



GSK and Theravance announce positive phase 2b results for once-daily fluticasone furoate in the treatment of asthma

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Issued: Wednesday 4 February 2009, London UK & South San Francisco, CA

GlaxoSmithKline (GSK) and Theravance, Inc. (NASDAQ: THRX) today announced positive results from three, separate phase 2b studies assessing efficacy and safety of GSK's inhaled corticosteroid (ICS) fluticasone furoate (FF or GW685698) across a range of eight doses (25 - 800 mcg) in over 1,800 patients with mild, moderate and severe asthma. Once-daily FF produced statistically significant improvements in patients' lung function (trough FEV1) compared to placebo ($p < 0.05$) in each of the three study populations and at all doses, with the exception of the very lowest dose tested. In all studies numerically greater improvements in lung function were observed with a lower total daily dose of FF compared to fluticasone propionate (FP).

"The strong results from these three studies demonstrate that fluticasone furoate shows promise as an efficacious, once-daily ICS. Additionally, the consistent responses seen demonstrate the robust nature of these data," commented Darrell Baker, SVP GSK Respiratory Medicines Development Centre. "These outcomes, combined with the positive findings from the recent studies of the long-acting beta agonist (LABA) '444, bring us a step closer to selecting the appropriate doses of FF and '444 for future studies and increase the potential of this combination to be a significant, once-daily treatment for asthma and COPD. This is, of course, particularly important for those patients where compliance and asthma control are difficult."

"We are delighted by the outcomes of these studies," said Rick E Winningham, CEO, Theravance. "The compelling results give us continuing confidence in the Horizon clinical development programme and improve our understanding of the efficacy and safety of FF. We are moving closer to achieving our objective of delivering effective, once-a-day inhaled medicines to patients with asthma and COPD."

The three dose-ranging studies fully characterised FF's dose response curve, with only the lowest dose (25 mcg) showing no statistically significant difference from placebo on the primary efficacy endpoint (trough FEV1) and with only the highest dose (800 mcg) associated with a statistically significant reduction in urinary cortisol levels (a known side effect of inhaled corticosteroids). FF was well tolerated throughout the course of the eight-week treatment period across the three studies. Adverse events occurred at a similar or lower frequency than FP in each study, with the most common adverse event being headache. A low frequency of serious adverse events occurred on all treatments, including placebo, FP and FF, and for FF were not dose dependant.

Study design

Patient populations with varying severities of asthma were randomised in three separate double-blind, double-dummy, placebo-controlled studies. In each study, patients aged 12 years and older received one of four doses of FF once daily, placebo or FP twice daily. FF was administered via a novel single step activation inhaler and FP was administered via DISKUS®. All patients were permitted to use a short-acting beta-agonist (albuterol) as rescue medication to relieve symptoms of asthma as needed.

The dosing regimen for each study was as follows:

Mild asthmatic population: 601 patients with persistent asthma, symptomatic on short-acting beta-agonist asthma therapy with no use of inhaled corticosteroid were randomised to receive 25, 50, 100 or 200 mcg once daily, FP 100 mcg twice daily or placebo.

Moderate asthmatic population: 622 patients with persistent asthma, symptomatic on low-dose ICS were randomised to receive 100, 200, 300 or 400 mcg once daily, FP 250 mcg twice daily or placebo.

Severe asthmatic population: 627 patients with persistent asthma, symptomatic on moderate-dose ICS were randomised to receive 200, 400, 600 or 800 mcg once daily, FP 500 mcg twice daily or placebo.

The primary endpoint to assess efficacy was mean change from baseline to the end of the eight week treatment period in trough (measured 24 hours after the last dose) forced expiratory volume (FEV1).

The Horizon programme

Overall the Horizon programme has enrolled in excess of 3,000 asthma and COPD patients globally. Positive data from two

phase 2b studies with the LABA '444 in asthma and COPD were reported at the end of 2008. Enabling studies involving '444 and FF given in combination are ongoing.

Conference Call and Webcast Information

Theravance has scheduled a conference call to discuss this announcement today at 8:30 a.m. Eastern Standard Time. To participate in the live call by telephone, please dial 877-795-3638 from the U.S., or 719-325-4800 for international callers. Those interested in listening to the conference call live via the internet may do so by visiting Theravance's web site at www.theravance.com. To listen to the live call, please go to Theravance's web site 15 minutes prior to its start to register, download, and install any necessary audio software.

A replay of the conference call will be available on Theravance's web site for 30 days through March 6, 2009. An audio replay will also be available through 11:59 p.m. Eastern Standard Time on February 18, 2009 by dialing 888-203-1112 from the U.S., or 719-457-0820 for international callers, and entering confirmation code 9687412.

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. 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 gastrointestinal motility dysfunction. The company's key programs include: telavancin for the treatment of serious Gram-positive bacterial infections with Astellas Pharma Inc., the Horizon program and Bifunctional Muscarinic Antagonist-Beta2 Agonist (MABA) program with GlaxoSmithKline plc, and the Gastrointestinal Motility Dysfunction program. By leveraging its proprietary insight of multivalency toward drug discovery focused primarily on validated targets, Theravance is pursuing a next generation strategy designed to discover superior medicines in areas of significant unmet medical need. For more information, please visit the company'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

Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, 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 'Risk Factors' in the 'Business Review' in the company's Annual Report on Form 20-F for 2007.

Theravance forward-looking statements

This press release contains and the conference call will contain 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 Exchange Act and the Private Securities Litigation Reform Act of 1995. Examples of such statements include statements relating to the goals, timing and expected results of clinical studies, statements regarding the potential benefits of drug candidates, statements concerning the goals and 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, expectations for product candidates through development and commercialization and projections of revenue 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 the conference call 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 the potential that results of clinical or preclinical studies indicate product candidates are unsafe or ineffective, delays or failure to achieve regulatory approvals, 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 Item 1A of Theravance's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 6, 2008 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.

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