

December 4, 2012

## **Theravance Announces Initiation of Phase 2 Study With TD-9855 for the Treatment of Fibromyalgia**

SOUTH SAN FRANCISCO, CA -- (Marketwire) -- 12/04/12 -- Theravance, Inc. (NASDAQ: THRX) announced today the initiation of a fibromyalgia Phase 2 study with TD-9855, the lead compound in Theravance's Monoamine Reuptake Inhibitor program. TD-9855 is an investigational norepinephrine and serotonin reuptake inhibitor (NSRI) for the treatment of central nervous system (CNS) conditions such as chronic pain and Attention-Deficit/Hyperactivity Disorder (ADHD).

"We are enthusiastic about the potential of TD-9855 to treat patients suffering from fibromyalgia," said Mathai Mammen, M.D., Ph.D., Senior Vice President of Research and Early Clinical Development. "There remains a substantial opportunity for therapies with an acceptable tolerability profile that effectively manage both fibromyalgia and commonly experienced comorbid symptoms such as fatigue. We believe TD-9855's balance of inhibition of norepinephrine and serotonin reuptake may provide a compelling and differentiated profile versus current alternatives."

### *About the Phase 2 Study in Fibromyalgia*

This Phase 2 proof-of-concept study will evaluate the safety and efficacy of two doses of TD-9855 in patients with fibromyalgia. Approximately 375 patients will be randomized to TD-9855 or placebo. Study medication will be administered once-daily for up to 9 weeks. The primary endpoint of the study is improvement in pain. Additional secondary or exploratory endpoints will assess improvement in other established fibromyalgia measures and impact on important comorbidities, such as fatigue.

### *About TD-9855 and the Monoamine Reuptake Inhibitor Program*

TD-9855 is an investigational NSRI discovered by Theravance for the treatment of CNS conditions such as chronic pain and ADHD. TD-9855 has been administered to healthy volunteers in ascending single- and multiple-dose studies evaluating safety, tolerability and pharmacokinetics. The results of these studies showed that TD-9855 was generally well tolerated, had a predictable and linear pharmacokinetic profile and a long pharmacokinetic half-life supportive of once-daily dosing. Data collected from a Phase 1 positron emission tomography (PET) study confirmed CNS penetration and selectivity for norepinephrine over serotonin transporters. TD-9855 exhibits broad preclinical antinociceptive activity across a range of models of pain, including acute inflammatory, neuropathic and osteoarthritis models. TD-9855 does not interact with opioid receptors but augments the analgesic effects of morphine. The antinociceptive activity of TD-9855 reflects occupancy of both norepinephrine and serotonin transporters, at exposures that were associated with submaximal occupancy of central serotonin transporters. In addition to the Phase 2 study in fibromyalgia, TD-9855 is being evaluated in an ongoing Phase 2 safety and efficacy study in adults with ADHD. The goal of the Monoamine Reuptake Inhibitor program is to develop a best-in-class monoamine reuptake inhibitor for the treatment of various CNS conditions such as chronic pain, ADHD, and potentially depressive disorders.

### *About Fibromyalgia*

Fibromyalgia is a chronic functional illness that is characterized by pain, stiffness, and tenderness of muscles, tendons, and joints. It has been estimated to affect as many as 5 million individuals in the United States. In addition to widespread pain, fibromyalgia is associated with other symptoms that may include sleep disturbances, fatigue, anxiety, depression and problems with memory and concentration.

### *About Theravance*

Theravance is a biopharmaceutical company with a pipeline of internally discovered product candidates and strategic collaborations with pharmaceutical companies. 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 central nervous system (CNS)/pain. Theravance's key programs include: Relvar™ or Breo™ (FF/VI), umeclidinium bromide/vilanterol (UMEC/VI) and MABA (Bifunctional Muscarinic Antagonist-Beta2 Agonist), each partnered with GlaxoSmithKline plc, and its oral Peripheral Mu Opioid Receptor Antagonist program. By leveraging its proprietary insight of multivalency to drug discovery, Theravance is pursuing a best-in-class strategy designed to discover superior medicines in areas of significant unmet medical need. For more information, please visit Theravance's web site at [www.theravance.com](http://www.theravance.com).

THERAVANCE®, the Theravance logo, and MEDICINES THAT MAKE A DIFFERENCE® are registered trademarks of

Theravance, Inc.

Relvar™ or Breo™ (FF/VI) is an investigational medicine and is not currently approved anywhere in the world. Relvar™ a Breo™ are trademarks of the GlaxoSmithKline group of companies. The use of these brand names has not yet been approved by any regulatory authority.

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 Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. Examples of such statements include statements relating to the status and timing of clinical studies, statements regarding the potential benefits and mechanisms of action of drug candidates, statements concerning 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 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 non-clinical studies indicate product candidates are unsafe or ineffective, our dependence on third parties in the conduct of our clinical studies, delays or failure to achieve regulatory approvals for product candidates, risks of relying on third-party manufacturers for the supply of our product and product candidates 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 Theravance's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on October 31, 2012 and the risks discussed in our other period filings with 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.

(THRX-G)

Contact Information:

Michael W. Aguiar

Senior Vice President and Chief Financial Officer

650-808-4100

[investor.relations@theravance.com](mailto:investor.relations@theravance.com)

Source: Theravance, Inc.

News Provided by Acquire Media