GLAXOSMITHKLINE PLC
Form 6-K
April 16, 2008

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 April 16, 2008

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 - Tuesday, 15 April 2008, London, UK - LSE Announcement

TREXIMET(TM) (SUMATRIPTAN AND NAPROXEN SODIUM) TABLETS APPROVED BY FDA FOR ACUTE TREATMENT OF MIGRAINE

Clinical studies show Treximet provided significantly more patients migraine

pain relief compared to sumatriptan 85 mg

GlaxoSmithKline (LSE & NYSE: GSK) and POZEN Inc. (NASDAQ: POZN) announced today that the FDA has approved Treximet for the acute treatment of migraine attacks with or without aura in adults. Treximet is the first and only migraine product designed to target multiple mechanisms of migraine by combining a triptan, a class of migraine-specific medicines pioneered by GSK, and an anti-inflammatory pain reliever in a single tablet.

Treximet contains 85 mg sumatriptan, formulated with RT TechnologyTM, and 500 mg naproxen sodium. Sumatriptan is the active ingredient in Imitrex(R) Tablets, available in 25 mg, 50 mg and 100 mg strengths. In clinical trials, Treximet provided a significantly greater percentage of patients migraine pain relief at two hours compared to sumatriptan 85 mg or naproxen sodium 500 mg alone. In addition, Treximet provided more patients sustained migraine pain relief from two to 24 hours compared to the individual components.

"Migraine patients want their medicine to work early, and to continue to provide relief," said Dr. Stephen Silberstein, professor of neurology and director of the Jefferson Headache Center at Thomas Jefferson University and an investigator who participated in clinical trials. "The FDA approval of Treximet is good news for migraine patients because clinical trials showed that Treximet produced sustained migraine pain relief for a significant number of patients." Further, Silberstein said, significantly fewer patients on Treximet required the use of a rescue medication to treat their migraine attack than those taking sumatriptan 85 mg.

Treximet is well studied, with more than 3,700 migraine sufferers treating nearly 30,000 migraine attacks in clinical studies. The product is expected to be available in U.S. pharmacies by mid-May.

Clinical Trials Demonstrated Superior Efficacy to Individual Components

The approval of Treximet was based on data from two identical double-blind, randomized, placebo-controlled, parallel-group, multicenter studies of more than 2,900 migraine sufferers.

Findings from these pivotal studies demonstrated that Treximet provided more patients migraine pain relief at two and four hours compared to sumatriptan 85 mg, naproxen sodium 500 mg or placebo alone. Importantly, in these studies, Treximet was effective at relieving the pain of a migraine attack and maintaining that relief from two to 24 hours. In addition, Treximet effectively relieved migraine associated symptoms - nausea and sensitivity to light and sound - compared to placebo.

Treximet was generally well-tolerated in these pivotal studies The most common

treatment-related adverse events reported within 24 hours of taking Treximet were dizziness; nausea; somnolence; chest discomfort and chest pain; neck, throat and jaw pain, tightness and pressure; numbness/tingling; upset stomach; and dry mouth.

Treximet was also studied in a one-year open-label tolerability and safety study of 565 patients who treated nearly 24,500 migraine attacks with the active drug. Patients completing the one-year study treated an average of five migraine attacks per month with Treximet.

Migraines Impact Millions of Americans

Migraine headaches continue to be a significant problem for the estimated 29.5 million Americans, nearly half of which are undiagnosed. According to the International Headache Society's diagnostic criteria, migraine is characterized by recurrent headaches which, if untreated, typically last four to 72 hours, with symptoms including moderate to severe headache pain, throbbing head pain, head pain located on one side of the head, head pain aggravated by routine activity, nausea, vomiting, and sensitivity to light and sound.

In the past, many clinicians believed that migraine was a vascular condition, induced by blood vessel dilation alone. Today, new insight suggests that migraine is much more complex, involving a chain of events that are both neurovascular and inflammatory. Treximet contains sumatriptan that mediates vasoconstriction, which correlates with the relief of migraine headache. It also contains naproxen, an anti-inflammatory agent. Therefore, sumatriptan and naproxen sodium contribute to the relief of migraine through pharmacologically different mechanisms of action.

Important Safety Information About Treximet

Prescription Treximet is indicated for the acute treatment of migraine attacks, with or without aura, in adults. Treximet should only be used where a clear diagnosis of migraine headache has been established. Treximet may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk. Treximet contains a non-steroidal anti-inflammatory drug (NSAID). NSAID-containing products cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events. Treximet is contraindicated in patients with history, symptoms, or signs of ischemic cardiac, cerebrovascular, or peripheral vascular syndromes and in patients with other significant underlying cardiovascular diseases. Treximet should not be given to patients in whom unrecognized coronary artery disease is predicted by the presence of risk factors without a prior cardiovascular evaluation. Treximet should not be given to patients with uncontrolled hypertension because the components have been shown to increase blood pressure. Concurrent administration of MAO-A inhibitors or use of Treximet within two weeks of discontinuation of MAO-A inhibitor therapy is contraindicated. Treximet and any ergotamine-containing or ergot-type medication (like dihydroergotamine and mthysergide) should not be used within 24 hours of each other. Since Treximet

contains sumatriptan, it should not be administered with another 5-HT1 agonist. Treximet is contraindicated in patients with hepatic impairment. Treximet is contraindicated in patients who have had allergic reactions to products containing naproxen. It is also contraindicated in patients in whom aspirin or other NSAIDs/analgesic drugs induce the syndrome of asthma, rhinitis, and nasal polyps. Both types of reactions have the potential of being fatal. Treximet is contraindicated in patients with hypersensitivity to sumatriptan, naproxen, or any other component of the product. Cerebrovascular events have been reported in patients treated with sumatriptan. In a number of cases, it appears possible that the cerebrovascular events were primary. It is important to advise patients not to administer Treximet if a headache being experienced is atypical. The development of a potentially life-threatening serotonin syndrome may occur with triptans, including treatment with Treximet, particularly during combined use with selective serotonin reuptake inhibitors (SSRIs) or selective norepinephrine reuptake inhibitors (SNRIs). NSAID-containing products, including Treximet, should be prescribed with extreme caution in those with a prior history of ulcer disease or gastrointestinal bleeding. Treximet should not be used in late pregnancy because NSAID-containing products have been shown to cause premature closure of the ductus arteriosus. Treximet should not be used during early pregnancy unless the potential benefit justifies the potential risk to the fetus.

For complete Prescribing Information please visit www.gsk.com.

About GlaxoSmithKline (LSE & NYSE: GSK)

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 detailed company information, see GlaxoSmithKline's website: www.gsk.com.

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 2007.

About POZEN (NASDAQ: POZN)

POZEN is a pharmaceutical company committed to developing therapeutic advancements for diseases with unmet medical needs where it can improve efficacy, safety, and/or patient convenience. Since its inception, POZEN has focused its efforts primarily on the development of pharmaceutical products for the treatment of acute and chronic pain, migraine and other pain related conditions. POZEN is also exploring the development of product candidates in other pain-related therapeutic areas. POZEN has a development and commercialization alliance with GlaxoSmithKline. The company's common stock is traded on The Nasdaq Stock Market under the symbol "POZN". For detailed company information, including copies of this and other press releases, see POZEN's website: www.pozen.com.

Safe Harbor Statement

Statements included in this press release that are not historical in nature are "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. You should be aware that our actual results could differ materially from those contained in the forward-looking statements, which are based on management's current expectations and are subject to a number of risks and uncertainties, including, but not limited to, our failure to successfully commercialize our product candidates; costs and delays in the development and/or FDA approval of our product candidates, including as a result of the need to conduct additional studies, or the failure to obtain such approval of our product candidates, including as a result of changes in regulatory standards or the regulatory environment during the development period of any of our product candidates; our inability to know with certainty what standards the FDA will use to evaluate drug candidates and how that may change or evolve over time; uncertainties in clinical trial results or the timing of such trials, resulting in, among other things, an extension in the period over which we recognize deferred revenue or our failure to achieve milestones that would have provided us with revenue; the receipt of future development, regulatory or sales milestones and royalty payments from our collaboration partners; our inability to maintain or enter into, and the risks resulting from our dependence upon, collaboration or contractual arrangements necessary for the development, manufacture, commercialization, marketing, sales and distribution of any products; competitive factors; our inability to protect our patents or proprietary rights and obtain necessary rights to third party patents and intellectual property to operate our business; our inability to operate our business without infringing the patents and proprietary rights of others; general economic conditions; the failure of any products to gain market acceptance; our inability to obtain any additional required financing; technological changes; government regulation; changes in industry practice; and one-time events, including those discussed herein and in our Annual Report on Form 10-K for the period ended December 31, 2007. We do not intend to update any of these factors or to publicly announce the results of any revisions to these forward-looking statements.

Simon Bicknell

Company Secretary

15th April 2008

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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: April 16, 2008

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on behalf of GlaxoSmithKline plc