Theravance Biopharma, Inc. Announces Enrollment of First Patient in YUPELRI® Phase 4 Study

January 10, 2022

DUBLIN, Jan. 10, 2022 /PRNewswire/ -- Theravance Biopharma, Inc. ("Theravance Biopharma" or the "Company") (NASDAQ: TBPH) today announced enrollment of the first patient in a Phase 4 study of YUPELRI® (revefenacin) inhalation solution, the first and only once-daily, nebulized bronchodilator approved in the US for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). Success in this study is intended to capture more of YUPELRI's addressable market and further strengthen its competitive advantage.

"YUPELRI, discovered and developed by Theravance, is one of the key pillars of value creation for the go-forward organization. We, and our partner Viatris, believe we have just scratched the surface of YUPELRI's contribution to the COPD community," said Rick E Winningham, Chief Executive Officer. "The enrollment of the first patient in the Phase 4 PIFR-2 study demonstrates, through continued investment in controlled clinical studies, our commitment to provide healthcare professionals with the evidence needed to design personalized treatment plans in order to make better informed decisions for their COPD patients."

About the PIFR-2 Study

This study (NCT05165485) is a randomized, double-blind, parallel-group study, comparing improvements in lung function in adults with severe to very severe COPD and suboptimal inspiratory flow rate following once-daily treatment over 12 weeks with either YUPELRI (revefenacin) inhalation solution delivered via standard jet nebulizer or SPIRIVA® (tiotropium) delivered via a dry powder inhaler (Spiriva® HandiHaler®) (n=366).

The Company expects to report top-line results in first quarter 2023.

About Theravance Biopharma / Viatris Collaboration

Theravance Biopharma and Viatris Inc. and their respective affiliates have established a strategic collaboration to develop and commercialize nebulized revefenacin products for COPD and other respiratory diseases. Theravance Biopharma and Viatris co-promote YUPELRI® (revefenacin) in the US, with their combined sales infrastructure targeting healthcare professionals who treat COPD patients suitable for YUPELRI. The Company is entitled to a share of US profits and losses (65% to Viatris; 35% to Theravance Biopharma) received in connection with commercialization of YUPELRI® (revefenacin), and the Company is entitled to low double-digit tiered royalties on ex-US net sales.

About YUPELRI®

YUPELRI® (revefenacin) inhalation solution is a once-daily nebulized long-acting muscarinic antagonist (LAMA) approved for the maintenance treatment of COPD in the US. LAMAs are recognized by international COPD treatment guidelines as a cornerstone of maintenance therapy for COPD, regardless of severity of disease. Our market research indicates there is an enduring population of COPD patients in the US that either need or prefer nebulized delivery for maintenance therapy. The stability of revefenacin in both metered dose inhaler and dry powder inhaler ("MDI/DPI") formulations suggests that revefenacin could also serve as a foundation for novel handheld combination products.

Important Safety Information

What is YUPELRI®?

- YUPELRI is a prescription medicine used to treat chronic obstructive pulmonary disease (COPD), a long-term (chronic) lung disease that includes chronic bronchitis, emphysema, or both.
- It is an anticholinergic medicine which helps the muscles around the airway in your lungs stay relaxed to prevent symptoms such as wheezing, cough, chest tightness, and shortness of breath.
- It is used long-term as 1 vial of YUPELRI, 1 time each day inhaled through your nebulizer to improve symptoms of COPD for better breathing.

Who should not use YUPELRI?

- **Do not use YUPELRI if you** have sudden breathing problems. Always have a rescue inhaler with you.
- **Do not use YUPELRI if you** have had an allergic reaction to revefenacin, or any of the other ingredients in YUPELRI (sodium chloride, citric acid, sodium citrate).
- Do not use in children. It is not known if YUPELRI is safe and effective in children.

Before using YUPELRI, tell your healthcare provider about all your medical conditions, including if you:

- have eye problems such as glaucoma. YUPELRI may make your glaucoma worse.
- have prostate or bladder problems, or problems passing urine. YUPELRI may make these problems worse.
- have liver problems.
- are allergic to any of the ingredients in YUPELRI, or any other medicines.

- are pregnant or planning to become pregnant. It is not known if YUPELRI may harm your unborn baby.
- are breastfeeding. It is not known if the medicine in YUPELRI passes into your breast milk and if it can harm your baby.

Tell your healthcare provider about all the medicines you take including prescription and over-the-counter medicines, vitamins, and herbal supplements. YUPELRI and certain other medicines may interact with each other. This may cause serious side effects.

Especially tell your healthcare provider if you take:

- Other anticholinergics (including tiotropium, ipratropium, aclidinium, umeclidinium, glycopyrrolate)
- Atropine

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist each time you get a new medicine.

What are the possible side effects with YUPELRI?
YUPELRI can cause serious side effects, including:

- **Sudden breathing problems immediately after inhaling your medicine.** If you have sudden breathing problems immediately after inhaling your medicine, stop using YUPELRI and call your healthcare provider right away.
- **New or worsened eye problems including acute narrow-angle glaucoma.** Acute narrow-angle glaucoma can cause permanent loss of vision if not treated. Symptoms may include:
    - Red eyes
    - Blurred vision
    - Seeing halos or bright colors around lights
    - Eye pain or discomfort
    - Nausea or vomiting
- **Urinary retention.** People who take YUPELRI may develop new or worse urinary retention. Symptoms of urinary retention may include:
    - difficulty urinating
    - urinating frequently
    - urination in a weak stream or drips
    - painful urination

If you have any of these symptoms, call your healthcare provider right away before taking another dose.

- **Serious allergic reactions.** Call your healthcare provider or get emergency medical care if you get any of the following symptoms of a serious allergic reaction:
    - rash
    - hives
    - severe itching
    - swelling of your face, mouth, and tongue
    - difficulty breathing or swallowing

If you have any of these symptoms, stop taking YUPELRI, and call your healthcare provider right away before taking another dose.

Common side effects of YUPELRI include:

- Cough
- Runny nose
- Upper respiratory tract infection
- Headache
- Back pain

Tell your healthcare provider if you get any side effects that bother you or that do not go away. These are not all the possible side effects with YUPELRI. Ask your healthcare provider or pharmacist for more information. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I use YUPELRI?

Read the step by step instructions for using YUPELRI at the end of this Patient Information Leaflet

- **YUPELRI is only for use with a nebulizer.**
- **Do not** use YUPELRI more often than prescribed.
- **Do not** mix YUPELRI with other medicines in your nebulizer.
- **Do not use other medicines that contain an anticholinergic for any reason.**
- **Do not** stop using YUPELRI, even if you are feeling better, unless your healthcare provider tells you to because your symptoms might get worse.

- Call your healthcare provider or get emergency medical care right away if
  - your breathing problems get worse.
  - you need to use your rescue inhaler medicine more often than usual.
  - your rescue inhaler medicine does not relieve your symptoms.

This summary does not include all the information about YUPELRI and is not meant to take the place of a discussion with your healthcare provider about your treatment.

About Theravance Biopharma

Theravance Biopharma, Inc. is a biopharmaceutical company primarily focused on the discovery, development and commercialization of respiratory medicines. Its core purpose is to create medicines that help improve the lives of patients suffering from respiratory illness.

In pursuit of its purpose, Theravance Biopharma leverages decades of respiratory expertise to discover and develop transformational medicines that make a difference. These efforts have led to the development of FDA-approved YUPELRI® (revefenacin) inhalation solution indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). Its respiratory pipeline of internally discovered programs is targeted to address significant patient respiratory needs.

Theravance Biopharma has an economic interest in potential future payments from Glaxo Group Limited or one of its affiliates (GSK) pursuant to its agreements with Innoviva, Inc. relating to certain programs, including TRELEGY.

For more information, please visit www.theravance.com.

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YUPELRI® is a registered trademark of Mylan Specialty L.P., a Viatris Company. Trademarks, trade names or service marks of other companies appearing on this press release are the property of their respective owners.

Forward-Looking Statements

This press release contains certain "forward-looking" statements as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding, among other things, statements relating to goals, plans, objectives, expectations and future events. Theravance Biopharma intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. Examples of such statements include statements relating to: the Company's goals, designs, strategies, plans and objectives, 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 market for products being commercialized, potential regulatory actions and commercialization (including differentiation from other products or potential products and addressable market), and product sales or profit share revenue. These statements are based on the current estimates and assumptions of the management of Theravance Biopharma as of the date of the press release and are subject to risks, uncertainties, changes in circumstances, assumptions and other factors that may cause the actual results of Theravance Biopharma to be materially different from those reflected in the forward-looking statements. Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements include, among others, risks related to: 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. In addition, while we expect the effects of COVID-19 to continue to adversely impact our business operations and financial results, the extent of the impact on our ability to generate revenue from YUPELRI® (revefenacin), our clinical development programs, and the value of and market for our ordinary shares, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time. These potential future developments include, but are not limited to, the ultimate duration of the COVID-19 pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the United States and in other countries, other measures taken by us and those we work with to help protect individuals from contracting COVID-19, and the effectiveness of actions taken globally to contain and treat the disease, including vaccine availability, distribution, acceptance and effectiveness. 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. In addition to the risks described above and in Theravance Biopharma's filings with the SEC, other unknown or unpredictable factors also could affect Theravance Biopharma's results. No forward-looking statements can be guaranteed, and actual results may differ materially from such statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Theravance Biopharma assumes no obligation to update its forward-looking statements on account of new information, future events or otherwise, except as required by law.

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