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Anoro(R) Ellipta(R) (Umeclidinium/Vilanterol) Gains Approval in Japan for the Treatment of COPD

LONDON, UNITED KINGDOM and SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 07/07/14 -- GlaxoSmithKline plc (LSE: GSK) (NYSE: GSK) and Theravance, Inc. (NASDAQ: THRX) today announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) has approved Anoro[®] Ellipta[®] (umeclidinium/vilanterol) for the relief of various symptoms due to airway obstruction with chronic obstructive pulmonary diseases (chronic bronchitis, pulmonary emphysema) (in the case where concurrent use of long-acting inhaled muscarinic antagonist and long-acting inhaled beta₂ agonist is required).

Anoro is a once-daily combination treatment comprised of two bronchodilators, umeclidinium (UMEC), a long-acting muscarinic antagonist (LAMA), and vilanterol (VI), a long-acting beta₂ agonist (LABA), in a single inhaler, the Ellipta. The approved dose in Japan is UMEC/VI 62.5/25mcg delivered once daily.

Darrell Baker, SVP & Head, GSK Global Respiratory Franchise, said, "There are many people living with COPD in Japan whose ability to breathe is compromised by their condition. Our goal at GSK is to provide physicians with an expanded range of COPD medicines which enable a patient-centric approach to treatment, as recommended by global guidelines. We are delighted that Anoro Ellipta is now approved in Japan, making it the first GSK COPD treatment to gain Japanese regulatory approval in five years, and we believe it will be an important new once-daily dual bronchodilator treatment option for appropriate COPD patients."

"We are very pleased with this latest regulatory approval for Anoro Ellipta," said Rick E Winningham, Chief Executive Officer of Theravance. "This milestone is a further demonstration of the ongoing successful Theravance and GSK collaboration in respiratory medicine and we are looking forward to being able to make this new medicine available for appropriate COPD patients in Japan."

Under the terms of the 2002 LABA collaboration agreement, Theravance is obligated to make a milestone payment of \$10 million (USD) to GSK following MHLW approval of UMEC/VI in Japan.

Following this approval, it is expected that launch will take place in Japan in Q3 2014.

The MHLW assessment of UMEC/VI involved a review of eight phase III clinical trials, evaluating approximately 6,000 COPD patients worldwide, including a specific 52 week, open-label, long-term safety study in Japanese patients.

Japanese Drug Information will be available soon at <http://glaxosmithkline.co.jp/healthcare/>. Prior to the label being posted online, a copy of the label may be requested from one of the GSK Media or Investor Relations contacts listed in the "GlaxoSmithKline Enquiries" section at the end of this document.

About Chronic Obstructive Pulmonary Disease (COPD)

COPD is a disease of the lungs that includes chronic bronchitis, emphysema or both. It is characterised by obstruction to airflow that interferes with normal breathing. COPD is thought to affect approximately 8.6% of the population aged over 40 in Japan.¹

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.²

Important Safety Information for Anoro Ellipta

The following Important Safety Information (ISI) is based on a summary of the Japanese Drug Information for Anoro Ellipta. Please consult the full Drug Information for all the labeled safety information for Anoro Ellipta.

Anoro Ellipta is contraindicated in patients with narrow-angle glaucoma, impaired urination or a history of hypersensitivity to any component of Anoro Ellipta.

Anoro Ellipta should be administered with care in patients with hyperthyroidism, cardiac disease, hypertension, diabetes

mellitus or prostatic hyperplasia.

Anoro Ellipta is not intended to treat bronchial asthma, and therefore should not be used as such. If Anoro Ellipta is used in patients with COPD complicated with bronchial asthma, care should be taken to ensure that bronchial asthma is sufficiently managed.

Anoro Ellipta is not intended to treat an acute exacerbation of COPD. In patients who do not respond to Anoro Ellipta even when it is given in accordance with the recommended dosage and administration, Anoro Ellipta should be discontinued.

Anoro Ellipta can produce paradoxical bronchospasm, which may be life threatening. If paradoxical bronchospasm occurs Anoro Ellipta should be discontinued immediately and alternative therapy should be instituted.

When excessive use of Anoro Ellipta is continued, arrhythmia, and cardiac arrest in some cases, may occur. Patients should be instructed not to use more than the recommended dose of Anoro Ellipta.

In two global phase III clinical studies, adverse reactions including laboratory abnormalities were reported in 61 (7.5%) of a total of 816 patients (including 39 Japanese patients) treated with Anoro Ellipta or UMEC/VI 125/25mcg*. The most common adverse reactions were headache reported in 7 patients (0.9%), dry mouth in 7 patients (0.9%), cough in 6 patients (0.7%) and taste disorder in 5 patients (0.6%).

In a Japanese 52 week long-term administration study, adverse reactions including laboratory abnormalities were reported in 8 (6.0%) of a total of 130 patients treated with UMEC/VI 125/25mcg*. The most common adverse reaction was hypertension reported in 2 patients (1.5%).

* The approved dose of Anoro Ellipta in Japan is UMEC/VI 62.5/25mcg once daily.

Atrial fibrillation may occur. If any abnormality is observed, treatment should be discontinued and appropriate measures should be taken.

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, Inc., A Royalty Management Company -- is focused on maximizing the potential value of the respiratory assets partnered with Glaxo Group Limited (GSK), including RELVAR[®]/BREO[®] ELLIPTA[®] and ANORO[™] ELLIPTA[®] with the intention of providing capital returns to stockholders. Under the Long-Acting Beta₂ Agonist (LABA) Collaboration Agreement with GSK,

Theravance is eligible to receive the associated royalty revenues from RELVAR[®]/BREO[®] ELLIPTA[®] (fluticasone furoate/vilanterol, "FF/VI"), ANORO[™] ELLIPTA[®] (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-Beta₂ 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[®]/BREO[®] ELLIPTA[®], ANORO[™] ELLIPTA[®] and VI monotherapy). For more information, please visit Theravance's web site at www.thrxinc.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 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: 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 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)

¹ Fukuchi Y. 2004. COPD in Japan: the Nippon COPD Epidemiology study. *Respirology*. 2004 Nov;9(4):458-65.

² 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>

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