Theravance Receives FDA Approvable Letter for Telavancin for the Treatment of Complicated Skin and Skin Structure Infections

SOUTH SAN FRANCISCO, CA and DEERFIELD, IL/OCTOBER 22, 2007 – Theravance, Inc. (NASDAQ: THRX) and Astellas Pharma US, Inc. announced today that the U.S. Food and Drug Administration (FDA) issued an Approvable Letter for telavancin, a novel bactericidal, once-daily injectable antibiotic discovered by Theravance, for the treatment of complicated skin and skin structure infections (cSSSIs) caused by Gram-positive bacteria, including resistant pathogens such as methicillin-resistant *Staphylococcus aureus* (MRSA).

The Approvable Letter indicates that the telavancin application is approvable, subject to: resolution of current good manufacturing practices (cGMP) compliance issues not specifically related to telavancin at a third-party manufacturer; and submission of revised labeling or re-analyses of clinical data or additional clinical data. Theravance and Astellas believe that no additional clinical studies will need to be initiated to respond to the Approvable Letter.

"We are committed to submitting a timely and complete response to this Approvable Letter," said Rick E Winningham, Chief Executive Officer of Theravance. "We will work with the FDA to resolve the outstanding issues and to ensure a label that accurately reflects the data from our clinical studies, which included the largest group of patients with cSSSI and the largest group of patients infected with MRSA ever studied. Recent reports from the Centers for Disease Control and Prevention, the subject of an article and editorial in the Journal of the American Medical Association concerning MRSA infections, only serve to highlight the urgent need for additional therapeutic options."

Conference Call and Webcast Information

Theravance has scheduled a conference call to discuss this announcement today at 8:00 a.m. Eastern Daylight Time. To participate in the live call, please dial 800-289-0743 from the U.S. and Canada, or 913-312-0723 for international callers. The live webcast can be accessed from Theravance's web site at www.theravance.com. Please go to the web site 15 minutes prior to its start to register, download, and install any necessary audio software.

A replay of the conference call and webcast will be available on the company's web site for 30 days through Wednesday, November 21, 2007. An audio replay will also be available through 11:59 p.m. Eastern Standard Time on November 5, 2007 by dialing 888-203-1112 from the U.S., or 719-457-0820 for international callers, and entering passcode 5454919.

About Telavancin Collaboration

In November 2005, Theravance entered into a collaboration arrangement with Astellas Pharma Inc. (Astellas) 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 will lead the development of telavancin for the treatment of cSSSI and hospital-acquired pneumonia, and will collaborate substantially with Astellas in marketing in the United States for the first three years. Astellas will lead all other development, regulatory, manufacturing, sales and marketing activities.

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. Of the five programs in development, four are in late stage – its telavancin program focusing on treating serious Gram-positive bacterial infections with Astellas Pharma Inc., the Gastrointestinal Motility Dysfunction program, the Beyond Advair collaboration with GlaxoSmithKline plc and TD-1792 for the treatment of serious Gram-positive infections. By leveraging its proprietary insight of multivalency toward drug discovery focused on validated targets, Theravance is pursuing a next generation strategy designed to discover superior medicines in large markets. For more information, please visit the company's web site at www.theravance.com.

About Astellas

Astellas Pharma US, Inc., located in Deerfield, Illinois, is a U.S. affiliate 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 category leader in focused areas by combining outstanding R&D and marketing capabilities. In the U.S., Astellas markets products in the areas of immunology, urology, anti-infectives,

cardiovascular and dermatology. For more information about Astellas Pharma US, Inc., please visit our website at www.astellas.com/us.

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This press release contains and the conference call will contain 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, timing and expected results of regulatory review including statements regarding any expectation that we will be able to respond fully or adequately to FDA's requests using currently existing clinical data, any expectation that the third-party manufacturer will successfully address the cGMP issues FDA has noted, and any expectation that the FDA will approve the current NDA for telavancin on the basis of existing preclinical or clinical data or at all, statements regarding the potential benefits and mechanisms of action of drug candidates, the enabling capabilities of Theravance's approach to drug discovery and its proprietary insights, and 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 the conference call 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 and preclinical studies, the potential that results of clinical or preclinical studies indicate product candidates are unsafe, ineffective, inferior or not superior, delays or failure to achieve regulatory approvals, 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 Item 1A of Theravance's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 8, 2007 and the risks discussed in our other 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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