

## **Theravance Biopharma Initiates Patient Registry Study for VIBATIV(R) (telavancin)**

### **First Patient Enrolled in Telavancin Observational Use Registry (TOUR); Large-Scale Study to Create Knowledge Base to Guide Optimal Clinical Use and Future Development of VIBATIV(R)**

GEORGE TOWN, GRAND CAYMAN -- (Marketwired) -- 02/10/15 -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today announced enrollment of the first patient in the Company's Telavancin Observational Use Registry (TOUR). The study is designed to assess how VIBATIV<sup>®</sup> (telavancin), the Company's proprietary FDA-approved antibiotic, is being used by healthcare practitioners to treat patients. By broadly collecting and examining real-world data related to VIBATIV treatment patterns, clinical effectiveness and safety outcomes in medical practice, the Company aims to create an expansive knowledge base to guide optimal clinical use and future development of the drug.

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 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. Recently presented study analyses further supplement the extensive and well-documented evidence of the drug's *in vitro* potency and *in vitro* activity against a broad collection of bacterial pathogens, including those that are considered difficult-to-treat and multidrug-resistant.

"We are undertaking this observational use study as an important component of our strategy to enhance our understanding of the clinical use of VIBATIV," said Frank Pasqualone, Senior Vice President, Development and Operations at Theravance Biopharma. "With the extensive data we collect on how VIBATIV therapy is managed by healthcare practitioners in the clinic, we will be able to further educate the broader healthcare community about the drug's optimal clinical use."

TOUR is a multi-center, observational 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 prior to patient enrollment. Study patients will have treatment initiated in both hospital-based settings and 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.

Theravance Biopharma believes that results from the patient registry may serve several important objectives including:

- Assisting in optimizing VIBATIV use in patients currently being treated with the drug;
- Assessing the types of patients that are best suited for treatment, potentially highlighting subsets of patients that may be appropriate for treatment with VIBATIV; and
- Illustrating current healthcare practitioners' patterns of VIBATIV use in combating antibiotic resistance.

"With a number of recent, highly visible developments related to the fight against antibiotic resistance, including a comprehensive call-to-action by President Obama, we believe TOUR is an important and timely study for the anti-infective industry," stated Rick E Winningham, Chairman and Chief Executive Officer. "Data from this study can support VIBATIV as an essential tool in the antibiotic arsenal of physicians and healthcare practitioners."

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.

#### **About VIBATIV<sup>®</sup> (telavancin)**

VIBATIV was discovered by Theravance, Inc. 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 where the drug is approved 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. Discussions continue regarding potential partnering relationships in other parts of the world.

### **VIBATIV<sup>®</sup> Important Safety Information (US)**

#### **Mortality**

Patients with pre-existing moderate/severe renal impairment (CrCl  $\leq$  50 mL/min) who were treated with VIBATIV<sup>®</sup> for hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia had increased mortality observed versus vancomycin. Use of VIBATIV<sup>®</sup> in patients with pre-existing moderate/severe renal impairment (CrCl  $\leq$  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<sup>®</sup>. 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<sup>®</sup> prior to initiation of treatment, during treatment, and at the end of therapy. If renal function decreases, the benefit of continuing VIBATIV<sup>®</sup> 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<sup>®</sup>. Avoid use of VIBATIV<sup>®</sup> 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<sup>®</sup> treatment.

#### **Contraindication**

Intravenous unfractionated heparin sodium is contraindicated with VIBATIV<sup>®</sup> administration due to artificially prolonged activated partial thromboplastin time (aPTT) test results for up to 18 hours after VIBATIV<sup>®</sup> administration.

VIBATIV<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> to patients taking drugs known to prolong the QT interval. In a study involving healthy volunteers, VIBATIV<sup>®</sup> prolonged the QTc interval. Use of VIBATIV<sup>®</sup> 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<sup>®</sup>) 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](http://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<sup>®</sup> (telavancin), our first commercial product, is a once-daily dual-mechanism antibiotic approved in the US and Europe for difficult-to-treat infections. TD-4208 is a long-acting muscarinic antagonist (LAMA) being developed as a potential once-daily, nebulized treatment for COPD. Axelopran (TD-1211) is a 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 -- our core areas of therapeutic focus -- and infectious disease. In addition, we have an economic interest in future payments that may be made by GSK pursuant to its agreements with Theravance, Inc. relating to certain drug programs, including the combination of umeclidinium, vilanterol and fluticasone furoate (or 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](http://www.theravance.com).

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*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 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. 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 of Theravance Biopharma from Theravance, Inc., 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 the*

*Company's 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 product candidates and risks associated with establishing and maintaining sales, marketing and distribution capabilities. 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 November 12, 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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Source: Theravance Biopharma

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