May 16, 2016

New Data Analyses From Phase 3 ATTAIN Trials Support VIBATIV(R) (Telavancin) as a Treatment for Staphylococcus Aureus HABP/VABP, Including Cases Caused by MRSA

Presentation at American Thoracic Society 2016 International Conference Suggests Potential Efficacy and Overall Mortality Benefits for Select HABP/VABP Patients With VIBATIV Therapy; Shows No Statistically Significant Differences in Nephrotoxicity and Mortality for Telavancin vs. Vancomycin

DUBLIN, IRELAND -- (Marketwired) -- 05/16/16 -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today announced that results from post hoc analyses of the previously completed Phase 3 Assessment of Telavancin for Treatment of Hospital-Acquired Pneumonia (ATTAIN) studies were the focus of a poster presentation at the American Thoracic Society (ATS) 2016 International Conference. The ATTAIN studies were registrational trials which supported the regulatory approval of telavancin (marketed as VIBATIV®) for the treatment of hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP).

Presented findings from the post hoc analyses suggest that VIBATIV may serve as an appropriate treatment of select types of monomicrobial *Staphylococcus aureus* (*S. aureus*) HABP/VABP. Data showed comparable clinical cure rates for telavancin and vancomycin among the ATTAIN trials' all-treated (AT) patients with monomicrobial *S. aureus*, including both methicillin-resistant *S. aureus* (MRSA) and methicillin-susceptible *S. aureus* (MSSA), and a vancomycin MIC ≥ 1.0 µg/mL across all evaluated patient comorbidities. In an exploratory analysis of the microbiologically evaluable (ME) population, telavancin treatment produced numerically higher clinical cure rates (confidence intervals did not cross zero) as compared to vancomycin when those patients were ≥ 65 years of age or were diagnosed with VABP. ME patients were those with a Gram-positive baseline respiratory pathogen known to cause pneumonia and who adhered to the study guidelines so that their clinical outcomes were reasonably associated with treatment.

"These post hoc analyses of the ATTAIN studies provide us with a deeper understanding of the therapeutic effect of VIBATIV in the treatment of *S. aureus* HABP/VABP, particularly as it compares to that of vancomycin, the most commonly prescribed treatment for MRSA and related bacterial infections," said Frank Pasqualone, Senior Vice President and Global Head, Acute Care Business at Theravance Biopharma. "We are pleased that the findings highlight that VIBATIV may be an important option in treating specific types of *S. aureus* HABP/VABP, including both MRSA and MSSA, particularly for elderly patients and those diagnosed with VABP. As the researchers concluded, the data suggest that these patients may experience efficacy and overall mortality benefits when treated with VIBATIV as opposed to vancomycin."

Additional findings from the post hoc analyses showed that rates of nephrotoxicity were comparable for telavancin and vancomycin treatment with no statistically significant differences. This is noteworthy as the initial analysis of the Phase 3 ATTAIN studies generated results suggesting a potential increased risk of nephrotoxicity in certain patients following treatment with telavancin as compared to vancomycin.

"The findings pertaining to comparable rates of nephrotoxicity between telavancin and vancomycin are of particular interest to Theravance Biopharma in light of previous conclusions regarding the risk for nephrotoxicity with telavancin treatment," stated Jon Bruss, M.D., Vice President Clinical Development & Medical Affairs at Theravance Biopharma. "We believe that the fact that there were no statistically significant differences in rates of nephrotoxicity between the telavancin or vancomycin treatment provides a rationale for a more careful evaluation of the potential risk of nephrotoxicity associated with telavancin treatment."

The purpose of the post hoc analyses was to further evaluate and compare the ATTAIN studies' clinical cure rates and safety results for telavancin vs. vancomycin across a range of comorbidities including patient age, type of infection and severity of disease. The analyses were conducted by researchers at Weill Cornell Medical Center/Medical College and Baystate Medical Center (Springfield, Mass), in collaboration with Theravance Biopharma.

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.

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 -- Europe, 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 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.

THERAVANCE®, the Cross/Star logo, MEDICINES THAT MAKE A DIFFERENCE® and VIBATIV® are registered trademarks of the Theravance Biopharma group of companies.

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 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 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

Source: Theravance Biopharma

News Provided by Acquire Media