

## **Theravance Biopharma Announces Health Canada Approval for VIBATIV(R) (telavancin) for Treatment of HAP/VAP Caused by Gram-Positive Bacteria, Including MRSA**

### **Latest Approval Expands Product Label in Canada and Further Strengthens Global Brand for Once-Daily, Dual Mechanism Antibiotic**

DUBLIN, IRELAND -- (Marketwired) -- 07/23/15 -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company") today announced that Health Canada has approved VIBATIV<sup>®</sup> (telavancin) for the treatment of adult patients with hospital-acquired bacterial pneumonia (HAP) and ventilator-associated bacterial pneumonia (VAP) known or suspected to be caused by susceptible isolates of *Staphylococcus aureus* including methicillin-susceptible and methicillin-resistant *S. aureus* (MSSA and MRSA). VIBATIV is a bactericidal, once-daily antibiotic with *in vitro* potency and a dual mechanism of action against Gram-positive bacteria, including difficult-to-treat pathogens such as MRSA. The antibiotic is also currently approved in Canada for the treatment of patients with complicated skin and skin structure infections (cSSSI) caused by susceptible strains of Gram-positive microorganisms.

VIBATIV will be marketed and sold in Canada by PENDOPHARM, a division of Pharmascience Inc., and is expected to become commercially available in 2016. This marketing clearance triggers a milestone payment to Theravance Biopharma under terms of its development and commercialization agreement with PENDOPHARM. Additional terms of this agreement call for Theravance Biopharma to receive potential future contingent payments and a royalty on net sales of VIBATIV from PENDOPHARM.

"This important approval in Canada comes on the heels of the recent VIBATIV marketing clearance in Russia for the treatment of multiple infections caused by Gram-positive bacteria, such as MRSA. These regulatory milestones, combined with our recent agreement with SciClone Pharmaceuticals to develop and commercialize VIBATIV in China, highlight the significant momentum we are generating in efforts to build the VIBATIV brand around the world," said Frank Pasqualone, Senior Vice President, Development and Operations at Theravance Biopharma. "VIBATIV has demonstrated efficacy against some of the difficult-to-treat and multidrug-resistant infections that are contributing to the rapid expansion of antibiotic resistance globally. As such, broadening the availability of the drug in key markets such as Canada and Russia may play an important role in combatting antibiotic resistance by providing healthcare practitioners in those countries with another important treatment option."

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 MRSA infections studied to date. Additionally, there is 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.

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

VIBATIV<sup>®</sup> was discovered internally 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 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 *Staphylococcus 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 *Staphylococcus aureus*, both methicillin-susceptible (MSSA) and methicillin-resistant (MRSA) strains.

Theravance Biopharma plans to market VIBATIV outside the United States 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<sup>®</sup> Important Safety Information (U.S.)**

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 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. 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**

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 U.S., Europe and certain other countries for difficult-to-treat infections. 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 GSK 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](http://www.theravance.com).

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

#### **About PENDOPHARM, a Division of Pharmascience Inc.**

PENDOPHARM is a division of Pharmascience Inc., a Canadian privately-owned company. Established in 1983, Pharmascience Inc. is Canada's 10th largest pharmaceutical company, with a highly-skilled workforce of 1,400 people. Pharmascience commercializes over 400 products, including branded prescription, OTC and BTC products as well as generic products in Canada and with its affiliates and distributors in over 60 countries worldwide.

Strategically committed to growth, PENDOPHARM is actively engaged in licensing, partnering, developing and marketing late-stage specialty prescription medicines as well as consumer brands. [www.pendopharm.com](http://www.pendopharm.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 May 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.*

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