

October 17, 2014

Data Published on Anoro(R) Ellipta(R) Demonstrate Improved Lung Function Compared to Tiotropium

LONDON, UNITED KINGDOM and SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 10/17/14 -- Theravance, Inc. (NASDAQ: THRX) -- [Respiratory Medicine](#) has published positive results from a third lung function study comparing the efficacy and safety of Anoro[®] Ellipta[®] (umeclidinium /vilanterol, 'UMEC/VI'), the combination long-acting muscarinic antagonist (LAMA) / long-acting beta₂-adrenergic agonist (LABA), with the LAMA tiotropium, administered in the HandiHaler[®] inhaler, in patients with chronic obstructive pulmonary disease (COPD).¹

In this study UMEC/VI 62.5/25 mcg showed a statistically significant improvement of 112mL compared with tiotropium 18mcg (95% confidence interval (CI) 81, 144, p < 0.001) for the primary endpoint measurement of lung function using trough forced expiratory volume in one second (FEV₁) at the end of the treatment period (day 169).

For the secondary endpoint measurement of lung function using weighted mean FEV₁ 0 - 6 hour, at the end of the treatment period (day 168) UMEC/VI 62.5/25mcg showed a statistically significant improvement of 105mL, (95% confidence interval (CI) 71, 140, p < 0.001) compared to tiotropium 18 mcg.

The most commonly reported side effects for both UMEC/VI and tiotropium included headache (9% UMEC/VI; 7% tiotropium), nasopharyngitis (6% UMEC/VI; 7% tiotropium), cough (3% UMEC/VI; 3% tiotropium) and back pain (2% UMEC/VI; 3% tiotropium). The overall incidence of on-treatment adverse events was 44% in the UMEC/VI group and 42% in the tiotropium group. The incidence of any on-treatment serious adverse event in both treatment arms was 4%.

Darrell Baker, SVP and Head, Global Respiratory Franchise, GSK said: "We are pleased to announce the publication of these important data comparing Anoro Ellipta with tiotropium. These results support the lung function benefit of Anoro Ellipta in the treatment of appropriate patients with COPD. We hope the publication will inform physicians as they consider which treatment option is best to meet their individual patient's needs."

Michael W. Aguiar, President and Chief Executive Officer of Theravance, said: "We believe the results from this positive study will provide physicians with additional useful data regarding the potential benefits of Anoro Ellipta as a treatment option for appropriate patients with COPD."

UMEC/VI previously demonstrated statistically significant improvements in trough FEV₁ compared with tiotropium in an earlier six-month active-comparator study (DB2113360), and numerically greater (although not statistically significant) improvements from tiotropium in another (DB2113374). These data were previously announced in July 2012.

Study Design

This study was a 24-week, blinded, parallel group, multicenter study to assess the efficacy and safety of UMEC/VI 62.5/25mcg inhalation powder administered once-daily in the dry powder inhaler, Ellipta[®], compared to tiotropium 18mcg administered once-daily in the HandiHaler[®] inhaler. A total of 905 patients with COPD were randomized 1:1 to UMEC/VI 62.5/25mcg inhalation powder or tiotropium 18mcg.

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.²

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.³

About Anoro Ellipta

Anoro Ellipta is a combination long-acting muscarinic antagonist (LAMA) (also known as an anticholinergic) / long-acting beta₂-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: http://us.gsk.com/products/assets/us_anoro_ellipta.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 Prescribing Information for Anoro Ellipta. Please consult the full Prescribing Information for all the labelled safety information for Anoro Ellipta.

Long-acting beta₂-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 beta₂-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.

As with other inhaled medicines, 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.

Beta₂-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 maximizing the potential value of the respiratory assets partnered with Glaxo Group Limited (GSK), including RELVAR[®]/BREQ[®] 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[®]/BREQ[®] 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 under agreements entered into prior to the spin-off of Theravance Biopharma, and since assigned to Theravance Respiratory Company, LLC, 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 these agreements with GSK (other than RELVAR[®]/BREQ[®] ELLIPTA[®], ANORO[®] ELLIPTA[®] and VI monotherapy). For more information, please visit Theravance's web site at www.thrxinc.com.

ANORO[®] and ELLIPTA[®] are trade marks of the GlaxoSmithKline group of companies. HandiHaler[®] is a trade mark of Boehringer Ingelheim.

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. Such forward-looking statements involve substantial risks, uncertainties and assumptions. Examples of such statements include statements relating to: the strategies, plans and objectives of the company, the timing, manner, amount and planned growth of anticipated potential capital returns to stockholders (including without limitation statements, 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: 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2014 filed with the Securities and Exchange Commission (SEC) on August 7, 2014. 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. (THR-X-G)

1. Maleki-Yazdi, M.R. et al. Efficacy and safety of umeclidinium/vilanterol 62.5/25 mcg and tiotropium 18 mcg in chronic obstructive pulmonary disease: results of a 24-week, randomized, controlled trial. *Respiratory Medicine*. 2014. DOI: 10.1016/j.rmed.2014.10.002

2. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis Management and Prevention of Chronic Obstructive Pulmonary Disease Updated 2014

3. 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:

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)

Melinda Stubbee

+1 919 483 2510

(North Carolina)

Sarah Alspach

+1 202 715 1048

(Washington, DC)

Analyst/Investor enquiries:

Ziba Shamsi
+44 (0) 20 8047 3289
(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)

Theravance Inc. Inquiries:

Investor Relations

Michael W. Aguiar

+1 650 238 9640

(San Francisco)

investor.relations@thrxinc.com

Source: Theravance, Inc.

News Provided by Acquire Media