May 20, 2015

Theravance Biopharma Presents Additional Positive Phase 2b Study Data on TD-4208 for Treatment of COPD at American Thoracic Society 2015 International Conference

Findings Support Potential for First Once-Daily Nebulized LAMA in COPD; Initiation of Phase 3 Registrational Trials Planned for 2015

GEORGE TOWN, GRAND CAYMAN -- (Marketwired) -- 05/20/15 -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today announced the presentation of additional positive data from its Phase 2b dose-ranging study of TD-4208, an investigational long-acting muscarinic antagonist (LAMA) in development for the treatment of chronic obstructive pulmonary disease (COPD). Previously released top-line study data demonstrated achievement of the study's primary and key secondary efficacy endpoints for doses of 88 mcg and above. Additional trial results presented today support the product's potential to offer patients rapid and sustained therapeutic benefit from once-daily administration and to reduce the requirement for short-acting rescue medication. These latest data are being presented at the American Thoracic Society (ATS) 2015 International Conference being held this week in Denver, Colorado.

The Phase 2b study evaluated four doses of TD-4208 (44, 88, 175 and 350 mcg) and placebo, administered once-daily for 28 days in a double-blind, parallel group study in a total of 355 patients with moderate-to-severe COPD. As previously reported, TD-4208 met the primary efficacy endpoint (change from baseline in trough FEV_1 [forced expiratory volume in one second] following the last dose on Day 28) at once-daily doses of 88, 175 and 350 mcg, with statistically significant changes versus placebo ($p < 0.001$) in trough FEV_1 of 187 mL, 167 mL and 171 mL, respectively. TD-4208 was generally well tolerated in the study with headache (3.1%), shortness of breath (2.8%) and cough (2.0%) as the most common adverse events in the study.

In new data from the Phase 2b study reported at ATS, TD-4208 resulted in a rapid onset of action, with a median time to achieve a clinically relevant improvement in lung function (at least 100mL increase in FEV_1) of 30 minutes for doses of 88 mcg and above. TD-4208 also reduced the requirement for short-acting inhaled rescue medication in a dose-dependent manner, with a mean reduction of more than one puff a day compared to placebo for doses of 88 mcg and above ($p < 0.001$).

In a separate presentation at ATS, Theravance Biopharma announced new population pharmacokinetic (PK) analyses from three Phase 2 studies of TD-4208 that support the product's profile as a well-tolerated, once-daily inhaled treatment with limited systemic exposure. Combined with safety and efficacy data from the Phase 2b dose ranging study, these findings reaffirm the sustained bronchodilator effects of TD-4208 in the lung and support the minimal antimuscarinic effects outside the lung at the intended clinical doses.

"The positive Phase 2b clinical study results with TD-4208 are encouraging, and particularly relevant in light of the fact that there are still limited treatment options for COPD patients who require long-acting nebulized bronchodilator therapy," said Brett Haumann, MD, Senior Vice President, Clinical Development at Theravance Biopharma. "Approximately 9% of COPD patients in the U.S. require or prefer nebulized therapy, but there are currently no once-daily bronchodilators of any class available via the nebulized route. We believe there is a compelling opportunity to provide these patients with access to a once-daily nebulized treatment. Importantly, data from our Phase 2b study of TD-4208 demonstrate a therapeutic profile that is consistent with once-daily dosing, an onset of action that provides prompt effect and the potential for a reduced dependence on short-acting rescue medication. We plan to evaluate these effects further in longer-term studies in Phase 3."

Following end-of-Phase 2 discussions with the FDA, Theravance Biopharma is preparing to start the TD-4208 Phase 3 registrational program, which is anticipated to begin later this year. The Phase 3 registrational program will include two replicate three-month efficacy studies and a single twelve-month safety study. The studies will include approximately 2,300 patients and test two doses: 88 mcg and 175 mcg administered once-daily via nebulizer.

In February 2015, Theravance Biopharma announced that it had entered into a partnership with Mylan Inc. and its affiliates for the development and, subject to FDA approval, commercialization of nebulized TD-4208 for COPD and other respiratory diseases. Under terms of the agreement, Theravance Biopharma will conduct development in the U.S. with all costs reimbursed by Mylan. Mylan is responsible for ex-U.S. development. Additionally, Theravance Biopharma is eligible to receive up to $220 million in development and sales milestone payments, as well as a profit-sharing arrangement with Mylan on U.S. sales and double-digit royalties on ex-U.S. sales. Theravance Biopharma retains worldwide rights to TD-4208 delivered through other dosage forms, such as a metered dose inhaler or dry powder inhaler (MDI/DPI), and the rights to nebulized TD-4208 in China.

About COPD

COPD is a growing and devastating disease that is the third leading cause of death in the U.S. An estimated 12.7 million American adults are diagnosed with COPD and an almost equal number are believed to be undiagnosed. More than 700,000 patients are admitted to hospitals annually in the U.S. with worsening of their COPD. The costs of managing COPD in the U.S. were estimated to be $50 billion in 2010, including $29.5 billion in direct health care expenditures, $8.0 billion in indirect morbidity costs and $12.4 billion in indirect mortality costs. Once-daily LAMAs are currently the cornerstone of maintenance therapy for patients with COPD, but existing LAMAs are only available in handheld devices.

Source: American Lung Association
http://www.lung.org/lung-disease/copd/resources/facts-figures/COPD-Fact-Sheet.html

About TD-4208

TD-4208 is an investigational, long-acting muscarinic antagonist ("LAMA") in development for the treatment of COPD. We believe that TD-4208 may become a valuable addition to the COPD treatment regimen and that it represents a significant commercial opportunity. Our market research indicates approximately 9% of the treated COPD patients in the U.S. either need or prefer nebulized delivery for maintenance therapy. LAMAs are a cornerstone of maintenance therapy for COPD, but existing LAMAs are only available in handheld devices that may not be suitable for every patient. TD-4208 has the potential to be a best-in-class once-daily single-agent product for COPD patients who require, or prefer, nebulized therapy. The therapeutic profile of TD-4208, together with its 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.

About Theravance Biopharma

The mission of Theravance Biopharma (NASDAQ: TBPH) is to create value from a unique and diverse set of assets: an approved product; a development pipeline of late-stage assets; and a productive research platform designed for long-term growth.

Our pipeline of internally discovered product candidates includes potential best-in-class opportunities in underserved markets in the acute care setting, representing multiple opportunities for value creation. VIBATIV® (telavancin), our first commercial product, is a once-daily dual-mechanism antibiotic approved in the U.S. and Europe for difficult-to-treat infections. TD-4208 is an investigational long-acting muscarinic antagonist (LAMA) being developed as a potential once-daily, nebulized treatment for COPD. Axelopran (TD-1211) is an investigational potential once-daily, oral treatment for opioid-induced constipation (OIC). Our earlier-stage clinical assets represent novel approaches for potentially treating diseases of the lung and gastrointestinal tract and infectious disease. In addition, we have an economic interest in future payments that may be made by GSK pursuant to its agreements with Theravance, Inc. relating to certain drug development programs, including the combination of fluticasone furoate, umeclidinium and vilanterol and (or the "Closed Triple").

With our successful drug discovery and development track record, commercial infrastructure, experienced management team and efficient corporate structure, we believe that we are well positioned to create value for our shareholders and make a difference in the lives of patients.

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

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 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 strategies, plans and objectives, the Company's regulatory strategies and timing and results of clinical studies, the potential benefits and mechanisms of action of the Company's product and product candidates and the Company's expectations for product candidates through development and commercialization. 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: delays or difficulties in commencing or completing clinical studies, the potential that results from clinical or non-clinical studies indicate the Company's product candidates are unsafe or ineffective, the feasibility of undertaking future clinical trials for our product candidates based on FDA policies and feedback, dependence on third parties to conduct clinical studies, delays or failure to achieve and maintain

regulatory approvals for product candidates, risks of collaborating with third parties to discover, develop and commercialize product and product candidates and risks associated with establishing and maintaining sales, marketing and distribution capabilities with appropriate expertise and supporting infrastructure. Other risks affecting Theravance Biopharma are described under the heading "Risk Factors" contained in Theravance Biopharma's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 13, 2015. In addition to the risks described above and in Theravance Biopharma's other 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.

Contact Information:

Renee Gala
Chief Financial Officer
650-808-4045
investor.relations@theravance.com

Tim Brons
Vida Strategic Partners (media)
646-319-8981
tbrons@vidasp.com

Source: Theravance Biopharma