THERAVANCE, INC.
A ROYALTY MANAGEMENT COMPANY

April 22, 2014

# GSK and Theravance Announce Phase III Study of Fluticasone Furoate/Vilanterol in COPD Commenced to Support Potential Future Filing in Japan

LONDON, UNITED KINGDOM and SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 04/22/14 -- GlaxoSmithKline (LSE: GSK) (NYSE: GSK) and Theravance, Inc. (NASDAQ: THRX) today announced the start of a Phase III efficacy and safety study of a combination treatment of the inhaled corticosteroid (ICS), fluticasone furoate and long-acting beta$_2$ agonist (LABA), vilanterol (FF/VI). The study will evaluate the contribution of the ICS component on lung function, in patients with Chronic Obstructive Pulmonary Disease (COPD). Positive results from this study will help support a potential filing of FF/VI for the treatment of patients with COPD in Japan.

The study is a 12 week, multicentre, randomised, double-blind, parallel-group study to evaluate the efficacy and safety of FF/VI 100/25mcg once daily compared with VI 25mcg once daily, administered via the Ellipta inhaler. Patients included in the study will have a history of COPD with at least one exacerbation in the year prior to screening and will demonstrate current symptoms of COPD. The study seeks to enrol approximately 1580 patients from across 250 study centres worldwide, including approximately 350 patients from centres in Japan.

***About the FF/VI clinical development programme in Japanese patients***
The FF/VI phase III clinical development programme in patients with COPD contained data from six studies in over 6,000 COPD patients. Specific Japanese patient efficacy data were only available from two 6-month efficacy studies. In these studies the contribution of FF 100mcg to the combination, on lung function, did not achieve statistical significance.

GSK chose to withdraw the COPD file in Japan while designing an additional study, as there were insufficient data to support the efficacy of the combination and its components in this specific patient group. Demonstration of a statistically significant contribution of FF 100mcg to the combination on lung function needs to be shown in this study, with a trend demonstrating a positive benefit in the Japanese patients sub-group, being pivotal for the approval of FF/VI 100/25mcg for treatment of COPD in Japan

***FF/VI Regulatory Activity in Japan***
FF/VI strengths of 100/25 mcg and 200/25 mcg were licensed by the Japanese Ministry of Health Labour and Welfare for the treatment of asthma under the trade name Relvar® Ellipta® in September 2013. Japanese Drug Information is available at ***http://glaxosmithkline.co.jp/healthcare/.***

FF/VI is not licensed in Japan for the treatment of patients with COPD.

***Important Safety Information for asthma patients in Japan receiving Relvar Ellipta***
FF/VI is contraindicated in patients with hypersensitivity to fluticasone furoate, vilanterol, or any of the excipients and in patients with infections or deep mycosis against which there is no effective anti-bacterial agent (symptoms may be exacerbated due to steroid effects).

Because FF/VI is not intended for immediate relief of symptoms that have occurred, the product should not be used to relieve acute symptoms. Any other appropriate drug such as short-acting inhaled beta$_2$ agonist (e.g. inhaled salbutamol sulphate) should be used for relief of acute symptoms.

FF/VI should be administered with caution in patients with tuberculosis or infections, patients with severe cardiac disease, and patients with hepatic impairment.

Patients should be cautioned to visit a medical institution as soon as possible to seek medical treatment if they notice increasing use or insufficient effect of the short-acting inhaled beta$_2$ agonist because asthma management may be inadequate.

Patients should be instructed not to stop inhaling FF/VI on their own since symptoms may be exacerbated after discontinuation of the product.

As with other inhaled drugs, paradoxical bronchospasm may occur with an increase in wheezing after inhalation of FF/VI. In

such a case, FF/VI should be discontinued immediately, and treatment with a short-acting inhaled bronchodilator should be given. The patient should be assessed and alternative therapy should be considered if necessary.

Asthma-related events and asthma exacerbations may occur during treatment with FF/VI. Patients should be instructed not to stop inhaling FF/VI on their own but to seek medical advice if asthma symptoms remain uncontrolled or are exacerbated after initiation of treatment with the product.

Systemic effects (including Cushing's syndrome, Cushingoid symptoms, adrenal suppression, growth retardation in children, decrease in bone mineral density, cataract, and glaucoma) may occur with inhaled steroids although these effects are less likely than with systemic steroids. Therefore, inhaled steroids should be used at the lowest dose to effectively control asthma for each patient. Particularly, patients who are treated at high doses for long periods should be monitored with regular examinations; in case systemic effects occur, appropriate measures should be taken while monitoring the patient's asthmatic symptoms.

It has been reported in a global clinical study and overseas clinical studies in patients with chronic obstructive pulmonary disease that the incidence of pneumonia showed a fluticasone furoate/vilanterol dose-dependent increase. Caution should be exercised when FF/VI is administered to patients who are generally at potentially high risk for developing pneumonia.

Caution should be exercised when considering the coadministration of FF/VI with long‐term ketoconazole and other known strong CYP3A4 inhibitors because increased systemic corticosteroid and cardiovascular adverse effects may occur. Caution should also be exercised when considering the coadministration of FF/VI with beta-blockers which may weaken the effect of FF/VI.

In three global phase III clinical studies, adverse reactions including laboratory abnormalities were reported in 100 (7.1%) of a total of 1,407 patients (including 61 Japanese patients) treated with FF/VI. The common adverse reactions were dysphonia and oral candidiasis reported in 19 (1.4%) and 12 (0.9%) patients, respectively. Of 61 Japanese patients, adverse reactions including laboratory abnormalities were reported in 7 patients (11.5%). The common adverse reactions were dysphonia and oral candidiasis reported in 3 (4.9%) and 2 (3.3%) patients, respectively (at the time of approval).

In a Japanese long-term administration study, adverse reactions including laboratory abnormalities were reported in 40 (26.1%) of a total of 153 patients treated with FF/VI. The common adverse reactions were oral candidiasis and dysphonia reported in 16 (10.5%) and 10 (6.5%) patients, respectively (at the time of approval).

An anaphylactic reaction may occur (incidence unknown). Patients treated with Relvar Ellipta should be monitored closely, and if an abnormality is observed, the treatment should be discontinued and appropriate measures should be taken.



***GSK*** -- 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®/BREO® ELLIPTA® (FF/VI), ANORO™ ELLIPTA (UMEC/VI) and MABA (Bifunctional Muscarinic Antagonist-Beta$_2$ Agonist) GSK961081, each partnered with GlaxoSmithKline plc (GSK), and its Long-Acting Muscarinic 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***
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. Such factors include, but are not limited to, those described under Item 3.D 'Risk factors' in the company's Annual Report on Form 20-F for 2013.

***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 Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 3, 2014 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.

(THRX-G)

***GSK enquiries:***

UK Media enquiries:
David Mawdsley
*+44 (0) 20 8047 5502*
(London)

Simon Steel
*+44 (0) 20 8047 5502*
(London)

David Daley
*+44 (0) 20 8047 5502*
(London)

Catherine Hartley
*+44 (0) 20 8047 5502*
(London)

Sarah Spencer
*+44 (0) 20 8047 5502*
(London)

US Media enquiries:
Melinda Stubbee
*+1 919 483 2510*
(North Carolina)

Robin Gaitens
*+1 919 483 2678*
(North Carolina)

Juan Carlos Molina
*+1 919 483 0471*
(North Carolina)

Bradd Pavur
*+1 919 483 0044*
(North Carolina)

Karen Collins

*+1 919 483 2527*
(North Carolina)

Analyst/Investor enquiries:
Ziba Shamsi
*+44 (0) 20 8047 5543*
(London)

Kirsty Collins (SRI & CG)
*+44 (0) 20 8047 5534*
(London)

Tom Curry
+ 1 215 751 5419
(Philadelphia)

Gary Davies
*+44 (0) 20 8047 5503*
(London)

James Dodwell
*+44 (0) 20 8047 2406*
(London)

Jeff McLaughlin
*+1 215 751 7002*
(Philadelphia)

Lucy Singah
*+44 (0) 20 8047 2248*
(London)

***Theravance, Inc. enquiries:***
Investor Relations
Michael W. Aguiar
*+1 650 808 4100*
(San Francisco)
investor.relations@theravance.com

Source: Theravance, Inc.