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## **GSK and Theravance Announce Regulatory Submissions for FF/VI in the US and Europe**

### **Relvar(TM) and Breo(TM) Proposed as Brand Names for FF/VI in EU and US; New Dry Powder Inhaler Proposed to be Named Ellipta(TM)**

LONDON and SOUTH SAN FRANCISCO, Calif., July 13, 2012 (GLOBE NEWSWIRE) -- GlaxoSmithKline plc (GSK) and Theravance, Inc. (Nasdaq:THRX) today announced the submission of regulatory applications in the US and European Union for the once-daily investigational medicine fluticasone furoate "FF"/vilanterol "VI" (FF/VI) for patients with chronic obstructive pulmonary disease (COPD) and a regulatory application for asthma in the European Union.

#### **European Submission:**

A Marketing Authorisation Application (MAA) for FF/VI, with the proposed brand name Relvar™, administered by a new dry powder inhaler called Ellipta™, has been submitted to the European Medicines Agency (EMA) for the following indications:

**Asthma (100/25mcg and 200/25mcg):** The regular treatment of asthma in adults and adolescents aged 12 years and older, where use of a combination product (long-acting beta<sub>2</sub>-agonist and inhaled corticosteroid) is appropriate.

**COPD (100/25mcg):** The symptomatic treatment of patients with COPD with a FEV1 < 70% predicted normal (post-bronchodilator) in patients with an exacerbation history.

#### **US Submission:**

A New Drug Application (NDA) for FF/VI, with the proposed brand name Breo™, administered by the Ellipta™ inhaler, has been submitted to the US Food and Drug Administration (FDA), for the following indication:

**COPD (100/25mcg):** The long-term once-daily maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema and to reduce exacerbations of COPD in patients with a history of exacerbations.

For asthma, GSK and Theravance are reviewing the strategy for a future US filing.

FF/VI is one of several late-stage assets in the GSK respiratory development portfolio, which also includes the investigational LAMA/LABA combination umeclidinium bromide/vilanterol (UMEC/VI), 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).

\***Relvar™ or Breo™** FF/VI and previously referred to as **Relovair™** is an investigational medicine and is not currently approved anywhere in the world. Relovair™, Relvar™, Breo™ and Ellipta™ are trademarks of the GlaxoSmithKline group of companies. The use of these brand names is not approved by regulatory authorities around the world.

**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: Relvar™/Breo™, LAMA/LABA (UMEC/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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## 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 'Financial review & risk' section in the company's Annual Report 2011 included as exhibit 15.2 to 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 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 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 2, 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.

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