

## **New Data for VIBATIV® (telavancin) Reported in Several Presentations at ECCMID 2017**

### **VIBATIV (telavancin) Demonstrates Greater in vitro and in vivo Potency Compared to Competitor Antibiotics Against Difficult-to-Treat Staphylococcus aureus Pathogens including MRSA and MSSA**

DUBLIN, April 25, 2017 /PRNewswire/ -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today announced the presentation of positive new data from several studies of VIBATIV® (telavancin), the Company's proprietary FDA-approved antibiotic. Study results highlighted greater in vivo and in vitro potency for VIBATIV against difficult-to-treat Staphylococcus aureus (S. aureus) pathogens as compared to other commercialized antibiotics. Additionally, presented findings included results from a study evaluating the pharmacokinetics of VIBATIV in obese subjects. These data were presented at the 27th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID), which is being held in Vienna, Austria, April 22-25, 2017.



*Highlights from the VIBATIV presentations at ECCMID include:*

#### *Activity Against Global Collection of S. aureus Clinical Isolates*

*Results of a study showed that VIBATIV possessed the greatest in vitro activity of all antibiotics evaluated against a broad, global collection of difficult-to-treat S. aureus clinical isolates, including those considered to be methicillin-resistant (MRSA) and methicillin-susceptible (MSSA). This activity for VIBATIV was seen against 100% of the evaluated S. aureus clinical isolates regardless of their type or resistance profile, including those considered to be multidrug-resistant (MDR). Overall, the minimum inhibitory concentrations (MICs) for VIBATIV were eight- to 16-fold lower than for vancomycin, daptomycin and linezolid against the MRSA or MDR isolates. MICs are a measure used to express in vitro activity of an antibiotic against a pathogen.*

#### *Activity Against S. aureus in Murine Infection Models*

*Researchers presented findings from a study designed to examine and compare the pharmacokinetic and pharmacodynamic properties of VIBATIV and vancomycin against S. aureus strains, including MRSA, in the neutropenic murine thigh and lung infection models. Results demonstrated greater in vivo potency for VIBATIV as compared to vancomycin against S. aureus in these models. Potency was measured by MICs and those measurements were determined to be excellent predictors of treatment efficacy against the target infections. The in vivo potency advantages seen in this study validate the ongoing use of VIBATIV in its approved indication of hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible S. aureus isolates, including MRSA.*

#### *Pharmacokinetics of VIBATIV in Obese Subjects*

*In a third presentation, researchers reported results of a study that evaluated the pharmacokinetic profile of VIBATIV when delivered in a single, stratified, fixed weight-based dose. With the understanding that body weight can be a key determinant of patients' exposure to a drug, researchers were interested in examining the pharmacokinetics of VIBATIV in obese subjects. Study results demonstrated that moderately obese subjects had higher VIBATIV distribution and clearance levels than normal weight or mildly obese subjects.*

"We are excited to continue to build our extensive collection of scientific data highlighting the range of product advantages that we believe favorably position VIBATIV against competitor antibiotics. By highlighting the activity of VIBATIV in multiple *in vitro* *S. aureus* infection models, as well as against a range of *S. aureus* clinical isolates, the presented data at ECCMID confirm the *in vivo* potency of VIBATIV," said Frank Pasqualone, Senior Vice President and Global Head, Acute Care Business at Theravance Biopharma. "These latest data complement the preliminary results from our ongoing TOUR™ patient registry study that were also presented at ECCMID."

## **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](http://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](http://www.theravance.com).

THERAVANCE®, the Cross/Star logo, and VIBATIV® are registered trademarks of the Theravance Biopharma group of companies. Trademarks, trade names or service marks of other companies appearing on this press release are the property of their respective owners.

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<sup>®</sup> (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.

**Contact Information:**

Alexander Dobbin  
Head of Investor Relations  
650-808-4045  
[investor.relations@theravance.com](mailto:investor.relations@theravance.com)

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

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/new-data-for-vibativ-telavancin-reported-in-several-presentations-at-eccmid-2017-300444508.html>

SOURCE Theravance Biopharma, Inc.

News Provided by Acquire Media