THERAVANCE, INC.
A ROYALTY MANAGEMENT COMPANY

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Regulatory Update: GSK and Theravance Announce Intention to File Relvar(R) Ellipta(R) for COPD in Japan

LONDON, UNITED KINGDOM and SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 09/24/15 -- GlaxoSmithKline (LSE: GSK) (NYSE: GSK) and Theravance, Inc. (NASDAQ: THRX) today announced the intention to file a supplemental Japanese New Drug Application (sJNDA) for Relvar® Ellipta® (fluticasone furoate "FF"/vilanterol "VI" or "FF/VI") for the treatment of chronic obstructive pulmonary disease (COPD) with the Japanese regulatory authority during the first quarter of 2016. This decision follows results from an additional global phase III efficacy and safety study.

As previously announced, Study 200820 was designed to provide additional data for the combination, FF/VI, compared with its component, VI, in Japanese patients with COPD, as there were insufficient efficacy data in this specific COPD patient group within the FF/VI phase III clinical development programme.

The study which included 1620 patients with COPD, of whom 370 were from Japan, showed that patients who received FF/VI 100/25mcg achieved a statistically significant improvement in lung function (as measured by change from baseline in trough FEV_1) compared with VI 25mcg at 12 weeks (p=0.001).

The most frequently reported adverse events in the study (greater than or equal to 3% in any group) were nasopharyngitis (6% VI, 6% FF/VI), COPD exacerbation (4% VI, 2% FF/VI) and headache (2% VI, 4% FF/VI).

Pneumonia as an adverse event of special interest was reported in 7 subjects in each treatment group (< 1%VI, < 1% FF/VI).

The full results from the study will be the subject of a future publication / presentation.

Study Design
The 12-week, phase IIIa, multi-centre, randomised, stratified (reversibility status), double-blind, parallel-group study evaluated the contribution of FF 100mcg to FF/VI 100/25mcg once daily to lung function (as measured by trough FEV_1) by comparison with VI 25mcg, in patients with moderate to severe COPD. Patients enrolled in the study were required to have had at least one COPD exacerbation that required systemic/oral corticosteroids and/or antibiotics and/or hospitalisation in the 12 months prior to screening and current symptoms of COPD, defined as a combined symptom score (combination of breathlessness, cough, sputum, and night-time awakenings requiring treatment with albuterol [salbutamol]) of ≥ 4 on at least 5 of the 7 days immediately preceding the Randomisation Visit.

Patients in the study were randomised 1:1 to receive FF/VI 100/25 mcg or VI 25 mcg. All treatments were administered once daily in the dry powder inhaler (DPI) Ellipta®. The study was conducted in 11 countries, with 23% of patients from Japan. The study is listed on www.clinicaltrials.gov (NCT02105974).

FF/VI is not currently indicated for the treatment of COPD in Japan. FF/VI was approved by the Japanese Ministry of Health, Labour and Welfare (MHLW) for the regular treatment of asthma in patients aged 15 years and older in September 2013.

Relvar Ellipta, or FF/VI, is also known as Breo Ellipta in some other markets, including the US.

Important Safety Information (ISI) for FF/VI (Breo Ellipta) in the US
The following ISI is based on the Highlights section of the US Prescribing Information for Breo Ellipta. Please consult the full Prescribing Information for all the labelled safety information for Breo Ellipta.

Long-acting beta$_2$-adrenergic agonists (LABA), 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. This finding with salmeterol is considered a class effect of all LABA. Currently available data are inadequate to determine whether concurrent use of inhaled corticosteroids (ICS) or other long-term asthma control drugs mitigates the increased risk of asthma-related death from LABA.

Breo Ellipta is contraindicated for primary treatment of status asthmaticus or other acute episodes of COPD or asthma where intensive measures are required and 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 asthma, or used for the relief of acute symptoms, i.e., 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 be advised to 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 Ellipta 100 mcg/25 mcg, in clinical trials. There was also an increased incidence of pneumonias resulting in hospitalisation. 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.

Breo Ellipta can produce paradoxical bronchospasm which may be life-threatening.

Hypersensitivity reactions such as anaphylaxis, angioedema, rash, and urticaria may occur after administration of Breo Ellipta.

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. Breo Ellipta should be used with caution in patients with cardiovascular disorders.

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.

Orally inhaled corticosteroids may cause a reduction in growth velocity when administered in children and adolescents.

For COPD, the most common adverse reactions (≥3% and more common than in placebo) reported in two 6-month clinical trials with Breo Ellipta 100/25 (and placebo) were nasopharyngitis, 9% (8%); upper respiratory tract infection, 7% (3%); headache, 7% (5%); and oral candidiasis, 5% (2%). In addition to the reactions reported in the 6-month studies, adverse reactions occurring in ≥3% of the subjects treated with Breo Ellipta 100/25 in two 1-year studies included back pain, pneumonia, bronchitis, sinusitis, cough, oropharyngeal pain, arthralgia, influenza, pharyngitis, and pyrexia.

For asthma, the most common adverse reactions in a 12-week trial (incidence ≥2% and more common than placebo) reported with Breo Ellipta 100/25 (and placebo) were nasopharyngitis 10% (7%), headache 5% (4%), oropharyngeal pain 2% (1%), oral candidiasis 2% (0%), and dysphonia 2% (0%). In a separate 12-week trial the most common adverse reactions (≥2% incidence) reported with Breo Ellipta 100/25 or 200/25 were headache, nasopharyngitis, influenza, upper respiratory tract infection, oropharyngeal pain, sinusitis, bronchitis, and cough. In addition to adverse reactions reported in the 12 week studies, adverse reactions (≥2% incidence) reported with Breo Ellipta 200/25 in a 24-week trial included viral respiratory tract infection, pharyngitis, pyrexia, and arthralgia, and with Breo Ellipta 100/25 or 200/25 in a 12-month trial included pyrexia, back pain,

extrasystoles, upper abdominal pain, respiratory tract infection, allergic rhinitis, pharyngitis, rhinitis, arthralgia, supraventricular extrasystoles, ventricular extrasystoles, acute sinusitis, and pneumonia.

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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, Inc. -is focused on bringing compelling new medicines to patients in areas of unmet need by leveraging its significant expertise in the development, commercialization and financial management of bio-pharmaceuticals. Theravance's portfolio is anchored by the respiratory assets partnered with Glaxo Group Limited (GSK), including RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®, which were jointly developed by Theravance and GSK. Under the agreement with GSK, Theravance is eligible to receive associated royalty revenues from RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and, if approved and commercialized, VI monotherapy, as well. In addition, Theravance retains a 15% economic interest in future payments made by GSK for earlier-stage programs under the agreements with GSK. For more information, please visit Theravance's website at www.thrxinc.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 2014.

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. Such forward-looking statements involve substantial risks, uncertainties and assumptions. Examples of such statements include statements relating to: the commercial and regulatory plans for RELVAR/BREO ELLIPTA, the strategies, plans and objectives of the company, the timing, manner and amount of anticipated potential capital returns to stockholders (including without limitation, expectations of future cash dividends or future share repurchases), the status and timing of clinical studies, data analysis and communication of results, the potential benefits and mechanisms of action of product candidates, expectations for product candidates through development and commercialization, the timing of seeking regulatory approval of product candidates, 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 the 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: the disruption of operations during the transition period following the spin-off, including the diversion of managements' and employees' attention, disruption of relationships with collaborators and increased employee turnover, lower than expected future royalty revenue from respiratory products partnered with GSK, delays or difficulties in commencing or completing clinical studies, the potential that results from clinical or non-clinical studies indicate product candidates are unsafe or ineffective, dependence on third parties to conduct its clinical studies, delays or failure to achieve and maintain regulatory approvals for product candidates, and risks of collaborating with third parties to discover, develop and commercialize products. Other risks affecting Theravance are described under the headings "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in Theravance's Annual Report on Form 10-K for the year ended December 31, 2014 and Theravance's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. In addition to the risks described above and in Theravance's other filings with the SEC, other unknown or unpredictable factors also could affect Theravance's results. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Theravance assumes no obligation to update its forward-looking statements on account of new information, future events or otherwise, except as required by law. (THRX-G)

Registered in England & Wales:
No. 3888792

Registered Office:
980 Great West Road
Brentford, Middlesex
TW8 9GS

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)

Claire Brough
+44 (0) 20 8047 5502
(London)

US Media enquiries:
Sarah Alspach
+1 202 715 1048
(Washington, DC)

Sarah Spencer
+1 215 751 3335
(Philadelphia)

Mary Anne Rhyne
+1 919 483 0492
(North Carolina)

Jenni Ligday
+1 202 715 1049
(Washington, DC)

Karen Hagens
+1 919 483 2863
(North Carolina)

Gwynne Oosterbaan
+1 215 751 7468
(Philadelphia)

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

Theravance, Inc. enquiries:
Investor Relations
Eric d'Esparbes
+1 650 238 9640
(San Francisco)
investor.relations@thrxinc.com

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