

July 12, 2013

Regulatory Update: Fluticasone Furoate / Vilanterol Submission in Japan

LONDON and SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 07/12/13 -- GlaxoSmithKline (GSK) and Theravance, Inc. (NASDAQ: THRX) today announced that the licence application for the use of fluticasone furoate (FF) and vilanterol (VI) (proposed brand name RELVAR™ ELLIPTA™) in patients with chronic obstructive pulmonary disease (COPD) has been withdrawn from the current Japanese New Drug Application (JNDA). The review of FF/VI for use in patients with asthma is continuing to progress through the normal Japanese regulatory process as part of this JNDA.

The submission for the once-daily investigational medicine FF/VI contained data from six studies in over 6,000 COPD patients. Japanese patient specific efficacy data were generated from two 6-month efficacy (lung function) studies. These studies demonstrated the benefit of the combination FF/VI compared with placebo on the co-primary endpoints of 0-4 hour weighted mean FEV₁ and trough FEV₁. However, in an assessment of the contribution of each of the individual components, while VI achieved a statistically significant improvement in weighted mean FEV₁ the contribution of FF on improvement of lung function did not achieve statistical significance in these studies.

As no Japanese patients were enrolled in either of the 52-week exacerbation studies also conducted with FF/VI, GSK believes that the data from the 6-month studies alone may be insufficient to support the efficacy of the combination and its components in this specific patient group. As a result, a decision has been taken to withdraw COPD from the current JNDA at this time. The application for FF/VI as a potential treatment for asthma remains under review in Japan.

GSK and Theravance are currently determining next steps and possible clinical studies of FF/VI for the treatment of Japanese patients with COPD to support the resubmission. Further details will be provided in due course.

RELVAR™ and ELLIPTA™ are trademarks of the GlaxoSmithKline group of companies. The use of the brand name RELVAR is not approved by any regulatory authority.

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 programmes include: RELVAR™ ELLIPTA™ or BREO ELLIPTA™ (FF/VI), ANORO™ ELLIPTA™ (UMEK/VI) and MABA (Bifunctional Muscarinic Antagonist/Beta₂ Agonist), each partnered with

GlaxoSmithKline plc, and its oral Peripheral Mu Opioid Receptor Antagonist programme. 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.

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Cautionary statement regarding forward-looking statements

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 Item 3.D 'Risk factors' in the company's Annual Report on Form 20-F for 2012.

Theravance forward-looking statements

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.

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