

August 1, 2013

Theravance Announces FDA Advisory Committee to Review ANORO(TM) ELLIPTA(TM) (UMEC/VI) for COPD

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 08/01/13 -- Theravance, Inc. (NASDAQ: THRX) today announced that on September 10, 2013, the U.S. Food and Drug Administration's Pulmonary-Allergy Drugs Advisory Committee will discuss the new molecular entity New Drug Application (NDA) 203975 for umeclidinium bromide and vilanterol dry powder for inhalation (proposed trade name ANORO™ ELLIPTA™), sponsored by Glaxo Group (d/b/a GSK) for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. The advanced display of the Federal Register notice on the advisory committee can be found at: http://www.ofr.gov/OFRUpload/OFRData/2013-18633_PI.pdf

UMEC/VI is a combination of two investigational bronchodilator molecules -- GSK573719 or umeclidinium bromide (UMEC), a long-acting muscarinic antagonist (LAMA) and vilanterol (VI), a long-acting beta₂ agonist (LABA), administered using the ELLIPTA™ inhaler. The Prescription Drug User Fee Act (PDUFA) goal date is December 18, 2013. UMEC/VI is in development under the LABA collaboration agreement between Glaxo Group Limited and Theravance, Inc.

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™ ELLIPTA™ or BREO™ ELLIPTA™ (FF/VI ANORO™ ELLIPTA™ (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.

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

RELVAR™, BREO™, ANORO™ and ELLIPTA™ are trademarks of the GlaxoSmithKline group of companies. The use of brand names ANORO™ and RELVAR™ 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, data analysis and communication of results, statements regarding the potential benefits and mechanisms of action of drug candidates, statements concerning the timing of seeking regulatory approval of our product 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 and projections of revenue, expenses and other financial items. 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 May 1, 2013 and the risks discussed in our other periodic filings with the 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

Source: Theravance, Inc.

News Provided by Acquire Media