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Data From New Retrospective Studies of VIBATIV(R) (Telavancin) Demonstrate Positive Clinical Outcomes for Patients With Difficult-to-Treat, Gram-Positive Infections, Including MRSA

Positive Findings Support Company's Current Development and Regulatory Efforts for VIBATIV

DUBLIN, IRELAND -- (Marketwired) -- 10/12/15 -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today announced new positive data from multiple retrospective studies of VIBATIV® (telavancin) demonstrating positive clinical outcomes for patients with *Staphylococcus aureus (S. aureus)* bacteremia and methicillin-resistant *S. aureus* (MRSA) osteomyelitis following treatment with VIBATIV. These study findings, which include clinical cure/improvement rates for VIBATIV-treated patients of 79.4% in bacteremia and 88.9% in osteomyelitis, demonstrate the potential of VIBATIV against two additional difficult-to-treat infections. Results from these studies were presented at IDWeek™ 2015, which was held in San Diego, CA, on October 7 - 11, 2015.

In a multicenter, retrospective study of 34 *S. aureus* bacteremia patients receiving VIBATIV, researchers assessed clinical outcomes and safety measures. Data showed that 27 patients (79.4%) were considered cured or improved at end of therapy (EOT), the study's primary outcome measure. When researchers excluded the seven patients who died before EOT, 95.8% of patients with 30-day follow-up post-EOT were considered cured or improved. It is important to note that the approximately 20% mortality rate observed in this study is consistent with reported mortality rates (20-30%) associated with *S. aureus* bacteremia, even with appropriate antibacterial therapy.[1-4] There were no adverse events in the study that led to discontinuation of VIBATIV for any patients.

In a second poster at IDWeek, researchers presented findings from a retrospective study in adult patients with hospital-onset MRSA pneumonia (HOMP). The study was designed to identify the frequency with which HOMP occurs concurrently with bacteremia and the clinical impact that concurrent bacteremia has on these patients. Results showed that it is common for bacteremia to occur concurrently with HOMP, with 58 out of 513 HOMP patients (11.3%) also presenting with bacteremia. Furthermore, HOMP patients with concurrent bacteremia experienced higher mortality (35.1% vs. 26.2%) and longer post-pneumonia hospital stays (an average increase of 13.5 days) as compared to patients with HOMP alone.

"These new data presented at IDWeek provide support for our current development and regulatory efforts for VIBATIV in the area of bacteremia, including our ongoing registrational Phase 3 trial and our recent supplemental NDA filing to expand the product's label to include concurrent bacteremia in both of the drug's two approved indications in the U.S.," said Frank Pasqualone, Senior Vice President, Development and Operations at Theravance Biopharma. "We are encouraged to see the presentation of study data that assess the potential of VIBATIV in *S. aureus* bacteremia, a difficult-to-treat infection. We are committed to fully exploring the potential of VIBATIV to address serious medical needs."

Highlights from additional VIBATIV-related presentations at IDWeek 2015 include:

- Findings from a retrospective study of 14 patients with methicillin-resistant *S. aureus* osteomyelitis showed that eight of nine clinically evaluable cases (88.9%) were considered cured/improved at EOT. Five of these patients maintained clinical cure at 12-month follow-up. Importantly, four of the 14 patients had concurrent MRSA bacteremia but had no further positive blood cultures for bacteremia following initiation of VIBATIV therapy. Adverse events were seen in seven of 14 patients with two individuals discontinuing treatment due to infusion-related chills/rigors. Theravance Biopharma believes these study findings demonstrate the potential of VIBATIV in MRSA osteomyelitis, a difficult-to-treat infection.

- Researchers showed that VIBATIV possessed greater *in vitro* activity than well-known competitor antibiotics against a broad collection of contemporary Gram-positive clinical isolates causing hospital-acquired bacterial pneumonia (HABP) in U.S. hospitals. Data showed that the minimum inhibitory concentrations (MICs) for VIBATIV were 16-fold lower than for vancomycin and linezolid against MRSA isolates. MICs are a common measure used to express an antibiotic's *in vitro* potency.

"We are pleased to continue to see positive indications of activity for VIBATIV in a growing number of difficult-to-treat infections. Bacteremia and osteomyelitis are just the latest examples of these infections for which we see encouraging data," stated Jon Bruss, M.D., Vice President Clinical Development & Medical Affairs at Theravance Biopharma. "At the same time, we also continue to supplement our collection of data that show greater *in vitro* activity for VIBATIV in its approved indications as

compared to well-known competitor antibiotics."

VIBATIV is a bactericidal, once-daily, injectable lipoglycopeptide antibiotic with *in vitro* potency and a dual mechanism of action whereby telavancin 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 MRSA 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.

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. VIBATIV is a bactericidal, once-daily, injectable lipoglycopeptide antibiotic with *in vitro* potency and a dual mechanism of action whereby telavancin both inhibits bacterial cell wall synthesis and disrupts bacterial cell membrane function. VIBATIV for injection is approved in the U.S. for the treatment of 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.

In addition to the U.S., VIBATIV is approved for use in Europe, Canada and Russia. The specific approved indications in these markets vary by region. 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 - Europe, Canada, Middle East, North Africa, Israel, Russia, and China.

VIBATIV® Important Safety Information (U.S.)

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

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., Europe and certain other countries for certain difficult-to-treat infections. Revefenacin (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 GlaxoSmithKline plc pursuant to its agreements with Theravance, Inc. relating to certain drug development programs, including the combination of fluticasone furoate, umeclidinium and vilanterol (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 August 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.

[1] Whitby M, McLaws ML, Berry G. Risk of death from methicillin-resistant Staphylococcus aureus bacteraemia: a meta-analysis. Med J Aust. Sep 3 2001;175(5):264-267.

[2] Benfield T, Espersen F, Frimodt-Møller N, Jensen AG, Larsen AR, Pallesen LV, Skov R, Westh H, Skinhøj P. Increasing incidence but decreasing in-hospital mortality of adult Staphylococcus aureus bacteraemia between 1981 and 2000. Clin Microbiol Infect. 2007 Mar;13(3):257-63.

[3] Turnidge JD, Kotsanas D, Munckhof W, Roberts S, Bennett CM, Nimmo GR, Coombs GW, Murray RJ, Howden B, Johnson PD, Dowling K; Australia New Zealand Cooperative on Outcomes in Staphylococcal Sepsis. Staphylococcus aureus bacteraemia: a major cause of mortality in Australia and New Zealand. Med J Aust. 2009 Oct 5;191(7):368-73.

[4] van Hal SJ, Jensen SO, Vaska VL, Espedido BA, Paterson DL, Gosbell IB. Predictors of mortality in Staphylococcus aureus bacteremia. Clin Microbiol Rev. Apr 2012;25(2):362-386.

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