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GSK and Theravance announce combination ICS/LABA Phase II results in the Relovair™ development programme.

Additional data presentations for fluticasone furoate and vilanterol trifenatate support the potential of developmental combination treatment, Relovair, in COPD and asthma

GlaxoSmithKline Plc (GSK) and Theravance, Inc. (NASDAQ: THRX) today announced results from a Phase II safety and efficacy study for developmental combination treatment Relovair in chronic obstructive pulmonary disorder (COPD).[1] Relovair is an investigational drug which combines fluticasone furoate (FF; an inhaled corticosteroid or ICS) and vilanterol trifenatate (VI; a newly developed long-acting beta agonist or LABA) in a once-daily treatment for patients with COPD or asthma. The results were presented at the European Respiratory Society congress in Barcelona where GSK presented a total of 13 clinical and pre-clinical abstracts for Relovair and its individual components in COPD and asthma.

Study Results
The Relovair (FFVI 400/25mcg) COPD Phase II study showed that the effect of FFVI on heart function and safety (as measured by weighted mean heart rate) was comparable to placebo (0.6bpm; 95% confidence interval (CI): -3.9, 5.1; upper CI was below non-inferiority limit).[1] The most common adverse events (FFVI; placebo) were nasopharyngitis (18%; 15%), headache (15%; 5%), dizziness (5%; 5%) and candidiasis (8%; 0%).[1] In the FFVI group, 68% of the patients reported adverse events versus 50% in the placebo group.[1] There were no clinically relevant effects seen in laboratory measures, vital signs or additional heart assessments.

Patients treated with Relovair showed greater improvements in lung function from baseline compared with placebo (as measured by pre-dose FEV_1, a standard measure of lung function) in the analysis of this secondary endpoint.[1] Placebo-adjusted trough FEV_1 for the Relovair patients on Day 29 was 183mL (95% CI: 87, 279mL) and the weighted mean FEV_1 for the Relovair patients on Day 28 was 236mL (95% CI: 154, 319mL).[1]

Darrell Baker, SVP GSK Respiratory Medicines Development Centre, commented, “These Phase II data are encouraging and show potential for Relovair as the first once-a-day combination in COPD. The development programme for Relovair builds on GSK’s extensive respiratory heritage and confirms our continued commitment to bring new respiratory medicines to patients.”

“We are very pleased with the results of this Phase 2 combination study. Our ongoing collaboration with GSK includes the Phase III programmes in both COPD and asthma, which are already underway for Relovair and its components. The Phase III studies are being conducted to help us confirm these early findings,” said Rick E Winningham, Chief Executive Officer at Theravance.

Study Design
The Phase II study employed a multicentre, randomised, double-blind, parallel-group, placebo-controlled design to assess the safety and efficacy of Relovair (FF 400mcg combined with VI 25mcg) administered once daily in 60 patients with COPD (GOLD Stage II-III) for four weeks.[1] The patients enrolled had a

mean age of 64 years.[1] The co-primary endpoints of the study were change from baseline in weighted mean heart rate 0-4 hours post-dose at the end of the 28-day treatment period and incidence of adverse events.[1] The secondary endpoints were change from baseline in trough FEV_1 (23–24 hours post-dose) and weighted mean FEV_1 (0–4 hours post-dose).

All patients in the study were dosed using a novel, single-step activation dry powder inhaler.[1]

Additional Relovair COPD Programme Results Presented at ERS
A Phase 2b study evaluated the dose response, efficacy[2] and safety[3] of five doses of VI in COPD patients. The study showed improvements in lung function observed in all doses after 4 weeks, compared with placebo; $p<0.001$ (as measured by change in pre-dose FEV_1).[2]

Relovair Asthma Programme Results Presented at ERS
Phase IIb data from the Relovair asthma programme, which evaluated the efficacy and safety of the VI and FF components of Relovair, were also presented at ERS. In three separate studies, significant improvements in lung function in patients who were not controlled by current standards of care including low[4] or moderate[5] dose ICS and non-steroidal therapy[6] were found with FF ($p<0.001$, <0.001 and <0.05 respectively). A fourth study demonstrated that the efficacy of FF taken once daily in the evening was comparable with half the dose taken twice daily.[7] A low incidence of adverse events (nasopharyngitis, headache, and candidiasis) were reported across all four FF studies.[4, 5, 6, 7]

Another study evaluated the dose response, efficacy and safety of five doses of VI in asthma patients aged from 12 years.[8] A significant relationship between the dose of VI and pre-dose FEV_1 was observed, compared with placebo ($p=0.003$ including placebo, $p=0.037$ excluding placebo).[8] The incidence of adverse events was low in all treatment groups (tremor 0-2%, palpitations 0-2%, glucose and potassium effects 0-1%).[8]

Relovair Phase III Programmes in COPD and Asthma
The Phase III programmes for Relovair in COPD and asthma commenced in October 2009 and March 2010 respectively. Both programmes are assessing the potential benefit of the combination FFVI versus the component products and existing treatments for asthma and COPD in over 11,000 patients.

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References

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7. Woodcock A et al. Fluticasone furoate (FF), a novel inhaled corticosteroid (ICS), demonstrates once-daily (OD) efficacy in asthma when dosed in the evening. Abstract presented at European Respiratory Society congress, September 18-22, 2010
8. Lötvall J et al. Dose-related efficacy of vilanterol trifenatate (VI), a long-acting $beta_2$ agonist (LABA) with inherent 24-hour activity, in patients with persistent asthma. Abstract presented at European Respiratory Society congress, September 18-22, 2010

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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 - 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: VIBATIV™ (telavancin) with Astellas Pharma Inc. and the RELOVAIR™ programme and Bifunctional Muscarinic Antagonist-Beta$_2$ Agonist (MABA) programme with GlaxoSmithKline plc. By leveraging its proprietary insight of multivalency toward drug discovery focused primarily on validated targets, 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.

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 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 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 August 4, 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.

GSK Enquiries:

UK Media enquiries:	David Mawdsley	(020) 8047 5502
	Claire Brough	(020) 8047 5502
	Stephen Rea	(020) 8047 5502
	Alexandra Harrison	(020) 8047 5502
	Jo Revill	(020) 8047 5502

US Media enquiries:	Nancy Pekarek	(919) 483 2839
	Mary Anne Rhyne	(919) 483 2839
	Kevin Colgan	(919) 483 2839
	Sarah Alspach	(919) 483 2839
European Analyst/Investor enquiries:	David Mawdsley	(020) 8047 5564
	Sally Ferguson	(020) 8047 5543
	Gary Davies	(020) 8047 5503
US Analyst/ Investor enquiries:	Tom Curry	(215) 751 5419
	Jen Hill Baxter	(215) 751 7002

Theravance, Inc. Enquiries:

Senior Vice President and Chief Financial Officer — Michael W. Aguiar (650) 808 4100

investor.relations@theravance.com

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