THERAVANCE, INC.
A ROYALTY MANAGEMENT COMPANY

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Anoro(R) (Umeclidinium/Vilanterol) Gains Marketing Authorisation in Europe for the Treatment of COPD

LONDON, UNITED KINGDOM and SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 05/08/14 -- GlaxoSmithKline plc (LSE: GSK) (NYSE: GSK) and Theravance, Inc. (NASDAQ: THRX) today announced that the European Commission has granted marketing authorisation for Anoro® (umeclidinium/vilanterol) as a once-daily, maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).

Anoro is a once-daily combination treatment comprising two bronchodilators, umeclidinium (UMEC), a long-acting muscarinic antagonist (LAMA), and vilanterol (VI), a long-acting beta$_2$ agonist (LABA), in a single inhaler, the Ellipta®. The licensed strength in Europe is UMEC/VI 55mcg / 22mcg.

Darrell Baker, SVP & Head, GSK Global Respiratory Franchise, said, "There are many people across Europe living with COPD who experience a variety of symptoms and for whom the disease represents a significant burden. GSK is committed to developing a range of new therapeutic options that provide physicians with treatment choices when considering individual patient needs. We are delighted by today's marketing authorisation for Anoro Ellipta which provides a new alternative for COPD patients for whom dual bronchodilator treatment in a single inhaler may be appropriate."

"We are very pleased that Anoro Ellipta is now licensed across 31 European countries for the treatment of COPD," said Rick E Winningham, Chief Executive Officer of Theravance. "We believe this will be an important treatment option for appropriate patients with COPD and is a further positive outcome from the collaboration between Theravance and GSK to bring to market new respiratory medicines that meet patient needs."

Under the terms of the 2002 LABA collaboration agreement, Theravance is obligated to make a milestone payment to GSK of $15 million (USD) following marketing authorisation for UMEC/VI by the European Commission. A further $15 million (USD) payment to GSK will follow the launch of UMEC/VI in Europe.

The first launch is expected to take place in Europe in Q2-3 2014 with additional launches to follow thereafter.

The EMA assessment of UMEC/VI included a review of eight phase III clinical trials which included over 6,000 COPD patients. Within this, 1,296 patients received the recommended dose of UMEC/VI 55/22mcg once-daily.

For the EU Summary of Product Characteristics for Anoro, please visit: http://ec.europa.eu/health/documents/community-register/index_en.htm. Prior to the prescribing information being posted online, a copy may be requested from one of the GSK Media or Investor Relations contacts listed in the "GSK Enquiries" section at the end of this document.

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 4-10% of the adult population in Europe.[i]

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.[ii]

Important Safety Information for Anoro

The following Important Safety Information is based on a summary of the Summary of Product Characteristics for Anoro. Please consult the full Summary of Product Characteristics for all the safety information for Anoro.

UMEC/VI is contraindicated in patients with hypersensitivity to either umeclidinium, vilanterol, or any of the excipients.

UMEC/VI should not be used in patients with asthma since it has not been studied in this patient population. Administration of UMEC/VI may produce paradoxical bronchospasm that may be life-threatening. UMEC/VI is not indicated for the treatment of acute episodes of bronchospasm.

In the event of deterioration of COPD during treatment with UMEC/VI, a re-evaluation of the patient and of the COPD treatment regimen should be undertaken.

Cardiovascular effects, such as cardiac arrhythmias e.g. atrial fibrillation and tachycardia, may be seen after the administration of muscarinic receptor antagonists and sympathomimetics, including UMEC/VI. Patients with clinically significant uncontrolled cardiovascular disease were excluded from clinical studies. Therefore, UMEC/VI should be used with caution in patients with severe cardiovascular disease.

Consistent with its antimuscarinic activity, UMEC/VI should be used with caution in patients with urinary retention or with narrow-angle glaucoma.

Beta$_2$-adrenergic agonists may produce significant hypokalaemia in some patients, which has the potential to produce adverse cardiovascular effects. The decrease in serum potassium is usually transient, not requiring supplementation. No clinically relevant effects of hypokalaemia were observed in clinical studies with UMEC/VI at the recommended therapeutic dose of 55mcg/22mcg. Caution should be exercised when UMEC/VI is used with other medicinal products that also have the potential to cause hypokalaemia.

Beta$_2$-adrenergic agonists may produce transient hyperglycemia in some patients. No clinically relevant effects on plasma glucose were observed in clinical studies with UMEC/VI at the recommended therapeutic dose of 55mcg/22mcg. Upon initiation of treatment with UMEC/VI, plasma glucose should be monitored more closely in diabetic patients.

UMEC/VI should be used with caution in patients with convulsive disorders or thyrotoxicosis and in patients who are unusually responsive to beta$_2$-adrenergic agonists.

This medicinal product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take UMEC/VI.

The most frequently reported adverse reaction with UMEC/VI was nasopharyngitis (9%). Other common adverse reactions (reported with a frequency of ≥1/100 to < 1/10) include: urinary tract infection, sinusitis, pharyngitis, upper respiratory tract infection, headache, cough, oropharyngeal pain, constipation and dry mouth.

Other Anoro Ellipta Regulatory Activity:
Since December 2013, Anoro Ellipta has been licensed for use in appropriate patients with COPD in several countries, including the US and Canada. In the US, Anoro Ellipta is indicated 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. Anoro Ellipta is not
indicated for the relief of acute bronchospasm or for the treatment of asthma. Full US prescribing information, including BOXED WARNING and Medication Guide are available at: http://us.gsk.com/products/assets/us_anoro_ellipta.pdf.

In Europe, the UMEC/VI strength of 55mcg / 22mcg is specified as the delivered dose (emitted from the inhaler) which is equivalent to the 62.5mcg / 25mcg pre-dispensed dose (contained inside the inhaler) authorised in the US and Canada.

Regulatory applications for UMEC/VI have been submitted and are undergoing assessment in a number of other countries, including Japan.

Anoro® and Ellipta® are trademarks of the GSK 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.

Theravance - is a biopharmaceutical company with a pipeline of internally discovered product candidates and strategic collaborations with pharmaceutical companies. Theravance is focused on the discovery, development and commercialization of small molecule medicines across a number of therapeutic areas including respiratory disease, bacterial infections, and central nervous system (CNS)/pain. Theravance's key programs include: RELVAR®/BREO® ELLIPTA® (FF/VI), ANORO® ELLIPTA ® (UMEC/VI) and MABA (Bifunctional Muscarinic Antagonist-Beta$_2$ Agonist) GSK961081, each partnered with GlaxoSmithKline plc (GSK), and its Long-Acting Muscarinic Antagonist program. By leveraging its proprietary insight of multivalency to drug discovery, Theravance is pursuing a best-in-class strategy designed to discover superior medicines in areas of significant unmet medical need. For more information, please visit Theravance's web site at www.theravance.com.

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 status and timing of clinical studies, data analysis and communication of results, statements regarding the potential benefits and mechanisms of action of drug candidates, statements concerning the timing of seeking regulatory approval of our product candidates, statements concerning the enabling capabilities of Theravance's approach to drug discovery and its proprietary insights and statements concerning expectations for product candidates through development and commercialization 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 its 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 of clinical or non-clinical studies indicate product candidates are unsafe or ineffective, our dependence on third parties in the conduct of our clinical studies, delays or failure to achieve regulatory approvals for product candidates, risks of relying on third-party manufacturers for the supply of our product and product candidates and risks of collaborating with third parties to develop and commercialize products. These and other risks are described in greater detail 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 our 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)

References

[i] European COPD Coalition. COPD Key Facts. Accessed March 2014. Available at: http://www.copdcoalition.eu/about-copd/key-facts

[ii] National Heart Lung and Blood Institute. Who is at risk for COPD? Accessed March 2014. Available at: https://www.nhlbi.nih.gov/health/health-topics/topics/copd/atrisk.html

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
+1 650 808 4100
(San Francisco)
investor.relations@theravance.com

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