



April 17, 2013

FDA Advisory Committee recommends approval of BREO™ ELLIPTA™ for the treatment of COPD

LONDON and SOUTH SAN FRANCISCO, Calif., April 17, 2013 /PRNewswire/ -- GlaxoSmithKline plc (LSE: GSK) and Theravance, Inc. (NASDAQ: THRX) today announced that the Pulmonary-Allergy Drugs Advisory Committee (PADAC) to the US Food and Drug Administration (FDA) voted that the efficacy and safety data provide substantial evidence to support approval of BREO™ ELLIPTA™ as a once-daily inhaled treatment for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD) (9 for, 4 against) and also for the reduction of COPD exacerbations in patients with a history of exacerbations (9 for, 4 against)*.

BREO™ ELLIPTA™, is the proposed proprietary name for FF/VI 100/25 mcg, a combination of the inhaled corticosteroid (ICS) fluticasone furoate "FF" and the long acting bronchodilator (LABA) vilanterol "VI" (FF/VI).

The FDA Advisory Committee also voted that the safety of FF/VI 100/25 mcg once daily in COPD has been adequately demonstrated for the proposed indications (10 for, 3 against).

Patrick Vallance, GSK's President of Pharmaceuticals, R&D, said: "We are pleased with the outcome of today's meeting. COPD is a debilitating and progressive disease. Its symptoms are often severe and can have a huge impact on patients' lives. This positive recommendation is a crucial first step towards making BREO ELLIPTA available for appropriate COPD patients across the US. We look forward to a final decision from the FDA later this year."

"After a decade of development in this programme, our collaboration with GSK is one step closer to providing an important therapeutic option to COPD patients," said Rick E Winningham, Chief Executive Officer of Theravance. "We are proud to collaborate with GSK on the development and potential commercialisation of treatments for COPD and other respiratory diseases. The panel's positive recommendation of BREO ELLIPTA represents an important achievement in a transformative year for Theravance."

In July 2012, a New Drug Application (NDA) was submitted to the FDA for the use of BREO™ administered by the ELLIPTA™ inhaler for 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.

In June 2012, a regulatory application for FF/VI was submitted in the European Union under the trade name RELVAR™ for the treatment of patients with COPD and asthma. In the United States, BREO ELLIPTA is not proposed for the relief of acute bronchospasm or for the treatment of asthma. GSK and Theravance are reviewing the strategy for a future US filing for asthma.

The FDA Advisory Committee provides non-binding recommendations for consideration by the FDA, with the final decision on approval made by the FDA. The Prescription Drug User Fee Act (PDUFA) goal date for FF/VI is 12 May 2013.

Safety Information

The adverse event profile of FF/VI was generally consistent with the known class effects of an ICS/LABA combination and the cardiovascular safety profile of VI and FF/VI was broadly consistent with the known pharmacology of LABAs in patients with COPD. Across the four pivotal COPD studies for BREO ELLIPTA, the most frequently reported adverse events in the FF/VI arms included nasopharyngitis, headache, upper respiratory tract infection, oropharyngeal candidiasis, COPD, back pain, pneumonia, bronchitis and sinusitis. COPD exacerbation was the most common serious adverse event reported followed by pneumonia.

About COPD

Chronic obstructive pulmonary disease (COPD) is a term referring to two lung diseases, chronic bronchitis and emphysema, that are characterized by obstruction to airflow that interferes with normal breathing. COPD is the third most common cause of death in the US and The National Heart, Lung and Blood Institute (NHLI) estimates that 13 million US adults have COPD and another 11 million are undiagnosed or developing COPD. (American Lung Association, COPD Fact Sheet, February 2011).

According to the NHLI, long-term exposure to lung irritants that damage the lungs and the airways are usually the cause of COPD and in the United States, the most common irritant that causes COPD is cigarette smoke. Breathing in second hand smoke, air pollution, or chemical fumes or dust from the environment or workplace also can contribute to COPD. Most people who have COPD are at least 40 years old when symptoms begin.

COPD-related exacerbations are typically defined as a worsening of symptoms that require medical intervention. A high rate of exacerbations is associated with significant disease progression.

About BREO ELLIPTA or RELVAR

FF/VI, previously referred to as RELOVAIR™, is an investigational medicine and is not currently approved anywhere in the world.

Other Respiratory Development Programmes:

BREO ELLIPTA is one of several late-stage assets in the GSK respiratory development portfolio, which includes LAMA/LABA (UMEC/VI, with proposed brand name ANORO™ ELLIPTA™), 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). These investigational medicines are not currently approved anywhere in the world.

ANORO™, RELVAR™, BREO™ and ELLIPTA™ are trademarks of GlaxoSmithKline group of companies. The use of these brand names is not approved by any regulatory authorities.

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.

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 programmes include: RELVAR™ or BREO ELLIPTA™ (FF/VI), ANORO ELLIPTA™ (UMEC/VI) and MABA (Bifunctional Muscarinic Antagonist/Beta₂ Agonist), each partnered with GlaxoSmithKline plc, and its oral Peripheral Mu Opioid Receptor Antagonist programme. 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.

THERAVANCE®, the Theravance logo, and MEDICINES THAT MAKE A DIFFERENCE® are registered trademarks of Theravance, Inc.

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. 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 February 26, 2013 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.

(THRX-G)

*One panel member indicated that he intended to vote no, however a vote cannot be changed once read into the official FDA record.

SOURCE GlaxoSmithKline plc

News Provided by Acquire Media