Astellas and Theravance Receive Positive Opinion from CHMP for European Approval of VIBATIV™ for Nosocomial Pneumonia Caused by MRSA

New Treatment Option for Adult Patients with Nosocomial Pneumonia, Including Critically Ill Patients with Ventilator Associated Pneumonia

Staines, United Kingdom / South San Francisco, CA, 20 May 2011, – Astellas Pharma Europe Ltd. (APEL) and Theravance, Inc. (NASDAQ: THRX) announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion, recommending the granting of marketing authorization for VIBATIV (telavancin hydrochloride) for the treatment of adults with nosocomial pneumonia including ventilator-associated pneumonia, known or suspected to be caused by methicillin-resistant *Staphylococcus aureus* (MRSA).

The CHMP, on the basis of quality, safety and efficacy data submitted, considered there to be a favorable benefit to risk balance for VIBATIV and therefore recommended the granting of the marketing authorization. The CHMP also noted that VIBATIV should be used only in situations where it is known or suspected that other alternatives are not suitable.

The CHMP's positive opinion is a critical step in the approval process, and it is expected that the European Commission will follow the advice of the CHMP and grant marketing authorization in approximately two to three months.

"This positive opinion from the CHMP for VIBATIV is great news for both doctors and patients who continue to battle serious life-threatening nosocomial pneumonia, including ventilator-associated pneumonia caused by MRSA," said Ken Jones, President and CEO, APEL.

"European approval for the treatment of nosocomial pneumonia due to MRSA is an important step in the further development of VIBATIV," said Leonard M. Blum, Senior Vice President and Chief Commercial Officer of Theravance. "This will be the first approval for VIBATIV for this indication, which is associated with high morbidity and mortality."

About VIBATIV

VIBATIV, which was discovered and developed by Theravance in a program dedicated to finding new antibiotics for serious infections due to *Staphylococcus aureus* and other Gram-positive bacteria, including MRSA, was licensed to Astellas for global commercialization. VIBATIV is a bactericidal, once-daily, injectable lipoglycopeptide antibiotic with a dual mechanism of action whereby VIBATIV both inhibits bacterial cell wall synthesis and disrupts bacterial cell membrane function. VIBATIV is approved in the United States and in Canada for the treatment of adult patients with complicated skin and skin structure infections (cSSSI) caused by susceptible isolates of the following Gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-susceptible and -resistant isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae, Streptococcus anginosus group (includes S. anginosus, S. intermedius* and *S. constellatus)* and *Enterococcus faecalis* (vancomycin-susceptible isolates only). VIBATIV has not been approved for the treatment of patients with nosocomial pneumonia in the United States and Canada.

VIBATIV Important Safety Information

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 ≤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 (≥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, please visit www.VIBATIV.com.

About the ATTAIN I and II Clinical Studies

ATTAIN I and ATTAIN 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 nosocomial pneumonia suspected or proven to be caused by Gram-positive bacteria were randomized (1:1) to receive either VIBATIV 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 nosocomial pneumonia. In both studies, VIBATIV achieved the objective of non-inferiority in the all-treated (AT) and clinically evaluable (CE) patient populations.

About the VIBATIV Collaboration

In November 2005, Theravance entered into a collaboration arrangement with Astellas Pharma Inc. for the development and commercialization of VIBATIV worldwide except Japan. In July 2006, Theravance and Astellas expanded the collaboration to include Japan. Under the terms of the collaboration, Theravance is responsible for substantially all the costs to develop and obtain U.S. regulatory approval for telavancin for its initial indications. Theravance will collaborate with Astellas in marketing in the United States for the first three years following approval.

About Astellas Pharma Europe Ltd.

Astellas Pharma Europe Ltd., located in the UK, is a European subsidiary of Tokyo-based Astellas Pharma Inc. Astellas is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceuticals. The organization is committed to becoming a global company by combining outstanding R&D and marketing capabilities and continuing to grow in the world pharmaceutical market. Astellas Pharma Europe Ltd. is responsible for 21 affiliate offices located across Europe, the Middle East and Africa, an R&D site and

three manufacturing plants. The company employs approximately 3,900 staff across these regions. For more information about Astellas Pharma Europe, please visit www.astellas.eu.

VIBATIV is a trademark of Astellas Pharma Inc.

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: RELOVAIR™, LAMA/LABA ('719/vilanterol (VI)) and MABA (Bifunctional Muscarinic Antagonist-Beta$_2$ Agonist), each partnered with GlaxoSmithKline plc, and its oral Peripheral Mu Opioid Receptor Antagonist (PμMA) 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 Exchange Act and the Private Securities Litigation Reform Act of 1995. Examples of such statements include statements concerning the timing of potential regulatory approval of product candidates, statements regarding the potential benefits and mechanisms of action of drug candidates, statements concerning enabling capabilities of Theravance's approach to drug discovery and its proprietary insights, and statements regarding 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 failure to achieve regulatory approvals for 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 May 4, 2011 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.

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