GLAXOSMITHKLINE PLC
Form 6-K
July 02, 2012

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION
Washington D.C. 20549

Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of
the Securities Exchange Act of 1934

For period ending July 2012

GlaxoSmithKline plc
(Name of registrant)

980 Great West Road, Brentford, Middlesex, TW8 9GS
(Address of principal executive offices)

Indicate by check mark whether the registrant files or
will file annual reports under cover Form 20-F or Form 40-F

Form 20-F x Form 40-F

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Indicate by check mark whether the registrant by furnishing the
information contained in this Form is also thereby furnishing the
information to the Commission pursuant to Rule 12g3-2(b) under the
Securities Exchange Act of 1934.

Yes No x

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This press release is intended for business journalists and analysts/investors. Please note that this release may not have been issued in every market in which GSK operates.

Issued: Monday 2 July 2012, London UK and South San Francisco, CA - LSE Announcement

GSK and Theravance announce positive results from four pivotal phase III studies for once-daily LAMA/LABA (UMEC/VI) in COPD

- Headline results from the pivotal efficacy studies support intention to commence global filings for UMEC/VI from end of 2012, ahead of schedule

GlaxoSmithKline plc (LSE: GSK) and Theravance, Inc. (NASDAQ: THRX) today announced the results of four pivotal phase III studies of investigational LAMA/LABA involving over 4,000 patients with chronic obstructive pulmonary disease (COPD). These four studies include two 24-week efficacy studies that compared the combination LAMA/LABA, its components and placebo and two 24-week active comparator studies that compared the combination with the LAMA tiotropium, a widely prescribed maintenance bronchodilator for COPD.

LAMA/LABA 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 by a new dry powder inhaler. UMEC/VI is a once-daily investigational medicine currently under development for the maintenance treatment of COPD.

Darrell Baker, SVP Respiratory Portfolio Optimisation Leader at GSK said: "We are very encouraged by the results of these initial studies for our LAMA/LABA, an important cornerstone of our broad respiratory development portfolio. These studies, together with our earlier dose-ranging work, give us confidence that this is a once-daily medicine with the potential to benefit many patients with COPD. Subject to successful completion of the ongoing studies, we plan to commence global regulatory filings from the end of this year."

Rick E Winningham, Chief Executive Officer of Theravance said: "There remains a great unmet medical need in COPD. In particular, physicians have stated that there is still a need to help patients breathe better. We believe the results of these initial studies demonstrate a potential benefit for patients with COPD."

Placebo-Controlled Efficacy Studies

The first 24-week, randomised, double-blind, placebo-controlled study evaluated the efficacy and safety of UMEC/VI 125/25mcg, VI 25mcg, UMEC 125mcg and placebo. This study randomised 1,493 patients. For the pre-specified primary endpoint of trough FEV1 at the end of the treatment period (Day 169), this study showed statistically significant improvements for UMEC and VI individually compared to placebo ($p<0.001$). The combination UMEC/VI showed statistically significant improvements when compared with the individual components UMEC and VI ($p<0.001$) and when compared to placebo (238mL, $p<0.001$).

The second 24-week, randomised, double-blind, placebo-controlled study evaluated the efficacy and safety of UMEC/VI 62.5/25mcg, VI 25mcg, UMEC 62.5mcg and placebo. This study randomised 1,536 patients. For the pre-specified primary endpoint of trough FEV1 at the end of the treatment period (Day 169), this study showed statistically significant improvements for UMEC and VI individually compared to placebo ($p<0.001$). The combination UMEC/VI showed statistically significant improvements when compared with the individual components UMEC and VI ($p\leq0.004$) and when compared to placebo (167mL, $p<0.001$).

Active Comparator Efficacy Studies

The first 24-week, randomised, double-blind, double-dummy, parallel-group study compared the efficacy and safety of UMEC/VI 62.5/25mcg and 125/25mcg with VI 25mcg and tiotropium 18mcg. This study randomised 846 patients. For the pre-specified primary endpoint of trough FEV1 at the end of the treatment period (Day 169), this study showed statistically significant improvements for both doses of UMEC/VI compared with VI (88-90mL, $p<0.001$) and tiotropium (88-90mL, $p<0.001$).

The second 24-week, randomised, double-blind, double-dummy, parallel-group study compared the efficacy and safety of UMEC/VI 62.5/25mcg and 125/25mcg with UMEC 125mcg and tiotropium 18mcg. This study randomised 872 patients. The pre-specified primary endpoint was trough FEV1 at the end of the treatment period (Day 169). For the first treatment comparison, UMEC/VI 125/25mcg showed a statistically significant improvement of 74mL compared with tiotropium ($p=0.003$). For the second comparison, UMEC/VI 125/25mcg showed a numerical but not statistically significant improvement (37mL) compared with UMEC 125mcg ($p=0.142$). UMEC/VI 62.5/25mcg showed a numerical difference from tiotropium of 60mL ($p=0.018$) and a numerical difference from UMEC 125mcg of 22mL ($p=0.377$) in trough FEV1.

In these four studies the most common adverse events across all treatment arms, including placebo, were headache, nasopharyngitis, upper respiratory tract infection, cough, oropharyngeal pain and back pain. Additionally, the incidence of cardiovascular adverse events across all treatment groups was similar (5-9% of placebo group, 7-11% of VI group, 10% of UMEC 62.5mcg group, 7-9% UMEC 125mcg group, 6-11% UMEC/VI 62.5/25mcg group, 6-7% of UMEC/VI 125/25mcg group and 4-8% tiotropium). The incidence of serious adverse events across all treatment groups was similar (3-6% of placebo group, 5-7% of VI group, 6% of UMEC 62.5mcg group, 5-7% UMEC 125mcg group, 5-10% UMEC/VI 62.5/25mcg group, 2-7% of UMEC/VI 125/25mcg group and 4-6% tiotropium).

These data form part of the overall evaluation of the efficacy and safety of the UMEC/VI combination and the individual components in approximately 6,000 COPD patients. The ongoing registration programme includes a 52-week safety study and two replicate 12-week crossover exercise studies. Subject to successful completion of these additional studies, GSK plans to commence global regulatory submissions for UMEC/VI from the end of 2012, ahead of schedule.

The full results of all these studies, together with additional data from phase IIb dose-ranging studies of UMEC, will be presented at future scientific meetings.

Other Respiratory Development Programmes

The data from these studies will also contribute to the future regulatory submissions for GSK's UMEC monotherapy, with global filings commencing in 2013.

UMEC/VI is one of several late-stage assets in the GSK respiratory development portfolio, which includes RELOVAIR™ fluticasone furoate/vilanterol (FF/VI), VI monotherapy and MABA (GSK961081), developed in collaboration with Theravance, as well as GSK's investigational medicines FF monotherapy, UMEC monotherapy and anti-IL5 MAb (mepolizumab).

Theravance Analyst Conference Call and Webcast Information

Theravance has scheduled an analyst conference call to discuss this announcement today at 8:00 a.m. Eastern Daylight Time. Analysts, who wish to participate in the live call by telephone, please dial (877) 837-3908 from the U.S., or (973) 890-8166 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 and to download the slide presentation, 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 August 1, 2012. An audio replay will also be available through 11:59 p.m. Eastern Daylight Time on July 9, 2012 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and entering confirmation code 97505831.

V A Whyte
Company Secretary
2 July 2012

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 programs include: RELOVAIR™, LAMA/LABA (UMEC/VI) and MABA (Bifunctional Muscarinic Antagonist-Beta2 Agonist), each partnered with GlaxoSmithKline plc, and its oral Peripheral Mu Opioid Receptor Antagonist (PμMA) program. 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.

*RELOVAIR™(FF/VI) is an investigational medicine and is not currently approved anywhere in the world. RELOVAIR™ is a trademark of the GlaxoSmithKline group of companies. The use of the brand name RELOVAIR™ for FF/VI is not approved by regulatory authorities around the world.

GlaxoSmithKline
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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 'Financial review & risk' section in the company's Annual Report 2011 included as exhibit 15.2 to the company's Annual Report on Form 20-F for 2011.

Theravance forward-looking statement

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 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 enabling capabilities of Theravance's approach to drug discovery and its proprietary insights, statements concerning 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 the conference call 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 2, 2012 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.

Registered in England & Wales:
No. 3888792

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980 Great West Road
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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorised.

GlaxoSmithKline plc
(Registrant)

Date: July 2, 2012

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc