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Theravance Biopharma Presents Interim Data from Ongoing Telavancin Observational Use Registry (TOUR™) at IDWeek™ 2016

TOUR Results Highlight Clinical Response Rates for VIBATIV® (telavancin) in a Range of Difficult-to-Treat Infections; Real-World Use of Antibiotic Observed in Approved Indications, as well as Bone and Joint Infections and Bacteremia

DUBLIN, Oct. 31, 2016 /PRNewswire/ -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today announced the presentation of interim data from the Company's ongoing Telavancin Observational Use Registry (TOUR™) study. TOUR is designed to assess how VIBATIV® (telavancin) is being used by healthcare practitioners to treat patients in real-world settings. An initial review of data from the first 200 patients enrolled in TOUR demonstrate clinical response rates of 74% in a range of difficult-to-treat infection types including the drug's approved indications of hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) and complicated skin & skin structure infections (cSSSI). Other serious infections reported to the TOUR database included bone and joint infections and bacteremia. Results show 17% of all patients were considered non-evaluable with 9% deemed to have failed treatment. Clinical response was defined as cure or improvement leading to step-down oral therapy. These interim TOUR results were presented at IDWeek™ 2016, which was held in New Orleans, LA on October 26 - 30, 2016.

In addition to clinical response, reported data also provide an overview of the types of patients that are receiving VIBATIV treatment in real-world clinical settings. Findings show that the most frequent primary infections being treated with the drug are cSSSI (44%), bone and joint infections (30%), bacteremia (13%) and pneumonia (6%). For these infections, the underlying pathogen was most often identified as methicillin-resistant *Staphylococcus aureus (S. aureus)* or MRSA (51%), methicillin-susceptible *S. aureus* or MSSA (15%) and coagulase negative staphylococci (10%). VIBATIV was generally well tolerated. Of the 199 patients with safety data, there were 47 adverse events (AE) reported in 34 patients.

"It is noteworthy that we are seeing VIBATIV used in complicated infections such as bone and joint and bacteremia in addition to the product's labeled indications," said Adam Bressler, M.D. Partner, Infectious Disease Specialists of Atlanta, Clinical Director of Medical Microbiology, Infection Prevention and Management, and Antimicrobial Stewardship DeKalb Medical Center and the presentation's lead author. "It will be interesting to see if these prescribing patterns persist or evolve throughout the remainder of the study and what conclusions can be drawn about these treatment decisions."

"It is not surprising that a majority of the infections treated to date in TOUR are tied to MRSA as the underlying pathogen. There is a growing collection of research supporting the *in vitro* potency of VIBATIV against challenging pathogens such as MRSA and the infections caused by these pathogens remain some of the most difficult to treat," stated Louis D. Saravolatz, Chairman, Department of Medicine at St. John Hospital and Medical Center and a TOUR study investigator. "An observational use registry of this type provides us with valuable information on a medicine like VIBATIV by compiling and evaluating the real-world clinical experience of approximately 1,000 patients. This level of detail, which would not be possible otherwise, can play an important role in helping guide the best use of VIBATIV in the clinical setting."

"We are pleased with the progress and results that we have seen to date with regard to TOUR. We have enjoyed a rapid rate of enrollment which now places us ahead of the registry's projected timeline. At the same time, we are seeing clinical response rates that are in line with our expectations and comparable to data included in the current VIBATIV label," said Frank Pasqualone, Senior Vice President and Global Head, Acute Care Business at Theravance Biopharma and Jon Bruss,

M.D., Vice President Clinical Development & Medical Affairs at Theravance Biopharma.

TOUR is a multi-center, observational study designed to enroll and report the treatment course of approximately 1,000 patients from about 50 sites in the US. As a non-interventional study, all treatment decisions are at the discretion of the patient's healthcare provider prior to patient enrollment. Study patients will have treatment initiated in both hospital-based settings and out-patient infusion sites. In order to qualify for enrollment in TOUR, patients must have received at least one dose of VIBATIV and meet specified inclusion criteria. By broadly collecting and examining real-world data related to VIBATIV treatment patterns, clinical effectiveness and safety outcomes in medical practice, Theravance Biopharma aims to create an expansive knowledge base to guide optimal clinical use and future development of the drug. More than 600 of the 1,000 target patients have been enrolled to date.

Theravance Biopharma believes that results from TOUR may serve several important objectives including:

- Assisting in optimizing use in patients currently being treated with VIBATIV;
- Assessing the types of patients that are best suited for treatment, potentially highlighting subsets of patients that may be most appropriate for treatment with VIBATIV; and
- Illustrating current healthcare practitioner's patterns of VIBATIV use in various infection types.

About VIBATIV® (telavancin)

VIBATIV® was discovered internally in a research program dedicated to finding new antibiotics for serious infections due to *Staphylococcus aureus (S. aureus)* and other Gram-positive bacteria, including MRSA and MSSA. VIBATIV is a bactericidal, once-daily, injectable lipoglycopeptide antibiotic with *in vitro* potency and a dual mechanism of action that both inhibits bacterial cell wall synthesis and disrupts bacterial cell membrane function. The drug's proven efficacy against difficult-to-treat Gram-positive infections has been demonstrated in several large, multinational registrational studies, which involved one of the largest cohorts of patients with *S. aureus* infections studied to date. Additionally, there is extensive and well-documented evidence of the drug's *in vitro* potency and *in vivo* activity against a broad collection of Gram-positive bacterial pathogens, including those that are considered difficult-to-treat and multidrug-resistant. VIBATIV is approved in the U.S. for the treatment of adult patients with hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *S. aureus* when alternative treatments are not suitable. In addition, VIBATIV is approved in the U.S. for the treatment of adult patients with complicated skin & skin structure infections (cSSSI) caused by susceptible isolates of Gram-positive bacteria, including *S. aureus*, both methicillin-susceptible (MSSA) and methicillin-resistant (MRSA) strains. The product labeling also describes the use of VIBATIV in treating patients with concurrent bacteremia (in addition to either skin infection or pneumonia).

VIBATIV is also approved for marketing in Europe, Canada and Russia. Theravance Biopharma plans to market VIBATIV outside the U.S. through a network of partners. To date, the company has secured partners for VIBATIV in the following geographies - Canada, Middle East, North Africa, Israel, Russia, China and India.

VIBATIV® Important Safety Information

Mortality

Patients with pre-existing moderate/severe renal impairment (CrCl ≤50 mL/min) who were treated with VIBATIV® for hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia had increased mortality observed versus vancomycin. Use of VIBATIV in patients with pre-existing moderate/severe renal impairment (CrCl ≤50 mL/min) should be considered only when the anticipated benefit to the patient outweighs the potential risk.

Nephrotoxicity

New onset or worsening renal impairment occurred in patients who received VIBATIV. Renal adverse events were more likely to occur in patients with baseline comorbidities known to predispose patients to kidney dysfunction and in patients who received concomitant medications known to affect kidney function. Monitor renal function in all patients receiving VIBATIV prior to initiation of treatment, during treatment, and at the end of therapy. If renal function decreases, the benefit of continuing VIBATIV versus discontinuing and initiating therapy with an alternative agent should be assessed.

Fetal Risk

Women of childbearing potential should have a serum pregnancy test prior to administration of VIBATIV. Avoid use of VIBATIV during pregnancy unless the potential benefit to the patient outweighs the potential risk to the fetus. Adverse developmental outcomes observed in three animal species at clinically relevant doses raise concerns about potential

adverse developmental outcomes in humans. If not already pregnant, women of childbearing potential should use effective contraception during VIBATIV treatment.

Contraindication

Intravenous unfractionated heparin sodium is contraindicated with VIBATIV administration due to artificially prolonged activated partial thromboplastin time (aPTT) test results for up to 18 hours after VIBATIV administration.

VIBATIV is contraindicated in patients with a known hypersensitivity to the drug.

Hypersensitivity Reactions

Serious and potentially fatal hypersensitivity reactions, including anaphylactic reactions, may occur after first or subsequent doses. VIBATIV should be used with caution in patients with known hypersensitivity to vancomycin.

Geriatric Use

Telavancin is substantially excreted by the kidney, and the risk of adverse reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection in this age group.

Infusion Related Reactions

VIBATIV is a lipoglycopeptide antibacterial agent and should be administered over a period of 60 minutes to reduce the risk of infusion-related reactions. Rapid intravenous infusions of the glycopeptide class of antimicrobial agents can cause "Red-man Syndrome" like reactions including: flushing of the upper body, urticaria, pruritus, or rash.

QTc Prolongation

Caution is warranted when prescribing VIBATIV to patients taking drugs known to prolong the QT interval. In a study involving healthy volunteers, VIBATIV prolonged the QTc interval. Use of VIBATIV should be avoided in patients with congenital long QT syndrome, known prolongation of the QTc interval, uncompensated heart failure, or severe left ventricular hypertrophy.

Most Common Adverse Reactions

The most common adverse reactions (greater than or equal to 10% of patients treated with VIBATIV) were diarrhea, taste disturbance, nausea, vomiting, and foamy urine.

Full Prescribing Information, including Boxed Warning and Medication Guide in the U.S., is available at www.VIBATIV.com.

About Theravance Biopharma

Theravance Biopharma is a diversified biopharmaceutical company with the core purpose of creating medicines that make a difference in the lives of patients suffering from serious illness.

Our pipeline of internally discovered product candidates includes potential best-in-class medicines to address the unmet needs of patients being treated for serious conditions primarily in the acute care setting. VIBATIV® (telavancin), our first commercial product, is a once-daily dual-mechanism antibiotic approved in the U.S., Europe and certain other countries for certain difficult-to-treat infections. Revefenacin (TD-4208) is a long-acting muscarinic antagonist (LAMA) being developed as a potential once-daily, nebulized treatment for chronic obstructive pulmonary disease (COPD). Our neprilysin (NEP) inhibitor program is designed to develop selective NEP inhibitors for the treatment of a range of major cardiovascular and renal diseases, including acute and chronic heart failure, hypertension and chronic kidney diseases, such as diabetic nephropathy. Our research efforts are focused in the areas of inflammation and immunology, with the goal of designing medicines that provide targeted drug delivery to tissues in the lung and gastrointestinal tract in order to maximize patient benefit and minimize risk. The first program to emerge from this research is designed to develop intestinally restricted pan-Janus kinase (JAK) inhibitors for the treatment of a range of inflammatory intestinal diseases.

In addition, we have an economic interest in future payments that may be made by Glaxo Group Limited or one of its affiliates (GSK) pursuant to its agreements with Innoviva, Inc. relating to certain drug development programs, including the Closed Triple (the combination of fluticasone furoate, umeclidinium, and vilanterol), currently in development for the

treatment of COPD and asthma.

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, 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 strategies, plans and objectives, the Company's regulatory strategies and timing of clinical studies, the potential benefits and mechanisms of action of the Company's product and product candidates, the Company's expectations for product candidates through development, potential regulatory approval and commercialization (including their potential as components of combination therapies) and the Company's expectations for product sales. 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 (including when our product candidates are studied in combination with other compounds),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 or relying on third parties to discover, develop and commercialize products, risks associated with establishing and maintaining sales, marketing and distribution capabilities with appropriate technical expertise and supporting infrastructure and risks of developing an institutional customer mix for VIBATIV® (telavancin) that meet the Company's plan for the product. Other risks affecting Theravance Biopharma are described under the heading "Risk Factors" contained in Theravance Biopharma's Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 9, 2016 and Theravance Biopharma's other filings 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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