

This press release is intended for business journalists and analysts/investors. Please note that this release may not have been issued in every market in which GSK operates.

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## **GSK and Theravance announce completion of the Relovair<sup>™\*</sup> registrational programme and topline results from Relovair<sup>™</sup> vs. Advair<sup>®</sup> phase III studies in COPD**

**COPD and asthma regulatory plans remain on track for submission from mid-2012**

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GlaxoSmithKline (GSK) and Theravance, Inc. (NASDAQ: THRX) today announced that the registrational programme for Relovair<sup>™</sup> is now complete. In addition, results from two studies for the once-daily investigational medicine Relovair<sup>™</sup> (fluticasone furoate “FF”/vilanterol “VI” (FF/VI)) in patients with chronic obstructive pulmonary disease (COPD) and results from a study to evaluate the efficacy and safety of FF and FP (fluticasone propionate) compared to placebo in the treatment of persistent asthma in adults and adolescents were announced.

The full results of all these studies will be presented at future scientific meetings.

### **COPD Non-Pivotal Phase III Studies**

Two replicate 12-week superiority studies evaluated the 24-hour lung function profile of once-daily FF/VI 100/25mcg compared with twice-daily Advair<sup>®</sup> 250/50mcg (fluticasone propionate “FP”/salmeterol “SAL” (FP/SAL)) in patients with COPD. Each study randomised approximately 500 patients. In the first study, FF/VI demonstrated superiority over FP/SAL on the predefined primary endpoint of 0-24 hour weighted mean FEV1 ( $p < 0.001$ ). In the second study, FF/VI demonstrated numerical improvements but not statistical superiority over FP/SAL on the predefined primary endpoint of 0-24 hour weighted mean FEV1 ( $p = 0.267$ ).

Across these two studies, the most common adverse events in the FF/VI arms were nasopharyngitis, headache, and oropharyngeal candidiasis.

### **Asthma Pivotal Phase III Programme Completed**

GSK has also completed the phase III registrational programme for FF/VI, following the completion of a study to evaluate the efficacy and safety of FF and FP compared to placebo in the treatment of persistent asthma in adults and adolescents. In this 24-week multi-centre study of approximately 330 patients, FF met the primary endpoint of a statistically significant change from baseline in trough evening FEV1 at the end of the 24-week treatment period ( $p = 0.009$ ) compared to placebo. FP also met this primary endpoint when compared to placebo ( $p = 0.011$ ).

In this study, the most common adverse events on the FF arm were bronchitis, headache, nasopharyngitis, upper respiratory tract infection, pharyngitis, and sinusitis.

## FF/VI Regulatory Plans

For COPD, GSK continues with its plans to submit regulatory applications for FF/VI in the US and Europe in mid-2012. For asthma, GSK plans to submit an application in Europe in mid-2012 and will continue discussions with the FDA on the regulatory requirements for a US asthma indication.

FF/VI is one of several late-stage assets in the GSK respiratory development portfolio, which includes LAMA/LABA (GSK573719/VI) and MABA (GSK961081), developed in collaboration with Theravance, as well as FLAP-inhibitor (GSK2190915), p-38 kinase inhibitor (losmapimod) and anti-IL5 MAb (mepolizumab). The phase III programme for LAMA/LABA is expected to complete in 2012.

\***Relovair™** (FF/VI) is an investigational medicine and is not currently approved anywhere in the world. Relovair™ is a trademark of the GlaxoSmithKline group of companies. The use of the brand name Relovair™ for FF/VI is not approved by regulatory authorities around the world.

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**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](http://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: Relovair™, LAMA/LABA ('719/VI) and MABA (Bifunctional Muscarinic Antagonist-Beta<sub>2</sub> 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 Theravance's web site at [www.theravance.com](http://www.theravance.com).

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### 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 Exchange Act 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, 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 enabling capabilities of Theravance's approach to drug discovery and its proprietary insights, 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on February 27, 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.