

October 30, 2013

## **BREO(R) ELLIPTA(TM) Now Available in the U.S. for the Treatment of COPD**

RESEARCH TRIANGLE PARK, NC and SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 10/30/13 -- GlaxoSmithKline plc (LSE: GSK) (NYSE: GSK) and Theravance, Inc. (NASDAQ: THRX) today announced that BREO ELLIPTA, a once-daily prescription medicine for chronic obstructive pulmonary disease (COPD), is now available to pharmacies throughout the U.S.

BREO ELLIPTA is a combination of the inhaled corticosteroid (ICS), fluticasone furoate "FF", and the long-acting beta<sub>2</sub>-agonist (LABA), vilanterol "VI" (FF/VI 100/25 mcg). It is indicated for the long-term, once - daily, maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. BREO ELLIPTA is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations. BREO ELLIPTA is NOT indicated for the relief of acute bronchospasm or for the treatment of asthma.

"Patients and physicians have a new treatment option with BREO ELLIPTA, the first once-daily ICS/LABA for the maintenance treatment of COPD," said Jorge Bartolome, Senior Vice President of GSK Respiratory Business Unit in the U.S. "This new option for healthcare providers to prescribe is good news for the millions of people in the U.S. affected by COPD."

"Launching BREO ELLIPTA and making this important new medicine available to COPD patients is a significant milestone, which has been built upon many years of research and development," said Rick E Winningham, Chief Executive Officer of Theravance. "We, like GSK, are proud to make the option of treatment with BREO ELLIPTA a reality for appropriate patients in the U.S."

Under the terms of its 2002 LABA collaboration agreement with GSK, Theravance agreed to make a milestone payment of \$30 million (USD) to GSK following the launch of BREO ELLIPTA in the U.S.

The FDA approved BREO ELLIPTA on May 10, 2013.

Full U.S. Prescribing Information, including BOXED WARNING and Medication Guide is available at [us.gsk.com](http://us.gsk.com)

For images and information about BREO ELLIPTA visit the [eKit](#).

### **About COPD**

Chronic obstructive pulmonary disease (COPD), which includes chronic bronchitis and emphysema, is characterised by obstruction to airflow that interferes with normal breathing. The National Heart, Lung and Blood Institute (NHLBI) estimates that as many as 27 million people in the US alone are affected by COPD, a number that is predicted to increase.

Many people with COPD periodically experience exacerbations, or flare-ups, a worsening of their COPD symptoms lasting a few days or longer, which may include an increase in shortness of breath, mucus production, cough, and a change in the color of sputum, fever, and fatigue. Exacerbations often require treatment with additional medications and sometimes hospitalization may be necessary. Daily COPD management is important to help prevent future flare-ups in patients with a history of flare-ups.

### **Other FF/VI Regulatory Activity:**

FF/VI 100/25 mcg was approved for the treatment of COPD by Health Canada in July 2013 under the trade name BREO ELLIPTA. On September 20, 2013, the Japanese Ministry of Health, Labour and Welfare (MHLW) approved FF/VI 100/25 mcg and 200/25 mcg for the treatment of bronchial asthma under the trade name RELVAR™ ELLIPTA™. FF/VI is not indicated for the relief of acute bronchospasm or the treatment of asthma in the US or Canada.

In June 2012, a regulatory application for FF/VI was submitted in the European Union under the trade name RELVAR ELLIPTA for the treatment of patients with COPD and asthma, and gained a positive opinion from the Committee for Medicinal Products for Human Use in September 2013. FF/VI is not approved or licensed in the European Union or anywhere outside of the US, Japan and Canada.

RELVAR, BREO and ELLIPTA are trademarks of the GlaxoSmithKline group of companies. The use of the brand name RELVAR is not approved by any regulatory authorities outside of Japan.

### **Important Safety Information (ISI)**

The following ISI is based on the Highlights section of the U.S. Prescribing Information for BREO ELLIPTA. Please consult the

full Prescribing Information for all the labeled safety information for BREO ELLIPTA.

**Long-acting beta<sub>2</sub>-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. The safety and efficacy of BREO ELLIPTA in patients with asthma have not been established. 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<sub>2</sub>-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 ELLIPTA 100 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 ( $\geq 3\%$  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  $\geq 3\%$  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.

**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](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 ELLIPTA or BREO ELLIPTA (FF/VI), ANORO ELLIPTA (UMEC/VI) and MABA (Bifunctional Muscarinic Antagonist-Beta<sub>2</sub> Agonist), GSK961081, each partnered with GlaxoSmithKline plc, and its oral Peripheral Mu Opioid Receptor 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](http://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. Factors that may affect GSK's operations are described under Item 3.D 'Risk factors' in the company's Annual Report on Form 20-F for 2012.

**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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 1, 2013 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. (THR-X-G)

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