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Theravance Biopharma Reports New Data from Ongoing TOUR™ Observational Patient Registry in Oral Presentation at SCCM Critical Care Congress

Study Results Show VIBATIV® (telavancin) Generates Positive Clinical Response Rate of Approximately 65% for Patients with Bacteremia or Infective Endocarditis

DUBLIN, Jan. 23, 2017 /PRNewswire/ -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today reported new interim data from the Company's ongoing Telavancin Observational Use Registry (TOUR™) study in an oral presentation at the Society of Critical Care Medicine's (SCCM) 46th Critical Care Congress. TOUR is designed to assess how VIBATIV® (telavancin) is being used by healthcare practitioners to treat patients in real-world clinical settings. The presented findings, which focused on a subset of registry patients with diagnoses of bacteremia or infective endocarditis (IE) (n=45), demonstrated positive clinical responses in 64.4% of patients, with 6.7% of patients failing treatment and 28.9% considered non-evaluable. Positive clinical response was defined as cure or improvement leading to step-down oral therapy. The SCCM 46th Critical Care Congress is being held in Honolulu, HI on January 20-25, 2017.

As of September 30, 2016, 593 patients had been enrolled in the TOUR study, with 45 of those having diagnoses of bacteremia or IE. In addition to clinical response results for these 45 patients, researchers reported that the pathogens causing bacteremia or IE in TOUR patients included methicillin-resistant *Staphylococcus aureus (S. aureus)* or MRSA (53% of patients), methicillin-susceptible *S. aureus* or MSSA (13%), coagulase negative staphylococci (9%), and enterococcus (7%), among others. For these patients, the median VIBATIV daily dose and duration of treatment were 750 mg and 14 days, respectively. VIBATIV was generally well tolerated in these patients with adverse event type and frequency similar to those reported in previous clinical trials.

"We are pleased to see positive clinical response rates of approximately 65% in these patients with bacteremia and infective endocarditis. Based on these results, we believe that VIBATIV may represent an alternative treatment option for these patients," said Kerry Cleveland, M.D., Professor of Medicine, University of Tennessee Health Science Center and one of the presentation's co-authors. "While the totality of data from TOUR will be extremely valuable in understanding how VIBATIV is being or can be used therapeutically, equally important will be the subsets of results that we compile for specific patient and infection types, such as those presented at SCCM."

"It is not surprising to see that a majority of the bacteremia and infective endocarditis patients in TOUR had their infections caused by *S. aureus,* which is the leading cause of bacteremia and can result in serious secondary infections such as IE. Importantly, *S. aureus* bacteremia represents a significant unmet medical need and treatment failure is common with the only two currently approved antibiotics," said Bruce Friedman, M.D., Critical Care and Co-Director JM Still Burn Center, Professor of Medicine, Anesthesiology and Perioperative at Medicine Medical College of Georgia and the presentation's first author. "The latest data from TOUR on clinical response rates adds to the large and growing collection of data that demonstrates the activity of VIBATIV against *S. aureus*, including both MRSA and MSSA strains. This provides support for the belief that patients with infections caused by *S. aureus* are potentially appropriate targets for VIBATIV treatment."

"The results reported at SCCM build upon the initial interim TOUR data that were recently presented at IDWeek, which showed comparable clinical response rates in bone and joint infections and bacteremia, as well as the product's labeled indications. Furthermore, in bacteremia patients, these latest TOUR findings are in line with the data that was recently

added to the VIBATIV label for concurrent bacteremia in the drug's approved indications," said Frank Pasqualone, Senior Vice President and Global Head, Acute Care Business at Theravance Biopharma. "TOUR continues to progress on schedule with more than 900 patients enrolled to date and we look forward to additional presentations of data from the study at future scientific conferences."

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. Study patients may have treatment initiated in either 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 900 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;
- Potentially highlighting subsets of patients that may be most appropriate for treatment with VIBATIV; and
- Illustrating current healthcare practitioner's patterns of VIBATIV use .

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/or 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 (aPTTwq) 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 GI-targeted 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 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 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, potential regulatory approval 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 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. 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 November 9, 2016. 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