

April 22, 2013

GSK and Theravance Announce Regulatory Submission for ANORO™ ELLIPTA™ (UMEC) in Japan

LONDON and SOUTH SAN FRANCISCO, CA--(Marketwired - Apr 22, 2013) - GlaxoSmithKline plc (GSK) and Theravance, Inc. (NASDAQ: [THRX](#)) today announced the submission of a regulatory application to the Japanese Ministry of Health, Labour and Welfare (MHLW) for the investigational once-daily LAMA/LABA combination medicine, UMEC/VI, for patients with chronic obstructive pulmonary disease (COPD). GSK and Theravance announced the submission of a regulatory application for UMEC/VI for patients with COPD in the United States (US) on 18th December 2012 and in Europe on 9th January 2013.

UMEC/VI is a combination of two investigational bronchodilator molecules - GSK573719 or umeclidinium bromide (UMEC), a long-acting muscarinic antagonist (LAMA) and vilanterol (VI), a long-acting beta2 agonist (LABA), administered using the ELLIPTA™ inhaler.

Japanese Submission:

A New Drug Application (NDA) for UMEC/VI (62.5/25mcg and 125/25mcg doses), with the proposed proprietary name ANORO™ ELLIPTA™, has been submitted to the Japanese Ministry of Health, Labour and Welfare (MHLW) as a maintenance bronchodilator treatment to relieve symptoms of obstructive airway disorder due to chronic obstructive pulmonary disease (COPD) (chronic bronchitis and emphysema).

Future Regulatory Submissions:

GSK intends to commence global regulatory submissions for UMEC monotherapy later this year.

Other Respiratory Development Programmes:

UMEC/VI is one of several late-stage assets in the GSK respiratory development portfolio, which includes fluticasone furoate/vilanterol (FF/VI, with proposed brand names RELVAR™ ELLIPTA™ and BREO™ ELLIPTA™), VI monotherapy MABA (GSK961081), developed in collaboration with Theravance, as well as GSK's investigational medicines FF monotherapy, UMEC monotherapy and anti-IL5 MAb (mepolizumab). These investigational medicines are not currently approved anywhere in the world.

ANORO™, RELVAR™, BREO™ and ELLIPTA™ are trademarks of the GlaxoSmithKline group of companies. The use of brand names is not approved by any regulatory authorities.

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.com

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. Theravance's key programmes include: RELVAR™ or BREO™ ELLIPTA™ (FF/VI), ANORO™ ELLIPTA™ (UMEC/VI) and MABA (Bifunctional Muscarinic Antagonist/Beta2 Agonist), each partnered with GlaxoSmithKline plc, and its oral Peripheral Mu Opioid Receptor Antagonist programme. 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.

THERAVANCE®, the Theravance logo, and MEDICINES THAT MAKE A DIFFERENCE® are registered trademarks of Theravance, Inc.

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. 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on February 26, 2013 and the risks discussed in our other period filings with 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)

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