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GSK and Theravance announce progression of LAMA/LABA combination treatment into Phase III development for COPD

- Relovair™ programme expanded by start of large Phase IIIb COPD outcomes study

GlaxoSmithKline (GSK) and Theravance, Inc. (NASDAQ: THRX) today announced major milestones in two clinical development programmes focused on new treatments for patients with chronic obstructive pulmonary disease (COPD), a leading cause of chronic illness and death worldwide.

The first is the initiation of the Phase III programme for the once-daily LAMA/LABA dual bronchodilator GSK573719/vilanterol ('719/VI), which will evaluate over 5,000 patients globally. Patients are now being enrolled in a large safety study, which will be followed shortly by four large pivotal studies that will compare improvements in lung function between '719/VI, its components, placebo and tiotropium. The programme will also include two further studies assessing the effect of '719/VI on exercise endurance.

The second is the start of an extensive study of 16,000 patients to assess the potential for Relovair to improve survival in those with COPD and a history of, or at risk from, cardiovascular disease. Relovair is a once-daily inhaled corticosteroid (ICS)/long-acting beta-agonist (LABA) combination treatment, currently under development, comprising fluticasone furoate and vilanterol (FF/VI).

About the '719/VI Phase III Programme

'719/VI combines two bronchodilator molecules currently under development - '719, a long-acting muscarinic antagonist (LAMA) and VI, a long-acting beta agonist (LABA). These molecules act through two mechanisms: antagonism of acetylcholine muscarinic receptors and agonism of beta₂ adrenoreceptors. The medicine will be administered using a new dry powder inhalation device.

The study initiated today is a 52-week randomised study to evaluate the long term safety and tolerability of '719 (125mcg) alone, as well as the combination with '719/VI (125/25mcg). The Phase III programme will investigate two doses of '719 (125mcg and 62.5mcg) and '719/VI (125/25mcg and 62.5/25mcg) across the six further studies, which will all commence within the next quarter.

About the Relovair Outcomes Study

FF/VI commenced Phase III development for COPD in October 2009 and the programme now includes approximately 6,000 patients across five pivotal registration studies.

The additional study is an extensive outcomes trial across 1,100 global sites and will run alongside the existing COPD programme.

The primary objective is to prospectively evaluate the effect of the combination (FF/VI, 100/25mcg) compared with placebo on survival in COPD patients with moderate disease and a history of, or at risk from, cardiovascular disease. Secondary objectives will evaluate the effect of FF/VI compared with placebo on the rate of decline in lung function, as well as on cardiovascular endpoints including cardiovascular death, heart attacks and strokes.

This study will evaluate the clinical outcomes of patients receiving standard cardiovascular care (including cardiovascular medications) versus patients receiving FF/VI in addition to receiving standard cardiovascular care (including cardiovascular medications).

Darrell Baker, Senior Vice President for the GSK Respiratory Medicines Development Centre, commented, "This Relovair study demonstrates our commitment to evaluating survival outcomes for patients with COPD throughout the world. Cardiovascular risk factors remain a very important cause of morbidity and mortality in this disease and this study is crucial to assessing whether Relovair can benefit these patients".

This is a four arm, multicentre, randomised, double-blind, parallel-group study, with treatment administered once daily via a novel dry powder inhaler. The total duration of the study will be determined by the number of events in the study, with each patient being treated for between 15 and 44 months based on current estimates.

The results are not expected prior to the anticipated regulatory submission and will not form part of the initial New Drug Application (NDA)/Marketing Authorisation Application (MAA).

Relovair is also in Phase III clinical development for the treatment of asthma.

Relovair™ is a trademark 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.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 programmes include: the RELOVAIR™ programme and Bifunctional Muscarinic Antagonist-Beta₂ Agonist (MABA) programme, both with GlaxoSmithKline plc, and VIBATIV™ (telavancin) with Astellas Pharma Inc. By leveraging its proprietary insight of multivalency toward 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 the company's web site at www.theravance.com.

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GlaxoSmithKline 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 2009.

Theravance forward-looking statement

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 Exchange Act and the Private Securities Litigation Reform Act of 1995. Examples of such statements include statements relating to the goals and timing of clinical studies and product commercialization, 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 enabling capabilities of Theravance's approach to drug discovery and its proprietary insights, and statements regarding 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 preclinical 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 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 October 29, 2010 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.