

February 9, 2015

GSK and Theravance Announce Start of Phase III Lung Function Study With 'Closed' Triple Combination Treatment FF/UMEC/VI for COPD

LONDON, UNITED KINGDOM and SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 02/09/15 -- GlaxoSmithKline plc (LSE: GSK) (NYSE: GSK) and Theravance, Inc. (NASDAQ: THRX) today announced the start of a second global phase III study to evaluate the effects of the investigational once-daily closed triple combination of fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI) in patients with chronic obstructive pulmonary disease (COPD).

Enrolling approximately 1,800 patients, the FULFIL study will assess whether the inhaled corticosteroid, long-acting muscarinic antagonist and long-acting beta₂-adrenergic agonist (ICS/LAMA/LABA) combination, all delivered in GSK's Ellipta[®] inhaler, can improve lung function and health-related quality of life compared with budesonide/formoterol, a twice-daily ICS/LABA combination delivered via the Turbohaler[®] dry powder inhaler. Secondary objectives include investigating the effect on the rate of exacerbations with FF/UMEC/VI compared with budesonide/formoterol, and the safety profile of FF/UMEC/VI compared with budesonide/formoterol. Adverse events of particular interest include pneumonia and cardiovascular risk. Patient perspectives of efficacy and physical activity will also be evaluated versus budesonide/formoterol.

The first, larger study in the phase III programme, known as IMPACT, started in July 2014 to assess whether FF/UMEC/VI can reduce the rate of moderate and severe exacerbations compared with two approved once-daily COPD treatments, Relvar/Breo Ellipta (FF/VI), an ICS/LABA combination, and Anoro Ellipta (UMEC/VI), a LAMA/LABA combination.

Dave Allen, Head, GSK Respiratory Therapy Area Unit, R&D, said: "Triple combination therapy is already a reality for one in three patients with COPD and is often dispensed in different inhalers with differing doses. By providing all three medicine components in a single inhaler we hope to offer more convenient dosing to patients, reduce the risk of exacerbation compared to dual therapy and, as a result, contribute to the improved management of their disease."

Michael W. Aguiar, Chief Executive Officer of Theravance, added: "With FULFIL, we hope to demonstrate that a once-daily triple combination can reduce exacerbations in patients with COPD and deliver meaningful improvements in lung function and health related quality of life. If successful, a once-daily triple combination would be an important addition to our portfolio of combination respiratory products partnered with GSK including Relvar[®]/Breo[®] Ellipta[®] and Anoro[®] Ellipta[®]."

About the FULFIL study

FULFIL (Lung **F**unction and quality of **L**ife assessment in COPD with closed triple therapy) is a randomised, double-blind, double-dummy, parallel group multicentre study evaluating once-daily FF/UMEC/VI (100mcg/62.5mcg/25mcg) inhalation powder versus twice-daily budesonide/formoterol (400mcg/12mcg). The study aims to enrol 1,800 patients across approximately 180 study centres globally.

The co-primary endpoints are: to evaluate the effects of FF/UMEC/VI on lung function and health related quality of life compared with budesonide/formoterol after 24 weeks of treatment. Other endpoints include the effect of FF/UMEC/VI on the annual rate of exacerbations compared with budesonide/formoterol, and the safety profile of FF/UMEC/VI compared with budesonide/formoterol over 24 weeks and 52 weeks of treatment. To provide additional longer term safety data, a sub-set of approximately 400 patients will remain on blinded study treatment for up to a total of 52 weeks.

The closed triple combination of FF/UMEC/VI is not approved for use anywhere in the world.

About COPD

Chronic obstructive pulmonary disease, or COPD, is a disease of the lungs that includes chronic bronchitis, emphysema or both. COPD is characterised by obstruction to airflow that interferes with normal breathing. COPD-related exacerbations are typically defined as a worsening of symptoms that require medical intervention.¹

Long-term exposure to lung irritants that damage the lungs and the airways are usually the cause of COPD¹. Cigarette smoke, breathing in second-hand smoke, air pollution, chemical fumes or dust from the environment or workplace can all contribute to COPD¹. Most people who have COPD are at least 40 years old when symptoms begin.

Despite improvements in the way COPD is managed it continues to pose a burden to patients and healthcare systems. The World Health Organisation estimates that currently 210 million people in the world have COPD and this number is increasing. It is estimated that over 20% of COPD patients are already prescribed triple combination therapy however no medication is currently available that combines all three components in one device.

About Relvar[®]/Breo[®] Ellipta[®] (fluticasone furoate + vilanterol)

Relvar/Breo Ellipta is a once-daily dual combination treatment comprising fluticasone furoate, an inhaled corticosteroid and vilanterol, a long-acting beta₂-agonist, in a single inhaler, the Ellipta[®]. Full US prescribing information, including BOXED WARNING and Medication Guide is available at us.gsk.com or [US Prescribing Information for Breo Ellipta](#).

About Anoro[®] Ellipta[®] (umeclidinium + vilanterol)

Anoro Ellipta is a once-daily combination treatment comprising two bronchodilators: umeclidinium, a long-acting muscarinic antagonist, and vilanterol, a long-acting beta₂ agonist, in a single inhaler, the Ellipta[®]. Full US prescribing information, including BOXED WARNING and Medication Guide is available at: http://us.gsk.com/products/assets/us_anoro_ellipta.pdf.

About Theravance

Theravance, Inc. is focused on maximizing the potential value of the respiratory assets partnered with Glaxo Group Limited (GSK), including RELVAR[®]/BREO[®] ELLIPTA[®] and ANORO[®] ELLIPTA[®], with the intention of providing capital returns to stockholders. Under the Long-Acting Beta2 Agonist (LABA) Collaboration Agreement with GSK, Theravance is eligible to receive the associated royalty revenues from RELVAR[®]/BREO[®] ELLIPTA[®] (fluticasone furoate/vilanterol, "FF/VI"), ANORO[®] ELLIPTA[®] (umeclidinium bromide/vilanterol, "UMEC/VI") and if approved and commercialized, VI monotherapy. Theravance is also entitled to a 15% economic interest in any future payments made by GSK under agreements entered into prior to the spin-off of Theravance Biopharma, and since assigned to Theravance Respiratory Company, LLC, relating to the combination of UMEC/VI/FF and the Bifunctional Muscarinic Antagonist-Beta2 Agonist (MABA) program, as monotherapy and in combination with other therapeutically active components, such as an inhaled corticosteroid, and any other product or combination of products that may be discovered and developed in the future under these agreements with GSK (other than RELVAR[®]/BREO[®] ELLIPTA[®], ANORO[®] ELLIPTA[®] and VI monotherapy). For more information, please visit Theravance's website at www.thrxinc.com.

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.

RELVAR[®], BREO[®], ANORO[®] and ELLIPTA[®] are trade marks of the GlaxoSmithKline group of companies. TURBOHALER[®] is a trade mark of AstraZeneca.

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. Such forward-looking statements involve substantial risks, uncertainties and assumptions. Examples of such statements include statements relating to: the strategies, plans and objectives of the company, the timing, manner, amount and planned growth of anticipated potential capital returns to stockholders (including without limitation statements, expectations of future cash dividends and the potential for 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 filed with the Securities and Exchange Commission (SEC) on November 4, 2014. 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.

References

¹ Global Initiative for Chronic Obstructive Lung Disease (GOLD). Pocket guide to COPD diagnosis, management and prevention

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Source: Theravance, Inc.

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