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GSK and Theravance Announce FDA Acceptance of New Drug Application (NDA) Submission in the US for ANORO ELLIPTA(TM) for COPD

LONDON and SOUTH SAN FRANCISCO, CA -- (Marketwire) -- 02/19/13 -- GlaxoSmithKline plc (LSE: GSK) and Theravance, Inc. (NASDAQ: THRX) today announced that the New Drug Application (NDA) for the investigational once-daily LAMA/LABA combination medicine, UMEC/VI, for patients with chronic obstructive pulmonary disease (COPD), has been accepted by the U.S. Food and Drug Administration (FDA) indicating that the application is sufficiently complete to permit a substantive review. The Prescription Drug User Fee Act (PDUFA) goal date has also been confirmed as 18 December 2013.

In December 2012 and January 2013, GSK and Theravance announced the submission by GSK of regulatory applications in the United States and the European Union, respectively, for UMEC/VI for patients with COPD. The Marketing Authorisation Application (MAA) for UMEC/VI has been validated for assessment by the European Medicines Agency (EMA).

UMEC/VI, with proposed brand name ANORO™, 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.

Future Regulatory Submissions:
Regulatory submissions for UMEC/VI are planned in other countries during the course of 2013. In addition, GSK intends to commence global regulatory submissions for UMEC monotherapy, administered using the ELLIPTA™ inhaler, for COPD patients later this year.

Other Respiratory Development Programmes:
UMEC/VI is one of several late-stage assets in the GSK respiratory development portfolio, which includes fluticasone furoate/vilanterol (FF/VI, with proposed brand names RELVAR™ and BREO™), VI monotherapy and MABA (GSK961081), developed in collaboration with Theravance, as well as GSK's investigational medicines FF monotherapy, UMEC monotherapy and anti-IL5 MAb (mepolizumab). These investigational medicines are not currently approved anywhere in the world.

ANORO™, RELVAR™, BREO™ and ELLIPTA™ are trademarks of the GlaxoSmithKline group of companies. The use of these brand names is not approved by any regulatory authorities.

GlaxoSmithKline - one of the world's leading research-based pharmaceutical and healthcare companies - is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit www.gsk.com.

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), ANORO™ (UMEC/VI) a 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.

Cautionary statement regarding forward-looking statements
Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect GSK' s operations are described under 'Risk Factors' in the 'Business Review' in the company' s Annual Report on Form 20-F for 2011.

Theravance forward-looking statement
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 the discovery, development and commercialization of our product candidates. 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 and non-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 discover, 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 in Theravance's prospectus supplement filed with the SEC on January 18, 2013 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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