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# Theravance Biopharma Reports Positive Clinical Response Rates for Patients in TOUR™ Observational Patient Registry in Several Presentations at ECCMID 2017

## Clinical Response Rates with VIBATIV® (telavancin) Treatment Range from 58 - 75% for Patients with Complicated Skin and Skin Structure Infections, Bone and Joint Infections, or Lower Respiratory Tract Infections

DUBLIN, April 24, 2017 /PRNewswire/ -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today announced that new preliminary data from the ongoing Telavancin Observational Use Registry (TOUR™) study are the focus of three poster presentations at the 27th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID). TOUR, which has enrolled its target of 1,000 patients, is designed to report how VIBATIV® (telavancin) is being used by healthcare practitioners to treat patients in real-world clinical settings. The presented findings, which focus on data from registry patients with diagnoses of complicated skin & skin structure infections (cSSSIs), bone and joint infections, or lower respiratory tract infections (LRTIs), report positive clinical responses for VIBATIV treatment ranging from 58.3% to 75.3% in these infection types. Positive clinical response was defined as cure or improvement leading to step-down oral therapy. The Company plans to present additional collections of data from the ongoing TOUR study at appropriate upcoming scientific conferences. The 27th ECCMID is being held in Vienna, Austria, April 22-25, 2017.

The TOUR findings being reported at ECCMID are based on a review of preliminary data collected from the 593 patients that were enrolled in the registry as of September 30, 2016. The Company expects future TOUR analyses to be updated as additional data becomes available and the study is completed. Details from the three TOUR-related ECCMID presentations are as follows:

Complicated Skin and Skin Structure Infections (cSSSIs):

Researchers presented preliminary data reported for 279 patients captured in the TOUR study with confirmed cSSSIs. 62% of patients had been previously treated with other agents unsuccessfully. Positive clinical response was reported for 75.3% of these patients, with 9.3% of patients failing treatment and 15.4% considered non-evaluable. The predominant subtypes of cSSSIs included cellulitis (50.5%), abscess (22.2%), and surgical wound (15.4%), while the underlying pathogens causing the infections included methicillin-resistant *Staphylococcus aureus (S. aureus)* or MRSA (30.1%), methicillin-susceptible *S. aureus* or MSSA (9.3%), and coagulase negative staphylococci (6.5%). For these patients, the median VIBATIV daily dose and duration of treatment were 750 mg and 10 days, respectively. Outpatient treatment was reported in 60.9% of the patients. VIBATIV was generally well tolerated in these patients with adverse event type and frequency comparable to those reported in previous clinical trials.

Bone and Joint Infections:

Researchers presented preliminary data reported for 174 patients captured in the TOUR study with confirmed bone and joint infections. 72.4% of patients had been previously treated with other agents unsuccessfully. Positive clinical response was reported for 68.4% of these patients, with 10.3% of patients failing treatment and 21.3% considered non-evaluable. The underlying pathogens causing the infections included MRSA (40.2%), MSSA (13.8%), and coagulase negative staphylococci (6.3%). For these patients, the median VIBATIV daily dose and duration of treatment were 750 mg and 26 days,

respectively. Outpatient treatment was reported in 61.5% of the patients. Of the 174 patients, 33 patients had at least one adverse event and seven patients had at least one serious adverse event. There were three deaths within 28 days of the first VIBATIV dose and 20 patients discontinued treatment due to an adverse event.

"Bone and joint infections are one of those challenging infection types in which we are interested, particularly when those are caused by MRSA or MSSA," said Charles R Sims, M.D., an infectious disease specialist at Baylor CHI St. Luke's Health, The Woodlands, Texas, and lead author of one of the TOUR presentations at ECCMID. "One of the most exciting elements of the TOUR study is the opportunity to examine real-world prescribing trends and clinical outcomes for VIBATIV in difficult-to-treat infection types. We are encouraged to observe that more than 68% of bone and joint infection patients enrolled in TOUR have experienced a positive clinical response to VIBATIV treatment."

Lower Respiratory Tract Infections (LRTIs):

Researchers presented preliminary data reported for 36 patients captured in the TOUR study with confirmed LRTIs. 77.8% of patients had been previously treated with other agents unsuccessfully. Positive clinical response was reported for 58.3% of these patients, with 13.9% of patients failing treatment and 27.8% considered non-evaluable. The predominant subtypes of LRTIs were hospital-acquired bacterial pneumonia or HABP (44.4%) and ventilator-associated bacterial pneumonia or VABP (13.9%), while the most common underlying pathogen causing the infections was MRSA (61.1%). For these patients, the median VIBATIV daily dose and duration of treatment were 750 mg and 9 days, respectively. Of the 36 patients, eight patients had at least one adverse event and four patients had at least one serious adverse event. There were six deaths within 28 days of the first VIBATIV dose and two patients discontinued treatment due to an adverse event.

"Despite a majority of the LRTIs in the TOUR study being caused by MRSA, one of the most difficult-to-treat pathogens in the medical field, treatment with VIBATIV delivered a positive clinical response in more than 58% of all LRTI patients," stated Dino Delaportas, M.D., an infectious disease specialist at Monongalia General Hospital in Morgantown, West Virginia, and lead author of one of the TOUR presentations at ECCMID. "Importantly, these LRTIs spanned HABP and VABP, for which VIBATIV is currently approved, as well as other infection types such as community-acquired pneumonia, lung abscess, and cystic fibrosis exacerbations, among others. The ability to combat this broad range of challenging infections highlights the effectiveness of VIBATIV as an antibiotic treatment against Gram-positive bacteria."

***About TOUR***

TOUR is a multi-center, observational study that has enrolled 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 or 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.

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 once-daily, injectable lipoglycopeptide antibiotic with *in vitro* potency, bactericidal activity within six hours, and penetration into target infection sites. 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 help improve 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-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 (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-K filed with the Securities and Exchange Commission (SEC) on March 1, 2017 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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