

ASTRAZENECA PLC  
Form 6-K  
October 16, 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 the month of October 2015

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 RECEIVES COMPLETE RESPONSE LETTER FROM US FDA FOR SAXAGLIPTIN /  
DAPAGLIFLOZIN  
FIXED-DOSE-COMBINATION

AstraZeneca today announced that the US Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) regarding the New Drug Application (NDA) for the investigational fixed-dose combination of saxagliptin and dapagliflozin for the treatment of adult patients with type 2 diabetes.

The CRL states that more clinical data are required to support the application. This includes clinical trial data from ongoing or completed studies and may require information from new studies. AstraZeneca will work closely with the FDA to determine the appropriate next steps for the NDA and remains committed to the development of the saxagliptin/ dapagliflozin fixed-dose combination.

This announcement does not affect ongoing interactions with other health authorities as part of these individual application procedures. Based on the information available, the CRL is not expected to affect individual components of saxagliptin or dapagliflozin, which are approved for the treatment of adult patients with type 2 diabetes.

#### About Type 2 Diabetes

Diabetes is estimated to affect 29.1 million people in the US and more than 387 million people worldwide. The prevalence of diabetes is projected to reach more than 592 million people worldwide by 2035 and type 2 diabetes accounts for approximately 90-95 percent of all diagnosed cases in the US. Type 2 diabetes is a chronic and progressive disease characterised by multiple pathophysiologic defects leading to elevated glucose levels. Significant unmet needs still exist, as many patients remain inadequately controlled on their current glucose-lowering regimen. It is estimated that nearly half of people living with type 2 diabetes are not achieving recommended HbA1c goals based on guidelines established by professional societies and advocacy organizations for diabetes management.

#### About AstraZeneca in Diabetes

AstraZeneca is pushing the boundaries of science with the goal of developing life-changing medicines that aim to reduce the global burden and complications of diabetes. Our current portfolio consists of the three newest classes of non-insulin, anti-diabetic treatments that support individualised treatment approaches: SGLT-2 inhibitors, GLP-1 receptor agonists and DPP-4 inhibitors.

As a strategic therapy area for the company, we are focusing our research and development efforts on diverse populations and patients with significant co-morbidities, such as cardiovascular disease, heart failure, obesity, non-alcoholic steatohepatitis (NASH), and chronic kidney disease.

Our commitment to diabetes is exemplified by the depth and breadth of our global clinical research programme. This commitment is advancing understanding of the treatment effects of our diabetes medicines in broad patient populations, as well as exploring combination treatment approaches to help more patients achieve treatment success earlier in their disease progression. Our ambition is to reduce the long-term impact of diabetes.

#### About DPP-4 Inhibition

Incretin hormones are released into the bloodstream in response to meals and increase insulin release in a glucose-dependent manner but are inactivated by the DPP-4 enzyme within minutes. DPP-4 inhibitors slow the inactivation of the incretin hormones, thereby reducing fasting and postprandial glucose concentrations in a glucose-dependent manner.

#### About SGLT-2 Inhibition

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

The kidney plays a contributing role in maintaining normal glucose balance, in part by filtering and subsequently reabsorbing glucose back into circulation. SGLT-2, a sodium-glucose cotransporter found predominantly in the kidney, is responsible for the majority of glucose reabsorption. Selective inhibition of SGLT-2 reduces the reabsorption of glucose and lowers the renal threshold for glucose thereby enabling its removal via the urine.

### 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		UK/Global	+44 20 7604 8030
Vanessa Rhodes		UK/Global	+44 20 7604 8037
Ayesha Bharmal		UK/Global	+44 20 7604 8034
Karen Birmingham		UK/Global	+44 20 7604 8120
Jacob Lund		Sweden	+46 8 553 260 20
Michele Meixell		US	+1 302 885 2677
Investor Enquiries	<a href="mailto:irteam@astrazeneca.com">irteam@astrazeneca.com</a>		
UK			
Thomas Kudsk Larsen Oncology		+44 20 7604 8199	+44 7818 524185
Eugenia Litz	RIA	+44 20 7604 8233	+44 7884 735627
Nick Stone	CVMD	+44 20 7604 8236	+44 7717 618834
Craig Marks	Finance	+44 20 7604 8591	+44 7881 615764
Christer Gruvris		+44 20 7604 8126	+44 7827 836825

US			
Lindsey Trickett	Oncology, ING	+1 301 398 5118	+1 240 543 7970
Mitch Chan	Oncology	+1 301 398 1849	+1 240 477 3771
Dial / Toll-Free		+1 301 398 3251	+1 866 381 7277
Key: RIA - Respiratory, Inflammation and Autoimmunity, CVMD - Cardiovascular and Metabolic Disease, ING - Infection, Neuroscience and Gastrointestinal			

16 October 2015

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: 16 October 2015

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