



Theravance Announces Initiation of Proof of Concept Phase 2 Clinical Study with its PUMA Compound, TD-1211, for the Treatment of Opioid-Induced Constipation

SOUTH SAN FRANCISCO, CA/April 14, 2010 – Theravance, Inc. (NASDAQ: THRX) announced today that the first patient with opioid-induced constipation (OIC) has been dosed in a Phase 2 clinical study with TD-1211, an orally-administered peripherally selective mu opioid receptor antagonist (PUMA). TD-1211 is a potent, multivalent inhibitor of the mu opioid receptor designed to alleviate gastrointestinal side effects of opioid analgesic therapy without affecting analgesia. This “proof of concept” study is designed to assess the efficacy, tolerability and safety of TD-1211 in patients with OIC.

TD-1211 has been administered to healthy volunteers in ascending single and repeat dose studies evaluating safety, tolerability and pharmacokinetics. The results of these studies showed that TD-1211 was well tolerated at all doses administered, and had a predictable and linear pharmacokinetic profile supportive of once-daily dosing.

“TD-1211 is a multivalent compound that was designed to contact both a primary and secondary binding pocket on the mu opioid receptor,” said Mathai Mammen, M.D., Ph.D., Senior Vice President of Research and Early Clinical Development. “The secondary binding moiety confers excellent selectivity over non-opioid receptors, and limits penetration into the CNS. We are excited that our core technology continues to yield promising differentiated clinical candidates for patients in need.”

“We are very pleased with the initiation of the Phase 2 study with TD-1211, a compound discovered by Theravance through the application of our multivalent approach to drug discovery,” said Rick E Winningham, Chief Executive Officer, Theravance, Inc. “There is a significant unmet medical need as there are currently no oral drugs approved in the U.S. to treat constipation resulting from the chronic use of opioids in treating and managing pain. We look forward to the results of this proof of concept study later this year.”

Study Design

The Phase 2 clinical study is a randomized, double-blind, multiple-ascending dose study that will evaluate the constipation-relieving effects, safety and tolerability of TD-1211 in patients experiencing constipation while receiving chronic opioid therapy. Approximately 50 patients experiencing OIC will be randomized to TD-1211 or placebo in addition to their opioid treatment. Therapy will be administered orally once-daily over 14 days of treatment. The primary efficacy endpoint of the study is the frequency of spontaneous bowel movements (SBMs). The study will compare the frequency of SBMs in patients receiving TD-1211 to those in patients receiving placebo.



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 RELOVAIR™ program and Bifunctional Muscarinic Antagonist-Beta₂ Agonist (MABA) program with GlaxoSmithKline plc. By leveraging its proprietary insight of multivalency toward drug discovery, Theravance is pursuing a 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.

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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. 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 enabling capabilities of Theravance's approach to drug discovery and its proprietary insights, and statements regarding expectations for product candidates through development. 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, risks related to delays or difficulties in commencing or completing clinical studies, the potential that results of clinical or preclinical studies indicate product candidates are unsafe or ineffective and our dependence on third parties in the conduct of our clinical studies. These and other risks are described in greater detail under the heading "Risk Factors" contained in Theravance's Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on February 26, 2010 and in Theravance's prospectus supplement filed with the SEC on March 19, 2010 pursuant to Rule 424(b)(5). 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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