ASTRAZENECA PLC
Form 6-K
May 21, 2018

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 2018

Commission File Number: 001-11960

AstraZeneca PLC

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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-_____

AstraZeneca PLC

INDEX TO EXHIBITS

1.
AZ regulatory submission in Japan for Forxiga

21 May 2018 07:00 BST

Regulatory submission in Japan for Forxiga in type-1 diabetes

Japan submission follows European regulatory submission acceptance in March 2018

AstraZeneca has submitted a supplemental new drug application (sNDA) to Japan's Pharmaceuticals and Medical Devices Agency (PMDA) for the use of Forxiga (dapagliflozin), a selective sodium-glucose co-transporter 2 (SGLT2) inhibitor, as an oral adjunct treatment to insulin in adults with type-1 diabetes (T1D).

The Japan sNDA is based on Phase III data from the DEPICT (Dapagliflozin Evaluation in Patients with Inadequately Controlled Type 1 Diabetes) clinical programme for Forxiga in T1D and a dedicated trial in Japanese patients (trial D1695C00001). Results showed that Forxiga, when given as an oral adjunct to adjustable insulin in patients with inadequately-controlled T1D, demonstrated significant and clinically-meaningful reductions from baseline in HbA1c, weight and total daily insulin dose at 24 and 52 weeks, compared to placebo, at both 5mg and 10mg doses.

Forxiga is also under regulatory review in Europe for use as an oral adjunct treatment to insulin in adults with T1D.

About the DEPICT Clinical Programme
The DEPICT clinical programme consists of two clinical trials: DEPICT-1 (NCT02268214) and DEPICT-2 (NCT02460978). DEPICT-1 and DEPICT-2 are 24-week, randomised, double-blind, parallel-controlled trials designed to assess the effects of Forxiga 5mg or 10mg on glycaemic control in patients with T1D inadequately controlled by insulin. All patients will be evaluated at week 24 and after a 28-week extension (52 weeks in total).

About Forxiga (dapagliflozin)
Forxiga is a first-in-class selective inhibitor of human SGLT2 indicated as both monotherapy and as part of combination therapy to improve glycaemic control. Although not indicated for these uses, Forxiga provides the added benefits of blood pressure reductions and weight loss in adult patients with type-2 diabetes (T2D).

AstraZeneca continues to push the boundaries of science with Forxiga through the largest and broadest patient-centric clinical programme. The DapaCare clinical programme will enrol nearly 30,000 patients in randomised clinical trials, include a wide range of mechanistic studies, and is supported by a multinational real-world evidence study (CVD-REAL). DapaCare and complimentary clinical research will generate first-in-class data for Forxiga across a spectrum of people with T2D, T1D, established CV disease, CV risk factors and varying stages of renal disease, both with and without T2D, providing healthcare providers with evidence needed to improve patient outcomes. DapaCare underscores our commitment to following the science with Forxiga, as the first SGLT2 inhibitor to be tested in these diverse patient populations, pursuing a holistic patient approach to address the multiple risk factors associated with

CV, metabolic and renal diseases.

About AstraZeneca in Cardiovascular, Renal & Metabolism (CVRM)
Cardiovascular, renal and metabolic diseases together form one of AstraZeneca's main therapy areas and platforms for future growth. By following the science to understand more clearly the underlying links between the heart, kidney 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 even 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. The Company also is selectively active in the areas of autoimmunity, neuroscience and infection. 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 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: 21 May 2018

By: /s/ Adrian Kemp
Name: Adrian Kemp

Title: Company Secretary