May 18, 2016

GSK Present New Data From Breo(R) Ellipta(R) SUMMIT Study in Patients With COPD at ATS Conference

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 05/18/16 -- GlaxoSmithKline (LSE: GSK) (NYSE: GSK) and Innoviva, Inc. (NASDAQ: INVA) today announced that GlaxoSmithKline plc (GSK) presented new data at the American Thoracic Society (ATS) Conference from two pre-specified analyses from the Study to Understand Mortality and MorbidITy (SUMMIT) trial. One demonstrated that patients with Chronic Obstructive Pulmonary Disease (COPD) and moderate airflow limitation receiving Breo® Ellipta® (fluticasone furoate/vilanterol or FF/VI 100/25mcg) achieved improvements in exacerbations compared with placebo. The second analysis demonstrated these patients reported similar rates of pneumonia when taking FF/VI 100/25mcg compared with placebo.

The SUMMIT trial was designed to evaluate the effect of FF/VI 100/25mcg once-daily on all-cause mortality compared with placebo in patients with moderate COPD who had, or were at high risk for Cardiovascular Disease (CVD). Results of the primary endpoint were announced in 2015 and showed that all cause mortality was not affected by combination therapy or the individual components.

The first analysis presented investigated the impact of FF/VI 100/25mcg, an inhaled corticosteroid/long-acting beta$_2$ agonist combination (ICS/LABA), on exacerbations in COPD patients with moderate airflow limitation (mean FEV$_1$ 60% predicted). In patients treated with FF/VI 100/25mcg the risk of a COPD exacerbation, measured by time to first exacerbation, was decreased by 20% (HR 0.80, 95% confidence interval 0.73 - 0.86) versus placebo. In addition, FF/VI 100/25mcg led to a 29% reduction in the rate of a moderate to severe exacerbation of COPD compared with placebo.

A second analysis of all reported pneumonia events amongst the 16,568 patients in the SUMMIT trial showed that rates were similar for patients randomised to FF/VI 100/25mcg compared with those on placebo. Reported pneumonia related adverse-events on FF/VI 100/25mcg were 6% compared with placebo 5%, reported pneumonia related serious adverse-events on FF/VI 100/25mcg were 3% compared with placebo 3%.

Dr Courtney Crim, Director Clinical Development, R&D Respiratory, GSK said: "We believe these data are important for COPD physicians and are clinically relevant. These findings from SUMMIT show that COPD patients with moderate airflow limitation experienced both a lower risk of having an exacerbation and fewer exacerbations when treated with FF/VI than patients on placebo. In the same patients with moderate airflow limitation we also saw a similar incidence of pneumonia in patients on FF/VI and those on placebo. In previous studies, in more severe patients, an increase in the incidence of pneumonias has been observed in ICS-containing treatment arms. The finding from this study is therefore interesting and will require further investigation."

These data were presented at the ATS 2016 Conference 13 - 18 May, San Francisco, US:

F.J. Martinez, et al. The impact of vilanterol, fluticasone furoate, or their combination on exacerbations in COPD patients with moderate airflow obstruction: the SUMMIT trial. D36-COPD: LABA, LAMA, ICS, AND COMBINATIONS, Thematic Poster Session. Wednesday, May 18, 2016. 9:00 AM-3:30 PM

C. Crim, et al. Reported Pneumonia Events in the SUMMIT trial. B44-COPD: COMORBIDITIES. Thematic Poster Session. Monday May 16, 2016. 9:00 AM-4:15 PM

About the SUMMIT Study
SUMMIT is an international, multi-centre, placebo-controlled, double blind, randomised, parallel group trial designed to determine the impact of FF/VI 100/25 (fluticasone furoate/vilanterol or FF/VI) on the survival of COPD patients with moderate airflow limitation and a history of or increased risk of cardiovascular disease (CVD).

COPD patients with moderate airflow limitation (≥50 and ≤70% predicted FEV$_1$) and a history or risk of CVD were randomised 1:1:1:1 to one of four double-blind treatment groups: FF/VI 100/25mcg, FF 100mcg, VI 25mcg or placebo. All treatments were administered once daily via the Ellipta dry powder inhaler.

The study showed a 12.2% reduction in the risk of dying from any cause for patients who were treated with FF/VI 100/25mcg when compared with those who received placebo (p=0.137). This did not achieve statistical significance.

The impact of vilanterol, fluticasone furoate, or their combination on exacerbations in COPD patients with moderate airflow obstruction and the reported pneumonia events in the SUMMIT trial, were pre-specified analyses. As the primary endpoint of the SUMMIT was not met, statistical significance cannot be inferred from the results of these newly-published analyses.

The study is listed on www.clinicaltrials.gov (NCT01313676).

About COPD and CVD

Chronic Obstructive Pulmonary Disease (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. Cigarette smoke, breathing in second-hand smoke, air pollution including biomass fuels, chemical fumes and dust from the environment or workplace can all contribute to COPD.

COPD mortality is increasing and is the third leading cause of death globally. COPD often coexists with other chronic diseases and epidemiological data suggests that CVD or CV risk occurs in nearly half of all patients with COPD. CVD is the number one killer of mild to moderate COPD patients and patients with both COPD and CVD or CV risk were observed to have a mortality rate double that of COPD patients without CVD in studies of up to 15 years in duration.

About FF/VI 100/25mcg

FF/VI 100/25mcg, under the brand name Breo® Ellipta® 100/25mcg is licensed in the US 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 and to reduce exacerbations of COPD in patients with a history of exacerbations. Breo® Ellipta® 100/25mcg is the only strength indicated for the treatment of COPD.
- Breo Ellipta100/25mcg is not indicated for the relief of acute bronchospasm.

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

FF/VI 100/25mcg, under the brand name Relvar® Ellipta® is approved in Europe 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.

For the EU Summary of Product Characteristics for Relvar Ellipta, please visit:
http://ec.europa.eu/health/documents/community-register/html/h886.htm

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.

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.

About Innoviva - Innoviva 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. Innoviva'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 Innoviva and GSK. Under the agreement with GSK, Innoviva is eligible to receive associated royalty revenues from RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and, if approved and commercialized, VI monotherapy, as well. In addition, Innoviva retains a 15 percent economic interest in future payments made by GSK for earlier-stage programs partnered with Theravance BioPharma, Inc. For more information, please visit Innoviva's website at www.inva.com. RELVAR®, BREO®, ANORO® and ELLIPTA® are trademarks of the GlaxoSmithKline group of companies.

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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 2015.

Innoviva 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. Innoviva 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: prescription and market share trends, payor coverage, 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 share repurchases or cash dividends), 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 products, and projections of revenue, expenses and other financial items. These statements are based on the current estimates and assumptions of the management of Innoviva 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 Innoviva 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: 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 Innoviva are described under the headings "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in Innoviva's Annual Report on Form 10-K for the year ended December 31, 2015 and Innoviva's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, 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 Innoviva's other filings with the SEC, other unknown or unpredictable factors also could affect Innoviva's results. Past performance is not necessarily indicative of future 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. Innoviva assumes no obligation to update its forward-looking statements on account of new information, future events or otherwise, except as required by law. (INVA-G)

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