

GSK Files Regulatory Submission in European Union for Once-Daily Closed Triple Combination Therapy FF/UMEC/VI for Patients with COPD

LONDON & BRISBANE, Calif.--(BUSINESS WIRE)-- GlaxoSmithKline plc (LSE/NYSE: GSK) and Innoviva, Inc. (NASDAQ: INVA) today announced the filing by GSK of a regulatory submission with the European Medicines Agency for once-daily, closed triple combination therapy fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI 100/62.5/25 mcg) for patients with chronic obstructive pulmonary disease (COPD). This follows the announcement of the submission of a New Drug Application for FF/UMEC/VI in the US in November 2016.

Closed triple combination therapy comprises three medicines: fluticasone furoate, an inhaled corticosteroid (ICS), umeclidinium, a long-acting muscarinic antagonist (LAMA) and vilanterol, a long-acting beta₂-adrenergic agonist (LABA), delivered once-daily in GSK's Ellipta[®] dry powder inhaler.

The EU regulatory submission of closed triple therapy comprises a Marketing Authorisation Application for a maintenance treatment to relieve symptoms of adult patients with COPD. It is based on data from the closed triple combination therapy development programme including [data from the phase III FULFIL study](#), as well as data from studies with FF, UMEC and VI either alone or in combination.

Dave Allen, Head, Respiratory Therapy Area Unit, R&D, said, "Many patients with COPD are already at an advanced stage when they are diagnosed. Prescribing patterns show the importance of having a range of options available to meet the differing needs of individual patients. An approval of our closed triple therapy in Europe would complement our portfolio of inhaled therapies designed for once-daily dosing in a single inhaler, offering patients a convenient, alternative option."

Mike Aguiar, CEO of Innoviva, Inc., added, "The EU filing of the closed triple combination is the latest development in our long-standing collaboration with GSK. If approved, FF/UMEC/VI as once daily triple combination in a single inhaler could be a meaningful addition to the treatment options available for advanced COPD patients."

Regulatory submissions of closed triple therapy for COPD are anticipated in the rest of the world beginning in 2017. The closed triple combination of FF/UMEC/VI is not approved for use anywhere in the world.

About COPD

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 is thought to affect 329 million people worldwide.

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

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., including the closed triple combination therapy for COPD. For more information, please visit Innoviva's website at www.inva.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.

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GSK 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, including the development, regulatory and commercial plans for closed triple combination therapy and the potential benefits and mechanisms of action of closed triple combination therapy. 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. 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 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 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. 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. The information in this press release is provided only as of the date hereof, and 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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