

**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 10, 2022**

THERAVANCE BIOPHARMA, INC.

(Exact Name of Registrant as Specified in its Charter)

Cayman Islands
(State or Other Jurisdiction of
Incorporation)

001-36033
(Commission File Number)

Not Applicable
(I.R.S. Employer Identification
Number)

**PO Box 309
Ugland House, South Church Street
George Town, Grand Cayman, Cayman Islands KY1-1104
(650) 808-6000**

(Addresses, including zip code, and telephone numbers, including area code, of principal executive offices)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary Share \$0.00001 Par Value	TBPH	NASDAQ Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01. Regulation FD Disclosure.

The information in this Current Report (including 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 40th Annual J.P. Morgan Healthcare Conference on January 13, 2022 and, from January 10-13, 2022, 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 Appendix Slides to Investor Presentation](#)

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 10, 2022

By: /s/ Andrew Hindman

Andrew Hindman

Senior Vice President and Chief Financial Officer



Medicines That Make a Difference®

JP Morgan Healthcare Conference

January 13, 2022

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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 goals, designs, strategies, plans and objectives, the impact of the Company's restructuring plan, ability to provide value to shareholders, 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 and the market for products being commercialized, the Company's expectations regarding its allocation of resources, potential regulatory actions and commercialization (including differentiation from other products or potential products and addressable market), 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, disagreements with Innoviva, Inc. and TRC LLC, the uncertainty of arbitration and litigation and the possibility that the results of these proceedings could be adverse to the Company, additional future analysis of the data resulting from our clinical trial(s), 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, products or product candidates are unsafe, ineffective or not differentiated, risks of decisions from regulatory authorities that are unfavorable to the Company, the feasibility of undertaking future clinical trials 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, ability to retain key personnel, the impact of the Company's restructuring actions on its employees, partners and others.

Other risks affecting Theravance Biopharma are in the company's Form 10-Q filed with the SEC on November 8, 2021, and other periodic reports filed with the SEC.

Rapid transition to a streamlined, respiratory focused Theravance Biopharma

Focus on leveraging expertise in developing and commercializing respiratory therapeutics

- ▶ Track record of innovation leading to several approved COPD and asthma medicines, including:
 - TRELEGY: a respiratory medicine developed by Glaxo Group Limited in collaboration with the Company's predecessor, Theravance, Inc.
 - YUPELRI[®]: discovered and developed by Theravance Biopharma, launched in 2019, and is now commercialized in partnership with Viatriis Inc.
- ▶ Strong, growing cash flows from TRELEGY and YUPELRI provide significant value to shareholders
- ▶ TRELEGY and YUPELRI have significant potential for future growth
 - TRELEGY: high growth, long patent life respiratory medicine expected to generate global peak-year sales of \$3.2 billion¹
 - YUPELRI: remains early in its lifecycle, has demonstrated quarter-over-quarter market share growth, with potential US peak-year sales ~\$400 million²

Streamlined R&D investment to focus on highest value core respiratory opportunities

- ▶ PIFR-2 clinical study, in partnership with Viatriis, intended to capture more of the addressable market and further strengthen its competitive advantage
- ▶ Investigational inhaled JAK inhibitor portfolio; includes nezulcitinib (TD-0903), initially targeting acute lung injury and fibrotic disease

Leverage partnerships to unlock value of pipeline assets

Significant cost reduction program reduces Company size to become sustainably cash-flow positive beginning 2H 2022

- ▶ Headcount reduced by ~75% (~270 positions³); majority of reduction completed November 2021, remainder February 2022
- ▶ Total annualized operating expense⁴ savings of ~\$170 million in 2022

Overarching goal: maximize shareholder value



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. 1. Source: Bloomberg GSK Analysts Consensus December 16, 2021; 2. Source: TBPH Analysts Consensus [8] December 9, 2021. 3. Regular and contingent workers; 4. Excluding share-based compensation (SBC) and one-time restructuring, severance and termination costs (estimated \$18–20M between 2021 and 2022, of which the majority will be incurred by Q1 2022). COPD, chronic obstructive pulmonary disease; JAK, Janus kinase; PIFR, peak inspiratory flow rate.

Key pillars of respiratory-focused value creation plan



YUPELRI®

- ▶ Consensus US peak year sales of ~\$400 million¹
- ▶ Q3 2021 net sales of \$39 million implies run rate annual sales of ~\$160 million
- ▶ YUPELRI remains early in its product lifecycle; has demonstrated quarter-over-quarter market share growth
- ▶ TBPH hospital-based and Viatrix community-based sales forces continue driving growth
- ▶ PIFR-2 study intended to capture more of the addressable market and further strengthen its competitive advantage
- ▶ Long patent life

Core Respiratory Pipeline

Near-term catalysts will inform upside potential of focused pipeline:

- ▶ Inhaled JAK inhibitor portfolio, with the most advanced candidate being nezulcitinib (TD-0903), initially targeting acute lung injury and fibrotic disease
- ▶ Dry-powder inhaled JAK inhibitors to proceed into clinic with next generation compounds after securing partnership

TRELEGY

- ▶ Consensus global peak year sales of ~\$3.2 billion²
- ▶ Q3 2021 net sales of \$449 million implies run rate annual sales of ~\$1.8 billion³
- ▶ Long patent life
- ▶ TRELEGY-related cash flows to TBPH to increase substantially (once non-recourse note is fully repaid)³



FDA-approved for maintenance treatment of COPD
First and only once-daily, LAMA (long-acting muscarinic
agent) nebulized maintenance medicine for COPD



YUPELRI® (revefenacin) inhalation solution

FDA-approved for 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 COPD¹
- ▶ 9% of COPD patients (~800,000) use nebulizers for ongoing maintenance therapy; 41% use nebulizers at least occasionally for bronchodilator therapy²



- ▶ **TBPH** and **VTRS** worldwide strategic collaboration to develop and commercialize nebulized YUPELRI (revefenacin)
- ▶ Companies co-promote under US profit/loss share

Theravance
Biopharma



VIATRIS™

Where the market has been



COVID-19 outbreak coincided with critical period of YUPELRI® launch



COVID-19 placed unprecedented demands on pulmonologists

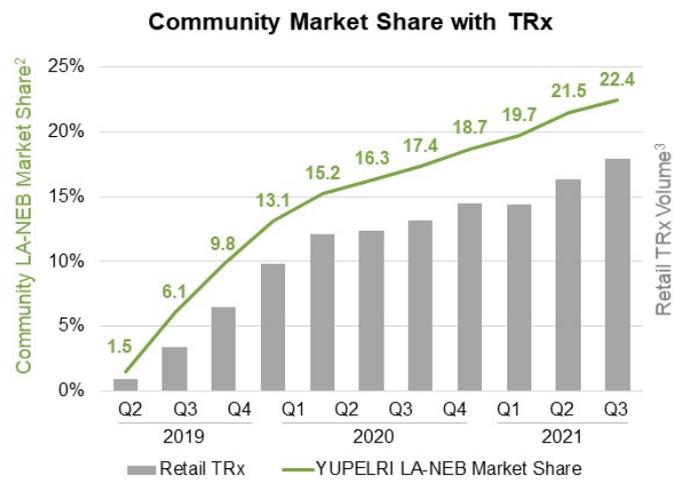
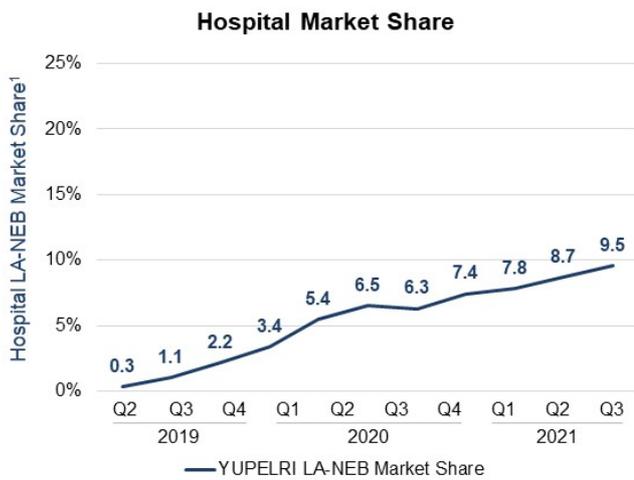


Despite impact, YUPELRI® sales still increasing

- ▶ Universal brand challenges
 - Reduced office visits
 - Reduced/limited new treatment starts
- ▶ Pulmonologists enlisted for ER, ICU, hospital, COVID outpatient evaluation
- ▶ Overall new product starts for pulmonologists still down compared with 2019; lag behind other specialties¹
- ▶ Hospital purchasing for the entire LA-NEB market declined markedly in Q1 2020; today still below 2019 levels
- ▶ Despite down market, YUPELRI shows steady market share and volume growth

YUPELRI® hospital sales and community TRx trends

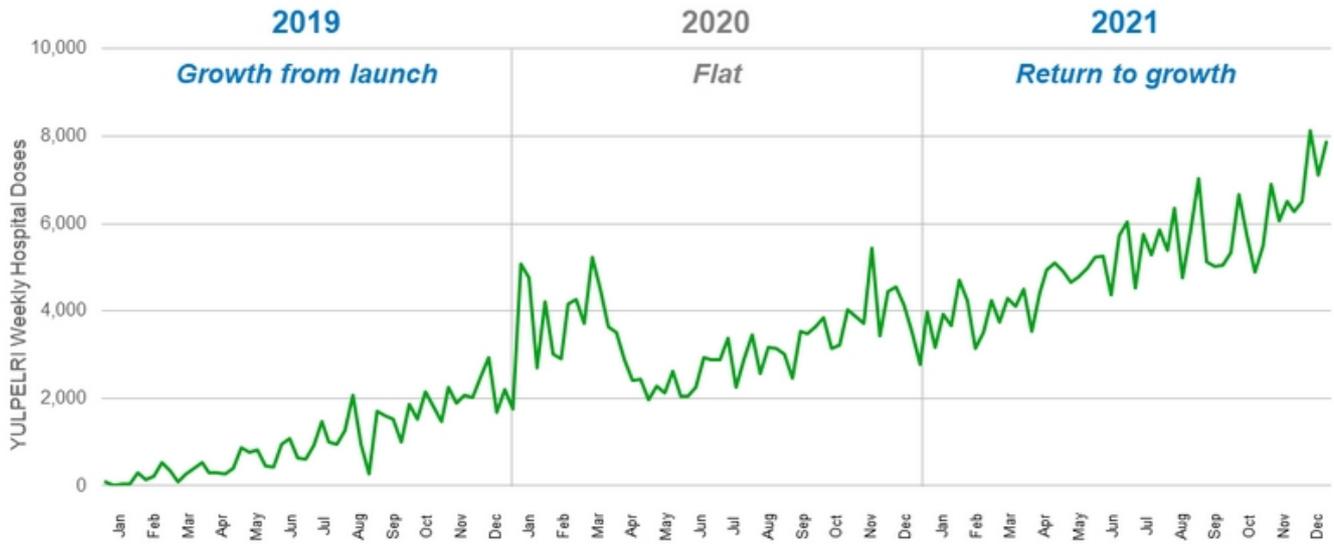
Continued market share growth across both the hospital and retail channels



Most patients who receive YUPELRI in the hospital are discharged with an Rx⁴

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

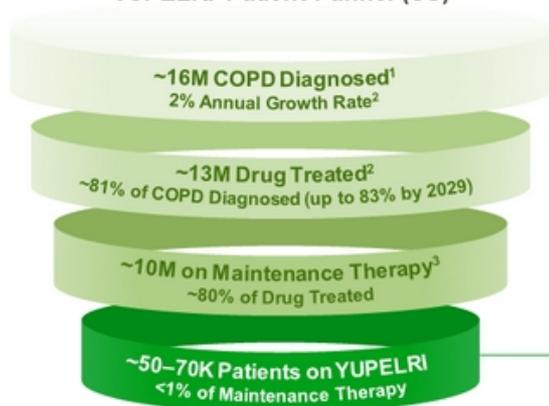
YUPELRI® hospital volume has returned to growth



Substantial opportunity for further YUPELRI[®] growth

Market share of COPD maintenance therapy just scratching the surface

Estimated 2021 YUPELRI Patient Funnel (US)



- ▶ COPD is **under-diagnosed**¹
- ▶ COPD patients with or without symptoms may be treated with rescue and/or maintenance therapies
- ▶ Estimated patient counts from volume using average 'days of therapy' assumptions vary considerably across DME and retail channels

Growth opportunities within numerous patient segments

YUPELRI may be appropriate for COPD patients, including but not limited to:

- ▶ **Moderate-to-very-severe COPD** (73–92%⁴); once-daily LAMAs are first-line therapy for moderate-to-very severe COPD patients
- ▶ Patients with **suboptimal PIFR** (19–78% of COPD patients⁵)
- ▶ Patients with **cognitive or dexterity challenges**
 - ~36% of COPD patients present episodes of cognitive impairment; ~33% of elderly patients have inadequate hand strength for inhalers⁶
- ▶ Patients **transitioning from hospital to home care** after being stabilized on nebulized treatment during hospitalization

Favorable YUPELRI® outlook in 2022 and beyond



Observations from the field¹

- ▶ Pulmonologists / other HCPs have resumed routine testing to evaluate and diagnose COPD patients
- ▶ In office nebulization for COPD patients has resumed
- ▶ 99% of hospital-based HCPs support nebulization regardless of COVID-19 status if proper PPE is worn
- ▶ More hospitals becoming or are “all neb”
- ▶ QD dosing important to alleviate health systems overwhelmed by rising COVID-19 cases (over-taxed hospitals and long-term care facilities)



Additional potential growth opportunities

- ▶ **PIFR-2 study:** intended to capture more of the addressable market and further strengthen its competitive advantage
- ▶ **China opportunity:** China approval projected for 2024; ~\$100M PYS opportunity—potential development and sales milestones totaling \$54M / low double-digit tiered royalties on net sales

Pipeline focused on highest value core respiratory opportunities

New Theravance: Core Respiratory

Focused pipeline of core respiratory programs¹

- ▶ PIFR-2 Phase IV study intended to capture more of the addressable market and further strengthen its competitive advantage
- ▶ Inhaled JAK inhibitor portfolio which includes nezulcitinib

Implement partnering strategy to maximize value of pipeline assets

A new, respiratory focused Theravance Biopharma

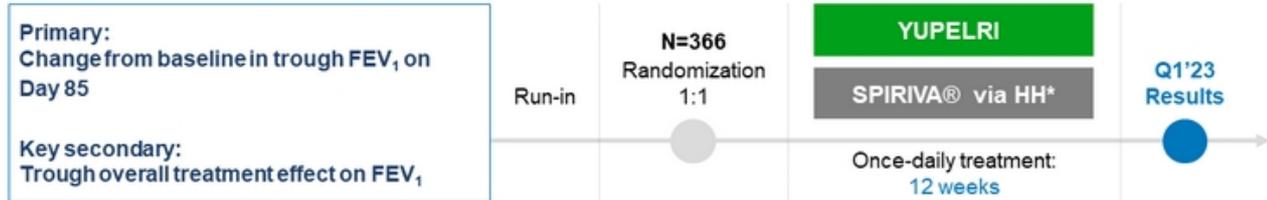
	Program	Indication	US Patients ¹	Research	Phase 1	Phase 2	Phase 3	Filed	Marketed	Phase 4	Collaborator
Respiratory Assets	YUPELRI (revefenacin) LAMA	COPD patients with suboptimal PIFR	>8mm	Marketed						Phase 4 PIFR-2 Study	VIATRIS
	Nezulcitinib (TD-0903) Inhaled JAKi	Acute and chronic lung inflammation, fibrotic disease	>32mm	Phase 2							
	Inhaled JAKi	Asthma	~25mm	Phase 1							
Economic Interests	TRELEGY ² FF/UMEC/Vi	COPD	>8mm	Marketed							GSK & Innoviva, Inc.
		Asthma	~25mm	Marketed							
	Skin-selective JAKi	Dermatological diseases	>8mm	Research							Pfizer
Non-Core Assets*	Ampreloxetine (TD-9855) NRI	Symptomatic nOH	~350k	Phase 3							
	Izencitinib (TD-1473) GI JAKi	UC	~900k	Phase 2b/3							
		CD	~800k	Phase 2							
	TD-5202 Irreversible JAK3i	Celiac disease UC CD	~5mm	Phase 1							
	Inhaled ALK5i	Idiopathic pulmonary fibrosis	~140k	Phase 1							

*Limited additional capital investment planned post Q1 2022

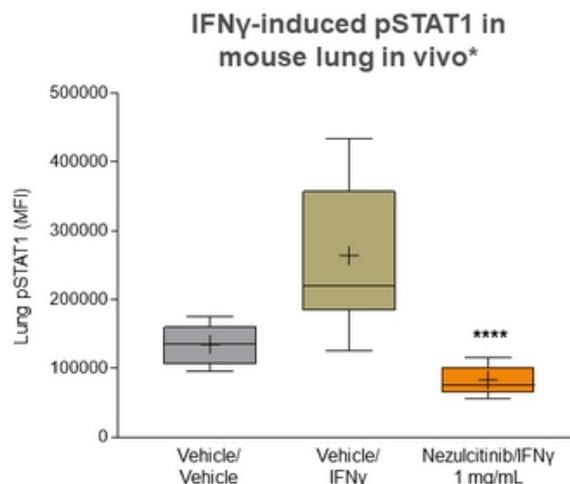
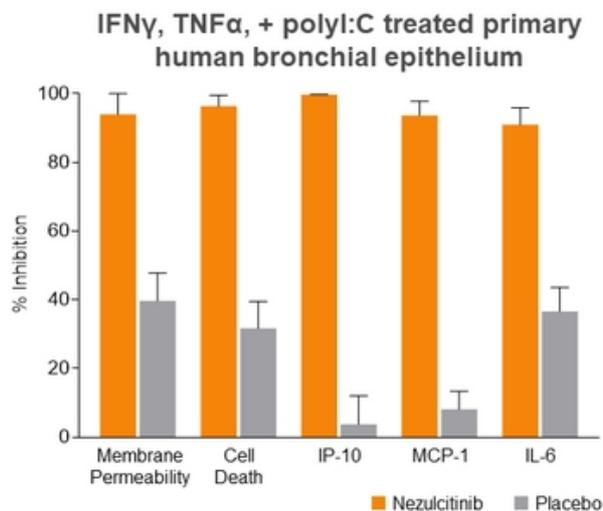
YUPELRI®:

Phase 4 randomized, double-blind, parallel-group study (PIFR-2)

Study Endpoints

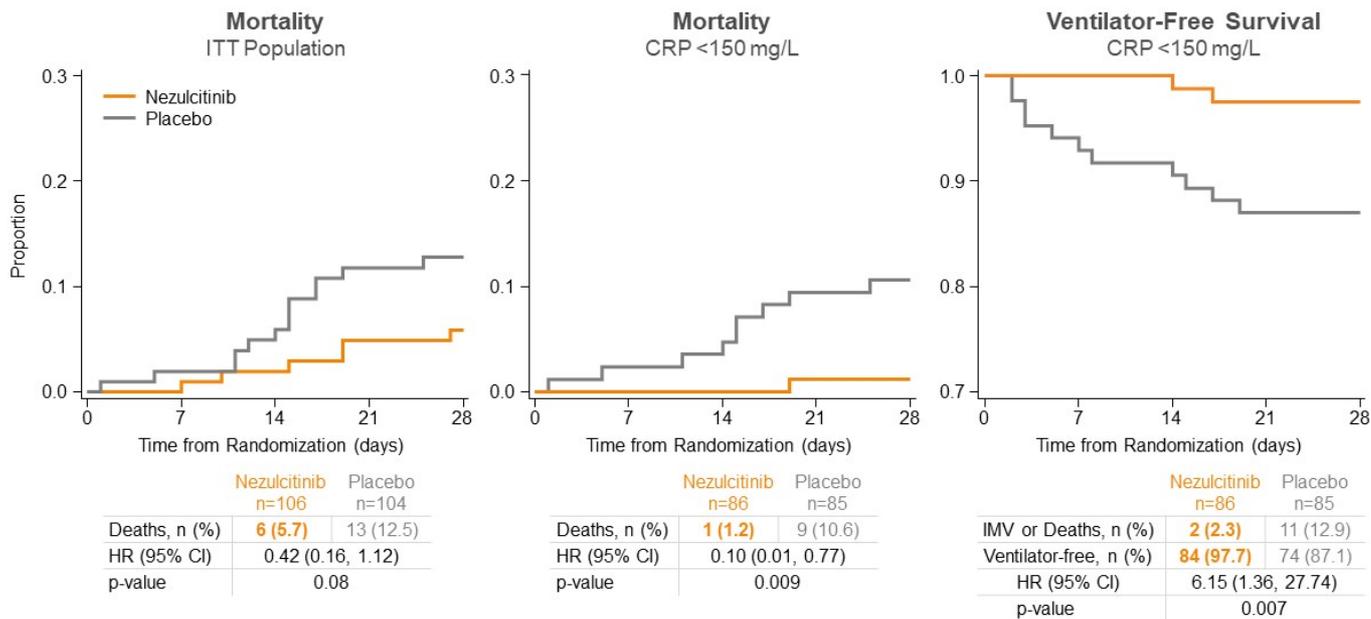


Lung-selective JAK inhibitor nezulcitinib demonstrates potential to protect lungs in an IFN γ -driven viral ARDS hyperinflammatory environment



Potential mechanistic rationale for several acute and chronic lung diseases

Phase 2 study: hospitalized patients with severe COVID-19



Outcomes of the UK COVID Therapeutics Advisory Panel



355 candidate drug submissions received via open submission system

33 recommended drugs to

7 national publicly funded platform trials



Nezulcitinib (TD-0903)

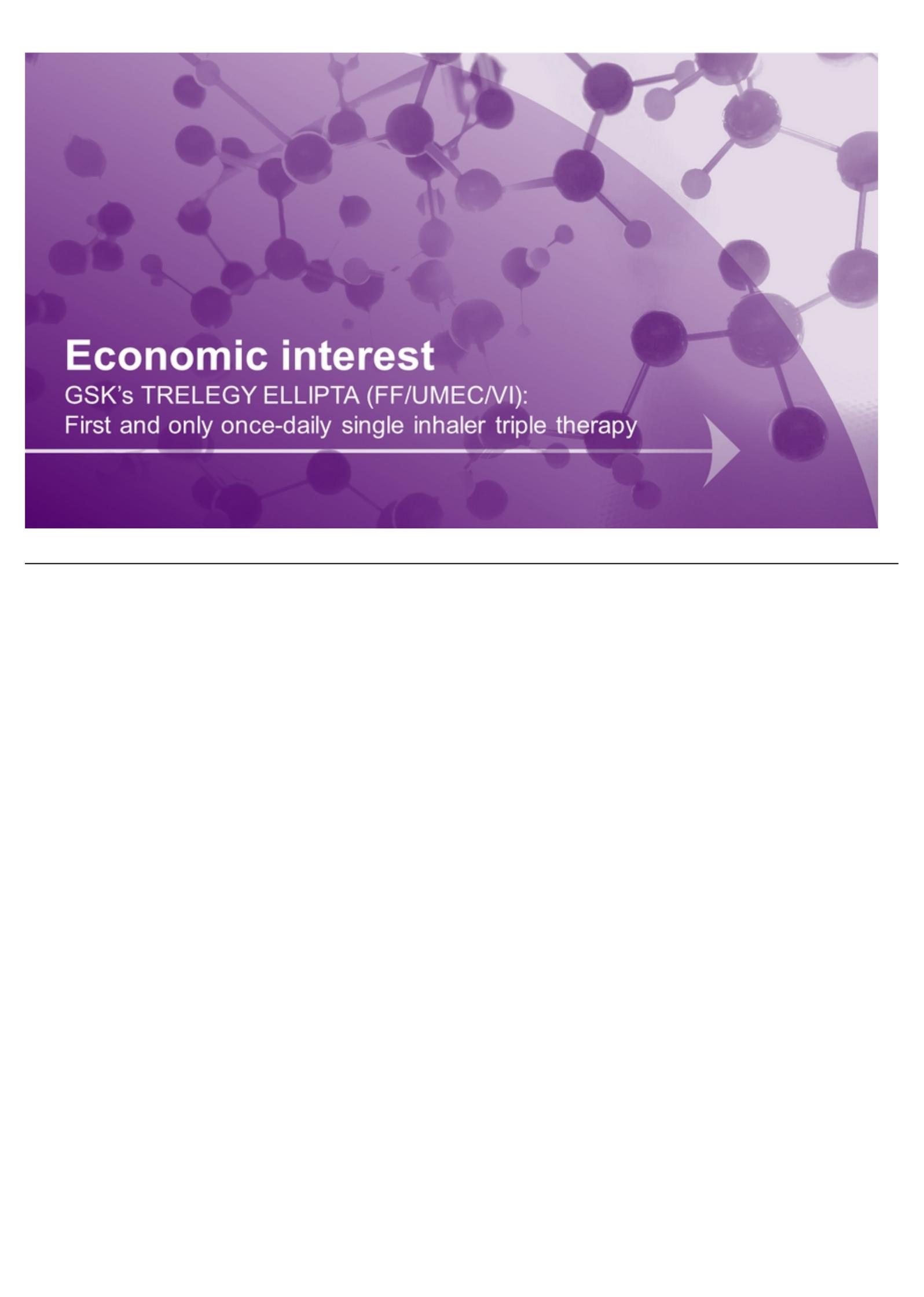
Trial recommended to: **REMAP-CAP**

Date: **10 October 2021**

Why it was recommended

In people with severe COVID-19, parts of the immune system are very active, which causes inflammation and organ damage, particularly in the lungs. ***TD-0903 has a unique inhaled formulation which allows it to block inflammation and tissue damage directly in the lung. This might reduce severe COVID illness and the risk for patients to require to be put in ICU under ventilation.***





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 global net sales¹

Strongest US ELLIPTA Launch



Launched in US in November 2017

Source: GSK, Symphony Health Metys monthly TRx data for the time period Sept'13 to Nov'21.

TRELEGY

- ✓ Q3 global net sales of \$449M
- ✓ Year-over-year sales growth of 77% from the same period in 2020
- ✓ TRELEGY now has 53% of US triple therapy patients for COPD and 73% global share

Financial Guidance

Execution of cost-cutting initiatives results in lowered 2021 OPEX guidance¹:

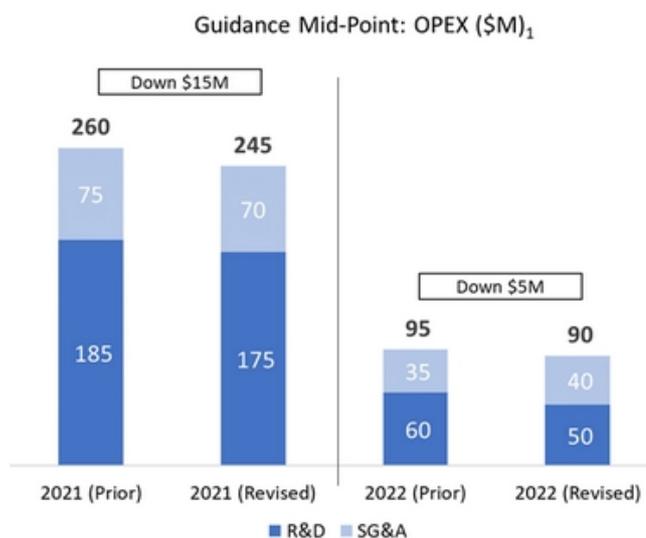
- R&D: updated range of \$170–\$180M
- SG&A: updated range of \$65–\$75M

As a result of **continued refinement** of cost-cutting initiatives, we are also reducing 2022 total OPEX guidance¹:

- R&D: updated range of \$45–\$55M
- SG&A: updated range of \$35–\$45M

2022 guidance includes **~\$10M in non-recurring spend**, mostly in R&D:

- Majority in Q1 to support completion of late-stage programs
- OPEX Q2 and onward will reflect recurring spend only



Theravance Biopharma is projected to be sustainably cash-flow positive beginning in 2H 2022

Rapid transition to a streamlined, respiratory focused Theravance Biopharma

Focus on leveraging expertise in developing and commercializing respiratory therapeutics

Streamlined R&D investment to focus on highest value core respiratory opportunities

Leverage partnerships to unlock value of pipeline non-core assets

Significant cost reduction program reduces Company size to become sustainably cash-flow positive beginning 2H 2022

Overarching goal: maximize shareholder value

Rick E Winningham
Chairman and Chief Executive Officer



Andrew A. Hindman
Senior Vice President, Chief Financial Officer



Q&A Session

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.

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.



Appendix Slides to Investor Presentation

January 2022

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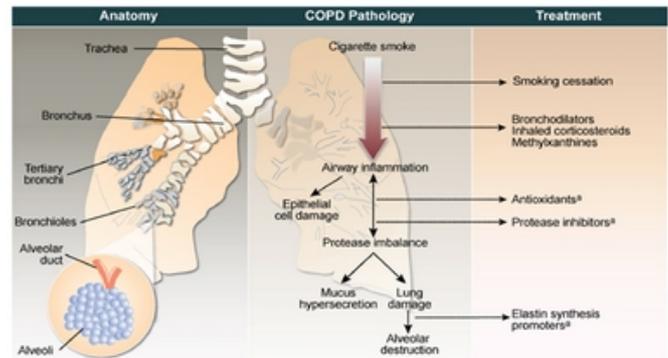
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COPD and Asthma Background

COPD is characterized by persistent airflow limitation that is not fully reversible

- ▶ Progressive, partially irreversible airway damage
 - Chronic bronchitis: Chronic inflammation of bronchi with mucus hypersecretion, leading to airway narrowing and obstruction of airflow
 - Emphysema: Destruction of alveolar walls, leading to fewer, larger alveoli and loss of lung elastic recoil, causing chronic lung hyperinflation and compromising expiratory flow
- ▶ Clinically defined as post-bronchodilator FEV₁:FVC ratio <70% in a spirometry test
- ▶ Symptoms, which can become acute and lead to exacerbation, include chronic cough, shortness of breath, and chronic sputum production
 - Symptoms typically progress slowly
 - Environmental stimuli including pollutants and bacterial / viral infections can cause acute worsening
- ▶ Most common risk factor is tobacco smoking; others include occupational exposure to dusts and chemicals



Three classes of inhaled medicines form backbone of long-term maintenance therapy for both COPD and asthma

Class	Mechanism of Action	Key Brands* (Mfg., 2020 Global Net Sales)
LABA Long-acting beta agonists	Activate beta ₂ -adrenergic receptors to reduce free intracellular calcium, thereby relaxing smooth muscle, reducing mucus secretion, and increasing mucociliary function.	Brovana (Sunovion, \$273 M) Perforomist (VTRS, \$213 M) Serevent (GSK, \$62 M)
LAMA Long-acting muscarinic antagonists	Also known as anticholinergics. Bind to muscarinic receptors and inhibit bronchoconstriction and mucus secretion stimulated by the interaction of acetylcholine with these receptors.	Spiriva (BI, \$2.0 B) Incruse (GSK, \$283 M) YUPELRI (VTRS/TBPH, \$143 M)
ICS Inhaled corticosteroids	Bind to glucocorticoid receptors, reducing transcription of genes involved in inflammatory response, reducing number of immune cells in mucosa, inhibiting T-cell activation, promoting eosinophil apoptosis, inhibiting nitric oxide synthase, reducing mucus secretion, and increasing beta ₂ -adrenergic receptor production.	Pulmicort (AZ, \$1.0 B) Flovent (GSK, \$535 M) Asmanex (Merck, \$231 M)

Types of Delivery Devices



MDI (metered dose inhaler)



DPI (dry powder inhaler)



SMI (soft mist inhaler)



Nebulizer

Dual combinations – and more recently triple combinations – have become market leaders

Dual Combinations		Triple Combos	Dosing & Components	COPD Status	Asthma Status
ICS / LABA	Key Brands (Mfg., 2020 Global Net Sales)	Trelegy GSK \$1.1 B	QD Multi-dose DPI Vilanterol, umeclidinium & fluticasone furoate	Approved • US, Sep-17 • EU, Jul-17 • Japan, Nov-20 • China, Nov-19	Approved • US, Sep-20 • Japan, Nov-20 Rejected in EU with no plans to pursue further
Indicated for both COPD & asthma	Symbicort (AZ, \$2.7 B) Advair (GSK, \$2.0 B) Breo (GSK, \$1.4 B) Generics (\$930 M)	Trimbow Chiesi \$281 M	BID HFA-pMDI Formoterol, glycopyrrolate & beclometasone	Approved • EU, Jul-17 US Phase 3 trial listed in Mar-20 but has not yet started	Approved • EU, Feb-21
LABA / LAMA	Stiolto (BI, \$730 M) Anoro (GSK, \$713 M) Ultibro (Novartis, \$623 M) Bevespi (AZ, \$48 M)	Breztri AstraZeneca \$28 M	BID HFA-pMDI Formoterol, glycopyrronium & budesonide	Approved • US, Jul-20 • EU, Dec-20 • Japan, Jun-19 • China, Dec-19	Phase 3 on-going with expected completion in Q3 2023
Indicated only for COPD		Energair Novartis \$3 M	QD Single-dose DPI Indacaterol, glycopyrronium & mometasone	Not in development for COPD	Approved • EU, Jul-20 • Japan, Jun-20 Not in development for US (would not be QD)

Overview of nebulized products for maintenance therapy

Nebulized Products Used for Maintenance Therapy	Class	Dosing & Components	Launch / Gx Status
YUPELRI Viartis (formerly Mylan)	LAMA	QD (1x per day) Revefenacin	• US, Nov-18
Lonhala Sunovion	LAMA	BID (2x per day) Glycopyrrolate	• US, Feb-18
Brovana Sunovion	LABA	BID (2x per day) Arformoterol Tartrate	• US, Mar-07 • Gx, Jun-21
Perforomist Viartis (formerly Mylan)	LABA	BID (2x per day) Formoterol Fumarate	• US, Aug-07 • Gx, Jun-21
DuoNeb Viartis (formerly Mylan)	SABA/ SAMA	QID (4x per day, up to 6x) Ipratropium Albuterol	• US, Jun-01 • Gx, Jul-07

Long-Acting Neb Market:
Indicated for Long-Acting,
Nebulized Maintenance Therapy

Short-Acting (rescue) which is used for
regular daily (maintenance) therapy

Nebulizers provide a user-friendly option for providers and their COPD patients:

- ▶ Require only normal tidal breathing and do not require extra effort generating adequate inspiratory flow rate
- ▶ No hand-breath coordination is needed
- ▶ Many patients are 100% covered as durable medical equipment (DME) through Medicare Part B



FDA-approved for the maintenance treatment of COPD
First and only once-daily, LAMA (long-acting muscarinic
agent) nebulized maintenance medicine for COPD



YUPELRI® (revefenacin) is the first and only once-daily, nebulized maintenance medicine for COPD

Unmet Need for Nebulized LAMA therapy

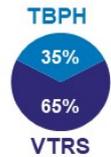
- ▶ Once-daily LAMAs are first-line therapy for moderate-to-severe COPD patients
- ▶ YUPELRI is the only once-daily nebulized LAMA available

Enduring Patient Niche

- ▶ ~45% of COPD patients in the US have a nebulizer at home
- ▶ Nebulized therapy associated with reduced hospital readmissions in low PIFR patients
- ▶ Patients with cognitive or dexterity challenges may be candidates for nebulized therapy

Growing Market Opportunity

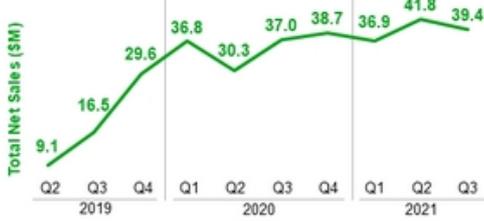
- ▶ Viatris partnership brings commercial strength in nebulized segment
- ▶ YUPELRI complementary to existing nebulized LABA treatments
- ▶ Planned PIFR-2 clinical study aimed at helping to better inform decisions when physicians are designing a personalized COPD treatment plan with their patients.
 - Success in this study is intended to capture more of YUPELRI's addressable market and further strengthen its competitive advantage



Companies co-promote under US profit/loss share

Where the market has been

COVID-19 outbreak coincided with critical period of YUPELRI® launch



- ▶ Universal brand challenges
 - Reduced office visits
 - Reduced/limited new treatment starts

COVID-19 placed unprecedented demands on pulmonologists

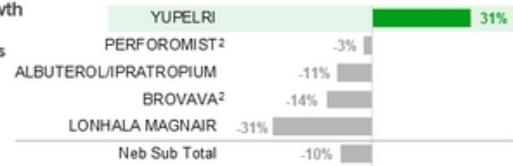
- ▶ Pulmonologists enlisted for ER, ICU, hospital, COVID outpatient evaluation
- ▶ Overall new product starts for pulmonologists still down vs 2019; lag behind other specialties¹
 - 17% New-to-product Rx growth
 - 8% TRx growth

Despite impact, YUPELRI® sales still increasing²



- ▶ Hospital purchasing for the entire LA-NEB market declined markedly in Q1 2020 and remains below 2019 levels
- ▶ Despite down market, YUPELRI shows steady market share and volume growth

Nebulized Product Growth YoY TRx Growth¹ 12 Months Ending Jul'21 vs Same Time Last Year



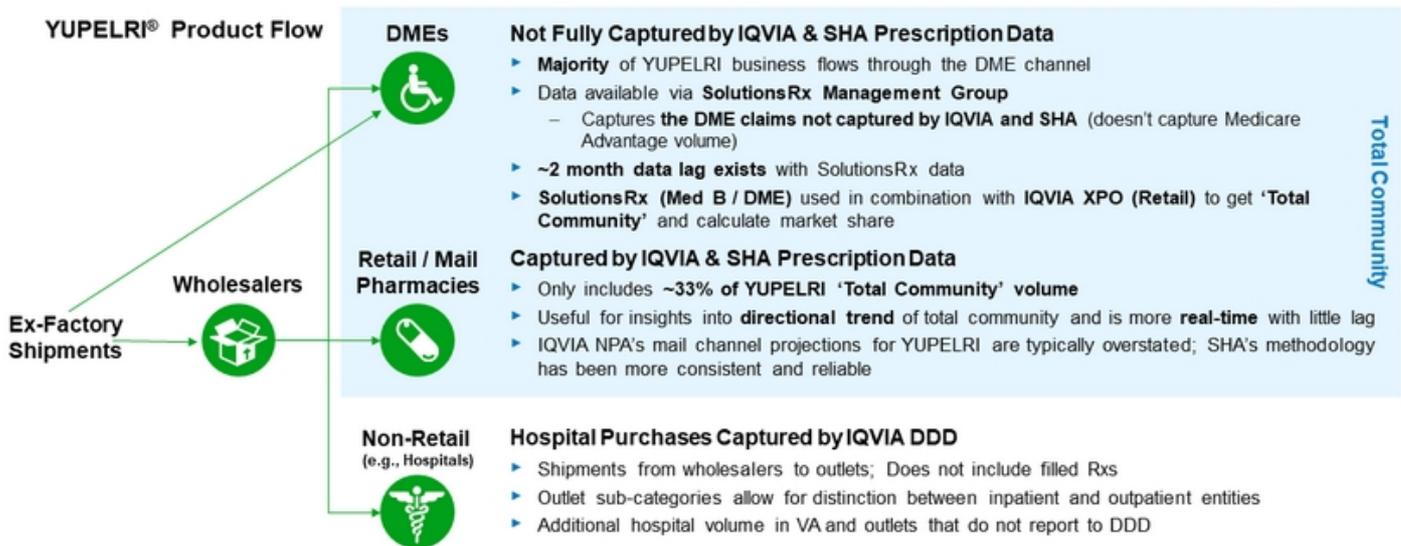
YUPELRI® more likely to be added to Neb LABA than be a conversion from long-acting Neb competitors

YUPELRI Source of Business

- ▶ Budesonide (ICS), Perforomist and Brovana are the products most often used in combination with YUPELRI
 - 40–50% of YUPELRI patients are also on Neb LABA
 - 35–40% of YUPELRI patients are on open triple therapy (LAMA/LABA/ICS) with the majority being all nebulized
- ▶ Conversions mostly come from SA Nebs and LA Handhelds with fewer conversions from Neb LABAs
- ▶ Generic availability of Neb LABAs allows for cheaper patient OOP costs with combo use
- ▶ Drivers to nebulized therapy continue to be:
 - Cognitive/dexterity challenges
 - Patient preference based on prior experience
 - Access and low out of pocket costs for Medicare Part B patients
 - Transition from hospital to home care
 - Suboptimal PIFR

DME channel hinders visibility into tracking performance

Traditional 'Retail' data vendors do not fully capture DME volume



Educating health-care providers via publications

Publication	Audience	Summary
Nebulized Treatments and the Possible Risk of Coronavirus Transmission: Where is the Evidence? ¹	Pulmonology	"The data should not lead to the conclusion that AGP's are without risk but point out the need to have a balanced approach towards the use of nebulizers."
Nebulized Therapy in the COVID-19 Era: The Right Tool for the Right Patient ²	Respiratory therapists	At a time when public health information is in a state of rapid flux, rather than using a "one size fits all" policy, the more sensible approach would be to use "the right tool for the right patient" strategy based on what we know. Thus, nebulizers may remain the preferred option for some patients who require this treatment, especially in light of the severe shortage of MDIs. This approach does not conflict with recent COVID-19 guidance
Evidence-based treatment during the SARS-CoV-2 pandemic: Identifying the knowns and unknowns of nebulization ³	Pharmacy	Lack of evidence to suggest that nebulization can transmit viral particles. HCPs across all settings should take the necessary precautions to minimize the risk of infection
The use of nebulized pharmacotherapies during the COVID-19 pandemic ⁴	All HCPs	Challenges the data currently available on nebulization and viral transmission
Publications pending from Nebulization Task Force clinical research		<ol style="list-style-type: none"> 1) Porcine Lung Model on Nebulization 2) Fluorescent visualization during nebulization 3) Measure of viral spread in COVID-19 patients

About YUPELRI® (revefenacin) inhalation solution

YUPELRI® (revefenacin) inhalation solution is a once-daily nebulized LAMA approved for the maintenance treatment of COPD in the US.

Market research by Theravance Biopharma indicates approximately 9% of the treated COPD patients in the US use nebulizers for ongoing maintenance therapy.¹ LAMAs are a cornerstone of maintenance therapy for COPD and YUPELRI® is positioned as the first once-daily single-agent bronchodilator product for COPD patients who require, or prefer, nebulized therapy. YUPELRI®'s stability in both metered dose inhaler and dry powder device formulations suggest that this LAMA could also serve as a foundation for novel handheld combination products.

YUPELRI® (revefenacin) inhalation solution

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

Important Safety Information (US)

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

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

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

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

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

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

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

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

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