THERAVANCE, INC.
A ROYALTY MANAGEMENT COMPANY

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GSK Presents Post-Hoc Analysis of Anoro(R) Ellipta(R) Data Assessing Markers of COPD Deterioration Compared to Tiotropium or Placebo Using a Novel Composite Endpoint

LONDON, UNITED KINGDOM -- (Marketwired) -- 09/27/15 -- GlaxoSmithKline plc (GSK) and Theravance, Inc. (NASDAQ: THRX) today announced data presented by GSK at the European Respiratory Society (ERS) International Congress (poster PA1001), from an exploratory post-hoc analysis of phase III data, which showed that patients with moderate-to-severe chronic obstructive pulmonary disease (COPD) who received Anoro® Ellipta® (UMEC/VI 62.5/25mcg) had a reduced risk of experiencing a clinically important deterioration compared to tiotropium 18mcg or placebo over a 12-week treatment period.

This post-hoc analysis used a novel, composite endpoint, defined as a clinically important deterioration, to assess the effect of treatment on a number of factors that are each believed to represent a worsening of a patient's COPD. The analysis examined the time to a first clinically important deterioration which was determined by the occurrence of any of the following events: A decrease in lung function of ≥100 ml from baseline as measured by trough FEV_1; a deterioration in health-related quality of life defined as ≥4 unit increase from baseline in St George's Respiratory Questionnaire (SGRQ) total score; or the occurrence of an on-treatment moderate-to-severe COPD exacerbation.

The results of the analysis showed that the risk of experiencing a clinically important deterioration was significantly lower for patients on UMEC/VI 62.5/25mcg once daily compared to tiotropium 18mcg once daily (hazard ratio: 0.62; 95% confidence interval [CI]: 0.54, 0.71; $p < 0.001$) or placebo (hazard ratio: 0.37; 95% CI: 0.30, 0.45; $p < 0.001$) in an intention to treat population, based on analysis of time to first deterioration.

Eric Dube, Senior Vice President and Head, Global Respiratory Franchise at GSK, said: "Most studies are designed to show whether COPD medicines improve outcomes however, there are currently limited data to assess whether they also prevent a worsening, or deterioration, in a patient's condition which is a key part of the management of COPD. Helping physicians understand the relevance of our medicines as they make decisions in the treatment of COPD is important therefore we performed this post-hoc analysis to explore the potential impact of Anoro on disease deterioration. This is a new area of research and we will be conducting prospective studies to further evaluate these findings in the future."

Michael W. Aguiar, President and Chief Executive Officer of Theravance, Inc., said: "We already have a substantial amount of evidence which demonstrates the efficacy and safety of Anoro across a number of individual endpoints. However, this is a novel concept which evaluates time to a first clinically important deterioration, and may in the future help our understanding of the factors which drive clinical stability in COPD, once more evidence accumulates on this concept."

Study design

The findings are from a post-hoc analysis of data from four multicentre, randomised, blinded, parallel-group, 24-week trials: three comparing once-daily inhaled UMEC/VI 62.5/25mcg delivered in the Ellipta® inhaler, versus tiotropium 18mcg once daily delivered in the HandiHaler® inhaler (ZEP117115; DB2113360; DB2113374; data pooled into a single analysis) and one comparing once-daily inhaled UMEC/VI 62.5/25mcg to placebo (DB2113373).

These four studies (ZEP117115; DB2113360; DB2113374; DB2113373) also included additional treatment arms however, these data were not included in the poster presented at ERS 2015. Complete details of each of the study arms and the full results of these studies have been previously announced and are available on the GSK Clinical Study Register.

In the pooled analysis of ZEP117115, DB2113374 and DB2113360 trials, the intention to treat population (randomised and receiving at least one dose of study medication) comprised of 2,597 patients, 1,747 patients received either UMEC/VI 62.5/25mcg or tiotropium 18mcg. In the analysis of the DB2113373 study, the intention to treat population comprised of 1,532 patients, 693 patients received either UMEC/VI 62.5/25mcg or placebo.

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 around 329 million people worldwide.[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]

About Anoro Ellipta
Anoro Ellipta is a combination long-acting muscarinic antagonist (LAMA) (also known as an anticholinergic) / long-acting $beta_2$-adrenergic agonist (LABA). In the US, Anoro Ellipta is indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. Anoro Ellipta is not indicated for the relief of acute bronchospasm or for the treatment of asthma. The FDA-approved strength is umeclidinium/vilanterol 62.5/25mcg.

Full US prescribing information, including BOXED WARNING and Medication Guide are available at: https://www.gsksource.com/gskprm/htdocs/documents/ANORO-ELLIPTA-PI-MG.PDF.

In Europe, Anoro is indicated as a once-daily, maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). The approved strength in Europe is UMEC/VI 55mcg/22 mcg (delivered dose, equivalent to 62.5mcg/25mcg pre-dispensed dose).

For the EU Summary of Product Characteristics (SmPC), please visit: http://www.medicines.org.uk/emc/medicine/28949/SPC/Anoro+Ellipta+55+micrograms+22+micrograms+inhalation+powder%2c+pre-dispensed/

Important Safety Information for Anoro Ellipta
The following Important Safety Information (ISI) is based on the Highlights section of the US Prescribing Information for Anoro Ellipta. Please consult the full Prescribing Information for all the labelled safety information for Anoro Ellipta.

Long-acting $beta_2$-adrenergic agonists (LABAs), such as vilanterol, one of the active ingredients in Anoro Ellipta, increase the risk of asthma-related death. A placebo-controlled trial with another LABA (salmeterol) showed an increase in asthma-related deaths in subjects receiving salmeterol. This finding with salmeterol is considered a class effect of all LABAs, including vilanterol. The safety and efficacy of Anoro Ellipta in patients with asthma have not been established. Anoro Ellipta is not indicated for the treatment of asthma.

Anoro Ellipta is contraindicated in patients with severe hypersensitivity to milk proteins or who have demonstrated hypersensitivity to either umeclidinium, vilanterol, or any of the other ingredients.

Anoro Ellipta should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of COPD, or as rescue therapy for the treatment of acute episodes of bronchospasm, which should be treated with an inhaled, short-acting $beta_2$-agonist.

Anoro Ellipta should not be used more often than recommended, at higher doses than recommended, or in conjunction with additional medicine containing a LABA, as an overdose may result.

Anoro Ellipta should be used with caution when considering coadministration with long-term ketoconazole and other known strong cytochrome P450 3A4 inhibitors because increased cardiovascular adverse effects may occur.

Anoro Ellipta can produce paradoxical bronchospasm, which may be life-threatening.

Anoro Ellipta should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

Anoro Ellipta should be used with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, ketoacidosis, and in patients who are unusually responsive to sympathomimetic amines.

Anoro Ellipta should be used with caution in patients with narrow-angle glaucoma. Instruct patients to contact a physician immediately should any signs or symptoms of narrow-angle glaucoma occur.

Anoro Ellipta should be used with caution in patients with urinary retention, especially in patients with prostatic hyperplasia or bladder neck obstruction. Instruct patients to contact a physician immediately should any signs or symptoms of urinary retention occur.

Beta-adrenergic agonist medicines may produce significant hypokalemia and transient hyperglycemia in some patients.

The most common adverse reactions (incidence ≥1% and more common than placebo) reported in four 6-month clinical trials

with Anoro Ellipta (and placebo) were pharyngitis, 2% (< 1 %); sinusitis 1% (< 1%); lower respiratory tract infection, 1% (< 1%); constipation, 1% (< 1%); diarrhea, 2% (1%); pain in extremity 2% (1%); muscle spasms, 1% (< 1%); neck pain, 1% (< 1%); and chest pain 1% (< 1%). In addition to the 6-month efficacy trials with Anoro Ellipta, a 12-month trial evaluated the safety of umeclidinium/vilanterol 125 mcg/25 mcg in subjects with COPD. Adverse reactions (incidence ≥1% and more common than placebo) in subjects receiving umeclidinium/vilanterol 125 mcg/25 mcg were: headache, back pain, sinusitis, cough, urinary tract infection, arthralgia, nausea, vertigo, abdominal pain, pleuritic pain, viral respiratory tract infection, toothache, and diabetes mellitus.

Beta$_2$-agonists, such as vilanterol should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or drugs known to prolong the QTc interval or within 2 weeks of discontinuation of such agents, because the effect of adrenergic agonists on the cardiovascular system may be potentiated.

Use beta blockers with caution as they not only block the pulmonary effect of beta-agonists, such as vilanterol, but may produce severe bronchospasm in patients with COPD.

Use with caution in patients taking non-potassium-sparing diuretics, as electrocardiographic changes and/or hypokalemia associated with non-potassium-sparing diuretics may worsen with concomitant beta-agonists.

Avoid co-administration of Anoro Ellipta with other anticholinergic-containing drugs as this may lead to an increase in anticholinergic adverse effects such as cardiovascular effects, worsening of narrow-angle glaucoma, and worsening of urinary retention.

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. 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. Theravance'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 Theravance and GSK. Under the agreement with GSK, Theravance is eligible to receive associated royalty revenues from RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and, if approved and commercialized, VI monotherapy, as well. In addition, Theravance retains a 15% economic interest in future payments made by GSK for earlier-stage programs under the agreements with GSK. For more information, please visit Theravance's website at www.thrxinc.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 2014.

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. Such forward-looking statements involve substantial risks, uncertainties and assumptions. Examples of such statements include statements relating to: the commercialization of Anoro® Ellipta®, the strategies, plans and objectives of the company, the timing, manner and amount of anticipated potential capital returns to stockholders (including without limitation, expectations of future cash dividends or 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: the disruption of operations during the transition period following the spin-off, including the diversion of managements' and employees' attention, disruption of relationships with collaborators and increased employee turnover, 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 headings "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in Theravance's Annual Report on Form 10-K for the year ended December 31, 2014 and Theravance's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, 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 Theravance's other filings with the SEC, other unknown or unpredictable factors also could affect Theravance'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. Theravance assumes no obligation to update its forward-looking statements on account of new information, future events or otherwise, except as required by law.

(THRX-G)

References

1. Global, regional, and national incidence, prevalence, and years lived with disability for 301 acute and chronic diseases and injuries in 188 countries, 1990-2013: a systematic analysis for the Global Burden of Disease Study 2013. The Lancet; 2015. Available at: http://dx.doi.org/10.1016/S0140-6736(15)60692-4. Accessed September 2015.

2. National Heart Lung and Blood Institute. Who is at risk for COPD? Available at: https://www.nhlbi.nih.gov/health/health-topics/topics/copd/atrisk.html. Accessed September 2015.

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