Astellas and Theravance Announce Submission of Telavancin MAA for the Treatment of Nosocomial Pneumonia and Complicated Skin and Soft Tissue Infections in Europe

TOKYO, JAPAN AND SOUTH SAN FRANCISCO, CA/October 28, 2009 – Astellas Pharma Inc. (Astellas) and Theravance, Inc. (NASDAQ: THRX) announced today that Astellas Pharma Europe B.V. submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMEA) for telavancin, a bactericidal, once-daily injectable lipoglycopeptide antibiotic, for the treatment of nosocomial pneumonia (NP), including ventilator-associated pneumonia, and complicated skin and soft tissue infections (cSSTI) in adults.

"We are extremely pleased that this critical step has now been completed," said Mr. Masao Yoshida, President and CEO of Astellas Pharma Europe Ltd. "We look forward to working with the regulatory authorities and our partner, Theravance, to efficiently progress telavancin through the remaining steps to approval."

"The MAA submission represents an important step toward our goal of making telavancin globally available to physicians and patients," said Rick E Winningham, Chief Executive Officer at Theravance. "We will work closely with our partner Astellas in seeking the approval of telavancin in the European Union."

About Telavancin

Telavancin 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. Telavancin 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™ (telavancin) 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). The U.S. Food and Drug Administration is currently reviewing the telavancin New Drug Application for the treatment of nosocomial pneumonia.

About the Clinical Studies

The MAA is based on data from the ATLAS I and II and ATTAIN I and II clinical studies in adult patients.

ATLAS I and ATLAS II were two large, multinational, double-blind, randomized Phase III clinical studies, designed to compare the efficacy and safety of telavancin (10 mg/kg IV once daily) versus vancomycin (1 gm IV q 12hr) in adult patients with complicated skin and skin structure infections (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, telavancin achieved its primary endpoint of non-inferiority relative to the standard of care, vancomycin.

ATTAIN I and ATTAIN II were two large, multi-center, multinational, double-blind, randomized Phase III 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 telavancin 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, telavancin achieved the objective of non-inferiority in the all-treated (AT) and clinically evaluable (CE) patient populations.

About the Telavancin Collaboration

In November 2005, Theravance entered into a collaboration arrangement with Astellas Pharma Inc. for the development and commercialization of telavancin 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 the development of and U.S. FDA filings for telavancin for the treatment of (i) complicated skin and skin structure infections and (ii) nosocomial pneumonia. Theravance is also responsible for the manufacture of approximately six months of first commercial sale stock for launch of telavancin in the United States. Astellas is responsible for all other development, regulatory, manufacturing, sales and marketing activities. 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 pharmaceutical products. 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 is responsible for 20 affiliate offices located across Europe, the Middle East and Africa, two R&D sites and three manufacturing plants with approximately 3,400 staff. For more information, please visit the company's web site at www.astellas.eu.

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™ (telavancin) with Astellas Pharma Inc. and the Horizon program and Bifunctional Muscarinic Antagonist-Beta$_2$ 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.

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, 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, 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:

Astellas Pharma Europe Ltd.
Percival Barretto-Ko
Executive Director, Corporate Strategy & Communications
+44-779-510-6305
percival.barretto-ko@eu.astellas.com

Theravance, Inc.
Michael W. Aguiar
Senior Vice President and Chief Financial Officer
650-808-4100
investor.relations@theravance.com