THERAVANCE, INC.
A ROYALTY MANAGEMENT COMPANY

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Patient Recruitment Completes in Landmark RELVAR(R)/BREO(R) ELLIPTA(R) Study to Understand Mortality and MorbidITy (SUMMIT) in COPD

LONDON, UNITED KINGDOM and SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 03/13/14 -- GlaxoSmithKline plc (LSE: GSK) (NYSE: GSK) and Theravance, Inc. (NASDAQ: THRX) today announced that recruitment of patients into the "Study to Understand Mortality and MorbidITy", known as SUMMIT, has completed enrolment. The aim of this study, which has now enrolled approximately 16,000 patients, is to determine the impact of Relvar®/Breo® Ellipta® (fluticasone furoate 'FF'/vilanterol 'VI') on all cause mortality amongst patients with moderate chronic obstructive pulmonary disease (COPD) who have cardiovascular disease (CVD) or are at increased risk for CVD.

SUMMIT (NCT01313676) is a multicentre, double-blind, parallel-group, placebo-controlled study of approximately 16,000 patients with moderate COPD and a history of or increased risk for cardiovascular disease who are randomised to receive either once daily treatment with fluticasone furoate/vilanterol (100/25mcg), fluticasone furoate (100mcg), vilanterol (25mcg) or placebo. The primary objective is to evaluate the effect of FF/VI compared with placebo on survival evaluated by the primary endpoint of all-cause mortality. The secondary endpoints are rate of decline in forced expiratory volume in 1 second (FEV_1) and a composite cardiovascular endpoint.

As an event-driven study, the exact duration of the treatment phase will depend on the mortality rate within the study. However, it is anticipated that each patient will participate in the study for between 16-53 months.

Darrell Baker, SVP and Head, Global Respiratory Franchise, GSK said, "We are very pleased to have completed recruitment in this large study and initiated the final patient onto treatment. We hope that results from this study will increase our understanding of cardiovascular comorbidity in COPD, and of the effects of Relvar/Breo Ellipta when used to manage COPD."

Rick E Winningham, Chief Executive Officer of Theravance said, "There is limited understanding of the relationship between COPD and cardiovascular disease or the potential to affect patient outcomes. We believe that, once available, the results from this landmark study will enhance our knowledge of these co-morbid conditions and provide important information about treatment with Relvar/Breo in a COPD population with cardiovascular risk factors."

About COPD

COPD, which includes chronic bronchitis and emphysema, is characterised by obstruction to airflow that interferes with normal breathing, and is most frequently diagnosed in people aged 40 years or over.[1] Patients living with COPD often have other chronic diseases and comorbidities that can markedly influence their health status and prognosis. To date, there have been no trials assessing whether treatment of COPD will have a positive impact on adverse cardiovascular events in patients with both COPD and CVD and/or CV risk factors. SUMMIT is the first prospective study that aims to inform understanding of the interaction between these two diseases.

About FF/VI

Breo® Ellipta® (FF/VI 100/25mcg) was licensed in May 2013 by the US Food and Drug Administration for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Breo Ellipta is not indicated for the relief of acute bronchospasm or the treatment of asthma in the US.

Full US prescribing information, including BOXED WARNING and Medication Guide is available at us.gsk.com or US Prescribing Information Breo Ellipta.

Relvar Ellipta was also approved by the European Medicines Agency (EMA) in November 2013 for the symptomatic treatment of adults with chronic obstructive pulmonary disease (COPD) with a FEV_1 < 70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy. One strength has been licensed for the treatment of COPD (92/22 mcg) and is administered once-daily using Ellipta, a dry powder inhaler (DPI). EMA EPAR including summary of product characteristics

FF/VI is not approved or licensed anywhere in the world to reduce mortality due to CV co-morbidities associated with COPD.

Important Safety Information (ISI) for Breo Ellipta (FF/VI) in the US

The following ISI is based on the Highlights section of the U.S. Prescribing Information for Breo Ellipta for the maintenance treatment of airflow obstruction in patients with COPD and to reduce exacerbations of COPD in patients with a history of exacerbations. Please consult the full Prescribing Information for all the labeled safety information for Breo Ellipta.

Long-acting beta$_2$-adrenergic agonists (LABAs), such as vilanterol, one of the active ingredients in Breo Ellipta, increase the risk of asthma-related death. A placebo-controlled trial with another LABA (salmeterol) showed an increase in asthma-related deaths in subjects receiving salmeterol. This finding with salmeterol is considered a class effect of all LABAs, including vilanterol. In the US, the safety and efficacy of Breo Ellipta in patients with asthma have not been established and therefore Breo Ellipta is not indicated for the treatment of asthma.

Breo Ellipta is contraindicated in patients with severe hypersensitivity to milk proteins or who have demonstrated hypersensitivity to either fluticasone furoate, vilanterol, or any of the excipients.

Breo Ellipta should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of COPD, or as rescue therapy for the treatment of acute episodes of bronchospasm. Acute symptoms should be treated with an inhaled, short-acting beta$_2$-agonist.

Breo Ellipta should not be used more often than recommended, at higher doses than recommended, or in conjunction with other medications containing LABAs, as an overdose may result.

Oropharyngeal candidiasis has occurred in patients treated with Breo Ellipta. Patients should rinse their mouth with water without swallowing after inhalation to help reduce this risk.

An increase in the incidence of pneumonia has been observed in subjects with COPD receiving the fluticasone furoate/vilanterol combination, including Breo Ellipta100 mcg/25 mcg, in clinical trials. There was also an increased incidence of pneumonias resulting in hospitalization. In some incidences these pneumonia events were fatal.

Patients who use corticosteroids are at risk for potential worsening of existing tuberculosis; fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex. A more serious or even fatal course of chickenpox or measles may occur in susceptible patients.

Particular care is needed for patients who have been transferred from systemically active corticosteroids to inhaled corticosteroids because deaths due to adrenal insufficiency have occurred in patients with asthma during and after transfer from systemic corticosteroids to less systemically available inhaled corticosteroids.

Hypercorticism and adrenal suppression may occur with very high dosages or at the regular dosage of inhaled corticosteroids in susceptible individuals.

Caution should be exercised when considering the coadministration of Breo Ellipta with long‑term ketoconazole and other known strong CYP3A4 inhibitors because increased systemic corticosteroid and cardiovascular adverse effects may occur.

As with other inhaled medicines, Breo Ellipta can produce paradoxical bronchospasm which may be life-threatening. Vilanterol, the LABA in Breo Ellipta, can produce clinically significant cardiovascular effects in some patients as measured by increases in pulse rate, systolic or diastolic blood pressure, and also cardiac arrhythmias. Decreases in bone mineral density have been observed with long-term administration of products containing inhaled corticosteroids, as have glaucoma, increased intraocular pressure, and cataracts.

Breo Ellipta should be used with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, ketoacidosis, and in patients who are unusually responsive to sympathomimetic amines.

Beta-adrenergic agonist medicines may produce significant hypokalemia in some patients. Beta-adrenergic agonist medicines may produce transient hyperglycemia in some patients.

The most common adverse reactions (≥3% and more common than in placebo) reported in two 6-month clinical trials with Breo Ellipta (and placebo) were nasopharyngitis, 9% (8%); upper respiratory tract infection, 7% (3%); headache, 7% (5%); and oral candidiasis, 5% (2%). In addition to the events reported in the 6-month studies, adverse reactions occurring in ≥3% of the subjects treated with Breo Ellipta in two 1-year studies included COPD, back pain, pneumonia, bronchitis, sinusitis, cough, oropharyngeal pain, arthralgia, hypertension, influenza, pharyngitis, diarrhea, peripheral edema, and pyrexia.

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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), each partnered with GlaxoSmithKline plc, 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.

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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. 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)

References

1 Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) [online] 2013. Available from: http://www.goldcopd.org/uploads/users/files/GOLD_Report_2013_Feb20.pdf [Last accessed: June 2013]

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