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## **Theravance Announces Results From FAST 2 - A Phase 2 Clinical Study With Investigational Antibiotic Telavancin**

### **Phase 3 Clinical Program Underway for Serious Infections Caused by Gram-positive Bacteria**

South San Francisco, CA, December 7, 2004 - Theravance, Inc. (NASDAQ: THRX) today announced results from FAST 2, a Phase 2 clinical study with the investigational antibiotic telavancin (TD-6424).

FAST 2 was a randomized, double blind, multinational study of intravenous telavancin dosed once a day or standard therapy (vancomycin dosed twice a day or antistaphylococcal penicillins dosed four times a day) for the treatment of complicated Gram positive skin and skin structure infections (cSSSI). 201 patients at 18 clinical sites in the United States and South Africa were randomized to receive either standard therapy or 10 mg/kg telavancin. The clinical cure rates in the clinically evaluable population were 96.1% and 93.5% for patients treated with telavancin and standard therapy, respectively. Notably, in the group of microbiologically evaluable patients with methicillin-resistant *Staphylococcus aureus* (MRSA) infection, eradication was achieved in 92.3% of the telavancin-treated group versus 68.4% in the group receiving vancomycin ( $p=0.043$ ). The overall incidence and severity of adverse events were similar in the telavancin-treated and standard therapy groups.

Michael Kitt, MD, Senior Vice President of Development for Theravance noted, "The safety and tolerability results from FAST 2 are consistent with those obtained in our first Phase 2 study (FAST), where telavancin was dosed at 7.5 mg/kg. Together with the in vitro and experimental infection model data generated for telavancin, the clinical success, microbiological eradication and safety results are very encouraging and support the planned and ongoing Phase 3 program. Studies in this program are designed to demonstrate non-inferiority of telavancin compared to vancomycin for the treatment of serious Gram-positive infections and superiority over vancomycin in those patients whose infections are due to MRSA in both cSSSI and hospital-acquired pneumonia."

Telavancin, a rapidly bactericidal injectable antibiotic, is a novel lipoglycopeptide that was discovered by Theravance through the application of multivalent drug design. Previously presented data demonstrated that telavancin has a unique multiple mechanism of action that the company believes speeds bacterial killing and reduces the risks of inducing resistance. This antibacterial activity results from interaction with D-Ala-D-Ala-containing peptidoglycan intermediates that leads, at submicromolar concentrations, to inhibition of the transglycosylation step of peptidoglycan synthesis during cell wall synthesis. Also, at higher, clinically-achievable concentrations, direct effects on bacterial plasma membrane function, such as membrane potential depolarization and increased permeability, are observed. Telavancin is currently in Phase 3 studies for the treatment of complicated skin and skin structure infections.

### **About Theravance**

Theravance is a biopharmaceutical company with a pipeline of internally discovered product candidates. Of the five programs in development, two are in late stage - telavancin and the Beyond Advair collaboration with GlaxoSmithKline. Theravance is focused on the discovery, development and commercialization of small molecule medicines across a number of therapeutic areas including respiratory disease, bacterial infections, overactive bladder and gastrointestinal disorders. By leveraging its proprietary insight of multivalency to drug discovery focused on validated targets, Theravance is pursuing a next generation drug discovery strategy designed to discover superior medicines in large markets. 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. Examples of such statements include statements relating to the expected timing, scope and results of clinical and preclinical studies, statements regarding the potential benefits and mechanisms of action of drug candidates and the enabling capabilities of proprietary insights. 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 naturally 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 its 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, and delays or failure to achieve regulatory approvals. These and other risks are described in greater detail under the headings "Special Note Regarding Forward-Looking Statements," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Theravance's prospectus dated October 5, 2004 filed with the Securities and Exchange Commission pursuant to Rule 424(b)(4) and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Other Factors Affecting Operating Results" in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2004. 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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