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Theravance Announces Results From Pre-clinical And Clinical Studies With Investigational Antibiotic Telavancin

Rapid Bactericidal Activity, Multiple Mechanisms and Clinical Activity Observed

Phase 3 Clinical Study Underway for Complicated Infections Caused by Gram-positive Bacteria

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South San Francisco, CA, November 2, 2004 - Theravance, Inc. (NASDAQ: THRX) announced today that results from a Phase 2 clinical study with the investigational antibiotic telavancin (TD-6424) in patients with complicated Gram-positive skin and skin structure infections were recently presented at the 42nd annual Infectious Disease Society of America (IDSA) meeting in Boston. In addition, pre-clinical in vitro and in vivo studies with telavancin were recently presented at the 44th annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) meeting in Washington D.C.

Telavancin, a rapidly bactericidal injectable antibiotic with multiple mechanisms of action, is a novel lipoglycopeptide that was discovered by Theravance through the application of multivalent drug design in a research program dedicated to finding new antibiotics for serious infections due to *Staphylococcus aureus* (including multi-drug resistant strains) and other Gram-positive pathogens. Telavancin is currently in Phase 3 studies for the treatment of complicated skin and skin structure infections (cSSSI).

Among the highlights of the telavancin studies presented at IDSA and ICAAC were:

1. Results from FAST, an exploratory Phase 2 clinical study, comparing telavancin with standard therapy in 167 patients with complicated Gram-positive skin and skin structure infections.

- Efficacy of telavancin was similar to standard therapy.
- Among all-treated patients, in the subset with methicillin-resistant *S. aureus* (MRSA) at baseline, cure rates were 82% for patients treated with telavancin versus 69% for standard therapy.
- Minimum inhibitory concentrations (MICs) were lower for telavancin for all tested strains of *S. aureus* (0.25 mcg/mL or less) compared to vancomycin.
- The rate of adverse events (AEs) and discontinuations for AEs were similar in the telavancin-treated and standard therapy groups.

2. Results from a series of in vitro experiments that demonstrated telavancin's bactericidal activity against *S. aureus* is mediated by multiple mechanisms. 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.
- at higher concentrations, direct effects on bacterial plasma membrane function, such as potential dissipation and increased permeability, are observed. These results suggest a novel and important additional mechanism and provide a rational basis for the improved pharmacodynamic activity and low potential for resistance observed for telavancin.

3. Results from a series of in vitro experiments with vancomycin-sensitive enterococci (VSE) and vancomycin-resistant enterococci (VRE), showing that the antibacterial activity of telavancin is mediated by multiple mechanisms of action. In VRE, changes in cell permeability and the resulting dissipation of the membrane potential is likely the primary mechanism. In VSE and other vancomycin-sensitive organisms, the combined effects of cell wall synthesis inhibition and membrane permeability changes mediate the antibacterial activity of telavancin and may contribute to its rapid bactericidal effect.

4. In an in vivo model of meningitis using a strain of penicillin-resistant *Streptococcus pneumoniae*, telavancin was significantly more effective compared to a standard regimen (combination of ceftriaxone and vancomycin).

5. Results from an in vitro study comparing the activity of telavancin and vancomycin against a collection of *S. aureus*, enriched for isolates tolerant to vancomycin, demonstrated that telavancin produced significantly greater killing than equal concentrations of vancomycin.

6. In an in vitro comparison of telavancin with vancomycin, daptomycin, linezolid and quinupristin/dalfopristin against glycopeptide intermediate susceptible *Staphylococcus* species (GISS), including hetero-resistant GISS (hGISS), and vancomycin resistant *S. aureus* (VRSA), telavancin was shown to produce rapid, concentration-dependent bactericidal activity against GISS, hGISS and, to a lesser extent, VRSA. The rate of telavancin killing was diminished in the presence of human serum, however bactericidal activity was maintained.

7. In an in vitro study against *Bacillus anthracis*, the causative agent of anthrax, telavancin demonstrated potent activity against all 15 *B. anthracis* strains tested.

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.

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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). 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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