

November 29, 2012

Theravance Reports Favorable Outcome of FDA Advisory Committee Meeting on VIBATIV® (telavancin) for the Treatment of Nosocomial Pneumonia

SOUTH SAN FRANCISCO, CA -- (Marketwire) -- 11/29/12 -- Theravance, Inc. (NASDAQ: THRX) today announced a favorable outcome of the Anti-Infective Drugs Advisory Committee (AIDAC) of the U.S. Food and Drug Administration (FDA) meeting on VIBATIV® (telavancin) for the treatment of nosocomial pneumonia (NP) due to susceptible isolates of Gram-positive microorganisms.

"We are pleased that the advisory committee believes there is a role for VIBATIV® in the treatment of nosocomial pneumonia, a serious disease that causes significant morbidity and mortality, particularly given rising microbial resistance to existing therapies," said Rick E Winningham, Chief Executive Officer of Theravance. "We will continue to work closely with the FDA as it completes its review of the application."

The committee was asked to consider the totality of data presented including analyses of clinical cure and 28-day all-cause mortality.

The committee voted 6 (yes) and 9 (no) that the results provide substantial evidence of the safety and effectiveness of VIBATIV® for the requested indication of the treatment of NP, including ventilator-associated pneumonia, caused by susceptible isolates of the following Gram-positive microorganisms: *Staphylococcus aureus* (both methicillin-susceptible and -resistant) and *Streptococcus pneumoniae*.

The committee voted 13 (yes) and 2 (no) that the results provide substantial evidence of the safety and effectiveness of VIBATIV® for the treatment of NP when other alternatives are not suitable.

VIBATIV®, a bactericidal, once-daily, injectable lipoglycopeptide antibiotic, 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 methicillin-resistant *Staphylococcus aureus* (MRSA).

Advisory committees provide FDA with independent opinions and recommendations from outside experts on applications to market new drugs. The outside experts receive summary information about the applications and copies of FDA's review of the application documents. Based on this information, advisory committees may recommend approval or disapproval of a drug's marketing application. FDA generally follows an advisory committee's recommendation, but is not bound to do so.

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 United States for the treatment of adult patients with complicated skin and skin structure infections (cSSSI) caused by susceptible isolates of Gram-positive bacteria, including *Staphylococcus aureus*, both MRSA and methicillin-susceptible (MSSA) strains.

About the Nosocomial Pneumonia Clinical Studies

The NDA for the proposed indication of nosocomial pneumonia (NP) including ventilator-associated pneumonia is based on data from the ATAIN I and II clinical studies in adult patients. ATAIN I and ATAIN II were two large, multi-center, multinational, double-blind, randomized Phase 3 clinical studies, in which 1,503 patients were enrolled and treated, 464 of whom were infected with MRSA. Patients with NP 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 g IV every 12hr (the protocols allowed vancomycin dosage to be modified per site-specific guidelines). For patients with suspected or proven polymicrobial infections involving Gram-negative and/or anaerobic bacteria in addition to the Gram-positive organisms for which study medication therapy was used, aztreonam, piperacillin-tazobactam, and/or metronidazole were allowed. 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 NP. In both studies, the demonstration of non-inferiority in the all-treated (AT) and clinically evaluable (CE) patient populations was achieved.

VIBATIV® Important Safety Information (US)

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.

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. Clinical cure rates in telavancin-treated patients were lower in patients with baseline CrCl \leq 50 mL/min compared to those with CrCl $>$ 50 mL/min. Consider these data when selecting antibacterial therapy for use in patients with baseline moderate/severe renal impairment.

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.

Clostridium difficile-Associated Diarrhea

Clostridium difficile-associated diarrhea (CDAD) has been reported with nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis. CDAD must be considered in all patients who present with diarrhea following antibiotic use.

Development of Drug-Resistant Bacteria

Prescribing VIBATIV® in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria. As with other antibacterial drugs, use of VIBATIV® may result in overgrowth of nonsusceptible organisms, including fungi.

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.

Coagulation Test Interference

VIBATIV® does not interfere with coagulation, but does interfere with certain tests used to monitor coagulation such as prothrombin time, international normalized ratio, activated partial thromboplastin time, activated clotting time, and coagulation based factor Xa tests. Blood samples for these coagulation tests should be collected as close as possible prior to a patient's next dose of VIBATIV®.

Adverse Reactions

The most common adverse reactions (\geq 10% of patients treated with VIBATIV®) observed in the Phase 3 cSSSI clinical trials were taste disturbance, nausea, vomiting, and foamy urine.

In the Phase 3 cSSSI clinical trials, serious adverse events were reported in 7% of patients treated with VIBATIV® and most commonly included renal, respiratory, or cardiac events. Serious adverse events were reported in 5% of vancomycin-treated patients, and most commonly included cardiac, respiratory, or infectious events.

For full Prescribing Information, including Boxed Warning and Medication Guide in the US, please visit 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™ or Breo™ (FF/VI), umeclidinium bromide/vilanterol (UMEC/VI) and MABA (Bifunctional Muscarinic Antagonist-Beta2 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.

THERAVANCE®, the Theravance logo, and MEDICINES THAT MAKE A DIFFERENCE® are registered trademarks of Theravance, Inc.

Relvar™ or Breo™ (FF/VI) is an investigational medicine and is not currently approved anywhere in the world. Relvar™ a Breo™ are trademarks of the GlaxoSmithKline group of companies. The use of these brand names has not yet been approved by any regulatory authority.

VIBATIV® is a registered trademark of Theravance, Inc.

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, statements regarding the potential benefits and mechanisms of action of drug candidates, statements concerning the timing of seeking regulatory approval of our product candidates (including with respect to VIBATIV® statements regarding any expectation that we will be able to respond fully or adequately to FDA's requests using currently existing clinical data and any expectation that the FDA will approve the VIBATIV® NDA on the basis of existing preclinical and clinical data or at all), statements concerning the enabling capabilities of Theravance's approach to drug discovery and its proprietary insights, statements concerning expectations for product candidates through development and commercialization. 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 its 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 of clinical or non-clinical studies indicate product candidates are unsafe or ineffective, our dependence on third parties in the conduct of our clinical studies, delays or failure to achieve regulatory approvals for product candidates, risks of relying on third-party manufacturers for the supply of our product and product candidates and risks of collaborating with third parties to develop and commercialize products. These and other risks are described in greater detail under the heading "Risk Factors" contained in Theravance's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on October 31, 2012 and the risks discussed in our other period filings with 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.

Contact Information:

Michael W. Aguiar

Senior Vice President and Chief Financial Officer

650-808-4100

investor.relations@theravance.com

Source: Theravance, Inc.

News Provided by Acquire Media