September 9, 2014

Theravance Biopharma Provides VIBATIV(R) (telavancin) Product Update

Plans for New Clinical Studies, Expanded Commercial Program and New Study Analyses Further Supporting Drug's in Vitro Potency in Resolving Difficult-to-Treat Infections

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 09/09/14 -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today provided a product update for VIBATIV® (telavancin), the Company's proprietary FDA-approved bactericidal, once-daily, injectable lipoglycopeptide antibiotic. The Company detailed plans for additional VIBATIV clinical studies, its strategy for increasing the scope of US commercial efforts and new study analyses presented at recent scientific conferences underscoring VIBATIV's *in vitro* potency and activity. Today's announcement is being made in conjunction with the 54th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) being held September 5-9, 2014 in Washington D.C.

"VIBATIV's proven efficacy against difficult-to-treat infections has been demonstrated in several large, multinational registrational studies, which involved one of the largest cohorts of patients with methicillin-resistant *Staphylococcus aureus* (MRSA) infections studied to date. Given the increasingly urgent need to combat the growing public health threat of antibacterial resistance, we are undertaking a proactive program designed to expand VIBATIV's product profile, strengthen physicians' awareness and increase their utilization in the right patient populations," said Frank Pasqualone, Senior Vice President, Development and Operations at Theravance Biopharma. "Our plans to conduct a Phase 3 registrational trial in *Staphylococcus aureus* bacteremia, a large observational use patient registry study, a targeted and strategic expansion of our US commercialization efforts, and to build a global network of partnerships to commercialize VIBATIV worldwide, provide clear evidence of our ongoing commitment to building VIBATIV's success and playing a leadership role in the broader anti-infective market."

VIBATIV is approved in the US for the treatment of adult patients with hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *Staphylococcus aureus* when alternative treatments are not suitable, and for the treatment of cSSSI caused by susceptible isolates of Gram-positive bacteria, including *Staphylococcus aureus*, both methicillin-susceptible (MSSA) and methicillin-resistant (MRSA) strains. VIBATIV, which was discovered and developed internally, 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.

Phase 3 Registrational Study in Staphylococcus aureus Bacteremia

As part of its effort to explore additional potential infection types in which VIBATIV may offer patients therapeutic benefit, Theravance Biopharma plans to initiate a Phase 3 registrational study for the treatment of patients with *Staphylococcus aureus* bacteremia. Bacteremia is the presence of bacteria in the bloodstream and represents a serious medical condition that can lead to the spread of infection throughout the body, as well as the potentially fatal conditions of sepsis and septic shock. The condition represents a significant unmet medical need with only two antibiotic treatments currently approved for bacteremia.

Theravance Biopharma believes that VIBATIV's demonstrated *in vitro* potency, dual mechanism of action and efficacy in resolving difficult-to-treat infections position it as a potentially medically important treatment for *Staphylococcus aureus* bacteremia. It is important to note that VIBATIV possesses a dual mechanism of action, which differentiates the product from the two single-mechanism antibiotics currently approved for *Staphylococcus aureus* bacteremia.

The registrational trial will be a multicenter, randomized, open-label study and is expected to enroll its first patient by the end of 2014. The study is designed to evaluate the non-inferiority of VIBATIV in treating *Staphylococcus aureus* bacteremia as compared to standard therapy.

Telavancin Observational Use Registry (TOUR)

Theravance Biopharma is also planning to conduct an observational use registry study designed to assess the manner in which VIBATIV is used by healthcare practitioners to treat patients. By broadly collecting and examining data related to VIBATIV treatment patterns, clinical effectiveness and safety outcomes in the real world, the company aims to create an expansive knowledge base to guide future development and optimal use of the drug.

Named Telavancin Observational Use Registry (TOUR), the study is designed as a multi-center, observational, prospective

study that will enroll approximately 1,000 patients from about 50 sites in the US. As a non-interventional study, all treatment decisions will be at the discretion of the patient's healthcare provider. The Company is targeting enrollment of the registry's first patient in the fourth quarter of 2014.

Commercial Program Expansion

During the past year, Theravance Biopharma has undertaken a carefully planned, phased commercial strategy for VIBATIV in the US. This strategy has focused on a limited number of geographic territories across the country, and has succeeded in achieving the goals of the Company. Therefore, Theravance Biopharma is undertaking a targeted expansion into additional regional territories by the end of 2014.

The decision to expand is informed by the Company's analysis of treatment patterns in its initial target markets. Interactions with healthcare practitioners have shown that as they gain more experience with VIBATIV, their utilization of the treatment expands to broader usage in the product's approved indications.

Expanded Clinical Data Support

Theravance Biopharma is committed to conducting important research designed to further elucidate the potential therapeutic benefit and utilization of VIBATIV. Results from several new study analyses that further supplements the well-documented evidence of the drug's *in vitro* potency and activity were presented recently at the 54th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) and the 2014 International Symposium on Staphylococci & Staphylococcal Infections (ISSSI).

Combined, data from these presentations confirm the previously demonstrated *in vitro* potency of VIBATIV against a broad collection of difficult-to-treat clinical pathogens using a revised, FDA-approved susceptibility testing method. These data demonstrated greater *in vitro* potency for VIBATIV as compared to vancomycin against a variety of difficult-to-treat isolates with reduced susceptibility to the approved antibiotics vancomycin, daptomycin and linezolid. These isolates included a range of *Staphylococcus* strains such as MRSA, MSSA, vancomycin-resistant *Staphylococcus aureus* (VRSA), and methicillin-resistant *Staphylococcus epidermidis* (MRSE), as well as various biofilm-related infections.

Furthermore, in a number of *in vitro* studies, results with the revised testing method indicated that the activity of VIBATIV is greater than previously reported, providing a new reference for the drug's potency.

Theravance Biopharma believes that these latest findings, combined with previous study results, provide confirmation that VIBATIV is a key alternative for patients in those instances in which vancomycin is not effective or appropriate for treating infections that are susceptible to VIBATIV therapy.

"Theravance Biopharma is dedicated to patients requiring anti-infective therapy and committed to investigating the potentially broad utility of the compound. As is well documented in the medical, scientific and popular media, there is a critical need for antibiotic research and development given the growing threat from resistance to current therapies, and we believe that VIBATIV will play an important role in helping to address this serious medical problem," stated Rick E Winningham, Chairman and Chief Executive Officer. "We are proud to be the only company to discover, develop, secure approval for and commercialize a currently available branded antibiotic product. This demonstrates that Theravance Biopharma is not only committed to the anti-infective area today, but has been for nearly two decades."

About VIBATIV® (telavancin)

VIBATIV® was discovered by Theravance in a research program dedicated to finding new antibiotics for serious infections due to *Staphylococcus 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® is approved in the US for the treatment of adult patients with HABP/VABP when alternative treatments are not suitable and for cSSSI caused by susceptible isolates of Gram-positive bacteria, including *Staphylococcus aureus*, both methicillin-susceptible (MSSA) and methicillin-resistant (MRSA) strains.

Theravance Biopharma plans to market VIBATIV in markets outside the United States through a network of partners.

In Europe, VIBATIV® is indicated for the treatment of adults with nosocomial pneumonia (NP) including ventilator associated pneumonia, known or suspected to be caused by MRSA. VIBATIV® should be used only in situations where it is known or suspected that other alternatives are not suitable. VIBATIV® is not currently indicated for the treatment of cSSSI in Europe.

Clinigen Group holds the commercial rights to market and distribute VIBATIV® in Europe.

Theravance Biopharma also has partners in the following geographies -- Canada, Middle East, North Africa, Israel, and Russia. Partnering discussions continue in other parts of the world.

VIBATIV® Important Safety Information (US)

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

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 US, is available at www.VIBATIV.com.

About Theravance Biopharma

Theravance Biopharma is a biopharmaceutical company focused on the discovery, development and commercialization of small molecule medicines across a number of therapeutic areas, including respiratory disease, bacterial infections, central nervous system (CNS)/pain, and gastrointestinal (GI) motility dysfunction.

Theravance Biopharma has one approved product, VIBATIV® (telavancin), which was discovered and developed internally, a pipeline of internally discovered product candidates and strategic collaborations with pharmaceutical companies. In addition, the Company has an economic interest in future payments that may be made by GlaxoSmithKline plc (GSK) pursuant to its agreements with Theravance, Inc. relating to certain drug programs, including the combination of fluticasone furoate (FF), umeclidinium (UMEC), and vilanterol (VI) (FF/UMEC/VI), the combination of the bifunctional muscarinic antagonist-beta$_2$ agonist (MABA) GSK961081 ('081) and FF ('081/FF), and MABA monotherapy. By leveraging its proprietary insight of multivalency to drug discovery, the Company is pursuing a best-in-class strategy designed to discover superior medicines in areas of significant unmet medical need. Theravance Biopharma is a publicly-held corporation, with US headquarters located in South San Francisco, California, and trades on the NASDAQ Global Select Market under the symbol TBPH. For additional 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 strategies, plans and objectives of Theravance Biopharma, the status and timing of clinical studies, data analysis and communication of results, the potential benefits and mechanisms of action of product candidates, the enabling capabilities of Theravance Biopharma's approach to drug discovery and Theravance Biopharma's proprietary insights, expectations for product candidates through development and commercialization, and the timing of seeking regulatory approval of product candidates. 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: the disruption of operations during the transition period following the Spin-Off, including the diversion of management's and employees' attention from the business, adverse impacts upon the progress of discovery and development efforts, disruption of relationships with collaborators and increased employee turnover, delays or difficulties in commencing or completing clinical studies, the potential that results from clinical or non-clinical studies indicate product candidates are unsafe or ineffective, 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 products and risks associated with establishing distribution capabilities for telavancin 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 August 14, 2014. 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.

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Contact Information:

Rick E Winningham
Chief Executive Officer
650-808-4045
investor.relations@theravance.com

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

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