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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549

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FORM 8-K

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Current Report Pursuant  
to Section 13 or 15(d) of the  
Securities Exchange Act of 1934

Date of Report (Date of earliest event Reported): January 9, 2014

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**THERAVANCE, INC.**

(Exact Name of Registrant as Specified in its Charter)

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**Delaware**

(State or Other Jurisdiction of Incorporation)

**000-30319**

(Commission File Number)

**94-3265960**

(I.R.S. Employer Identification Number)

**901 Gateway Boulevard  
South San Francisco, California 94080  
(650) 808-6000**

(Addresses, including zip code, and telephone numbers, including area code, of principal executive offices)

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 8.01 Other Events.**

On January 9, 2014, GlaxoSmithKline plc (GSK) and Theravance, Inc. issued a press release announcing that ANORO™ ELLIPTA™ was approved in Canada on December 23, 2013 for the long-term once-daily maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. ANORO™ ELLIPTA™ (umeclidinium / vilanterol) dry powder for oral inhalation is a combination of a long-acting muscarinic antagonist (LAMA) and a long-acting beta<sub>2</sub>-agonist (LABA). ANORO™ ELLIPTA™ combines two bronchodilators in a single inhaler for the maintenance treatment of COPD. It contains umeclidinium (UMEC), a LAMA and vilanterol (VI), a LABA. The approved dosage of ANORO™ ELLIPTA™ in Canada is 62.5/25mcg. UMEC/VI has been developed under the LABA collaboration agreement between Glaxo Group Limited and Theravance, Inc. A copy of the press release is filed as Exhibit 99.1 to this report and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<b><u>Exhibit</u></b>	<b><u>Description</u></b>
<a href="#">Exhibit 99.1</a>	Press Release dated January 9, 2014

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**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**THERAVANCE, INC.**

Date: January 9, 2014

By: /s/ Michael W. Aguiar  
**Michael W. Aguiar**  
**Chief Financial Officer**

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EXHIBIT INDEX

**Exhibit No.**    **Description**

[Exhibit 99.1](#)    Press Release dated January 9, 2014

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**Theravance**  
Medicines That Make A Difference™

## PRESS RELEASE

# ANORO™ ELLIPTA™ approved for COPD treatment in Canada

## Approved as a new once-daily dual bronchodilator for the treatment of COPD in Canada

**Mississauga, ON – January 9, 2014** – GlaxoSmithKline Inc. and Theravance Inc. today announced that ANORO™ ELLIPTA™ was approved in Canada on December 23, 2013, for the long-term once-daily maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

ANORO™ ELLIPTA™ (umeclidinium/vilanterol) dry powder for inhalation is a combination of a long-acting muscarinic antagonist (LAMA) and a long-acting beta<sub>2</sub>-agonist (LABA).

ANORO™ ELLIPTA™ combines two bronchodilators in a single inhaler for the maintenance treatment of COPD. It contains umeclidinium bromide (UMEC), a LAMA and vilanterol trifenate (VI), a LABA. The approved dosage of ANORO™ ELLIPTA™ in Canada is 62.5/25mcg.

Paul Lirette, President, GSK Canada said: “The market authorization of Anoro Ellipta in Canada provides an important treatment option for appropriate patients with COPD. It is a new once-daily combination product that enables patients to receive two bronchodilators in a single daily inhalation.”

“We are delighted that ANORO™ ELLIPTA™ has achieved market authorization in Canada for the treatment of COPD,” said Rick E Winningham, Chief Executive Officer of Theravance. “This is an important step forward for Theravance and GSK, and reinforces our long-standing commitment to work together for patients with respiratory disease.”

The phase III pivotal programme for ANORO™ ELLIPTA™ included seven clinical studies with almost 6,000 patients with COPD.

### About COPD

Chronic obstructive pulmonary disease (COPD) is a term referring to two lung diseases, chronic bronchitis and emphysema, that are 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. 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.

### About ANORO™ ELLIPTA™

ANORO™ ELLIPTA™ (UMEC/VI) is a new once-daily LAMA/LABA dual bronchodilator approved in Canada for the long-term once-daily maintenance bronchodilator treatment of airflow obstruction in patients with COPD, including chronic bronchitis and emphysema. ANORO™ ELLIPTA™ is not indicated for the relief of acute deterioration of COPD, for the treatment of acute episodes of bronchospasm or for the treatment of asthma. ANORO™ contains 62.5 micrograms UMEC and 25 micrograms VI, in a single inhaler, the ELLIPTA™.

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## Important Safety Information

The following is important safety information for ANORO™ ELLIPTA™.

### Indications and Clinical Use:

ANORO™ ELLIPTA™ (umeclidinium/vilanterol) is a combination of a long-acting muscarinic antagonist (LAMA) and a long-acting beta2-agonist (LABA) indicated for the long-term once-daily maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

ANORO™ ELLIPTA™ is not indicated for the relief of acute deterioration of COPD or for the treatment of asthma.

### Contraindications:

- For the relief of acute deterioration of COPD.
- For the treatment of asthma.
- Patients with severe hypersensitivity to milk proteins.
- For the treatment of acute episodes of bronchospasm, i.e., as rescue therapy.

### Most Serious Warnings and Precautions

**Asthma-related death:** Long-acting beta<sub>2</sub>-adrenergic agonists (LABA) may increase the risk of asthma-related death. Data from a large placebo-controlled US study that compared the safety of salmeterol (SEREVENT® Inhalation Aerosol) or placebo added to patients' usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol. This finding with salmeterol is considered a class effect of LABA, including vilanterol, one of the active ingredients in ANORO™ ELLIPTA™. The safety and efficacy of ANORO™ ELLIPTA™ in patients with asthma have not been established.

### Other Warnings and Precautions:

- ANORO™ ELLIPTA™ is not indicated for the treatment of acute episodes of bronchospasm (i.e., as rescue therapy).
- ANORO™ ELLIPTA™ should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of COPD. Patients should be instructed to discontinue regular use of short-acting bronchodilators and to use them only for acute respiratory symptoms.
- Exacerbations may occur during treatment.
- ANORO™ ELLIPTA™ should not be used in conjunction with other medicines containing a LABA or a long-acting muscarinic antagonist (LAMA).
- There have been no studies investigating the effect of ANORO™ ELLIPTA™ on the ability to perform tasks that require judgement, motor or cognitive skills.
- **Anticholinergic Effects:** Use with caution in patients with narrow-angle glaucoma or urinary retention.
- **Cardiovascular effects:** ANORO™ ELLIPTA™ should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, acute myocardial infarction, cardiac arrhythmias, and hypertension. Cardiovascular effects such as cardiac arrhythmias, may be seen after the administration of ANORO™ ELLIPTA™. Treatment may need to be discontinued. ANORO™ ELLIPTA™ was associated with a dose-dependent increase in heart rate and QTcF prolongation in healthy subjects receiving steady-state treatment.
- **Endocrine and Metabolism:** Use with caution in patients with convulsive disorders, thyrotoxicosis and patients who are unusually responsive to sympathomimetic amines. Use with caution in patients predisposed to low levels of serum potassium and diabetic patients.
- **Respiratory:** Treatment should be discontinued if paradoxical bronchospasm occurs and alternative therapy instituted if necessary.
- **Hypersensitivity:** As with all medications, immediate hypersensitivity reactions may occur after administration of ANORO™ ELLIPTA™.

# PRESS RELEASE



- The use of ANORO™ ELLIPTA™ is not indicated for use in patients under 18 years of age.
- Use during pregnancy, labour and in breastfeeding women should only occur if the potential benefit justifies the potential risk.
- **Drug interactions:** Caution should be exercised when considering coadministration with inhibitors of cytochrome P450 3A4; sympathomimetic agents; beta-blocking agents; non potassium sparing diuretics; drugs known to prolong the QTc interval; monoamine oxidase inhibitors and tricyclic antidepressants; xanthine derivatives; oral corticosteroids. Avoid coadministration with other anticholinergics.

## Adverse Events:

Adverse reactions reported at a frequency of  $\geq 1\%$  and greater than placebo include: pharyngitis, sinusitis, lower respiratory tract infection, diarrhea, constipation, pain in extremity, muscle spasms, neck pain and chest pain.

## Recommended Dose:

- The recommended dose is one inhalation of ANORO™ ELLIPTA™ 62.5/25 mcg once daily.

## Dosing Considerations:

- No dosage adjustment is required in patients over 65 years of age, in patients with renal impairment, or in patients with mild or moderate hepatic impairment. ANORO™ ELLIPTA™ has not been studied in patients with severe hepatic impairment.

## For More Information:

Please consult the product monograph at [www.gsk.ca/](http://www.gsk.ca/) for complete safety information. The product monograph is also available by calling 1-800-387-7374.

ANORO™ and ELLIPTA™ are trademarks of the GlaxoSmithKline group of companies.

**GlaxoSmithKline** – 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.ca](http://www.gsk.ca).

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

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## **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. Factors that may affect GSK's operations are described under Item 3.D 'Risk factors' in the company's Annual Report on Form 20-F for 2012.

## **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 November 1, 2013 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)