

July 16, 2014

## **GSK and Theravance Announce Initiation of Phase III Programme With Fixed Dose Triple Combination Treatment FF/UMEC/VI in Patients With COPD**

LONDON, UNITED KINGDOM and SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 07/16/14 -- GlaxoSmithKline plc (LSE: GSK) (NYSE: GSK) and Theravance, Inc. (NASDAQ: THRX) today announced the start of a global phase III study, known as IMPACT, to evaluate the efficacy and safety of the 'closed' triple combination of FF/UMEC/VI in patients with chronic obstructive pulmonary disease (COPD). IMPACT is the first pivotal phase III study in a programme to evaluate a once-daily closed triple combination treatment of an inhaled corticosteroid (ICS); a long-acting muscarinic antagonist (LAMA); and a long-acting beta<sub>2</sub>-adrenergic agonist (LABA) in patients with COPD.

The IMPACT study will enrol approximately 10,000 patients and assess whether the combination of FF (fluticasone furoate, an ICS), UMEC (umeclidinium, a LAMA) and VI (vilanterol, a LABA), all delivered in GSK's Ellipta inhaler, can reduce the annual rate of moderate and severe exacerbations compared with two approved once daily COPD treatments, Relvar/Breo Ellipta (FF/VI), which is an ICS/LABA combination, and Anoro Ellipta (UMEC/VI), which is a LAMA/LABA combination.

Dave Allen, Head, GSK Respiratory Therapy Area Unit, R&D, said: "When developing our respiratory portfolio we recognised the need to offer a range of molecules that could be co-formulated in different combinations to meet the needs of individual patients. We know from the scientific literature and prescribing data that there are already COPD patients who receive three medicines in different inhalers, for whom a once-daily treatment in a single 'closed' device could be valuable. The IMPACT study will be important in advancing our understanding of how the combination of FF/UMEC/VI could be used in this setting when compared to dual combination therapy options."

Rick E Winningham, Chief Executive Officer of Theravance, said: "The start of the IMPACT study marks a significant milestone in our development programme with GSK and we are excited about the potential opportunity for a triple combination treatment approach. This phase III programme has the potential to demonstrate the safety and efficacy profile of a new and important therapy that could deliver additional benefits and convenience to the growing number of adults living with COPD worldwide."

### **About the IMPACT study**

**IMPACT** (InforMing the PAtHway of COPD Treatment) is a double-blind, three-arm, parallel group study enrolling a total of 10,000 patients across 38 countries. Eligible patients will be randomised to receive either FF/UMEC/VI 100/62.5/25mcg, FF/VI 100/25mcg or UMEC/VI 62.5/25mcg once-daily for a period of 52 weeks.

The co-primary endpoints of the study are: the annual rate of moderate and severe exacerbations comparing FF/UMEC/VI with FF/VI; and the annual rate of moderate and severe exacerbations comparing FF/UMEC/VI with UMEC/VI. Key secondary endpoints include baseline changes in lung function (trough FEV<sub>1</sub>) comparing FF/UMEC/VI and FF/VI; time to first moderate or severe exacerbation in all three arms of the study; and the annual rate of severe exacerbations in all three arms of the study.

### **About COPD**

Chronic obstructive pulmonary disease 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.

Long-term exposure to lung irritants that damage the lungs and the airways are usually the cause of COPD<sup>1</sup>. Cigarette smoke, breathing in second-hand smoke, air pollution, chemical fumes or dust from the environment or workplace can all contribute to COPD<sup>1</sup>. Most people who have COPD are at least 40 years old when symptoms begin.

### **About Relvar<sup>®</sup>/Breo<sup>®</sup> Ellipta<sup>®</sup> (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<sub>2</sub>-agonist, in a single inhaler, the Ellipta<sup>®</sup>. Full US prescribing information, including BOXED WARNING and Medication Guide is available at [us.gsk.com](http://us.gsk.com) or [US Prescribing Information for Breo Ellipta](#).

### **About Anoro<sup>®</sup> Ellipta<sup>®</sup> (umeclidinium + vilanterol)**

Anoro Ellipta is a once-daily combination treatment comprising two bronchodilators: umeclidinium, a long-acting muscarinic

antagonist, and vilanterol, a long-acting beta<sub>2</sub> agonist, in a single inhaler, the Ellipta<sup>®</sup>. Full US prescribing information, including BOXED WARNING and Medication Guide is available at: [http://us.gsk.com/products/assets/us\\_anoro\\_ellipta.pdf](http://us.gsk.com/products/assets/us_anoro_ellipta.pdf).

RELVAR<sup>®</sup>, BREO<sup>®</sup>, ANORO<sup>®</sup> and ELLIPTA<sup>®</sup> are trademarks of the GlaxoSmithKline group of companies.

**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](http://www.gsk.com).

**Theravance, Inc., A Royalty Management Company** -- is focused on maximizing the potential value of the respiratory assets partnered with Glaxo Group Limited (GSK), including RELVAR<sup>®</sup>/BREO<sup>®</sup> ELLIPTA<sup>®</sup> and ANORO<sup>®</sup> ELLIPTA<sup>®</sup>, with the intention of providing capital returns to stockholders. Under the Long-Acting Beta<sub>2</sub> Agonist (LABA) Collaboration Agreement with GSK, Theravance is eligible to receive the associated royalty revenues from RELVAR<sup>®</sup>/BREO<sup>®</sup> ELLIPTA<sup>®</sup> (fluticasone furoate/vilanterol, "FF/VI"), ANORO<sup>®</sup> ELLIPTA<sup>®</sup> (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 relating to the combination of UMEC/VI/FF and the Bifunctional Muscarinic Antagonist-Beta<sub>2</sub> 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 its LABA Collaboration Agreement with GSK (other than RELVAR<sup>®</sup>/BREO<sup>®</sup> ELLIPTA<sup>®</sup>, ANORO<sup>®</sup> ELLIPTA<sup>®</sup> and VI monotherapy). For more information, please visit Theravance's web site at [www.thrxinc.com](http://www.thrxinc.com).

## References

<sup>1</sup> The Global Initiative for Chronic Obstructive Lung Disease. Pocket guide to COPD diagnosis, management and prevention.

### **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. Examples of such statements include statements relating to: the strategies, plans and objectives of the company following the separation, the timing, manner, amount and planned growth of anticipated potential capital returns to stockholders (including without limitation statements concerning the intention to initiate a cash dividend in the third quarter of 2014, expectations of future cash dividend growth 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: 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 heading "Risk Factors" contained in Theravance's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 7, 2014 and the risks discussed in Theravance's other periodic filings with the 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)

### **GSK enquiries:**

UK Media enquiries:  
David Mawdsley

+44 (0) 20 8047 5502  
(London)

Simon Steel  
+44 (0) 20 8047 5502  
(London)

David Daley  
+44 (0) 20 8047 5502  
(London)

Catherine Hartley  
+44 (0) 20 8047 5502  
(London)

Sarah Spencer  
+44 (0) 20 8047 5502  
(London)

US Media enquiries:  
Melinda Stubbee  
+1 919 483 2510  
(North Carolina)

Robin Gaitens  
+1 919 483 2678  
(North Carolina)

Juan Carlos Molina  
+1 919 483 0471  
(North Carolina)

Bradd Pavur  
+1 919 483 0044  
(North Carolina)

Karen Collins  
+1 919 483 2527  
(North Carolina)

Analyst/Investor enquiries:  
Ziba Shamsi  
+44 (0) 20 8047 5543  
(London)

Kirsty Collins (SRI & CG)  
+44 (0) 20 8047 5534  
(London)

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)

Lucy Singah

+44 (0) 20 8047 2248  
(London)

***Theravance, Inc. enquiries:***

Investor Relations

Michael W. Aguiar

+1 650 238 9640

(S. San Francisco)

[investor.relations@thrxinc.com](mailto:investor.relations@thrxinc.com)

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