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## **GSK and Theravance announce results of two pivotal Phase III studies for Relovair™ in COPD**

### **Results support continuation of Relovair development programme in COPD**

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GlaxoSmithKline (GSK) and Theravance, Inc. (NASDAQ: THRX) today announced the results of two pivotal 6-month efficacy and safety phase III studies of Relovair for patients with chronic obstructive pulmonary disease (COPD). Results of both studies support the continuation of the Relovair development programme in the COPD patient population.

Relovair is a once-daily inhaled corticosteroid (ICS)/long-acting beta-agonist (LABA) combination treatment, comprising fluticasone furoate and vilanterol (FF/VI), currently under development for the treatment of COPD and asthma.

These data form part of the overall evaluation of the efficacy and safety of the Relovair combination in COPD that, together with data from ongoing 12-month exacerbation studies, will be included in regulatory submissions around the world.

For pre-specified co-primary endpoints analyses, both studies show statistically significant improvements for Relovair compared with placebo on 0-4 hour weighted mean FEV1 and trough FEV1. For the same endpoints, the studies also demonstrate statistically significant improvements for VI compared to placebo. In order to assess the contribution of VI to the performance of the combination, a further co-primary endpoint compared Relovair to FF on weighted mean FEV1; again this was statistically significant. In order to assess the contribution of FF to the performance of the combination, Relovair was compared to VI on trough FEV1. For this analysis, Relovair demonstrated numerical improvements but not consistent statistical significance compared with VI alone.

In both studies the most common adverse events across all treatment arms, including placebo, were nasopharyngitis, upper respiratory tract infection and headache. There were no clinically relevant effects seen in laboratory measures or vital signs.

Darrell Baker, SVP, Respiratory Portfolio Optimisation Leader at GSK said: "Successful completion of these two studies is an important milestone in the development of Relovair for COPD. These data will be reviewed together with the larger 12 month exacerbation studies still underway, to develop a complete evaluation of Relovair in treating patients with COPD."

These two six month FEV1 studies provide an initial insight into the pivotal programme for Relovair which is evaluating over 6,000 patients with COPD. Two larger 12-month exacerbation studies in over 3,000 patients are now fully recruited. The results of these additional studies will provide a fuller evaluation of the efficacy of Relovair compared with VI and FF on reduction of exacerbations and improvement in lung function. The full results of all the studies will be presented at future scientific meetings.

Relovair is also in Phase III clinical development for the treatment of asthma.

#### **About the 6-month Efficacy and Safety Studies**

The two studies were placebo-controlled, double-blind, parallel-group studies and randomised a total of approximately 2,200 patients with moderate to severe COPD. Patients (approximately n=200 per arm per study) received either FF alone (100mcg, 200mcg), VI alone (25mcg), a combination of FF and VI (50mcg, 100mcg, or 200mcg FF plus VI 25mcg) or placebo.

The studies evaluated two separate measures of lung function: improvements in lung function over the first four hours post dose on day 168 and the end of dose trough lung function on day 169.



Relovair™ is a trademark of the GlaxoSmithKline group of companies.

### Theravance Analyst Conference Call and Webcast Information

Theravance has scheduled an analyst conference call to discuss this announcement today at 8:00 a.m. Eastern Daylight Time. Analysts who wish to participate in the live call by telephone, please dial (877) 837-3908 from the U.S., or (973) 890-8166 for international callers. Those interested in listening to the conference call live via the internet may do so by visiting Theravance's web site at [www.theravance.com](http://www.theravance.com). To listen to the live call, please go to Theravance's web site 15 minutes prior to its start to register, download, and install any necessary audio software.

A replay of the conference call will be available on Theravance's web site for 30 days through July 2, 2011. An audio replay will also be available through 11:59 p.m. Eastern Daylight Time on June 9, 2011 by dialing (800) 642-1687 from the U.S., or (706) 645-9291 for international callers, and entering confirmation code 72929617.

**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/vilanterol (VI)) and MABA (Bifunctional Muscarinic Antagonist-Beta2 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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### **GlaxoSmithKline 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 2010.

### **Theravance forward-looking statement**

This press release contains and the conference call will contain 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, and statements regarding 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 the press release and the conference call 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 completing clinical studies, the potential that results of clinical or preclinical 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 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 4, 2011 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.

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.