



# First Quarter 2021 Financial Results and Business Update

May 4, 2021

# 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 goals, designs, 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 expenses, 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, 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-K filed with the SEC on February 26, 2021, and other periodic reports filed with the SEC.

# Agenda

## Introduction

**Gail B. Cohen**

Vice President, Corporate Communications

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## Overview

**Rick E Winningham**

Chief Executive Officer

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## Development and Commercial Update

**Richard A. Graham**

Senior Vice President, Development

**Frank Pasqualone**

Senior Vice President, Chief Business Officer

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## Financial Update

**Andrew A. Hindman**

Senior Vice President, Chief Financial Officer

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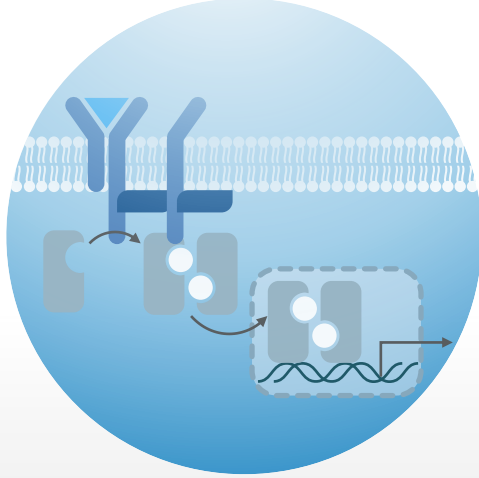
## Closing Remarks

**Rick E Winningham**

Chief Executive Officer

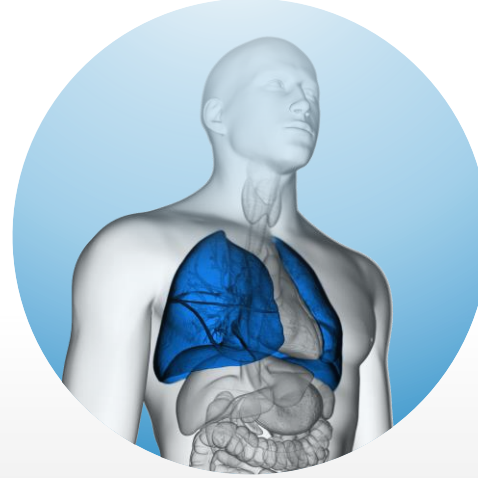
# Theravance Biopharma difference: Targeting disease with organ selective medicines

## Pathway



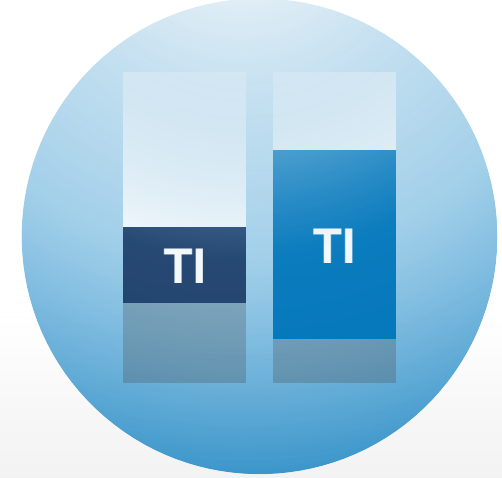
**Target disease biology**

## 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**

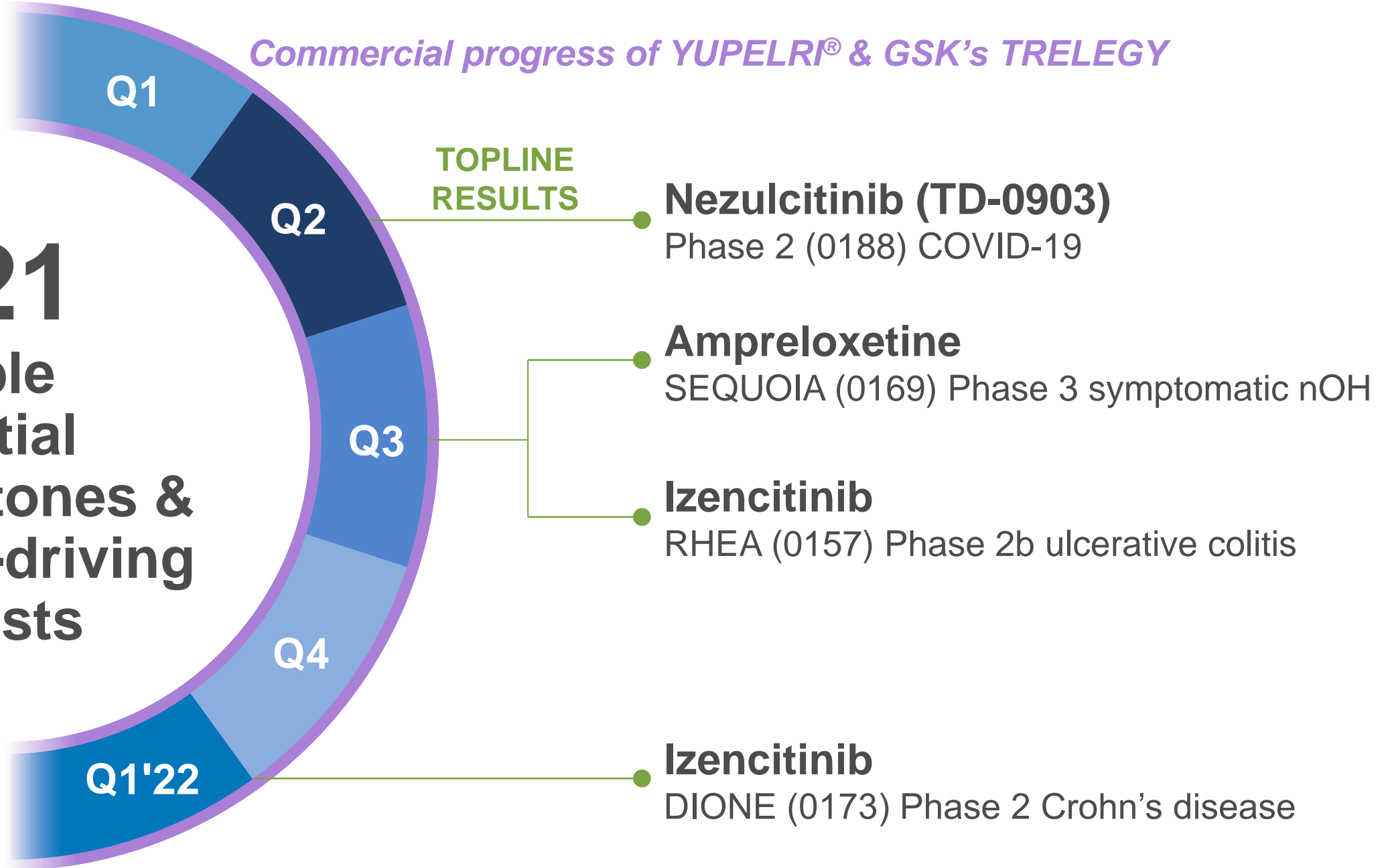
# Key programs supported by proven development and commercial expertise

	Program	Indication	Research	Phase 1	Phase 2	Phase 3	Filed	Marketed	Collaborator
	<b>Amprexetine (TD-9855)</b> NRI	Symptomatic nOH	Phase 3						Wholly-owned
Organ-Selective	<b>Izencitinib (TD-1473)</b> GI JAKi	UC	Phase 2b/3						Janssen Biotech, Inc.
		CD	Phase 2						
	<b>TD-5202</b> Irreversible JAK3i	Inflammatory intestinal diseases	Phase 1						
	<b>YUPELRI® (revefenacin)</b> LAMA	COPD	Marketed						
	<b>Nezulcitinib (TD-0903)</b> Inhaled JAKi	COVID-19	Phase 2						Wholly-owned
	<b>TD-8236</b> Inhaled JAKi	Asthma	Phase 2						
	<b>Inhaled ALK5i</b>	Idiopathic pulmonary fibrosis	Phase 1						

	Program	Indication	Research	Phase 1	Phase 2	Phase 3	Filed	Marketed	Rights	
Economic Interests	TRELEGY <sup>1</sup> FF/UMEC/VI	COPD							Marketed	GSK & Innoviva, Inc.
		Asthma							Marketed	
	Skin-selective JAKi	Dermatological diseases	Research							

## Commercial progress of YUPELRI® & GSK's TRELEGY

**2021**  
**Multiple  
potential  
milestones &  
value-driving  
catalysts**







# Nezulcitinib (TD-0903) Program

Nebulized lung-selective pan-JAK inhibitor to treat:

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

# Nezulcitinib (TD-0903): breaking new ground with inhaled JAKi

Focused execution in acute lung injury (ALI) driven by patient need

## COVID-19 MARKET DYNAMICS

>149M COVID-19 patients globally<sup>1</sup>;  
>32M patients in US<sup>2</sup>

56% of US population ≥1 vaccine  
dose; 40% fully vaccinated<sup>3</sup>

Virus still surging in communities /  
parts of the world<sup>1</sup>

5 variants of concern in US<sup>4</sup>

Declining but substantial proportion of  
population refusing vaccination<sup>5</sup>

Disproportionate burden on  
people of color<sup>6</sup>

Treatments needed for  
hospitalized COVID-19 patients  
with acute lung injury

### TD-0903 Dose finding placebo controlled data<sup>7</sup>

- ▶ Generally well-tolerated
- ▶ Low systemic exposure
- ▶ Positive trend in clinical status, reduced hospital stay
- ▶ No deaths in 3, 10 mg cohorts
- ▶ Improved oxygenation from baseline to Day 7
- ▶ Improved inflammatory biomarkers

Only therapeutic in development  
with nebulized  
lung-targeted approach

## BUILDING A PIPELINE IN A PRODUCT

*Potential areas for exploration:*

ALI in COVID-19 in hospitalized  
patients

Preventing progression of lung  
hyperinflammation that leads to  
hospitalization

Accelerated recovery of  
long-haul COVID-19 patients

Future applications for coronavirus  
and influenza inflammation

Prevention of lung transplant rejection

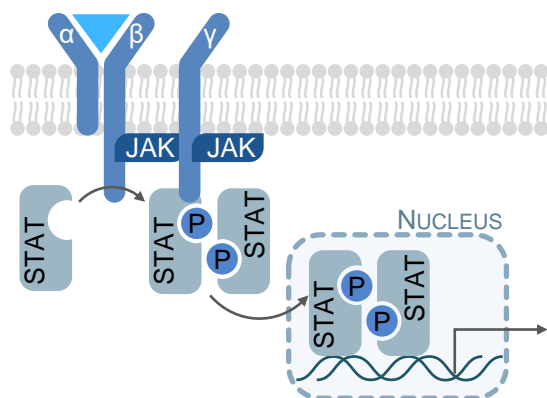


# Nezulcitinib: a lung-selective inhaled immunotherapy in development

## Broadly inhibits the pulmonary inflammatory cascade caused by viral infection

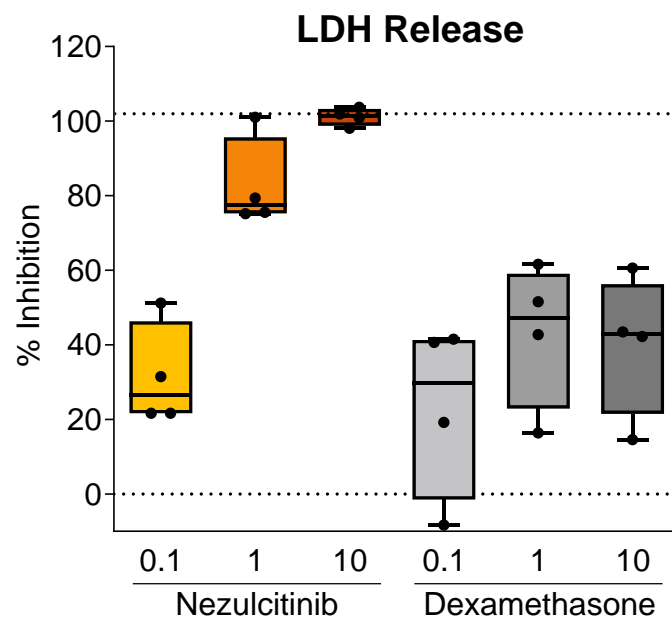
Potential therapeutic benefit via three activities:

### Potent pan-JAK inhibition

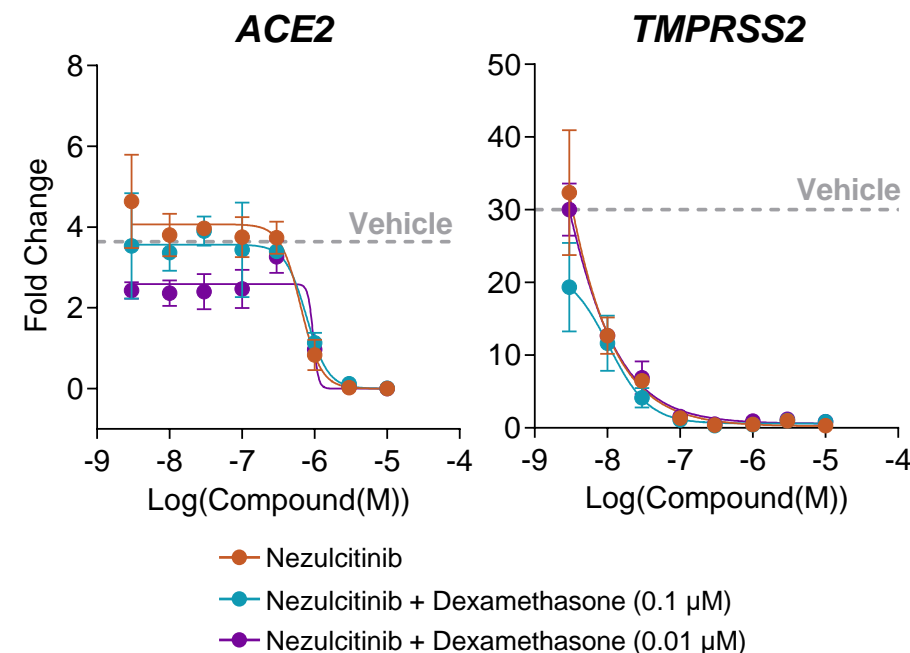


- Supresses release of key inflammatory markers associated with COVID-19 from epithelial and immune cells (IFN $\gamma$ , IL-6, IP-10, MCP-1, GM-CSF)

### Protection against virus-induced cell death



### Prevention of cell entry, limiting virus dissemination in lung



**Our goal: nezulcitinib to be the first inhaled treatment to broadly interrupt viral-induced activation and restore immune system balance in the lung**

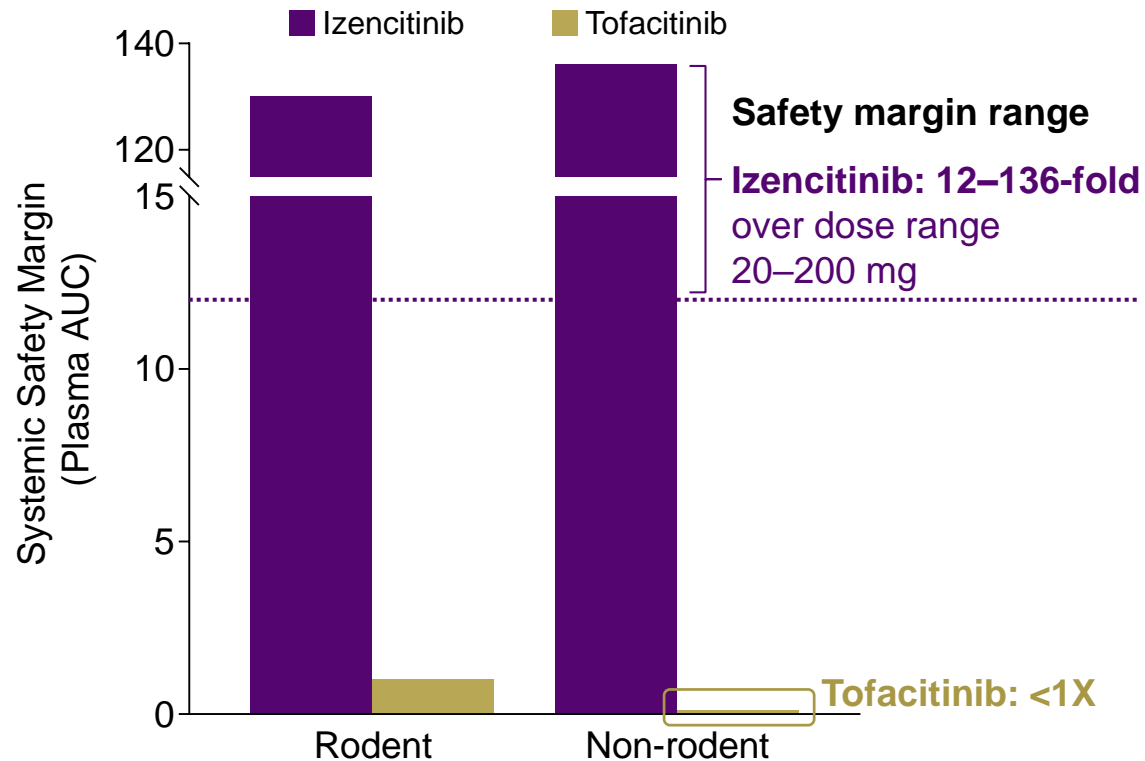


# **Izencitinib (TD-1473/JNJ-8398)**

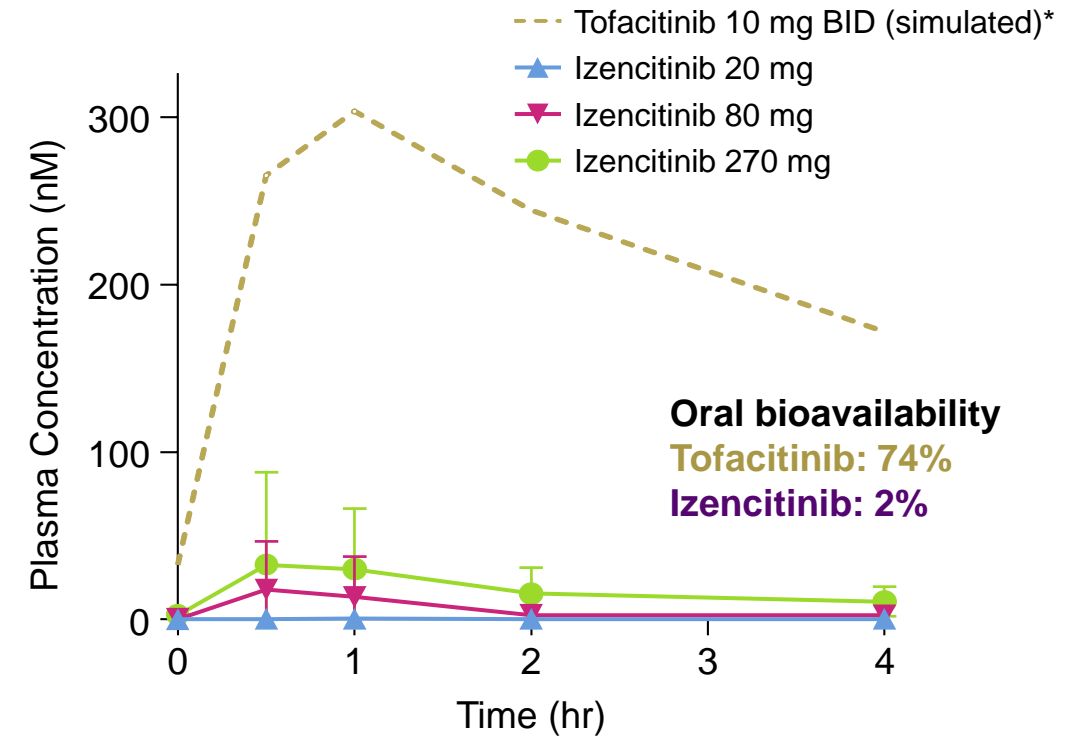
Oral gut-selective pan-JAK inhibitor to treat  
inflammatory bowel diseases

# Izencitinib's oral, gut-selective, pan-JAK approach is designed to reduce systemic side effects

## High margins of systemic safety in nonclinical studies



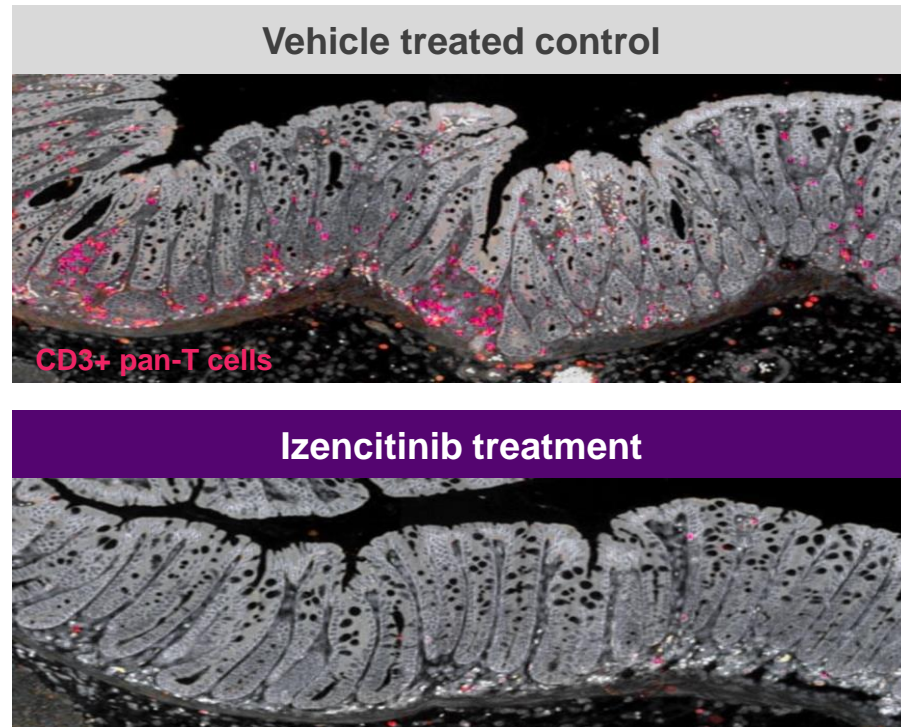
## Low systemic plasma concentrations in UC patients



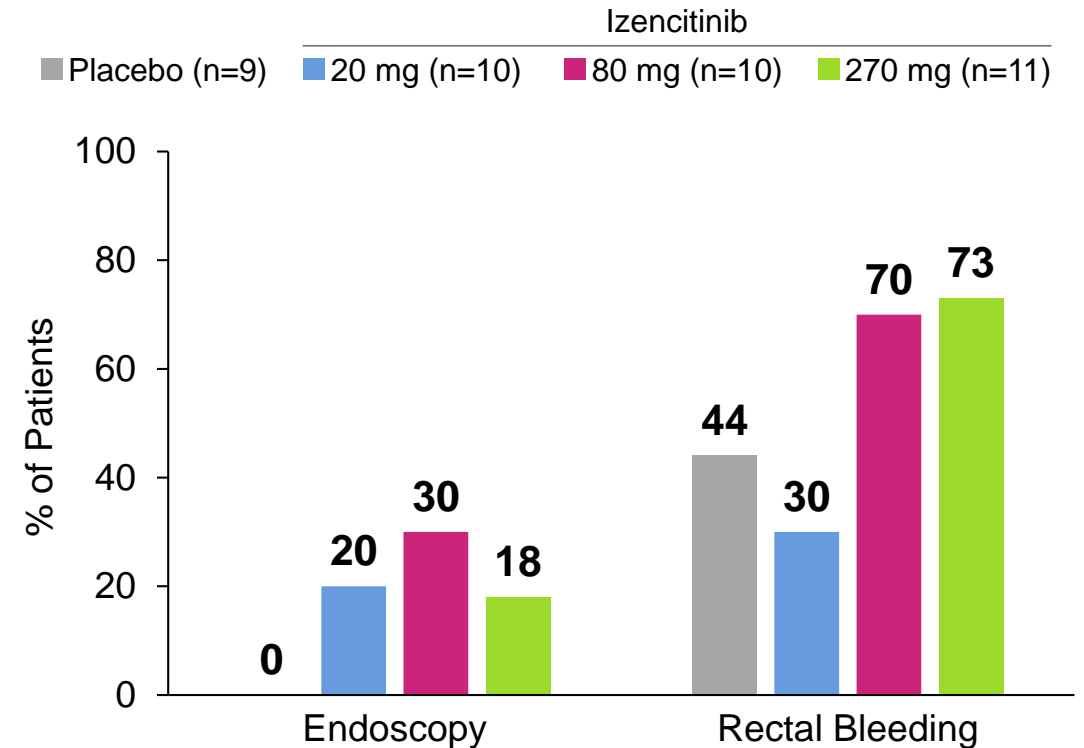
Gut selectivity confers low systemic exposure and offers the potential for reduced adverse effects

# Izencitinib's oral, gut-selective, pan-JAK approach is designed to maximize efficacy in IBD

**Blocks inflammation and penetrates deep within mouse colon**



**Demonstrates improvement in UC patients in Phase 1b**




**The gut-selective approach is intended to maximize concentration where it matters, at the site of action in the GI tract**





# Ampreloxetine (TD-9855)

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





# Ampreloxetine: new approach in nOH

## MARKET DYNAMICS

**~350K US patients<sup>1</sup>:**  
70–80% of MSA patients<sup>2</sup>  
30–50% of PD patients<sup>3</sup> have nOH<sup>4</sup>

**Specialist network in place:** concentrated group of neurologists/ cardiologists treat patients; ‘at risk’ patients already identified and managed by specialty institutions

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

**Established nOH Tx paradigm:** nOH included in medical treatment guidelines for PD/MSA patients; once diagnosed with nOH, patients prescribed drug

**nOH profoundly impacts QoL**

**Study 0169 primary endpoint:**  
Change from baseline in  
OHSA Question 1

**OHSA measures core nOH symptom:**  
Dizziness / lightheadedness  
due to brain hypoperfusion

**Clinically significant endpoint:** 1-point  
OHSA improvement

## SYMPTOMS

- ▶ Dizziness or lightheadedness
- ▶ Fatigue
- ▶ Difficulty walking
- ▶ Weakness
- ▶ Impaired cognition
- ▶ Pain (back of head/neck/shoulders)
- ▶ Blurred vision
- ▶ Tremulousness
- ▶ Vertigo

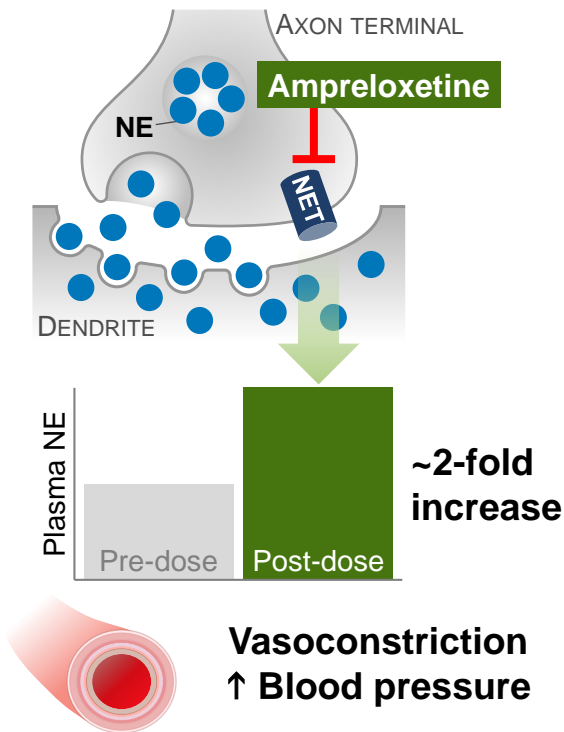
## IMPACT

Depression  
Social isolation  
Poor QoL  
Falls (fractures/head trauma)  
Morbidity

# Amprexetine: a once-daily, potent and selective norepinephrine reuptake inhibitor with a differentiated MOA for treating nOH

Amprexetine is designed to target and correct the norepinephrine imbalance...

NE Release at Neurovascular Junction

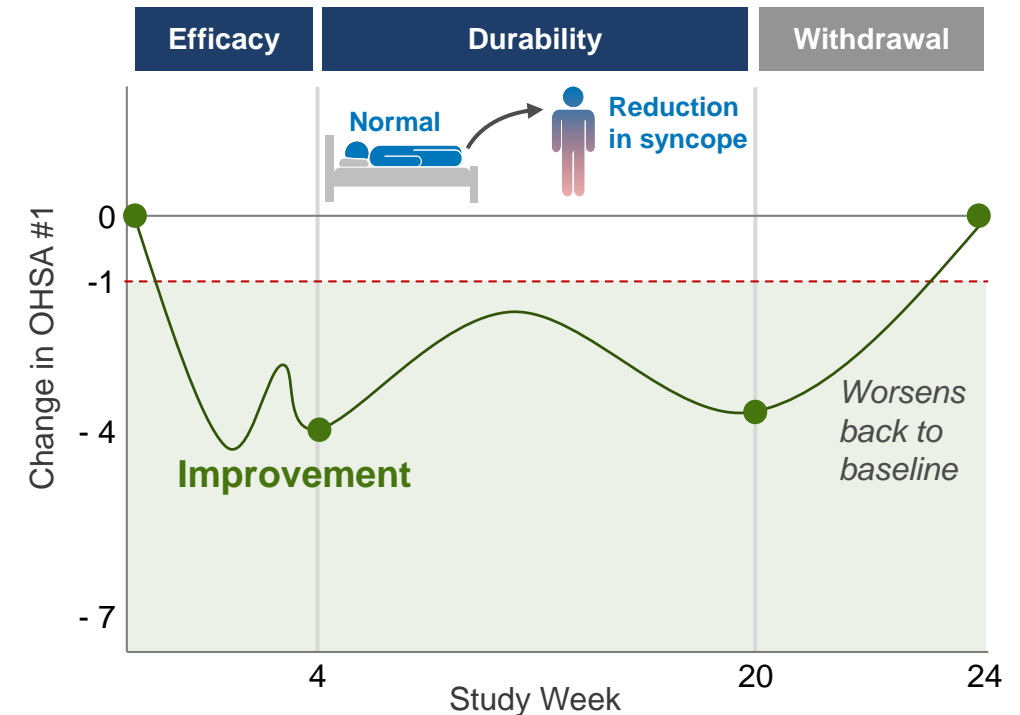


...with potential for market differentiation...

Current nOH treatment options:

- ▶ No durable effect
- ▶ Multiple daily dosing
- ▶ Black box warning for SH

...and demonstrated a clinically meaningful and durable impact<sup>1</sup>



Our goal: amprexetine to be the first treatment to demonstrate a sustained impact for patients managing the chronic and debilitating symptoms of nOH



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

# YUPELRI® (revefenacin) inhalation solution

FDA-approved for the maintenance treatment of COPD

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



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

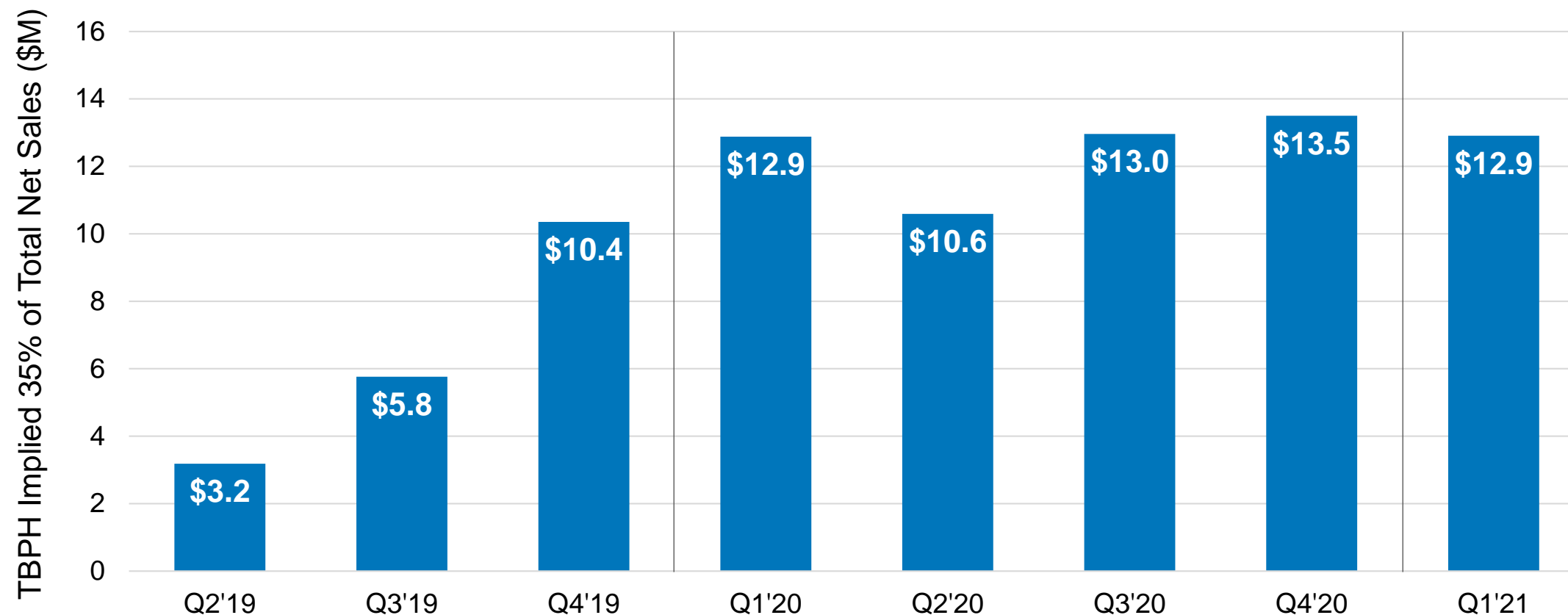
9% of COPD patients (~800,000) use nebulizers for ongoing maintenance therapy; 41% use nebulizers at least occasionally for bronchodilator therapy<sup>2</sup>

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



Companies co-promote under US profit/loss share

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

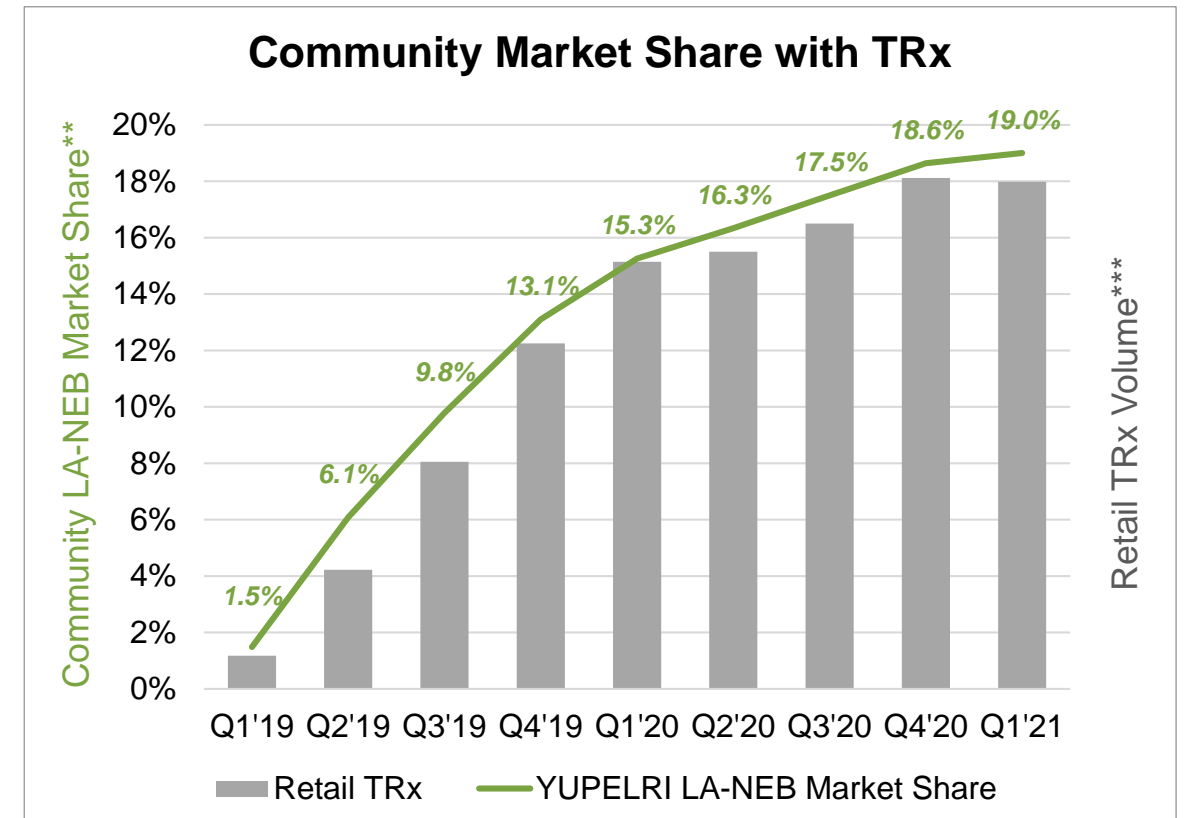
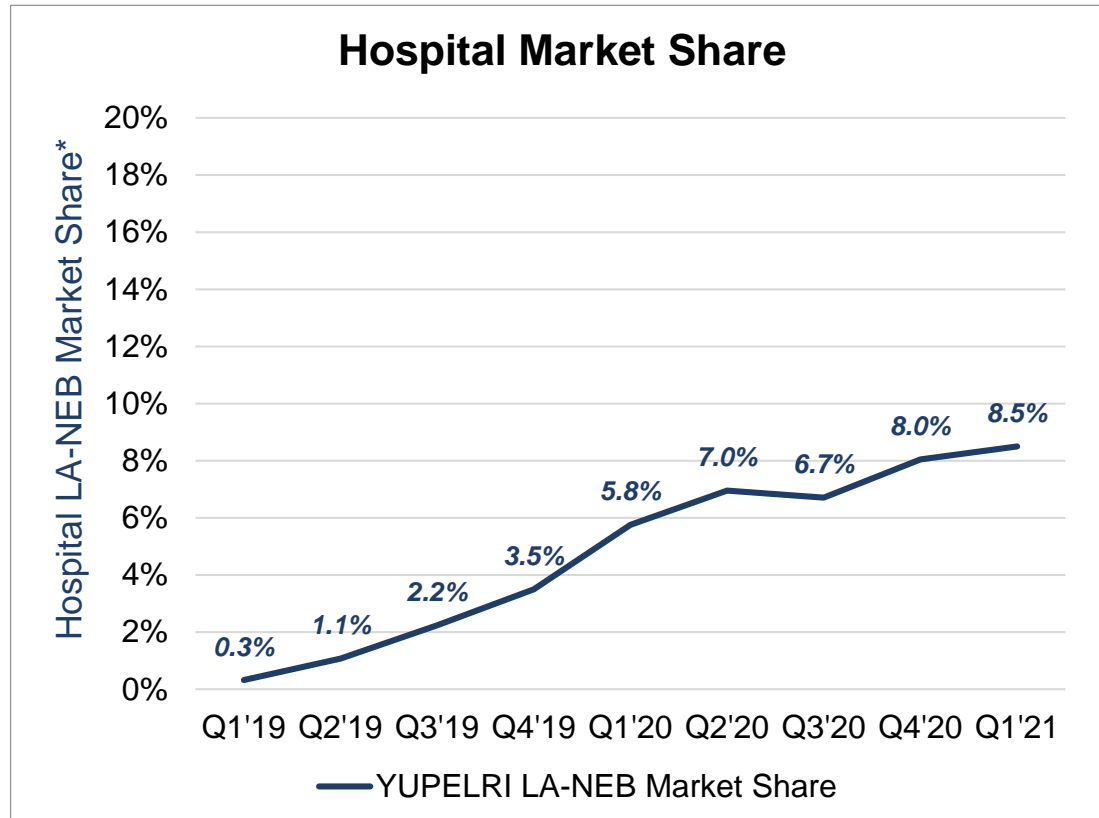


**TBPH implied 35% of YUPELRI US net sales represents TBPH's portion of the combined TBPH and VIATRIS net revenue**



# YUPELRI® hospital sales and community TRx trends

Continued market share growth across both the hospital and retail channels



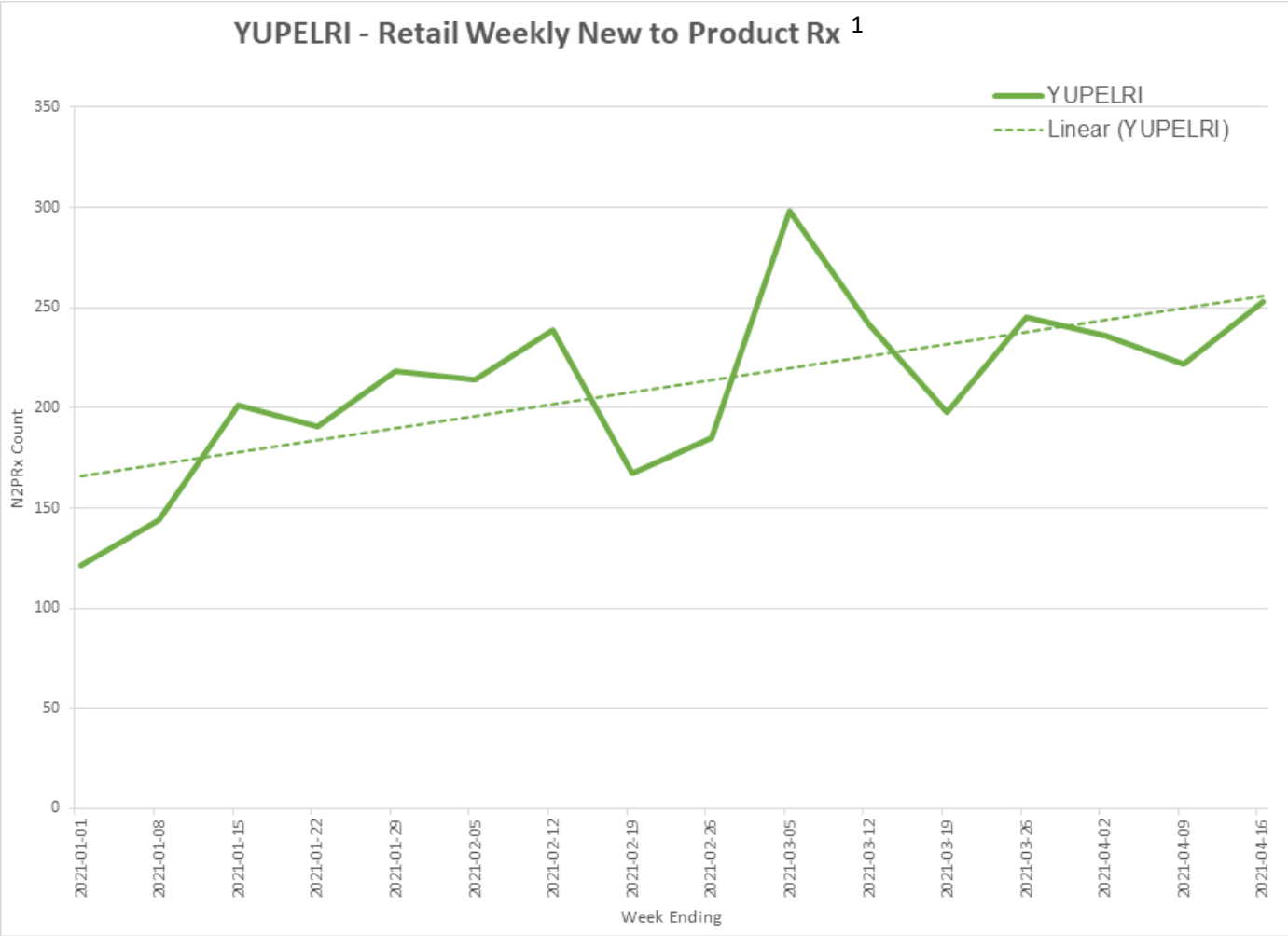
Most patients who receive YUPELRI® in the hospital are discharged with an Rx<sup>1</sup>

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

\*\*Community LA-NEB Market Share includes Retail + DME / Med B FFS through January '21

LA-NEB Market: YUPELRI, BROVANA, LONHALA, PERFOROMIST

# Positive growth trends for YUPELRI® continuing beyond March



*Increasing New Patient Starts Continue to Drive LA-NEB Market Share Growth*

## YUPELRI

- ✓ 719 hospital accounts have ordered<sup>2</sup>
  - ▶ 67% have ordered more than once
- ✓ 91% formulary win rate<sup>3</sup>
- ✓ Highest number of formulary support presentations in Q1'21 since launch
- ✓ 74% commercial coverage<sup>4</sup>

1. Symphony Health, Metys, Jan – Apr 2021, Weekly New to Product (N2P) Rx Volume.  
2. IQVIA DDD through March 2021.  
3. TBPH Commercial Data Warehouse.  
4. Decision Resources Group (DRG) as of May 2021.



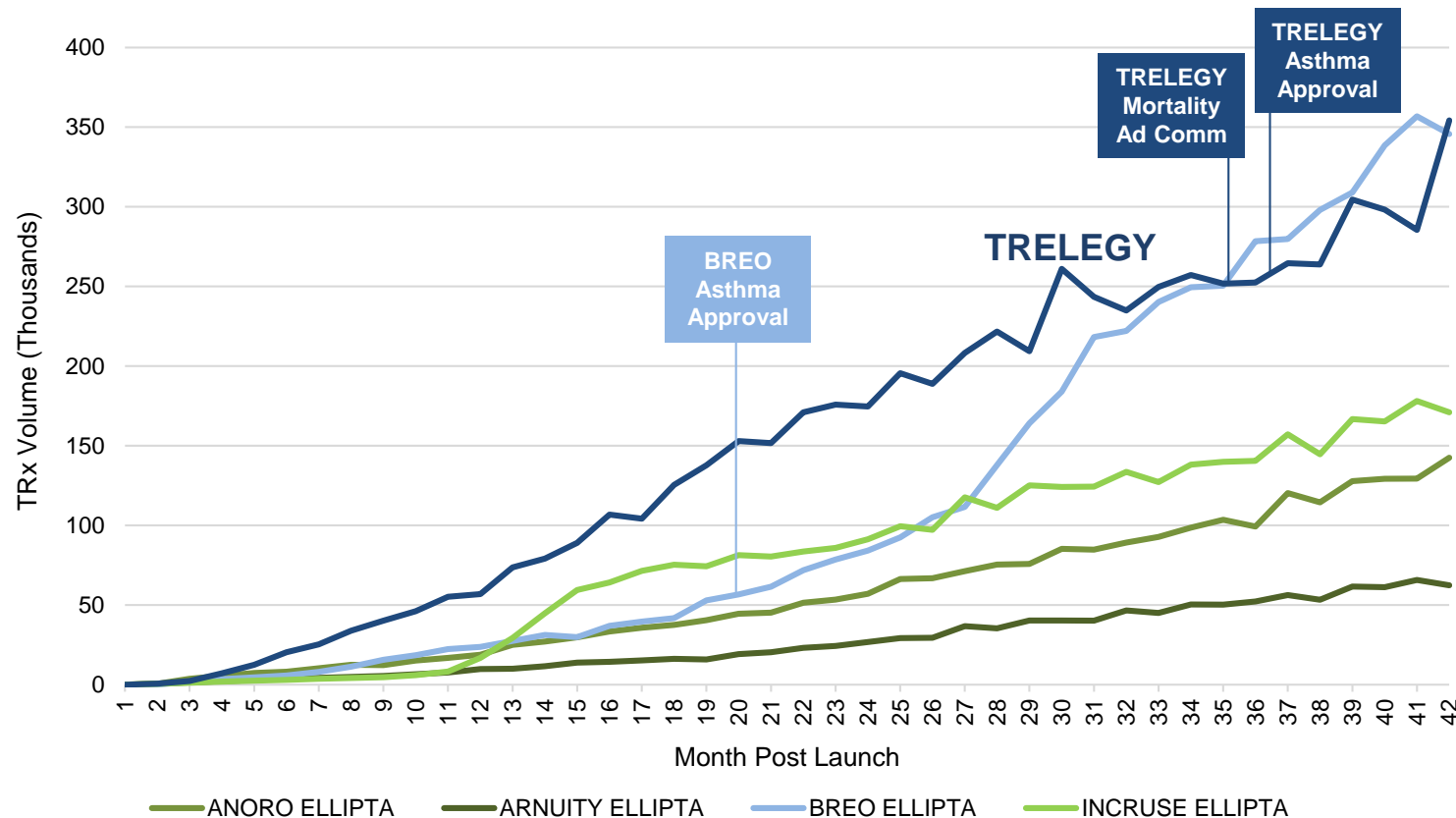
# Economic interest

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<sup>1</sup>

Strongest US ELLIPTA Launch



Launched in US in November 2017

Source: GSK, Symphony Health Metys monthly TRx data. Source: Symphony Health, Metys, September 2013 – March 2021, Monthly TRx Volume

## TRELEGY

- ✓ Q1 net sales of \$341MM
- ✓ Year-over-year sales growth of 37% from the same period in 2020
- ✓ US sales (\$238MM) benefited from new asthma indication approved and launched in Q3 2020
- ✓ International and EU sales grew to \$103M; asthma indication approved in Japan in Q4 2020

# First quarter 2021 financial highlights

\$210.0 million cash<sup>1</sup> as of March 31, 2021

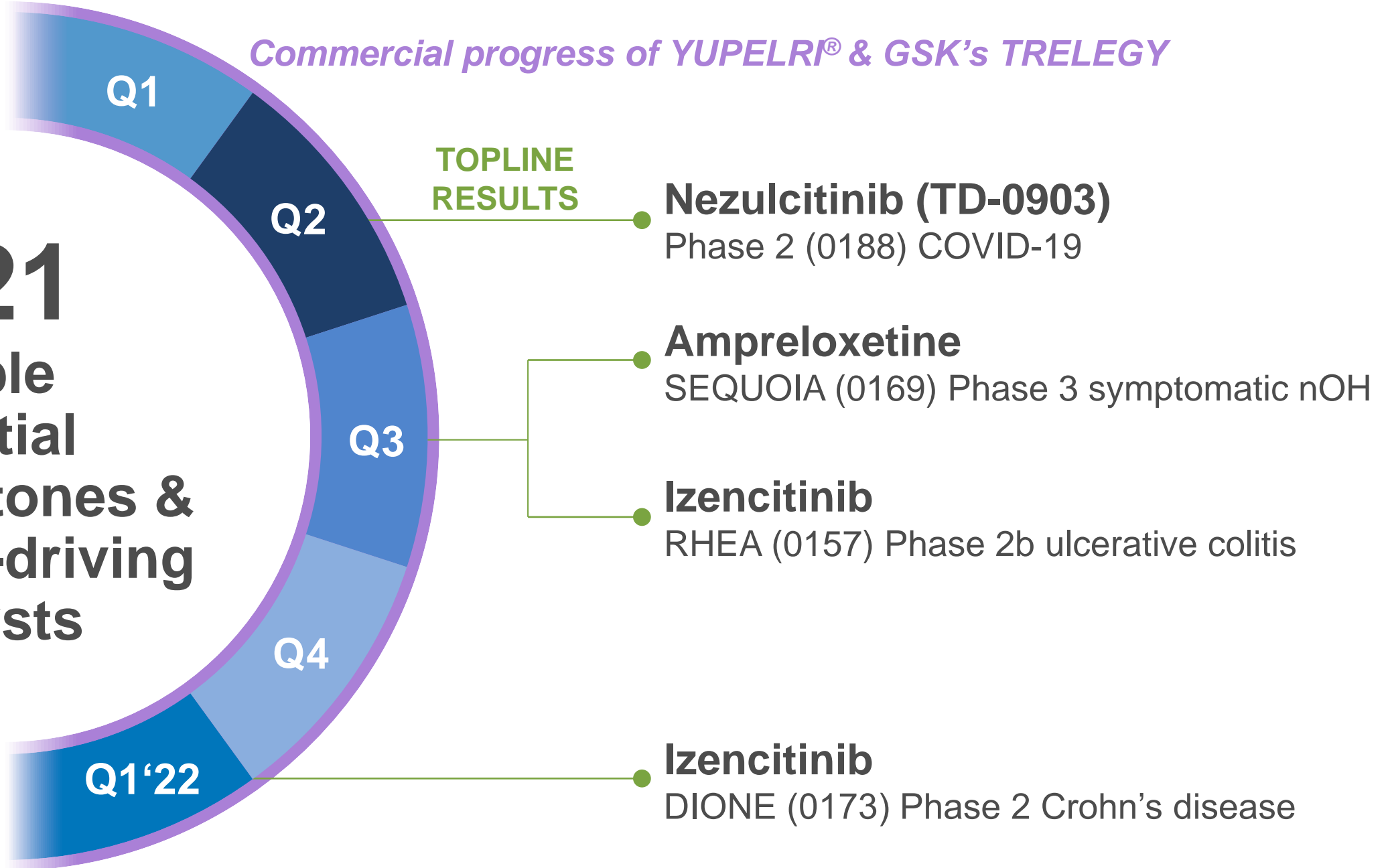
(\$, in thousands)

	Three Months Ended March 31,	
	2021	2020
	(Unaudited)	
<b>Revenue:</b>		
Collaboration revenue	\$ 3,872	\$ 6,632
Licensing revenue	-	1,500
Viartis collaboration agreement	10,385	11,730
Total revenue	14,257	19,862
<b>Costs and expenses:</b>		
Research and development <sup>2</sup>	67,599	66,013
Selling, general and administrative <sup>2</sup>	30,550	26,325
Total costs and expenses	98,149	92,338
<b>Loss from operations</b>	<b>(83,892)</b>	<b>(72,476)</b>
<b>Share-based compensation expense:</b>		
Research and development	7,921	7,865
Selling, general and administrative	7,911	7,411
Total share-based compensation expense	15,832	15,276
<b>Operating expense excluding share-based compensation:</b>		
Research and development operating expense excluding share-based compensation	59,678	58,148
Selling, general and administrative operating expense excluding share-based compensation	\$ 22,639	\$ 18,914



## Commercial progress of YUPELRI® & GSK's TRELEGY

**2021**  
**Multiple  
potential  
milestones &  
value-driving  
catalysts**



**Rick E Winningham**  
Chairman and Chief Executive Officer



**Andrew A. Hindman**  
Senior Vice President, Chief Financial Officer



**Frank Pasqualone**  
Senior Vice President, Chief Business Officer



# Q&A Session

**Richard A. Graham**  
Senior Vice President, Development





Medicines That Make a Difference®

# 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.<sup>1</sup> LAMAs are a cornerstone of maintenance therapy for COPD and YUPELRI® is positioned as the first once-daily single-agent bronchodilator product for COPD patients who require, or prefer, nebulized therapy. YUPELRI®'s stability in both metered dose inhaler and dry powder device formulations suggest that this LAMA could also serve as a foundation for novel handheld combination products.

# YUPELRI® (revefenacin) inhalation solution

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

## Important Safety Information (US)

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

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

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

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

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

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

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

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

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