ASTRAZENECA PLC
Form 6-K
May 03, 2019

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 May 2019

Commission File Number: 001-11960

AstraZeneca PLC

1 Francis Crick Avenue
Cambridge Biomedical Campus
Cambridge CB2 0AA
United Kingdom

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 X 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 X

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

INDEX TO EXHIBITS

1.
Qternmet XR approved in the US for type-2 diabetes

3 May 2019 07:00 BST

Qternmet XR approved in the US for the treatment of type-2 diabetes

The US Food and Drug Administration (FDA) has approved Qternmet XR (dapagliflozin, saxagliptin and metformin hydrochloride) extended release tablets as an oral adjunct treatment to diet and exercise to improve glycaemic control in adults with type-2 diabetes (T2D).

The approval is based on two Phase III trials, which evaluated combinations of dapagliflozin and saxagliptin on a background of metformin over 24 weeks, in patients with inadequately-controlled T2D.

In one trial, treatment with 5mg dapagliflozin/5mg saxagliptin in addition to metformin demonstrated statistically-significant decreases in HbA1c (average blood glucose levels), and an increase in the number of patients achieving the recommended HbA1c treatment goal of <7%. In the second trial, treatment with 10mg dapagliflozin/5mg saxagliptin in addition to metformin extended release demonstrated statistically-significant decreases in HbA1c, and an increase in the number of patients achieving an HbA1c <7%.

The safety results of the individual medicines in these trials were consistent with their known profile.

About Qternmet XR
Qternmet XR is a once-daily, oral medicine compromised of the selective sodium-glucose cotransporter-2 (SGLT-2) inhibitor dapagliflozin, the dipeptidyl peptidase-4 (DPP-4) inhibitor saxagliptin and metformin hydrochloride extended release. Qternmet XR is approved in the US as an adjunct to diet and exercise to improve glycaemic control in adults with type-2 diabetes.

About AstraZeneca in Cardiovascular, Renal & Metabolism (CVRM)
Cardiovascular, renal and metabolism together form one of AstraZeneca's main therapy areas and a key growth driver for the Company. By following the science to understand more clearly the underlying links between the heart, kidneys and pancreas, AstraZeneca is investing in a portfolio of medicines to protect organs and improve outcomes by slowing disease progression, reducing risks and tackling co-morbidities. Our ambition is to modify or halt the natural course of CVRM diseases and potentially regenerate organs and restore function, by continuing to deliver transformative science that improves treatment practices and cardiovascular health for millions of patients worldwide.

About AstraZeneca
AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three therapy areas - Oncology, Cardiovascular, Renal & Metabolism and Respiratory. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information, please visit astrazeneca.com and follow us on Twitter @AstraZeneca.

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Adrian Kemp
Company Secretary
AstraZeneca PLC

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: 03 May 2019

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