

ASTRAZENECA PLC
Form 6-K
July 10, 2009

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 June 2009

Commission File Number: 001-11960

AstraZeneca PLC

15 Stanhope Gate, London W1K 1LN, England

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

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

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 ☒

If "Yes" is marked, indicate below the file number assigned to the Registrant in connection with Rule 12g3-2(b): 82-_____

AstraZeneca PLC

INDEX TO EXHIBITS

1. Press release entitled, “AstraZeneca and Abbott submit New Drug Application to the FDA for the approval of CERTRIAD for the treatment of mixed dyslipidemia”, dated 4 June 2009.
 2. Press release entitled, “Favourable vote from FDA Advisory Committee on Seroquel paediatric supplemental New Drug Applications”, dated 11 June 2009.
 3. Press release entitled, “ONGLYZA (saxagliptin) receives positive opinion in Europe for the treatment of Type 2 diabetes”, dated 26 June 2009.
 4. Press release entitled, “Transparency Directive Voting Rights and Capital”, dated 30 June 2009.
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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 authorized.

AstraZeneca PLC

Date: 7 July 2009

By: /s/ Adrian C N Kemp
Name: Adrian C N Kemp
Title: Company Secretary

Item 1

ASTRAZENECA AND ABBOTT SUBMIT NEW DRUG APPLICATION TO THE FDA FOR THE APPROVAL OF CERTRIAD FOR THE TREATMENT OF MIXED DYSLIPIDEMIA

AstraZeneca and Abbott announced today that the companies have submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for an investigational compound for the treatment of mixed dyslipidemia, a combination of two or more lipid abnormalities including high LDL cholesterol (the “bad” cholesterol), high triglycerides and low HDL-cholesterol (the “good” cholesterol). The NDA submission for this investigational compound, containing the active ingredients of CRESTOR (rosuvastatin calcium) and TRILIPIX (fenofibric acid), is supported by data from multiple studies, including efficacy and safety studies with the 5mg, 10mg and 20mg doses of rosuvastatin combined with fenofibric acid. Pending approval of the NDA, the treatment will be marketed as CERTRIAD.

“This NDA submission is an important milestone in the development of CERTRIAD and demonstrates our commitment to developing treatments for dyslipidemia,” said Howard Hutchinson, Chief Medical Officer, AstraZeneca. “We look forward to continued discussions with the FDA about this potential new medicine.”

“Patients with mixed dyslipidemia are an underserved segment of the dyslipidemic population,” said Eugene Sun, M.D., vice president, Global Pharmaceutical Clinical Development, Abbott. “If approved, CERTRIAD could become an important treatment option for physicians looking to provide comprehensive management of mixed dyslipidemia to their patients.”

According to the American Heart Association, more than 100 million adults in the United States have dyslipidemia. Of those, approximately 34 million people are affected by mixed dyslipidemia. Treatment guidelines endorsed by the National Cholesterol Education Program (NCEP), the American College of Cardiology and the American Heart Association have called for more aggressive management of lipids, including a lower LDL goal for many patients, as well as more aggressive management of HDL and triglycerides.

About CERTRIAD

CERTRIAD is an investigational compound under joint development by AstraZeneca and Abbott for the treatment of mixed dyslipidemia. Phase III data for CERTRIAD have been presented and evaluate the efficacy and safety of this therapy in improving HDL-C and triglycerides compared to rosuvastatin monotherapy, and improving LDL-C compared to fenofibric acid monotherapy in patients with mixed dyslipidemia.

About AstraZeneca

AstraZeneca is a major international healthcare business engaged in the research, development, manufacturing and marketing of meaningful prescription medicines and supplier for healthcare services. AstraZeneca is one of the world's leading pharmaceutical companies with healthcare sales of US\$ 31.6 billion and is a leader in gastrointestinal, cardiovascular, neuroscience, respiratory, oncology and infectious disease medicines. For more information about AstraZeneca, please visit: www.astrazeneca.com

About Abbott

Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs more than 72,000 people and markets its products in more than 130 countries. Abbott's news releases and other information are available on the company's Web site at www.abbott.com.

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4 June 2009

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Item 2

FAVOURABLE VOTE FROM FDA ADVISORY COMMITTEE ON SEROQUEL PAEDIATRIC
SUPPLEMENTAL NEW
DRUG APPLICATIONS

On 10 June 2009, the U.S. Food and Drug Administration (FDA) Psychopharmacologic Drugs Advisory Committee conducted a review of the efficacy and safety of supplemental new drug applications (sNDAs) for SEROQUEL (quetiapine fumarate) proposed for the acute treatment of schizophrenia in adolescents (13-17 years of age), and the acute treatment of bipolar mania in children and adolescents (10-17 years of age).

The Advisory Committee voted as follows:

Questions to the Advisory Committee	Yes	No	Abstain
1. Has Seroquel been shown to be effective for the treatment of schizophrenia in paediatric patients ages 13-17?	17	1	0
2. Has Seroquel been shown to be acceptably safe for the treatment of schizophrenia in paediatric patients ages 13-17?	16	0	2
3. Has Seroquel been shown to be effective for the treatment of bipolar mania in paediatric patients ages 10-17?	17	0	1
4. Has Seroquel been shown to be acceptably safe for the treatment of bipolar mania in paediatric patients ages 10-17?	13	0	5

Howard Hutchinson, M.D., Chief Medical Officer of AstraZeneca, said: “We are pleased that the committee found SEROQUEL to be effective and acceptably safe for treating adolescents with schizophrenia and children and adolescents with bipolar mania, and we look forward to having further discussions with the FDA regarding the sNDAs.”

The current approved indications for SEROQUEL are unchanged. SEROQUEL is not approved for use in patients under the age of 18 in any country.

The FDA frequently convenes advisory committee meetings to obtain independent expert guidance and recommendations on clinical matters. While the FDA is not required to follow this guidance, the agency usually takes the advice into consideration when rendering its final decisions on pending applications and other public health matters.

ABOUT SEROQUEL

SEROQUEL was first approved in the US in 1997 and is currently approved for adults in the treatment of depressive episodes in bipolar disorder; acute manic episodes in bipolar I disorder, as either monotherapy or adjunct therapy to lithium or divalproex; for the maintenance treatment of bipolar I disorder as adjunct therapy to lithium or divalproex; and for the treatment of schizophrenia. The safety of SEROQUEL has been evaluated in clinical trials with thousands of adult patients and continues to be reviewed by the FDA.

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11 June 2009

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Item 3

ONGLYZA (SAXAGLIPTIN) RECEIVES POSITIVE OPINION IN EUROPE FOR THE TREATMENT OF TYPE 2 DIABETES

AstraZeneca and Bristol-Myers Squibb Company have announced that their marketing authorisation application for ONGLYZA (saxagliptin) received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) for the treatment of type 2 diabetes in adults as add-on therapy with metformin, a thiazolidinedione or a sulphonylurea.

The positive opinion was reached after the CHMP reviewed data from a comprehensive clinical development programme that included six core Phase III trials assessing the safety and efficacy of saxagliptin as a once daily therapy. These involved 4,148 patients with type 2 diabetes, including 3,021 patients treated with saxagliptin.

Saxagliptin belongs to the class of dipeptidyl peptidase-4 (DPP-4) inhibitors. These are designed to enhance the body's ability to decrease blood sugar (glucose) when it is elevated by acting on the natural hormones, incretins, thereby increasing insulin production, and by reducing the liver's production of glucose.

This application to the CHMP is for use as a once daily 5mg dose in adult patients with type 2 diabetes mellitus to improve glycaemic control:

- in combination with metformin, when metformin alone, with diet and exercise, does not provide adequate glycaemic control;
- in combination with a sulphonylurea, when the sulphonylurea alone, with diet and exercise, does not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate; or
- in combination with a thiazolidinedione, when the thiazolidinedione alone, with diet and exercise, does not provide adequate glycaemic control in patients for whom use of a thiazolidinedione is considered appropriate.

The CHMP's positive opinion on ONGLYZA will now be reviewed by the European Commission which has the authority to approve medicines for the European Union. AstraZeneca and Bristol-Myers Squibb expect the European Commission to issue its decision on a Marketing Authorisation for this type 2 diabetes investigational drug in the European Union in the coming months.

About DPP-4 Inhibitors

DPP-4 inhibitors are a class of compounds that work by affecting the action of natural hormones in the body called incretins. Incretins decrease elevated blood sugar levels (glucose) by increasing the body's utilisation of sugar, mainly through increasing insulin production in the pancreas and decreasing glucagon secretion.

AstraZeneca and Bristol-Myers Squibb partnership

AstraZeneca and Bristol-Myers Squibb entered into a collaboration in January 2007 to enable the companies to research, develop and commercialise two investigational drugs for type 2 diabetes – saxagliptin and dapagliflozin. The AstraZeneca/Bristol-

Myers Squibb diabetes collaboration is dedicated to global patient care, improving patient outcomes and creating a new vision for the treatment of type 2 diabetes.

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About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to extend and enhance human life.

ONGLYZA is a trademark of the Bristol-Myers Squibb Company.

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26 June 2009

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Item 4

Transparency Directive
Voting Rights and Capital

The following notification is made in accordance with the UK Financial Services Authority Disclosure and Transparency Rule 5.6.1. On 30 June 2009 the issued share capital of AstraZeneca PLC with voting rights is 1,448,032,428 ordinary shares of US\$0.25. No shares are held in Treasury. Therefore, the total number of voting rights in AstraZeneca PLC is 1,448,032,428.

The above figure for the total number of voting rights may be used by shareholders as the denominator for the calculations by which they will determine if they are required to notify their interest in, or a change to their interest in, AstraZeneca PLC under the FSA's Disclosure and Transparency Rules.

A C N Kemp
Company Secretary
30 June 2009
