

ASTRAZENECA PLC  
Form 6-K  
June 19, 2013

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 the month of June 2013

Commission File Number: 001-11960

AstraZeneca PLC

2 Kingdom Street, London W2 6BD

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 AND BRISTOL-MYERS SQUIBB ANNOUNCE TOP-LINE RESULTS FOR SAVOR-TIMI-53  
CARDIOVASCULAR OUTCOMES TRIAL OF ONGLYZA (SAXAGLIPTIN)

AstraZeneca and Bristol-Myers Squibb announced today top-line results of the Phase IV SAVOR-TIMI-53 (Saxagliptin Assessment of Vascular Outcomes Recorded in Patients with Diabetes Mellitus) clinical trial of Onglyza (saxagliptin). In this study of adult patients with type 2 diabetes with either a history of established cardiovascular disease or multiple risk factors, Onglyza met the primary safety objective of non inferiority, and did not meet the primary efficacy objective of superiority, for a composite endpoint of cardiovascular death, non-fatal myocardial infarction or non-fatal ischaemic stroke, when added to a patient's current standard of care (with or without other anti-diabetic therapies), as compared to placebo.

These preliminary SAVOR-TIMI-53 data are being analysed and the study results will be submitted to the European Society of Cardiology (ESC) for potential presentation at the ESC Congress in September.

About Onglyza (saxagliptin)

Onglyza is indicated as an adjunct to diet and exercise to improve glycemic (blood sugar) control in adults with type 2 diabetes mellitus in multiple clinical settings. Onglyza should not be used for the treatment of patients with type 1 diabetes mellitus or diabetic ketoacidosis (increased levels of ketones in the blood or urine), as it would not be effective in these settings. Onglyza has not been studied in patients with a history of pancreatitis.

Onglyza is contraindicated in patients with a history of a serious hypersensitivity reaction to Onglyza (e.g., anaphylaxis, angioedema or exfoliative skin conditions). There have been post-marketing reports of acute pancreatitis and serious hypersensitivity reactions in patients taking Onglyza. If pancreatitis or a serious hypersensitivity reaction is suspected, promptly discontinue Onglyza and institute appropriate medical treatment. It is unknown whether patients with a history of pancreatitis are at an increased risk for development of pancreatitis while using Onglyza.

When Onglyza was used in combination with a sulfonylurea or with insulin (two medications known to cause hypoglycemia), the incidence of confirmed hypoglycemia was increased over that of placebo used in combination with a sulfonylurea or with insulin. Therefore, a lower dose of the insulin secretagogue or insulin may be required to minimize the risk of hypoglycemia when used in combination with Onglyza.

As of June 2013, Onglyza has been submitted for regulatory review in 95 countries and is approved in 86 countries including those in the European Union, the United States, Canada, Mexico, India, Brazil and China.

About SAVOR

SAVOR-TIMI-53 was a randomized, double-blind, placebo-controlled trial that involved 16,500 patients in 25 countries with type 2 diabetes who had a history of established cardiovascular disease or multiple risk factors, with or without renal impairment. SAVOR was led by the academic research organizations TIMI Study Group and Hadassah University Medical Center and conducted at over 700 sites worldwide.

About Bristol-Myers Squibb and AstraZeneca Collaboration

## Edgar Filing: ASTRAZENECA PLC - Form 6-K

Dedicated to addressing the global burden of diabetes by advancing individualized patient care, AstraZeneca and Bristol-Myers Squibb are working in collaboration to research, develop and commercialize a versatile portfolio of innovative treatment options for diabetes and related metabolic disorders that aim to provide treatment effects beyond glucose control. Find out more about the Alliance and our commitment to meeting the needs of health care professionals and people with diabetes at [www.astrazeneca.com](http://www.astrazeneca.com) or [www.bms.com](http://www.bms.com).

### About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information, please visit <http://www.bms.com> or follow us on Twitter at <http://twitter.com/bmsnews>.

### About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: [www.astrazeneca.com](http://www.astrazeneca.com)

## CONTACTS

### Media Enquiries

|                  |                              |
|------------------|------------------------------|
| Esra Erkal-Paler | +44 20 7604 8030 (UK/Global) |
| Vanessa Rhodes   | +44 20 7604 8037 (UK/Global) |
| Ayesha Bharmal   | +44 20 7604 8034 (UK/Global) |
| Michele Meixell  | +1 302 885 2677 (US)         |
| Jacob Lund       | +46 8 553 260 20 (Sweden)    |

### Investor Enquiries

|                   |                  |                      |
|-------------------|------------------|----------------------|
| James Ward-Lilley | +44 20 7604 8122 | mob: +44 7785 432613 |
| Karl Hård         | +44 20 7604 8123 | mob: +44 7789 654364 |
| Colleen Proctor   | + 1 302 886 1842 | mob: +1 302 357 4882 |
| Ed Seage          | + 1 302 886 4065 | mob: +1 302 373 1361 |

19 June 2013

- ENDS -

## 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.

Edgar Filing: ASTRAZENECA PLC - Form 6-K

AstraZeneca PLC

Date: 19 June 2013

By: /s/ Adrian Kemp

Name: Adrian Kemp

Title: Company Secretary