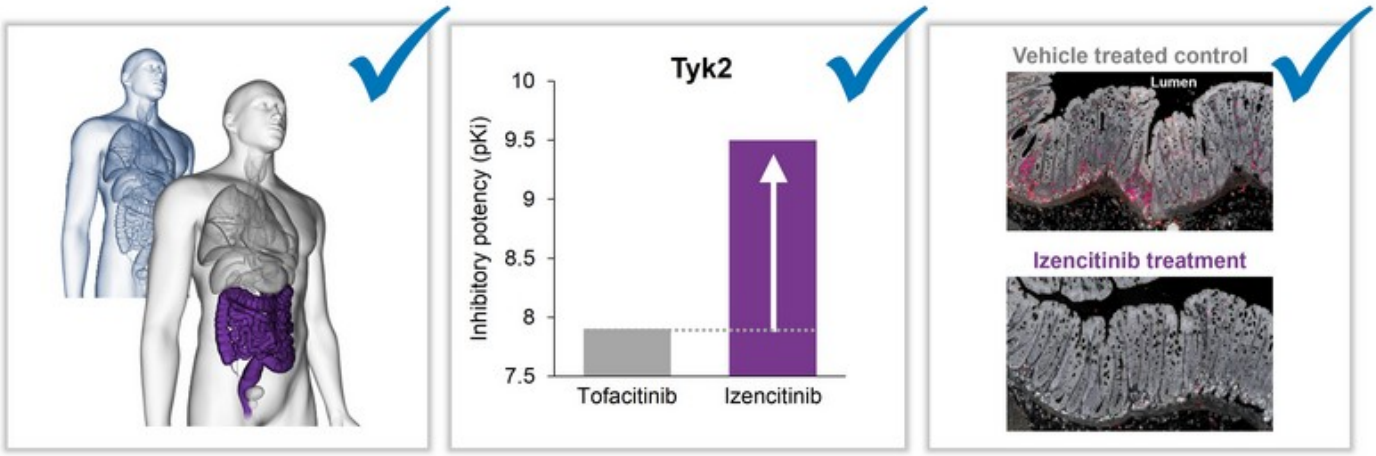


Theravance Biopharma
Medicines That Make a Difference

Clark JD, et al. J Med Chem 2014; 57:5023-5038.
EPO, erythropoietin; GM-CSF, granulocyte-macrophage colony-stimulating factor; TPO, thrombopoietin; Tyk, tyrosine kinase.

Izencitinib is an oral, gut-selective pan-JAK inhibitor

Preclinical data package for Izencitinib represents a potential breakthrough approach to the treatment of IBD

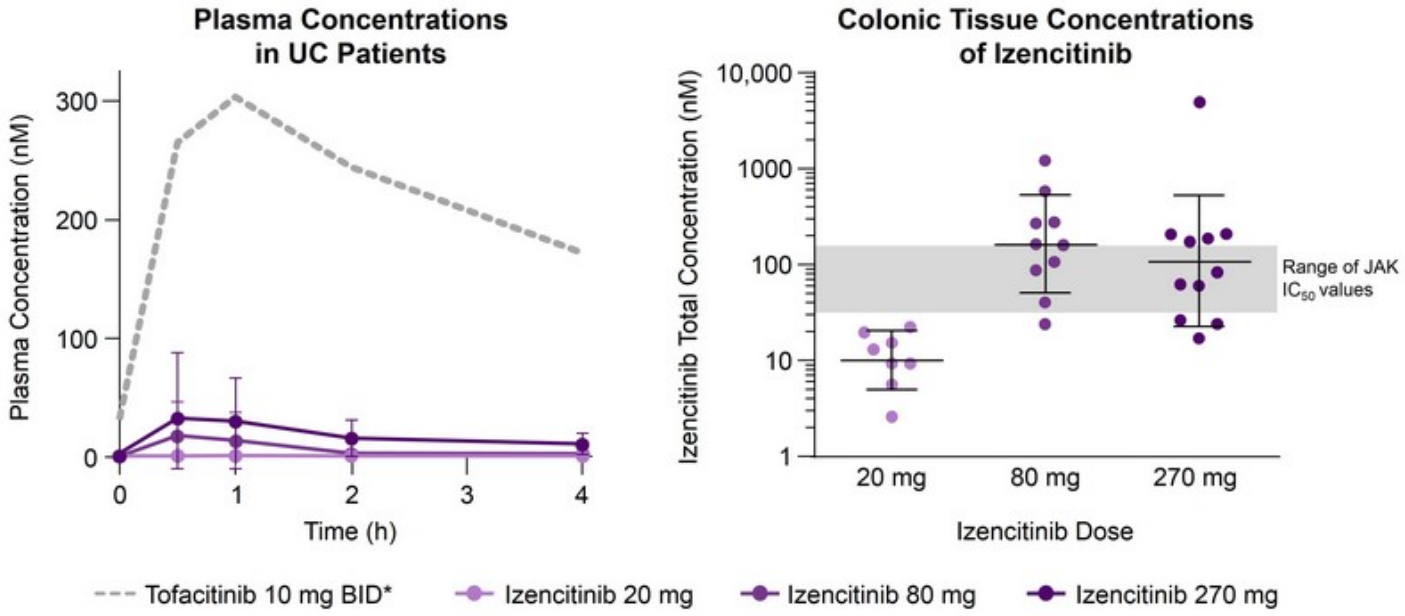


Gut selectivity

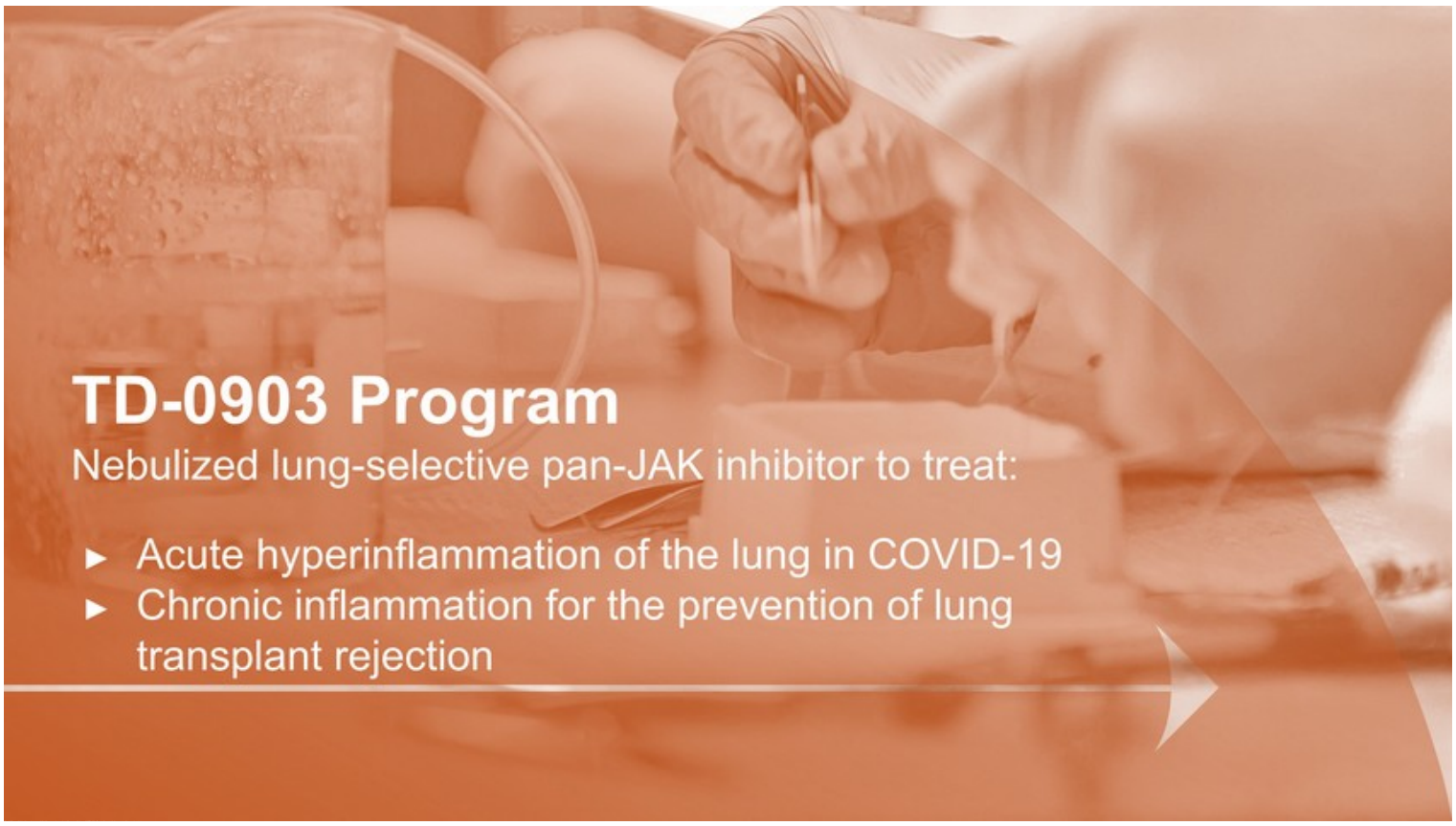
Potent inhibition of Tyk2

Anti-inflammatory activity in disease model

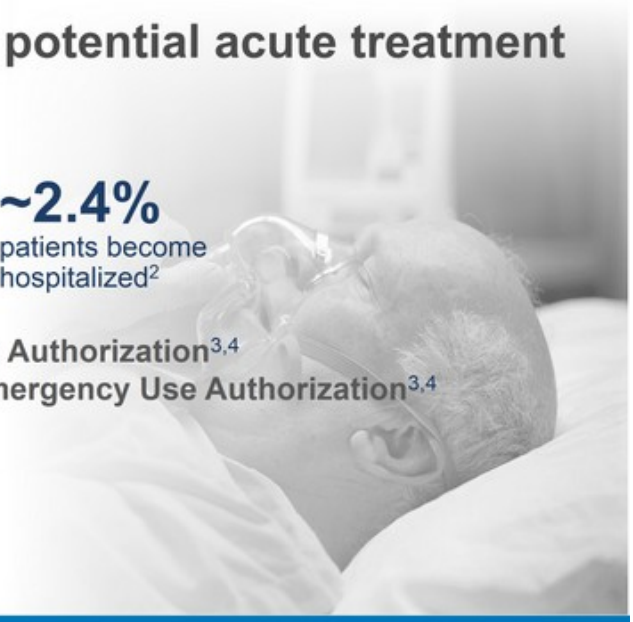
Systemic exposures low; tissue concentrations at or above JAK inhibition levels



*Tofacitinib concentrations extracted from J Pharmacol Exp Ther 348:165–173, January 2014.
BID, twice daily; IC_{50}, concentration to produce 50% maximal inhibition; PK, pharmacokinetics.


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



PATIENT POPULATION

>88M patients worldwide[1]

>22M US patients[1] → **~2.4%** patients become hospitalized[2]

CURRENT US TREATMENT LANDSCAPE

2 vaccines available via Emergency Use Authorization[3,4]
1 approved treatment; 8 available via Emergency Use Authorization[3,4]

370 active trials in US[5]

4,266 studies registered worldwide[6]

STRATEGIC OPPORTUNITY

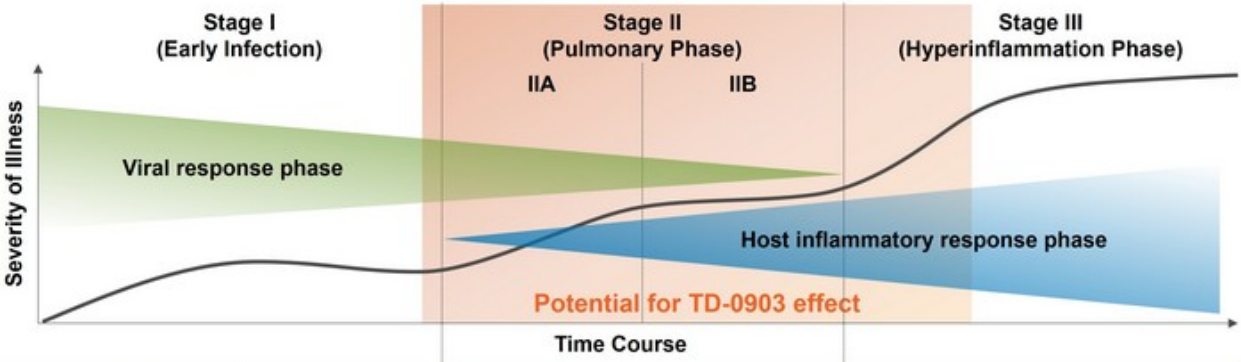
TD-0903

Inhaled lung-specific therapeutic: potential to be used in combination with other treatment modalities (e.g., antivirals) to provide additional therapeutic benefit with reduced risk of systemic immunosuppressive issues that may occur with systemic anti-inflammatories

Theravance Biopharma
Medicines That Make a Difference

1. https://coronavirus.jhu.edu/map.html, number as of 12/22. 2. IHME. 3. https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap#dashboard
4. https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#othercurrenteuas
5. https://www.fda.gov/media/136832/download#:~:text=This%20EUA%20authorizes%20the%20use,and%20who%20are%20at%20high. 6. https://www.statista.com/statistics/1106306/coronavirus-clinical-trials-worldwide/ According to ClinicalTrials.gov, there are 4,266 studies currently registered which are investigating the coronavirus disease (COVID-19). This statistic shows the total number of results from a search of "covid-19" on ClinicalTrials.gov database, as of December 22, 2020, by region.

Host inflammatory response to COVID-19 drives ALI and ARDS



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

ALI Acute Lung Injury; ARDS, Acute respiratory distress syndrome
Adapted from Siddiqi HK, et al. J Heart Lung Transplant 2020 Mar 20.
CRP, C-reactive protein; LDH, lactate dehydrogenase; NT-proBNP, ventricular natriuretic peptide; SIRS, severe inflammatory response syndrome.

TD-0903: Development plan designed to progress rapidly

Phase 1: Healthy volunteers

Single ascending dose: Single-dose safety, tolerability, PK → **Multiple ascending dose x 7 days:** Repeat-dose safety, tolerability, PK

✓ Complete

Phase 2: Hospitalized COVID-19 patients

Part 1 — Multiple-ascending dose study x 7 days: Repeat-dose safety, tolerability, PK, early dose-dependent efficacy

✓ Complete

Part 2 — Parallel group study x 7 days: Proof of concept efficacy and safety

- Dose 3 mg + SOC
- Placebo + SOC

→ *Ongoing*

SOC, standard of care.

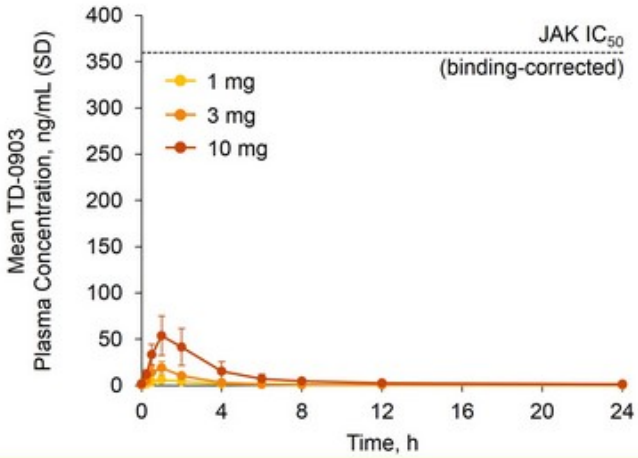
TD-0903 Phase 1 supports initiation of Phase 2 in COVID-19

Nebulized lung-selective pan-JAK inhibitor to treat acute hyperinflammation of the lung in COVID-19

Safety and Tolerability

- TD-0903 was well tolerated as single daily doses across a dose range from 1 mg to 10 mg for 7 days in healthy subjects
- Adverse events were assessed to be mild or moderate in severity, and none led to discontinuation of study treatment
- No clinically relevant changes in laboratory parameters, vital signs, or ECGs

Systemic Pharmacokinetics



Favorable safety and tolerability profile and PK below levels anticipated to exert systemic effects

IC_{50}, half-maximal inhibitory concentration; SD, standard deviation.

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

PATIENT POPULATION

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	**2,714**	**15%**	**~50%**	**$3.5B**
lung transplants worldwide, 2019[1]	lung transplants per year in US[2]	CAGR since 1988[2]	mortality at 6 years post transplant[3]	medical/productivity costs (2015–2025)[4]

CURRENT TREATMENT LANDSCAPE

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

Current standard of care: triple immunosuppression therapy

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

STRATEGIC OPPORTUNITY

TD-0903

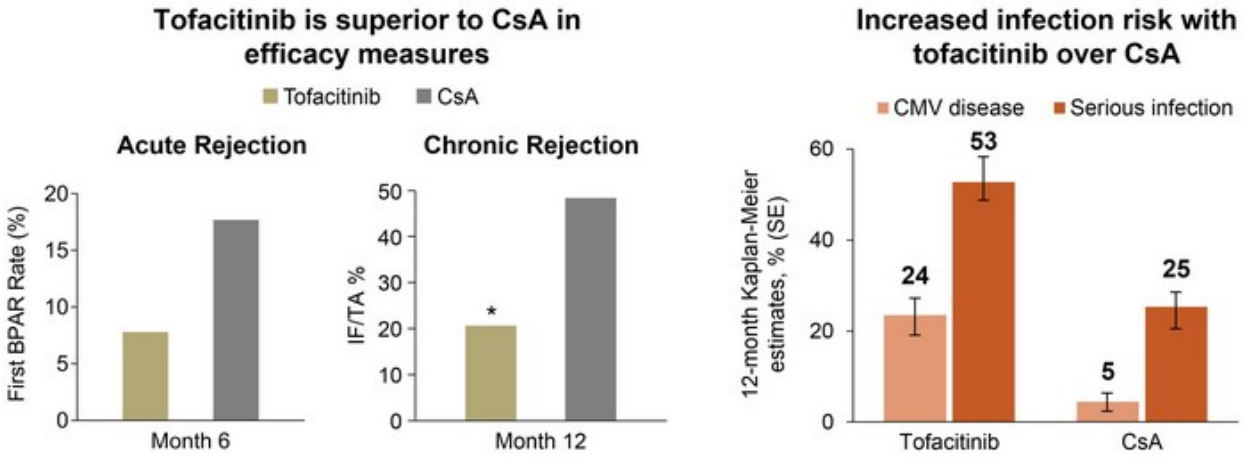
Potential first approved therapy specifically to prevent acute lung transplant rejection and development of CLAD
Use following lung transplantation could potentially improve patient morbidity and mortality risk, and reduce need for re-transplantation

Theravance Biopharma
Medicines That Make a Difference

1. http://www.transplant-observatory.org/data-charts-and-tables/.
2. United Network for Organ Sharing (UNOS), https://unos.org/data/transplant-trends.
3. Chambers DC et al, JHLT 2018; 37(10): 1169-1183. 4. JHEOR. 2015. CA Jones https://pdfs.semanticscholar.org/108c/5cb16aaab19fa9e9a1ccba64ae5869336f26.pdf
CAGR, compound annual growth rate; IPF, idiopathic pulmonary fibrosis; CF, cystic fibrosis; CLAD, chronic lung allograft dysfunction; mAb, monoclonal antibody; MMF, mycophenolate mofetil.

Pan-JAK inhibitors can prevent transplant rejections

Noninferiority trial of tofacitinib vs cyclosporine (CsA) in kidney transplant recipients[1]



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

Theravance Biopharma
Medicines That Make a Difference

1. Vincenti F, et al. Am J Transplant 2015;15:1644-53.
*p<0.001 vs CsA.
BPAR, biopsy-proven acute rejection; CMV, cytomegalovirus; IF/TA, Interstitial Fibrosis/Tabular Atrophy; SE, standard error; TWC2, time-weighted 2-h post-dose concentrations.


TD-8236
Potential first inhaled JAKi for asthma

High medical and economic burden in uncontrolled asthma

PATIENT POPULATION

339M cases worldwide[1]

25M US cases
8% of adults
8% of children[2]

Healthcare utilization[3]

~$58B US medical costs[4]

~$15B US asthma market (October 2020)[5]

CURRENT TREATMENT LANDSCAPE

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.

STRATEGIC OPPORTUNITY

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

Theravance Biopharma
Medicines That Make a Difference

*Asthma that requires high-dosage ICS + LABAs to prevent the disease from being uncontrolled) or asthma that remains uncontrolled despite treatment.

1. World Health Organization; 2. https://www.aafa.org/asthma-facts/; 3. Sadatsafavi, M., et al. Can Respir J 2010;17:74-80. 4. Nurmagambetov, T., et al., The economic burden of asthma in the United States, 2008-2013. Ann Am Thorac Soc. 2018; 15(3):348-356 5. TBPH estimate based on multiple data sources.

ICS, inhaled corticosteroids; IFN, interferon; LABA, long-acting β2 agonists; LTRA, leukotriene receptor antagonist; OCS, oral corticosteroid; T2, type 2; TSLP, thymic stromal lymphopoietin.

TD-8236: Phase 1 clinical trial design

Parts A & B completed September 2019; Part C enrollment completed — data reported in Q4 2020

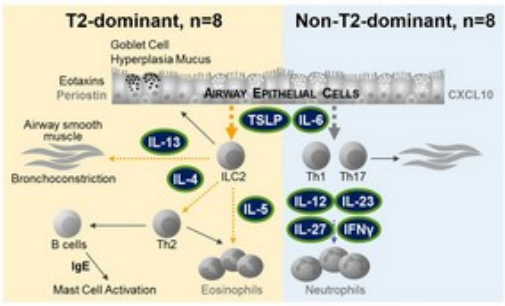
Part A: SAD (Healthy volunteers)
Safety, PK
All cohorts: N=6 active/2 Placebo

Part B: MAD (Mild asthmatics)
Safety, PK, PD (FeNO)

Part C: MoA Biomarkers
(Moderate-to-severe asthmatics + ICS)

N=16 active/8 placebo

D1 2 3 4 5 6 7
1500 µg



- Goal: build confidence in compound, MoA and dose in early-development
- **Endpoints: FeNO; pSTAT1 and pSTAT6 in bronchoalveolar lavage fluid; cytokines; epithelial gene expression**

Theravance Biopharma
Medicines That Make a Difference

FeNO, fractional exhaled nitric oxide; ICS, inhaled corticosteroids; MAD, multiple-ascending dose; MoA, Mechanism of Action; PK, pharmacokinetic; PD, pharmacodynamic; pSTAT, phosphorylated signal transducer and activator of transcription; SAD, single-ascending dose.

TD-8236: Positive Phase 1 trial in healthy subjects and patients with mild and moderate-to-severe asthma

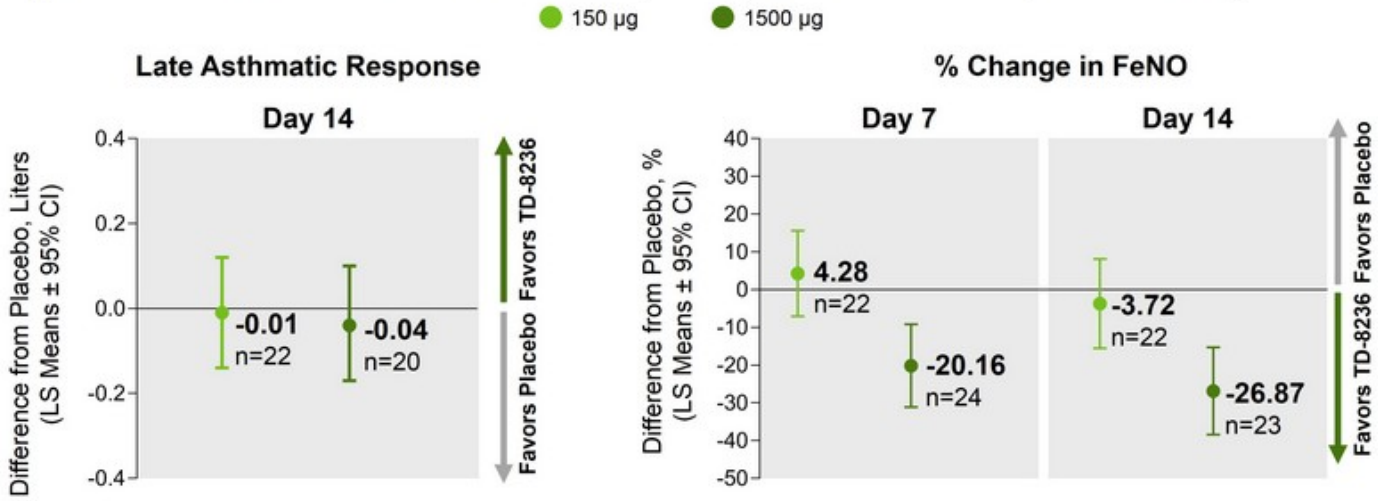
Phase 1 Profile	Healthy Volunteer Single Dose (Part A)	Mild Asthma Multiple Dose (Part B)	Moderate-to-Severe Asthma [+ ICS] Multiple Dose (Part C)
Generally well tolerated	✓	✓	✓
Minimal systemic exposure	✓	✓	✓
PK and PD profile consistent with once-daily dosing	✓	✓	✓
Biologic activity in lungs of patients with asthma		✓ ↓ FeNO	✓ ↓ FeNO, pSTAT1, pSTAT6

- Biomarkers of JAK target engagement (pSTAT1 and pSTAT6) significantly reduced in lungs of T2 high and T2 low moderate/severe asthmatics on top of inhaled corticosteroids
- Ongoing analysis of effect of TD-8236 on additional biomarkers including cytokines and gene expression

ICS, inhaled corticosteroids; PK, pharmacokinetic; PD, pharmacodynamic; FeNO, fractional exhaled nitric oxide

No impact of TD-8236 on the Late Asthmatic Response (LAR)

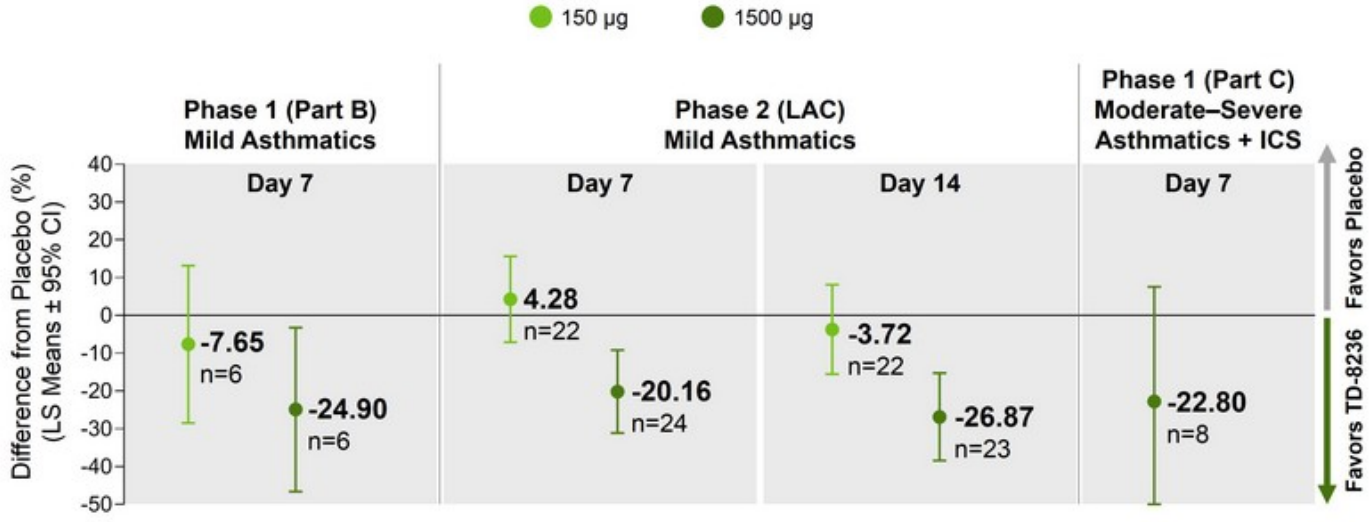
Significant reductions in inflammation marker (FeNO) and favorable safety and tolerability



- TD-8236 was generally well tolerated as a single-daily dose administered for 14 consecutive days

Primary Endpoint: Weighted Mean Area Under the Curve, 3–8 h.
LS, least-squares; CI, confidence interval.

TD-8236 FeNO reductions consistent across Phase 1 and 2



- FeNO reductions observed in moderate-to-severe asthmatics taking inhaled corticosteroids

ICS, inhaled corticosteroids; LAC, lung allergen challenge; LS, least-squares; CI, confidence interval.


TD-5202
Organ-gut selective irreversible JAK3 inhibitor
to treat inflammatory intestinal diseases

Celiac disease has no current treatments and serious health consequences

PATIENT POPULATION

1%
Global prevalence[1]

3.3M
US patients[2,3]

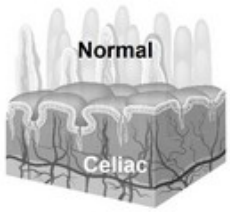
4–4.5x
increase in US over past 50 y[4]

>2x
higher healthcare costs than controls[5]

CURRENT TREATMENT LANDSCAPE

No approved treatment
Only available intervention is strict life-long gluten-free diet

30% of diagnosed patients are poorly controlled despite best dietary efforts[6]



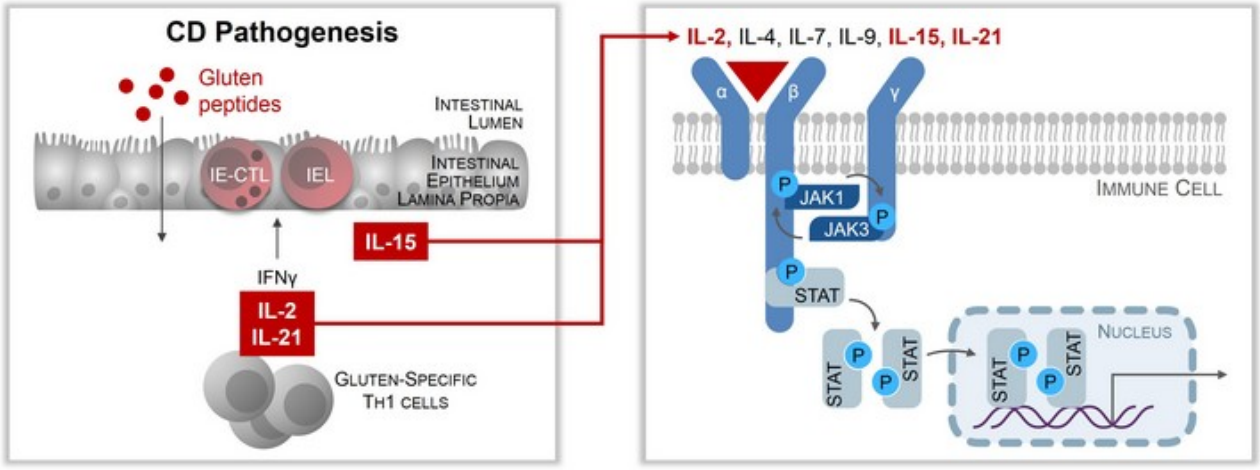
STRATEGIC OPPORTUNITY

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

Theravance Biopharma
Medicines That Make a Difference

1. http://www.drschaer-institute.com/us/celiac-disease/epidemiology-1033.html 2. 1% prevalence in US, BeyondCeliac.org. 3. 2018 US population 327M Census.gov.
4. Reunala T, et al. Dermatitis Herpetiformis: A Common Extraintestinal Manifestation of Coeliac Disease. Nutrients 2018;10(5). pii: E602
5. Guandalini et al. Direct Costs in Patients with Celiac Disease in the USA: A Retrospective Claims Analysis. Digestive Diseases Sciences 2016; 61(10):2823-30 6. Theravance Market Research.

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 has the potential to avoid systemic immunosuppression (genetic JAK3 deficiency leads to severe immunodeficiency)

Theravance Biopharma
Medicines That Make a Difference

Figure adapted from Jabri B and Sollid L. J Immunol 2017;198:3005-14.
IE-CTL, intraepithelial cytotoxic lymphocyte; IEL, intraepithelial lymphocyte.

TD-5202 First-in-human 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

AE, adverse event; $C_{max,ss}$, maximal steady-state concentration; NK, natural killer.

Inhaled ALK5i

Potential best-in-disease therapy for the treatment of idiopathic pulmonary fibrosis (IPF)

Idiopathic pulmonary fibrosis (IPF) remains a fatal chronic lung disease with limited treatment options

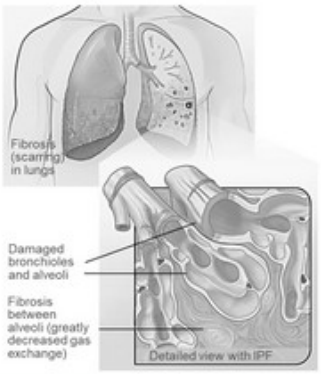
PATIENT POPULATION

140,000
US prevalence; currently orphan disease[1,2]

Profound dyspnea, unrelenting cough, impairment of activities of daily living

Mortality with IPF remains high

Lungs with IPF[3]



CURRENT TREATMENT LANDSCAPE

Limited treatment options

2 currently approved therapies, with modest efficacy and poor tolerability

STRATEGIC OPPORTUNITY

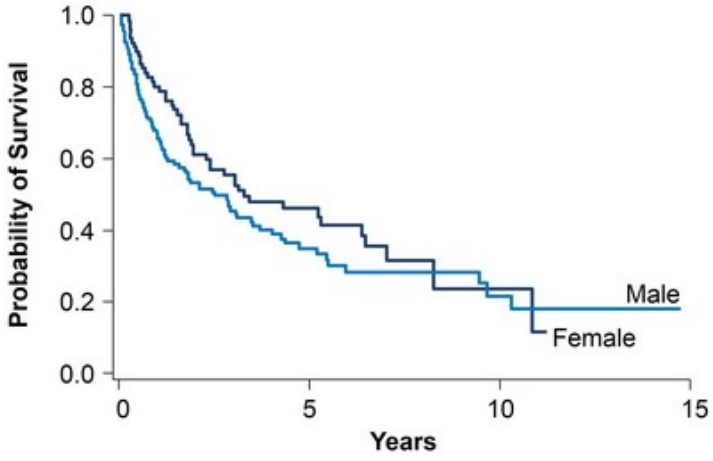
Inhaled ALK5i

Potential first-in-class inhaled ALK5 inhibitor anti-fibrotic agent for IPF
Despite treatment with the current SoC, IPF patients continue to experience disease progression and exacerbation

Theravance Biopharma
Medicines That Make a Difference

1. Raghu G, et al. Lancet Resp. 2014: 2(7):566-572.
2. Raghu G, et al. Eur Respir J. 2016: 48(1):179-186.
3. National Heart Lung and Blood Institute (NIH), Public Domain, https://commons.wikimedia.org/w/index.php?curid=29590103. Soc, Standard of Care.

Significant opportunity remains for effective IPF treatments



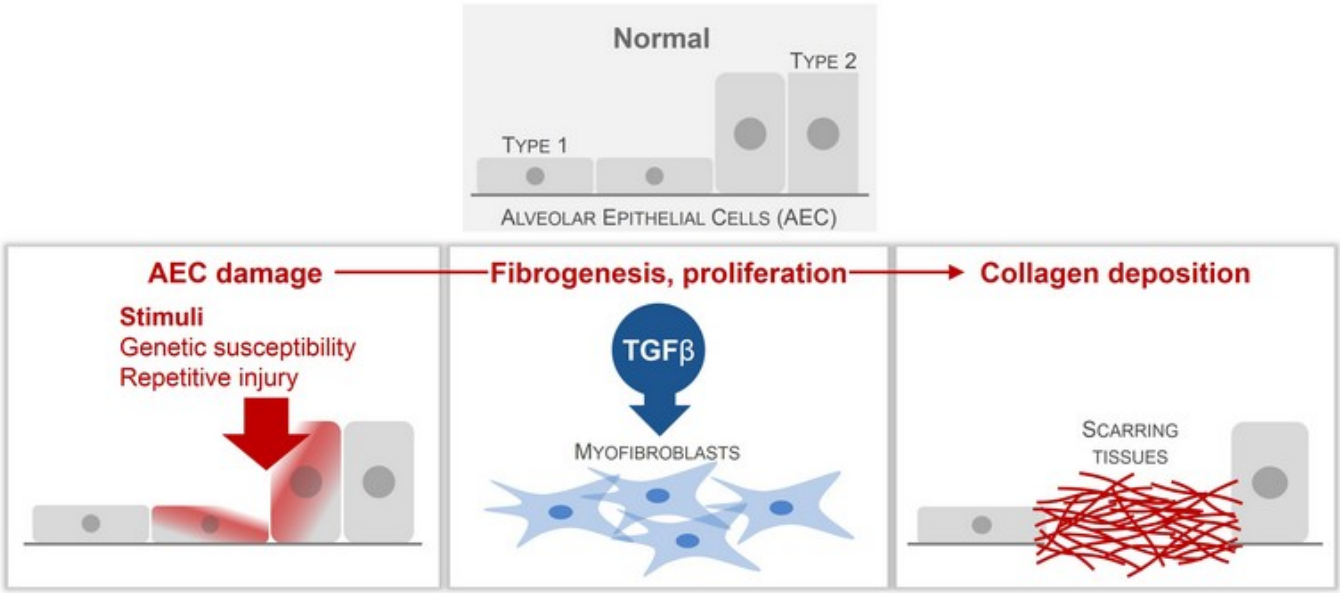
- Mortality with IPF remains high
  - <50% alive 3 years after diagnosis[1]

Goal To arrest disease progression with improved tolerability

1. King TE, et al. Am J Respir Crit Care Med 2001;164:1171-81.

Targeting the TGFβ pathway

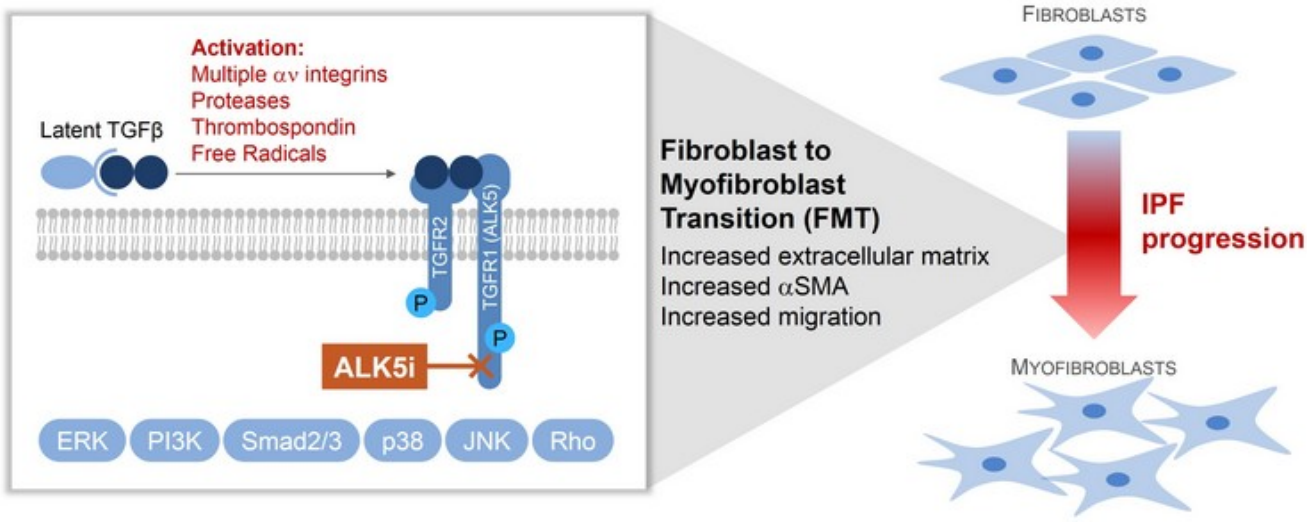
A core signaling pathway that drives fibrosis



TGFβ, transforming growth factor β.

Selectively targeting the TGFβ pathway through ALK5 inhibition

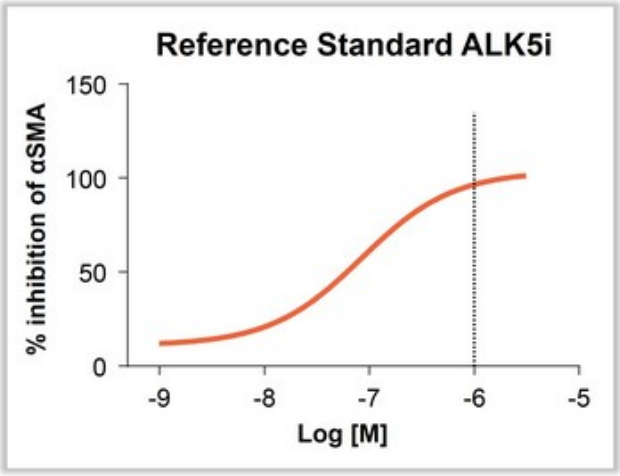
Inhibiting a core signaling pathway that drives fibrosis regardless of activation mechanism

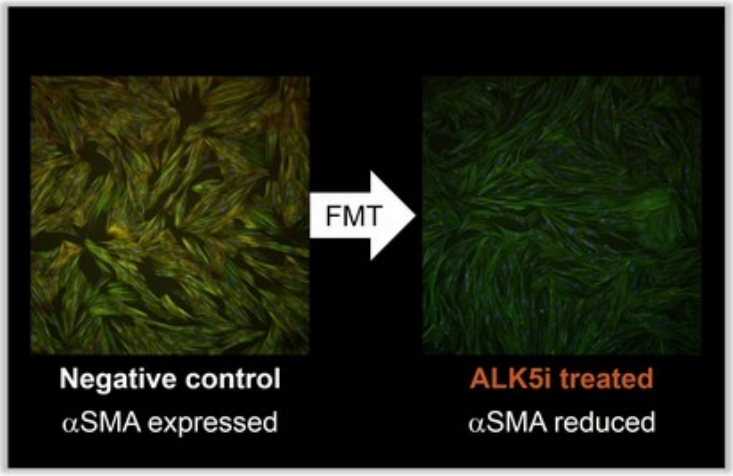


αSMA , α-smooth muscle actin; ERK, extracellular signal-regulated kinase; JNK, c-Jun N-terminal kinase; PI3K, phosphatidylinositol-4,5-bisphosphate 3-kinase; Smad2/3, mothers against decapentaplegic homolog 2/3; TGFR (ALK5), TGFβ receptor.

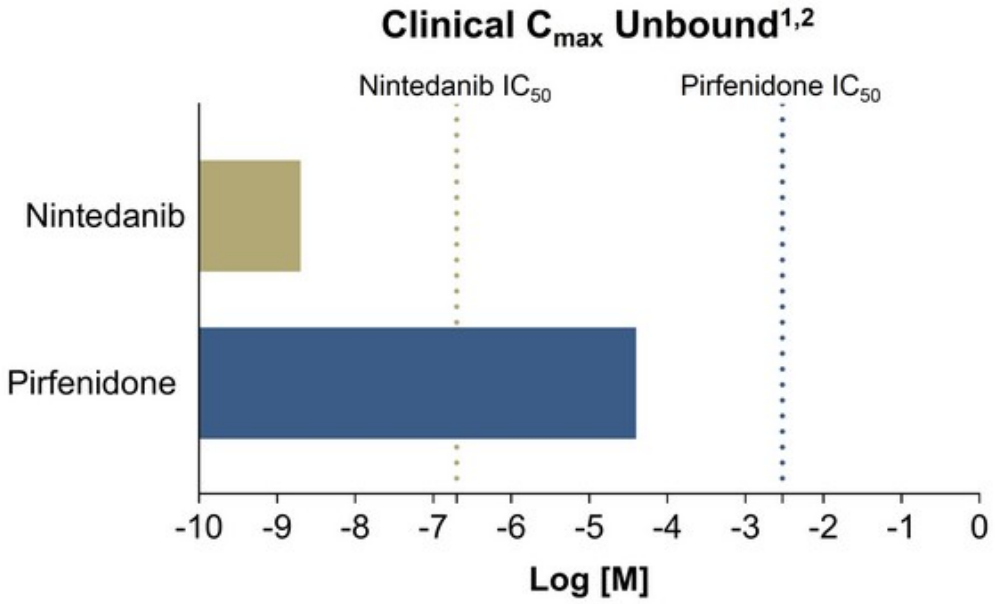
Adapted from: Neuzillet C, et al. Oncotarget 2013;5:78–94.

ALK5 inhibition directly interrupts FMT[1] in IPF





Current treatment options have no effect on FMT at clinically relevant concentrations

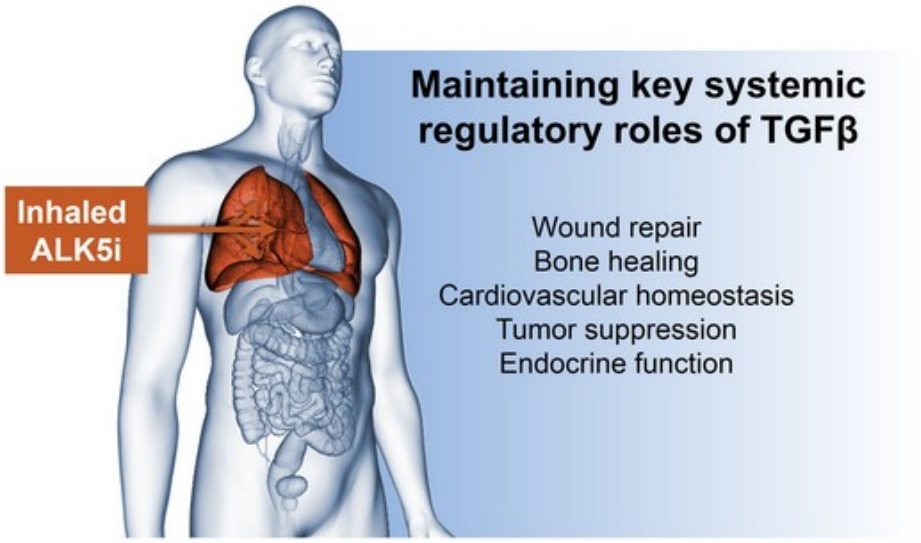


FTM, fibroblast to myofibroblast transition; C_{max}, maximal concentration; IC_{50}, half maximal inhibitory concentration.

1. https://www.tga.gov.au/sites/default/files/auspar-nintedanib-esilate-160208.pdf.
2. Ogura T, et al. Eur Respir J. 2015;45:1382-92.

Lung selectivity avoids unwanted systemic side effects

Minimizing systemic inhibition of a cytokine essential for homeostasis



Modified from: Akhurst RJ, Hata A. Nat Rev Drug Discov 2012;11:790-811.
TGFβ, transforming growth factor β.


Ocular JAKi
Potential best-in-disease, pan-JAK inhibitor with
long-acting ocular anti-inflammatory activity

Diabetic macular edema causes blindness in diabetics

PATIENT POPULATION

2.7 million US prevalence[1]

#1 cause of blindness in diabetes[2]

140% higher direct and indirect healthcare costs in patients with DME vs diabetics without ocular disease[3]

Normal vision | Vision with DME

CURRENT TREATMENT LANDSCAPE

1st **Anti-VEGF treatments** Most patients have suboptimal response

2nd **Intraocular steroids** Side effects limit utility

Nonpharmacological treatments (e.g. laser coagulation) limited efficacy and significant adverse events

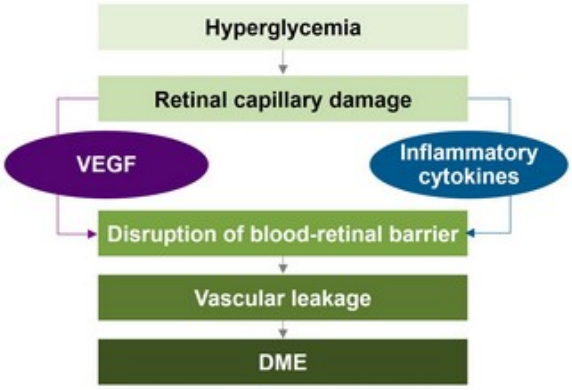
STRATEGIC OPPORTUNITY

Ocular JAKi

Potential to offer an alternative treatment for DME patients who are not optimally responding to treatment with VEGFi

2. Romero-Aroca, World J Diabetes 2011;2(6): 98-104. 3. Lee et al Curr Med Res Opin 2008;24:1549-59.
Images from Angiogenesis Foundation, www.scienceofdme.org. DME, Diabetic macular edema; VEGFi, vascular endothelial growth factor inhibitor.

Inflammation, not just VEGF, is a key driver of DME



Current Pharmacological Treatments

Intraocular anti-VEGF agents

- One third do not respond to anti-VEGF while another third have a suboptimal response[1]
- Require frequent intravitreal injections

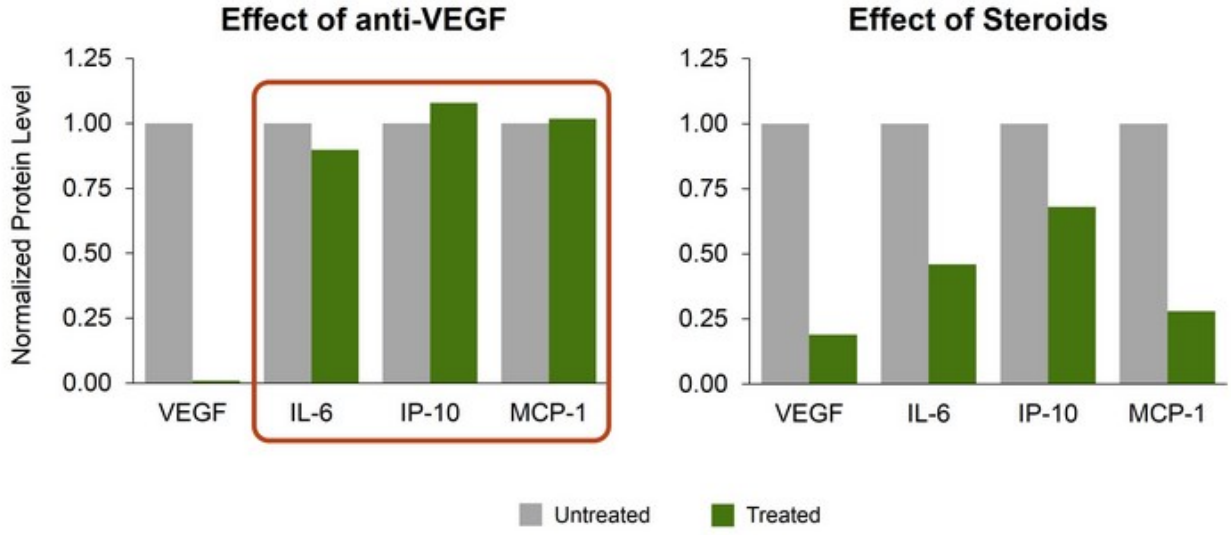
Intraocular steroids

- High frequency of formation of cataracts and glaucoma

Need for broad, sustained release, anti-inflammatory with a safer side-effect profile

Gonzalez VH, et al. Am J Ophthalmol 2016;172:72-79.
VEGF, vascular endothelial growth factor.

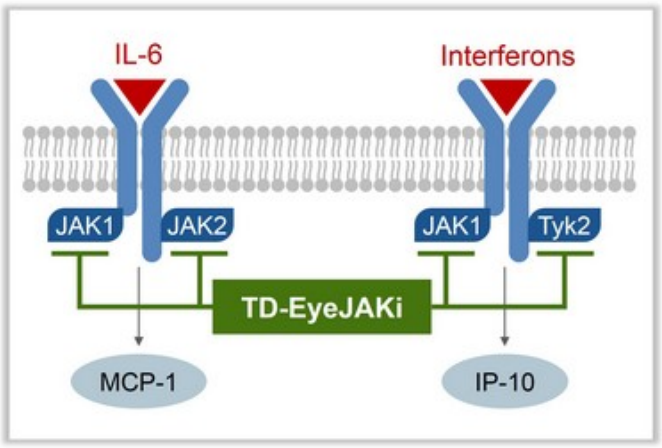
Unmet need for an anti-inflammatory drug: opportunity for eye-selective JAK inhibition



Theravance Biopharma
Medicines That Make a Difference

Adapted from Sohn HJ, et. al. Am J Ophthalmol 2011; 152:686-694.

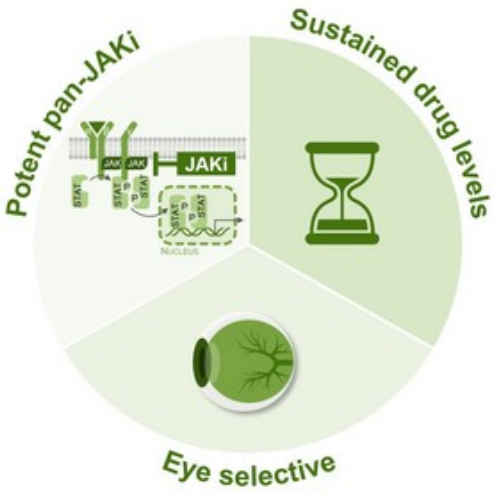
Ocular pan-JAK inhibition has the potential to address key disease pathways in DME

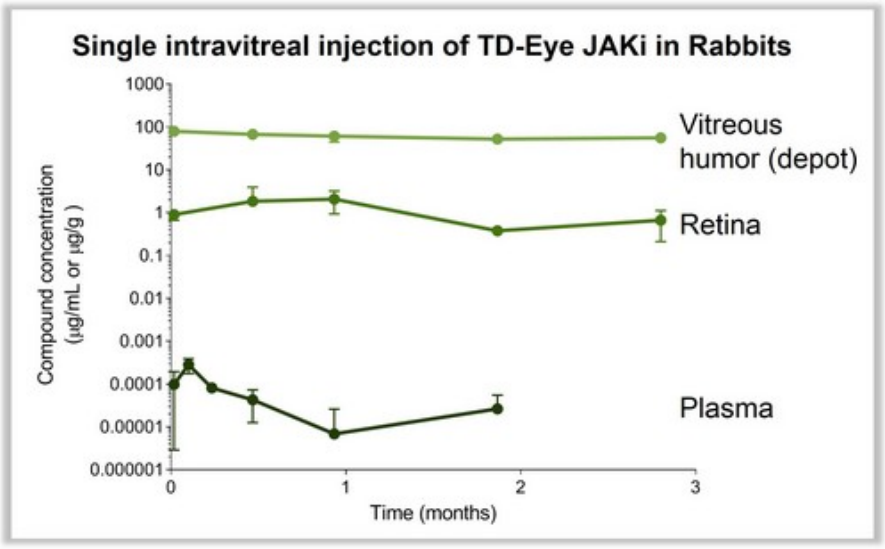


TD-EyeJAKi inhibits key DME inflammatory pathways:

- IL-6 and interferon signaling pathways in human primary cells
- IL-6 induced pSTAT3 and interferon-induced IP-10 in the back of the eye *in vivo*

A pan-JAK inhibitor designed for eye selectivity with projected dosing interval of at least three months





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.

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

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.

OATP, organic anion transporting polypeptide.