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GSK Receives Approval for BREO(R) ELLIPTA(R) for the Treatment of Adults With Asthma

LONDON, UNITED KINGDOM and SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 08/06/15 -- GSK (LSE: GSK) and Theravance, Inc. (NASDAQ: THRX) announce the approval in Canada of BREO® ELLIPTA® (fluticasone furoate/vilanterol dry powder for oral inhalation) for the once-daily maintenance treatment of asthma in patients aged 18 years and older with reversible obstructive airways disease.

BREO® ELLIPTA® is a fixed-dose combination of the inhaled corticosteroid (ICS) fluticasone furoate and the long-acting beta2-agonist (LABA) vilanterol. Two strengths, 100/25 mcg and 200/25 mcg, have been approved in Canada for use in asthma. BREO® is administered once daily via the dry powder inhaler called ELLIPTA®, which is also used across a range of other approved respiratory medicines in the GSK portfolio.

Sally Taylor, Country Medical Officer, Canada said: "BREO® ELLIPTA®, a GSK asthma treatment approved in Canada now provides physicians with a once-daily treatment option delivered via the ELLIPTA® inhaler to meet the needs of appropriate adult patients."

Michael W. Aguiar, President and Chief Executive Officer of Theravance, Inc., said: "With today's approval of BREO® ELLIPTA® in Canada, we are pleased to expand the number of patients able to benefit from this important medicine. As a once-daily ICS/LABA treatment for adults with asthma, people suffering from this chronic condition now have an additional option."

Please consult the Product Monograph that will be posted at www.gsk.ca for complete safety information. The Product Monograph is also available by calling 1-800-387-7374.

About Asthma

Asthma is a chronic lung disease that inflames and narrows the airways.[1] Approximately 2.5 million people in Canada currently have asthma.[2] Despite medical advances, more than half of patients continue to experience poor control and significant symptoms.[3]

The causes of asthma are not completely understood but likely involve an interaction between a person's genetic make-up and the environment. Key risk factors are inhaled substances that provoke allergic reactions or irritate the airways.

References

1. Global Initiative for Asthma. Pocket Guide for asthma management and prevention. Updated 2014.
2. Statistics. Canada. 2015
3. ODPRN Report: Inhaled Corticosteroids (ICS) + Long-Acting Beta Agonists (LABA) in the Treatment of Asthma "Final Consolidated Report" Apr 1st, 2015

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 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 BREO ELLIPTA in Canada, 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 March 31, 2015, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. Additional information will also be set forth in those sections of Theravance's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, which will be filed with the SEC in the third quarter of 2015. 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.

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