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Theravance Announces FDA Approval of VIBATIV(R) (telavancin) for the Treatment of Hospital-Acquired and Ventilator-Associated Bacterial Pneumonia

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 06/21/13 -- Theravance, Inc. (NASDAQ: THRX) today announced that the U.S. Food and Drug Administration (FDA) has approved VIBATIV[®] (telavancin) 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. VIBATIV[®], discovered and developed by Theravance, is a bactericidal, once-daily, injectable lipoglycopeptide antibiotic with a dual mechanism of action whereby telavancin both inhibits bacterial cell wall synthesis and disrupts bacterial cell membrane function. In 2009, VIBATIV[®] was approved in the U.S. for the treatment of complicated skin and skin structure infections (cSSSI) caused by susceptible isolates of Gram-positive bacteria, including *Staphylococcus aureus*, both methicillin-susceptible (MSSA) and methicillin-resistant (MRSA) strains.

"We are excited about the approval of VIBATIV[®] for this additional indication, as it provides an important option for doctors in the treatment of patients with life-threatening hospital-acquired pneumonia caused by *Staph. aureus*, including MRSA," said Rick E Winningham, Theravance's Chief Executive Officer. "Theravance plans to make VIBATIV[®] available for purchase through wholesalers in the third quarter of 2013 and is continuing to evaluate commercialization alternatives for the U.S. market. I would like to thank the Theravance team and the many external medical experts for their dedication in bringing this important medicine back to market."

"VIBATIV[®] will be a welcome addition for physicians treating hospital-acquired bacterial pneumonia," said Ralph Corey, M.D., Professor of Medicine at the Duke University Medical Center and a Principal Investigator for the studies that evaluated the safety and efficacy of VIBATIV[®] in HABP/VABP. "Pneumonia is associated with one of the highest mortality rates among hospital-acquired infections and increases hospital stay and costs of care. MRSA pneumonia, in particular, is an increasingly challenging infection as there are few approved treatments available today and resistance to current antibiotics remains a problem. VIBATIV[®] offers effectiveness in these difficult to treat infections when alternative therapies are not suitable."

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 a dual mechanism of action whereby telavancin both inhibits bacterial cell wall synthesis and disrupts bacterial cell membrane function. VIBATIV[®] is approved in the U.S. for the treatment of adult patients with HABP/VABP when alternative treatments are not suitable and cSSSI caused by susceptible isolates of Gram-positive bacteria, including *Staphylococcus aureus*, both methicillin-susceptible (MSSA) and methicillin-resistant (MRSA) strains.

About the Hospital-Acquired Bacterial Pneumonia Clinical Studies

ATTAIN I and ATTAIN II were two large, multi-center, multinational, double-blind, randomized Phase 3 clinical studies, in which 1,503 adult patients were enrolled and treated, 464 of whom were infected with MRSA. Patients with HABP suspected or proven to be caused by Gram-positive bacteria were randomized (1:1) to receive either telavancin 10 mg/kg IV once daily or vancomycin 1 gram IV every 12 hours. The objective of each study was non-inferiority of VIBATIV[®] versus vancomycin in clinical cure rate at the test-of-cure visit. Determination of clinical cure was based upon physician-judged resolution of clinical signs and symptoms of HABP.

VIBATIV[®] Important Safety Information (U.S.)

Mortality

Patients with pre-existing moderate/severe renal impairment (CrCl \leq 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 U.S., will be available soon at www.VIBATIV.com.

About Theravance

Theravance is a biopharmaceutical company with a pipeline of internally discovered product candidates and strategic collaborations with pharmaceutical companies. Theravance is focused on the discovery, development and commercialization of small molecule medicines across a number of therapeutic areas including respiratory disease, bacterial infections, and central nervous system (CNS)/pain. Theravance's key programs include: RELVAR[™] ELLIPTA[™] or BREO[™] ELLIPTA[™] (FF/VI ANORO[™] ELLIPTA[™] (UMEC/VI) and MABA (Bifunctional Muscarinic Antagonist/Agonist), each partnered with GlaxoSmithKline plc, and its oral Peripheral Mu Opioid Receptor Antagonist program. By leveraging its proprietary insight of

multivalency to drug discovery, Theravance is pursuing a best-in-class strategy designed to discover superior medicines in areas of significant unmet medical need. For more information, please visit Theravance's web site at 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 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 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's approach to drug discovery and its 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 as of the date of this press release and are subject to risks, uncertainties, changes in circumstances, assumptions and other factors that may cause the actual results of Theravance 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 potential that results from clinical or non-clinical studies indicate product candidates are unsafe or ineffective, our dependence on third parties to conduct our clinical studies, delays or failure to achieve regulatory approvals for product candidates, and risks of collaborating with third parties to discover, develop and commercialize products. Other risks affecting Theravance are described under the heading "Risk Factors" contained in Theravance's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 1, 2013 and the risks discussed in our other periodic filings with the SEC. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Theravance assumes no obligation to update its forward-looking statements.

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