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Theravance Study Results Confirm in vitro Potency of VIBATIV(R) (telavancin) and Efficacy in Patients With Complicated Skin and Skin Structure Infections Including MRSA

Oral and Poster Presentations at 2014 ECCMID Conference Reaffirm FDA-Approved Antibiotic as Alternative to Vancomycin for Appropriate Patients

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 05/09/14 -- Theravance, Inc. (NASDAQ: THRX) (the "Company") announced today new data from multiple studies of VIBATIV® (telavancin). These study results, which offer new insight into the product's *in vitro* potency, efficacy and safety, will be the focus of multiple presentations over the next several days at the 24th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in Barcelona, Spain. Combined, the data presentations confirm the *in vitro* potency of VIBATIV® and its efficacy in patients with complicated skin and skin structure infections (cSSSI) including methicillin-resistant *Staphylococcus aureus* (MRSA).

"Theravance is committed to meeting the growing needs of infectious disease (ID) physicians, pulmonologists/critical care (PUD/CC) physicians, ID/CC pharmacists, and other relevant healthcare practitioners. The most recent data presented at ECCMID reinforce that VIBATIV® is potent *in vitro* and an effective alternative antibiotic for MRSA and other difficult-to-treat Gram-positive infections in patients with cSSSI or HABP/VABP. In addition to being non-inferior to vancomycin in its approved indications, VIBATIV® is differentiated from vancomycin with regard to *in vitro* potency, dosing, convenience and its dual mechanism of action," said Frank Pasqualone, Senior Vice President, Operations at Theravance. "The range of important study results presented at the ECCMID conference bolsters our belief that VIBATIV® is an essential tool in the antibiotic arsenal of physicians and healthcare practitioners."

VIBATIV® is approved in the U.S. 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®, discovered and developed by Theravance, 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.

Retrospective Phase 3 VIBATIV® Analysis Demonstrates Non-Inferiority to Vancomycin, Confirms Clinical Response, and Suggests Reevaluation of Renal Impairment on Clinical Response to VIBATIV®

A retrospective analysis of the Company's Phase 3 ATLAS studies in cSSSI (newly classified by FDA as Acute Bacterial Skin and Skin Structure Infections or ABSSSI) will be highlighted in an oral presentation at the ECCMID conference. Results demonstrate the non-inferiority of VIBATIV® as compared to vancomycin using new guidance issued by FDA for assessing clinical response in ABSSSI patients. Additionally, VIBATIV® was shown to provide improved clinical response as compared to vancomycin when evaluated at certain time points following treatment.

Importantly, results of the retrospective analysis in a subset of patients from the overall treated (AT) population did not detect the same association between lower response rates in patients with severe renal impairment as did the original Phase 3 analysis. This finding suggests that factors other than VIBATIV®'s efficacy may have been responsible for the lower response rates seen in the original analysis and provides a rationale for further research into understanding the impact of renal dysfunction on clinical response to VIBATIV®.

"In light of the medical and scientific community's growing concern regarding the increasing prevalence of MRSA and potential for decreasing vancomycin susceptibility, having access to an antimicrobial with the efficacy of VIBATIV® (telavancin) is important. The results of this new data analysis, which demonstrates cure rates comparable to vancomycin, position VIBATIV® (telavancin) as a vancomycin alternative in serious, acute bacterial soft tissue infection," stated Samuel Wilson, M.D., Professor, Department of Surgery, Division of Vascular & Endovascular Surgery, University of California, Irvine, and a study investigator for

the Phase 3 ATLAS clinical trials. "Furthermore, the value of VIBATIV® (telavancin) will be enhanced if additional clinical research shows that renal impairment does not result in reduced clinical response to the treatment."

"We believe that these new data reconfirm the therapeutic value of VIBATIV® and provide physicians a much needed additional option for their patients with infections that are difficult-to-treat, do not respond to alternate treatment options or when these alternative options should not be used," stated Steve Barriere, Pharm.D., Vice President, Clinical and Medical Affairs at Theravance. "Importantly, we now have a rationale for re-evaluating previous conclusions regarding the impact of renal impairment on clinical response to VIBATIV®."

New Susceptibility Test Method Confirms VIBATIV® in vitro Potency

Results of two separate studies to be highlighted in poster presentations at ECCMID demonstrate the potent *in vitro* activity of VIBATIV® across a range of clinical pathogens utilizing a revised susceptibility test method. The new testing methodology for VIBATIV® was established to provide more reliable and reproducible susceptibility results. Using the new test, researchers confirmed the previously demonstrated *in vitro* potency of VIBATIV® against various uncommon clinical pathogens from hospitals worldwide, as well as common clinical isolates from European hospitals.

Vancomycin Immunoassays are Highly Variable in Measuring Telavancin Concentrations

A multi-site study assessed the ability of various currently available and commonly used vancomycin immunoassays to measure therapeutic drug levels of telavancin. Study results, to be highlighted in a poster presentation, show that none of the seven tested immunoassays were capable of accurately or consistently measuring telavancin plasma concentrations (levels of cross-reactivity ranged from < 1% to ~30-40%).

"As telavancin is re-engineered from vancomycin, there may be the assumption that vancomycin immunoassays can be effectively used to measure blood levels of telavancin. However, there are currently no data to suggest the clinical utility of measuring telavancin concentrations in plasma. Furthermore, we have demonstrated with these study results that use of vancomycin immunoassays produces highly variable results," said Dr. Barriere. "With approved dosing regimens, and appropriate adjustment for renal dysfunction, subsequently achieved concentrations of telavancin are well defined and predictable."

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 U.S. 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.

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.

Important Safety Information (U.S.)

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 U.S., is available 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®/BREO® ELLIPTA® (FF/VI), ANORO™ ELLIPTA® (UMEC/VI) and MABA (Bifunctional Muscarinic Antagonist-Beta$_2$ Agonist) GSK961068, each partnered with GlaxoSmithKline plc (GSK), and its Long-Acting Muscarinic 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.

About Clinigen Group (Clinigen SP)

The Clinigen Group is a specialty global pharmaceutical company headquartered in the UK, with offices in the US and Japan. The Group, dedicated to delivering 'the right drug, to the right patient at the right time', has three operating businesses; Specialty Pharmaceuticals (Clinigen SP), Clinical Trials Supply (Clinigen CTS), and Global Access Programs (Clinigen GAP). Clinigen SP is focused on acquiring its own intellectual property in licensed, niche, hospital-only critical care medicines, increasing the value of these medicines by developing new formulations and indications, then registering and marketing them in defined global markets.

For more information, please visit www.clinigengroup.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 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 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 from clinical or non-clinical studies indicate product candidates are unsafe or ineffective, Theravance's dependence on third parties to conduct Theravance's 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 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 7, 2014 and the risks discussed in Theravance's 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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