GLAXOSMITHKLINE PLC
Form 6-K
October 20, 2015

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 October 2015

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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Issued: 20th October 2015, London UK

GSK announces positive new data comparing
Incruse® Ellipta® to tiotropium and glycopyrronium in patients with COPD

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced positive results from two head-to-head studies directly comparing the efficacy and safety of Incruse® Ellipta® (umeclidinium) to two available bronchodilator treatments, tiotropium (study 201316) or glycopyrronium (study 201315), when used by patients with COPD.

Results from the randomised, blinded* study 201316 showed that umeclidinium 62.5mcg once daily achieved a statistically significant improvement in lung function measured by trough forced expiratory volume in one second (FEV1) at 12 weeks (P<0.001), compared to tiotropium 18mcg administered once daily. The difference in treatment effect observed was 59ml (95% CI: 29, 88) for umeclidinium compared to tiotropium based on a per protocol analysis. For the intention to treat population, the difference observed was 53ml (95% CI: 25, 81), which was also statistically significant (P<0.001).

Results from the randomised, open-label study 201315 showed that umeclidinium 62.5mcg once daily was non-inferior to glycopyrronium 44mcg administered once daily, also measured by trough FEV1 at 12 weeks. The difference in treatment effect observed was 24ml (95% CI: -5, 54) for umeclidinium compared to glycopyrronium based on a per protocol analysis. For the intention to treat population, the difference observed was 33ml (95% CI: 5, 61).

In study 201316, the most commonly reported on-treatment adverse events for both umeclidinium and tiotropium were headache (6% umeclidinium; 6% tiotropium) and nasopharyngitis (5% umeclidinium; 5% tiotropium). The overall incidence of on-treatment adverse events was 32% in the umeclidinium group and 30% in the tiotropium group. The incidence of any on-treatment serious adverse event in both treatment arms was 3%.

In study 201315, the most commonly reported on-treatment adverse events for both umeclidinium and glycopyrronium were headache (8% umeclidinium; 10% glycopyrronium) and nasopharyngitis (8% umeclidinium; 8% glycopyrronium). The overall incidence of on-treatment adverse events was 37% in the umeclidinium group and 36% in the glycopyrronium group. The incidence of any on-treatment serious adverse event in both treatment arms was 3%.

Study Designs

Umeclidinium vs tiotropium (study 201316)
This was a 12 week, multicentre, randomised, blinded study involving 1,259 patients, designed to compare the efficacy and safety of umeclidinium (62.5mcg once daily) administered via the Ellipta inhaler to tiotropium (18mcg once daily) administered via the Handihaler inhaler in subjects with COPD. Patients were randomised 1:1 to umeclidinium 62.5mcg inhalation powder or tiotropium 18mcg. The primary endpoint was change from baseline in trough FEV1 at Day 85. The primary analysis was to determine non-inferiority (based on a margin of -50ml) or superiority of umeclidinium to tiotropium.

Umeclidinium vs glycopyrronium (study 201315)
This was a 12 week, multicentre, non-US, randomised, open-label study involving 1,352 patients, designed to compare the efficacy and safety of umeclidinium (62.5mcg once daily) administered via the Ellipta inhaler to glycopyrronium (44mcg once daily) administered via the Breezhaler inhaler in subjects with COPD. Patients were randomised 1:1 to umeclidinium 62.5mcg inhalation powder or glycopyrronium 44mcg. The primary endpoint was change from baseline in trough FEV1 at Day 85. The primary analysis was to determine non-inferiority (based on a margin of -50ml) or superiority of umeclidinium to glycopyrronium.

The results for both of these studies have been posted on the GSK Clinical Study Register and will be presented at a future scientific meeting.

*Details of the blinding process for the tiotropium comparator study discussed in this press release (201316) can be found on page 474 in Decramer M et al. Lancet Respir Med 2014; 2:472-486.5.

About COPD
COPD is a disease of the lungs that includes chronic bronchitis, emphysema or both. COPD is characterised by obstruction to airflow that interferes with normal breathing.1 COPD is thought to affect 329 million people worldwide.2

Long-term exposure to lung irritants that damage the lungs and the airways are usually the cause of COPD. Cigarette smoke, breathing in second hand smoke, air pollution, chemical fumes or dust from the environment or workplace can all contribute to COPD. Most people who have COPD are at least 40 years old when symptoms begin.3

About Incruse Ellipta
Incruse Ellipta is an anticholinergic medication (also known as a long-acting muscarinic antagonist) approved in the US for the long-term once-daily maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. The FDA approved strength is 62.5mcg, administered once-daily using the Ellipta dry powder inhaler.

US Prescribing Information for Incruse Ellipta is available at:
https://www.gsksource.com/gskprm/htdocs/documents/INCRUSE-ELLIPTA-PI-PIL.PDF

Incruse Ellipta is approved in the EU as a once-daily, maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD. The approved strength in Europe is 55mcg (delivered dose, equivalent to 62.5mcg pre-dispensed dose). For the EU Summary of Product Characteristics (SmPC), please visit:
http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002809/WC500167430.pdf

Important Safety Information for umeclidinium (Incruse Ellipta)
The following Important Safety Information is based on the Highlights section of the US Prescribing Information for Incruse Ellipta. Please consult the full Prescribing Information for all the labeled safety information for Incruse Ellipta.

Incruse Ellipta is contraindicated in patients with severe hypersensitivity to milk proteins or who have hypersensitivity to either umeclidinium, or any of the other ingredients.

Incruse Ellipta should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of COPD, or as rescue therapy for the treatment of acute episodes of bronchospasm, which should be treated with an inhaled, short-acting beta2-agonist.

Incruse Ellipta can produce paradoxical bronchospasm, which may be life-threatening.

Incruse Ellipta should be used with caution in patients with narrow-angle glaucoma. Instruct patients to contact a physician immediately should any signs or symptoms of narrow-angle glaucoma occur.

Incruse Ellipta should be used with caution in patients with urinary retention, especially in patients with prostatic hyperplasia or bladder neck obstruction. Instruct patients to contact a physician immediately should any signs or symptoms of urinary retention occur.

The most common adverse reactions (incidence ≥2% and more common than placebo) with Incruse Ellipta (and placebo) were nasopharyngitis, 8% (7%); upper respiratory tract infection, 5% (4%); pharyngitis, 1% (<1%); viral upper respiratory tract infection, 1% (<1%); cough, 3% (2%); and arthralgia, 2% (1%); myalgia, 1% (<1%); upper abdominal pain, 1% (<1%); toothache, 1% (<1%); contusion, 1% (<1%); tachycardia, 1% (<1%). Other adverse reactions with Incruse Ellipta observed with an incidence less than 1% but more common than placebo included atrial fibrillation.

In addition to the two placebo-controlled clinical trials with Incruse Ellipta, a 12-month trial evaluated the safety of umeclidinium 125 mcg in subjects with COPD. Adverse reactions (incidence ≥1% and exceeded that in placebo) in subjects receiving umeclidinium 125 mcg were: nasopharyngitis, upper respiratory tract infection, urinary tract infection, pharyngitis, pneumonia, lower respiratory tract infection, rhinitis, supraventricular tachycardia, supraventricular extrasystoles, sinus tachycardia, idioventricular rhythm, headache, dizziness, sinus headache, cough, back pain, arthralgia, pain in extremity, neck pain, myalgia, nausea, dyspepsia, diarrhea, rash, depression, and vertigo.

Avoid co-administration of Incruse Ellipta with other anticholinergic-containing drugs as this may lead to an increase in anticholinergic adverse effects such as worsening of narrow-angle glaucoma, and worsening of urinary retention.

INCRUSE® and ELLIPTA® are trade marks of the GlaxoSmithKline group of companies. BREEZHALER® is a trade mark of the Novartis group of companies. HANDIHALER® is a trade mark of the Boehringer Ingelheim group of companies.

GSK - 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.

GSK enquiries:			
UK Media enquiries:	Claire Brough	+44 (0) 20 8047 5502	(London)
US Media enquiries:	Sarah Spencer	+1 215 751 3335	(Philadelphia)
	Karen Hagens	+1 919 483 2863	(North Carolina)
Analyst/Investor enquiries:	Ziba Shamsi	+44 (0) 20 8047 5543	(London)
	Tom Curry	+ 1 215 751 5419	(Philadelphia)
	Gary Davies	+44 (0) 20 8047 5503	(London)
	James Dodwell	+44 (0) 20 8047 2406	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)

Cautionary statement regarding forward-looking statements
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. Such factors include, but are not limited to, those described under Item 3.D 'Risk factors' in the company's Annual Report on Form 20-F for 2014.

References:
1. World Health Organization. Chronic Respiratory Diseases. Available from: http://www.who.int/gard/publications/chronic_respiratory_diseases.pdf
2. Global, regional, and national incidence, prevalence, and years lived with disability for 301 acute and chronic diseases and injuries in 188 countries, 1990-2013: a systematic analysis for the Global Burden of Disease Study 2013. The Lancet; 2015. Available at: http://dx.doi.org/10.1016/S0140-6736(15)60692-4. Accessed September 2015
3. National Heart Lung and Blood Institute. Who is at risk for COPD? Accessed March 2014. Available at:https://www.nhlbi.nih.gov/health/health-topics/topics/copd/atrisk.html

Registered in England & Wales:
No. 3888792

Registered Office:
980 Great West Road
Brentford, Middlesex
TW8 9GS

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: October 20, 2015

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc