

October 1, 2009

## **Astellas and Theravance Announce Approval of VIBATIV(TM) (telavancin) in Canada for the Treatment of Complicated Skin and Skin Structure Infections**

### ***VIBATIV(TM) Approved for the Treatment of cSSSI Caused by Susceptible Gram-positive Bacteria, Including MRSA and MSSA Strains***

**MARKHAM, ONTARIO, CANADA and SOUTH SAN FRANCISCO, CA - October 1, 2009** - Astellas Pharma Canada, Inc. (Astellas) and Theravance, Inc. (NASDAQ: THRX) announced today that Health Canada has approved VIBATIV™ (telavancin) for the treatment of adult patients with complicated skin and skin structure infections (cSSSI) caused by susceptible Gram-positive bacteria, including *Staphylococcus aureus*, both methicillin-resistant (MRSA) and methicillin-susceptible (MSSA) strains. VIBATIV is a bactericidal, once-daily injectable lipoglycopeptide antibiotic discovered by Theravance. This is the second approval for VIBATIV this year, following the approval on September 11, 2009 by the U.S. Food and Drug Administration.

"We believe VIBATIV can make important contributions to the ongoing fight against microbial resistance," said Fumiaki Sakurai, President, at Astellas Pharma Canada, Inc. "We look forward to being able to offer a new therapeutic option to physicians and the patients who may benefit from VIBATIV."

"The approval of VIBATIV in Canada and the recent approval in the U.S. focus attention on the urgent need for new antibiotics to treat Gram-positive infections caused by MRSA," said Rick E Winningham, Chief Executive Officer of Theravance. "We believe that VIBATIV will be an important option for the treatment of Gram-positive complicated skin and skin structure infections."

VIBATIV will be marketed and sold by Astellas and is expected to be commercially available in Canada in early 2010.

#### **About VIBATIV**

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 VIBATIV both inhibits bacterial cell wall synthesis and disrupts bacterial cell membrane function. VIBATIV is indicated for the treatment of adult patients with 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).

#### **About ATLAS I and ATLAS II Clinical Studies**

The VIBATIV Phase III clinical program consisted of two large, multinational, double-blind, randomized Phase III clinical studies, ATLAS I and ATLAS II designed to compare the efficacy and safety of VIBATIV (10 mg/kg IV once daily) versus vancomycin (1 gm IV q 12hr) in adult patients with cSSSI caused by Gram-positive bacteria. A total of 1,867 patients were enrolled and treated, 719 of whom had infections with MRSA. In both of these studies, VIBATIV achieved its primary endpoint of non-inferiority relative to the standard of care, vancomycin. VIBATIV has not been studied in children.

#### **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  $\leq$  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 III cSSSI clinical trials were taste disturbance, nausea, vomiting, and foamy urine.

In the Phase III 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 additional important safety information including boxed warning, please visit [www.VIBATIV.com](http://www.VIBATIV.com).*

#### **About Astellas Pharma Canada, Inc.**

Astellas Pharma Canada, Inc. is one of the Astellas Group of companies in North America and an affiliate of Astellas Pharma Inc., located in Tokyo. Astellas Pharma Inc. is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. The organization is committed to becoming a global category leader in focused areas by combining outstanding Research and Development (R&D) and marketing capabilities. Additional corporate information is available at [www.astellas.com/ca](http://www.astellas.com/ca).

VIBATIV is a trademark of Astellas Pharma Inc.

#### **About Theravance**

Theravance is a biopharmaceutical company with a pipeline of internally discovered product candidates. 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 gastrointestinal motility dysfunction. The company's key programs include: VIBATIV with Astellas Pharma Inc. and the Horizon program and Bifunctional Muscarinic Antagonist-Beta2 Agonist (MABA) program with GlaxoSmithKline plc. By leveraging its proprietary insight of multivalency toward drug discovery, Theravance is pursuing a next generation strategy designed to discover superior medicines in areas of significant unmet medical need. For more information, please visit the company's web site at [www.theravance.com](http://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 relating to the goals and timing of clinical studies and product commercialization, statements regarding the potential benefits and mechanisms of action of drug candidates, statements concerning the timing of seeking regulatory approval of our product 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 and projections of revenue and other financial items. 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, delays or failure to achieve regulatory approvals for, or to successfully launch, product candidates, risks of relying on third-party manufacturers for the supply of our 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 August 5, 2009 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.

**Contact Information:**

**Theravance, Inc.**

Michael W. Aguiar  
Senior Vice President and Chief Financial Officer  
650-808-4100  
[investor.relations@theravance.com](mailto:investor.relations@theravance.com)

**Astellas Pharma Canada, Inc.**

Corporate Communications  
Michelle Reale  
905-946-5621  
[michelle.reale@ca.astellas.com](mailto:michelle.reale@ca.astellas.com)