

Issued: Tuesday 21 December 2010, London UK & South San Francisco, CA

GlaxoSmithKline and Theravance commence MABA Phase IIb COPD study

GlaxoSmithKline (GSK) and Theravance (NASDAQ: THRX) announced today that the first patient has started treatment with an investigational inhaled bifunctional compound GSK961081 ('081) in a Phase IIb study to evaluate efficacy and safety in patients with moderate to severe chronic obstructive pulmonary disease (COPD).

'081 is a single molecule functioning as both a muscarinic antagonist and a beta₂ receptor agonist (MABA).

Darrell Baker, SVP, Respiratory & Immuno-Inflammation, Medicines Development Centre, GSK said "We are excited with the progress that we are making with this molecule, which has the potential to be an important new treatment option for patients living with COPD."

Mathai Mammen, SVP, Research & Early Clinical Development of Theravance said, "This MABA compound was developed through Theravance's research of secondary binding clefts on both the beta₂ and muscarinic receptors."

'081 is an investigational compound within the inhaled bifunctional muscarinic antagonist-beta₂ agonist (MABA) programme that was licensed to GSK from Theravance in 2005 under the terms of the companies' Strategic Alliance Agreement.

Study design

The overall aim of this Phase IIb study is to evaluate the safety and efficacy of '081 administered both once daily, QD and twice daily, BID, over a 28 day period to allow the selection of a well tolerated and efficacious dose and dosing interval to take forward into Phase III development.

The study is a multi-centre, randomised, double-blind and double dummy, placebo and active-controlled, eight-arm, parallel-group study with '081.

Approximately 425 patients with moderate/severe COPD will be randomised in order to achieve 357 evaluable patients.

The primary objective is to evaluate dose response, dose interval, efficacy, and safety of '081 by studying three QD doses (100mcg, 400mcg, and 800mcg) and three BID doses (100mcg, 200mcg, 400mcg) and the active comparator salmeterol 50mcg BID compared with placebo delivered by DISKUS™ in patients with COPD.

The primary efficacy endpoint will be change from baseline in a.m. trough forced expiratory volume in one second (FEV₁) on Day 29. Secondary endpoints will include serial FEV₁ measures and use of salbutamol rescue medication.



Theravance
Medicines That Make A Difference

The study is being conducted in centres throughout Europe and South Africa.

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.

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

VIBATIV is a trademark of Astellas Pharma Inc.

RELOVAIR is a trademark of Glaxo Group Limited. Mark is intended for U.S. and subject to FDA approval.

GlaxoSmithKline 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
	Jennifer Armstrong	(919) 483 2839

European Analyst/Investor enquiries:	Sally Ferguson	(020) 8047 5543
	Gary Davies	(020) 8047 5503
	Ziba Shamsi	(020) 8047 3289

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	



Theravance
Medicines That Make A Difference

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 Cautionary Statement Regarding 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 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 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.