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Theravance Announces Promising Results From Research And Clinical Studies With Investigational Antibiotic Telavancin

Rapid Bactericidal Activity and Efficacy Demonstrated in MRSA Pneumonia Model Phase 2 Trials Underway for Serious Infections Caused by Gram-Positive Bacteria

South San Francisco, CA, May 11, 2004 - Theravance, Inc. announced today that results from a series of four in vitro and in vivo studies as well as human clinical studies with the investigational antibiotic telavancin (TD-6424) were presented at the 14th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in Prague.

Telavancin, a rapidly bactericidal injectable antibiotic with multiple mechanisms of action, was discovered by Theravance through the application of its 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 2 clinical trials. These data build on other publicly presented studies and support the initiation of currently planned Phase 3 clinical trials later this year.

Among the highlights of the telavancin studies presented at ECCMID were:

- Rapid bactericidal activity and efficacy of telavancin in a mouse model of methicillin-resistant *Staphylococcus aureus* (MRSA) pneumonia. In this model, telavancin produced significantly greater reductions in lung titers of bacteria than linezolid or vancomycin, improvements in survival rate versus linezolid and reversal of lung pathology.
- Results of a Phase 1 clinical study demonstrating that no dose adjustments of telavancin are warranted in elderly subjects with normal renal and hepatic function. Single-dose pharmacokinetics and disposition of telavancin in elderly subjects were demonstrated to be similar to that found in young subjects based on historical data. Further, there was no apparent influence of gender on the disposition of telavancin.
- Results of a Phase 1 clinical study on the single-dose pharmacokinetics of telavancin in subjects with renal impairment, which found that telavancin administration should be modified in patients with creatinine clearance below 50 mL/min. This was based on the result that telavancin exposure increased 2- to 3-fold in subjects with severe renal impairment and those maintained on dialysis compared to subjects with normal or mild renal dysfunction. Further, it was shown that telavancin is poorly dialyzable and that binding to plasma proteins was not correlated with renal function.
- In vitro studies demonstrating that increasing the levels of bacteria did not significantly reduce telavancin's activity. Studies exploring the effect of pH, media and inoculum size on telavancin's activity showed that even increasing the inoculum size by 100-fold led to a very small increase of 2- to 4-fold in the MIC against *S. aureus* and *S. pneumoniae*, respectively. Telavancin remained bactericidal at 24-48 hours, even though the time to cidal activity was increased at the higher inocula of *S. aureus*.

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Theravance is a privately-held pharmaceutical company dedicated to utilizing its proprietary multivalent technology to discover, develop and market best-in-class medicines for a wide variety of serious medical conditions. Since its inception, Theravance has implemented an integrated model of drug discovery and exploratory development and applied its multivalent approach to create an impressive pipeline of clinical and pre-clinical compounds across diverse therapeutic areas. For more information, please visit the company's web site at www.theravance.com.

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