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GSK Starts Phase III Study of Once-Daily Closed Triple Combination Therapy FF/UMEC/VI in Patients with Asthma

LONDON & BRISBANE, Calif.--(BUSINESS WIRE)-- GlaxoSmithKline plc (LSE/NYSE: GSK) and Innoviva, Inc. (NASDAQ: INVA) today announced the start of a phase III study investigating the effects of once-daily closed triple combination therapy fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI) when compared to therapy with the once-daily dual combination therapy, Relvar/Breo® (FF/VI), as a treatment for patients with asthma.

The 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 beta$_2$-adrenergic agonist (LABA), delivered once-daily in GSK's Ellipta® dry powder inhaler.

In the phase III study, termed CAPTAIN (Clinical study of Asthma Patients receiving Triple therapy through A single INhaler), the primary endpoint is the change from baseline in trough Forced Expiratory volume in 1 second (FEV_1) at 24 weeks of treatment and the key secondary endpoint is the annualized rate of moderate/severe asthma exacerbations. Other secondary endpoints are assessing health-related quality of life and symptom control.

Dave Allen, Head of Respiratory R&D at GSK, said, "Despite the availability of treatments, many patients have asthma that is inadequately controlled. While some patients already receive triple therapy in two or more inhalers, we believe there will be real benefits from delivering the dual bronchodilators together with their inhaled steroid once a day in a single inhalation."

Mike Aguiar, CEO of Innoviva, Inc., added, "Closed triple therapy may provide a new once-a-day treatment option for asthma patients not adequately controlled by existing therapy. If successful, this would further expand the portfolio of respiratory therapy products delivered via the Ellipta inhaler for the treatment of asthma and COPD."

About the phase III study

CAPTAIN (**C**linical study of **A**sthma **P**atients receiving **T**riple therapy through **A** single **IN**haler) is a superiority study to demonstrate the add-on benefit of UMEC at two dosage strengths of 62.5 mcg and 31.25 mcg in a single inhaler when compared to FF/VI. It is a randomized, double-blind, active controlled, six-arm parallel group, global multicenter study evaluating FF/UMEC/VI (100/31.25/25, 100/62.5/25, 200/31.25/25 and 200/62.5/25 micrograms) versus FF/VI (100/25 and 200/25 micrograms) given once daily in the morning to patients whose asthma is inadequately controlled despite treatment with maintenance asthma medication. The study aims to randomize 2,250 patients, with 375 patients randomly assigned to each of the six treatment arms.

About asthma

Asthma is a chronic lung disease that inflames and narrows the airways. Asthma affects 242 million people worldwide. Despite medical advances, more than half of patients continue to experience poor control and significant symptoms.

The causes of asthma are not completely understood but likely involve an interaction between a person's genetic make-up and the environment. Key risk factors are inhaled substances that provoke allergic reactions or irritate the airways.

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 beta$_2$-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, EU Prescribing Information for Relvar Ellipta.

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®. 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.

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).

Registered in England & Wales:
No. 3888792

Registered Office:
980 Great West Road
Brentford, Middlesex
TW8 9GS

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GSK enquiries:
UK Media enquiries:
Simon Steel, +44 (0) 20 8047 5502 (London)
David Daley, +44 (0) 20 8047 5502 (London)
Sarah Macleod, +44 (0) 20 8047 5502 (London)
or
US Media enquiries:
Sarah Alspach, +1-202-715-1048 (Washington, DC)

Sarah Spencer, +1-215-751-3335 (Philadelphia)
Karen Hagens, +1-919-483-2863 (North Carolina)
or
Analyst/Investor enquiries:
Tom Curry, + 1-215-751-5419 (Philadelphia)
Gary Davies, +44 (0) 20 8047 5503 (London)
James Dodwell, +44 (0) 20 8047 2406 (London)
Jeff McLaughlin, +1-215-751-7002 (Philadelphia)
or
Innoviva, Inc. enquiries:
Investor Relations:
Eric d'Esparbes, +1-650-238-9605 (Brisbane, Calif.)
investor.relations@inva.com

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