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## **Theravance Announces Initiation of Phase 2b Study With Its LAMA Candidate, TD-4208, for the Treatment of COPD**

SOUTH SAN FRANCISCO, CA -- (Marketwire) -- 12/11/12 -- Theravance, Inc. (NASDAQ: THRX) announced the initiation of a dose ranging Phase 2b study with TD-4208 as a nebulized aqueous solution in patients with moderate to severe COPD. TD-4208 is an investigational inhaled long-acting muscarinic antagonist (LAMA), discovered using Theravance's multivalent approach to drug design. This compound is under development by Theravance for the treatment of chronic obstructive pulmonary disease (COPD).

"We are very pleased with the progression of TD-4208 into a Phase 2b study in patients with COPD," said Mathai Mammen, M.D., Ph.D., Senior Vice President of Research and Early Clinical Development. "We believe that certain patients may prefer long-acting medicines delivered in the aqueous nebulized platform used in this study over handheld inhalation devices. In addition, TD-4208 may offer these patients the convenience of once-a-day dosing compared to currently nebulized medicines which must be dosed multiple times daily."

### *About the Phase 2b Study*

The Phase 2b study will evaluate the bronchodilatory effect, pharmacokinetics, safety and tolerability of multiple doses of TD-4208 in patients with COPD. Approximately 60 patients will be randomized to receive four of six doses of TD-4208 (22 mcg, 44 mcg, 88 mcg, 175 mcg, 350 mcg or 700 mcg) and placebo once daily via a nebulizer during five 7-day study periods in an incomplete crossover study design. The primary endpoint of the study is trough forced expiratory volume in one second (FEV1) after the seventh dose of each treatment period. Secondary endpoints include measurements of FEV1: Peak and area under the curve from 0 to 24 hours (AUC0-24), AUC0-12, and AUC12-24 after the seventh dose of each treatment period.

### *About TD-4208 and the LAMA Program*

TD-4208 is an inhaled, long-acting muscarinic antagonist (LAMA) discovered by Theravance through the application of multivalent design in a drug discovery program dedicated to finding new medicines for respiratory diseases such as COPD and asthma. In preclinical studies, TD-4208 has demonstrated high specificity for muscarinic receptors, sustained activity in the lung after inhalation, and minimal effects outside of the lung. The goal of Theravance's LAMA program for respiratory disease is to develop a once-daily inhaled medicine in a nebulizer that offers improved efficacy and tolerability relative to current therapies, and provides the basis for combination nebulized products with other medicines. Positive results of a single-dose Phase 2a study in patients with COPD were previously reported.

### *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).

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Relvar™ or Breo™ (FF/VI) is an investigational medicine and is not currently approved anywhere in the world. Relvar™ and 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.

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