GLAXOSMITHKLINE PLC
Form 6-K
December 02, 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 December 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

--

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

--

Issued: 2 December 2015, London UK - LSE Announcement

GSK receives European marketing authorisation for Nucala® (mepolizumab) in 31 countries

- First anti-IL-5 treatment for patients with severe refractory eosinophilic asthma in the EU

GlaxoSmithKline (LSE/NYSE: GSK) today announced that the European Commission has granted marketing authorisation for Nucala® (mepolizumab) as an add-on treatment for severe refractory eosinophilic asthma in adult patients. As a result Nucala is now approved for use in the 31 European countries covered by the European Medicines Agency (EMA).

Nucala is the first and only approved biologic therapy that targets interleukin-5 (IL-5), which plays an important role in regulating the function of eosinophils, an inflammatory cell known to be important in asthma. It is administered as a 100mg fixed dose subcutaneous injection every four weeks in addition to the patient's normal respiratory medication, which often comprises high-dose inhaled corticosteroids plus additional medicines including oral corticosteroids.

"The marketing authorisation of Nucala in the EU is a significant treatment advance for appropriate asthma patients and reinforces GSK's leadership in respiratory. We are proud that our work in this area, to better understand the specific role eosinophils play in severe asthma, has resulted in the licensing of mepolizumab as the first anti-IL-5 biological treatment. We aim to offer this medicine to patients as soon as possible." said Eric Dube, Senior Vice President & Head, GSK Global Respiratory Franchise.

The lead investigator of the first proof of concept trial for mepolizumab and an investigator for the Phase III MENSA study,Professor Ian Pavord, University of Oxford, commented: "Patients with severe refractory eosinophilic asthma are not the typical 'asthma' patients many people are familiar with. Despite taking high doses of inhaled medications, they struggle to control their asthma. They have particular problems with frequent asthma attacks and can require hospitalisation. Many also take oral corticosteroids to control their symptoms, which we know can lead to side effects that patients often find very difficult to deal with. To be able to offer these patients a treatment that specifically targets the underlying cause of their disease will be an important option."