Theravance Announces Initiation of Phase 2 Study with Its MARIN Compound, TD-9855, for the Treatment of ADHD

SOUTH SAN FRANCISCO, CA/December 12, 2011 – Theravance, Inc. (NASDAQ: THRX) announced today the initiation of an Attention-Deficit/Hyperactivity Disorder (ADHD) Phase 2 study with TD-9855, the lead compound in Theravance's MonoAmine Reuptake INhibitor (MARIN) program. TD-9855 is an investigational norepinephrine and serotonin reuptake inhibitor (NSRI) for the treatment of central nervous system (CNS) conditions such as ADHD and chronic pain.

"We are excited that our internal discovery group has produced another compound with the potential to make a meaningful difference in the lives of patients. In preclinical studies, TD-9855 was shown to be a dual norepinephrine and serotonin reuptake inhibitor with modest selectivity for norepinephrine over serotonin. We are encouraged by this profile and believe TD-9855 has the potential to treat ADHD symptoms and provide additional benefit in the treatment of comorbid disorders such as depressive and anxiety spectrum disorders," said Mathai Mammen, M.D., Ph.D., Senior Vice President of Research and Early Clinical Development.

"We are pleased with the initiation of this Phase 2 study with TD-9855. We believe there is a specific need for medicines that are efficacious and well-tolerated treatments for multiple CNS conditions," said Rick E Winningham, Chief Executive Officer.

About the Phase 2 Study in ADHD

This Phase 2 proof-of-concept study will evaluate the safety and efficacy of two different doses of TD-9855 in adult male patients with ADHD. Approximately 285 patients will be randomized to TD-9855 or placebo. Therapy will be orally administered once-daily for 6 weeks. The primary endpoint of the study is improvement in symptoms as assessed by Adult ADHD Investigator Symptom Rating Scale (AISRS). A key secondary endpoint is improvement in executive function, which will be measured using the Barkley Deficits in Executive Functioning Scale (BDEFS).

About TD-9855 and the MARIN Program

TD-9855 is an investigational NSRI discovered by Theravance for the treatment of CNS conditions such as ADHD and chronic pain. 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. In addition, data collected from a Phase 1 positron emission tomography (PET) study confirm CNS penetration and selectivity for norepinephrine over serotonin transporters. The goal of the MARIN program is to develop a best-in-class monoamine reuptake inhibitor for the treatment of various CNS conditions such as ADHD, chronic pain and potentially depressive disorders.

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. The Company's key programs include: RELOVAIR™, LAMA/LABA ('719/vilanterol (VI)) and MABA (Bifunctional Muscarinic Antagonist-Beta$_2$ Agonist), each partnered with GlaxoSmithKline plc, and its oral Peripheral Mu Opioid Receptor Antagonist (PμMA) 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 the company's web site at www.theravance.com.

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 timing of clinical studies, 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 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 in completing clinical studies, the potential that results of clinical or preclinical 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 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 November 2, 2011 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.

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