ASTRAZENECA PLC
Form 6-K
March 25, 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 March 2019

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-_____

INDEX TO EXHIBITS

1.
Forxiga approved in Europe for type-1 diabetes

25 March 2019 07:00 GMT

Forxiga approved in Europe for type-1 diabetes

Forxiga is the first oral medicine approved in Europe
as an adjunct to insulin for adults with type-1 diabetes and the
first AstraZeneca medicine ever approved for type-1 diabetes

The European Commission (EC) has approved Forxiga (dapagliflozin) for use in type-1 diabetes (T1D) as an adjunct to insulin in patients with a BMI ≥ 27 kg/m2, when insulin alone does not provide adequate glycaemic control despite optimal insulin therapy. This is the first approval of Forxiga for the treatment of patients with T1D.

Elisabeth Björk, Senior Vice President, Head of late Cardiovascular, Renal and Metabolism, R&D BioPharmaceuticals, said: "Forxiga is the first oral medicine approved in Europe as an adjunct to insulin for people living with type-1 diabetes whose glucose levels are not adequately controlled with insulin alone. We look forward to bringing Forxiga to a patient population that has not had any approved oral medicines available before."

The approval is based on data from the Phase III DEPICT clinical programme for Forxiga in T1D. The short-term (24 week) and long-term (52 week) data from DEPICT-1, along with the short-term data from DEPICT-2, showed that Forxiga 5mg daily, when given as an oral adjunct to adjustable insulin in patients with inadequately-controlled T1D, demonstrated significant and clinically-meaningful reductions from baseline in average blood glucose levels HbA1c (primary endpoint), weight and total daily insulin dose (secondary endpoints) at 24 and 52 weeks.1,2,3

The safety profile of Forxiga in these T1D trials was consistent with its well-established profile in type-2 diabetes (T2D), with the exception of a higher number of diabetic ketoacidosis (DKA) events in Forxiga-treated patients. DKA is a known complication for adults with T1D that affects those with T1D more frequently than with T2D. Forxiga is already indicated as a monotherapy and as part of combination therapy in adults with T2D to improve glycaemic control, with the additional benefits of weight loss and blood pressure reduction, as an adjunct to diet and exercise.

Forxiga is currently under regulatory review in Japan and the US for use as an adjunct treatment to insulin in adults with T1D, with a decision expected in the first and second half of 2019, respectively.

About type-1 diabetes
T1D is a chronic disease in which the pancreas produces little or no insulin. Approximately five percent of people living with diabetes have type-1. The condition is caused by an autoimmune reaction that destroys the beta cells in the pancreas which make insulin.4 Different factors, including genetics and some viruses, may contribute to type-1 diabetes.5

About the DEPICT clinical programme
The DEPICT (Dapagliflozin Evaluation in Patients with Inadequately Controlled Type 1 Diabetes) clinical trial programme consists of two clinical trials: DEPICT-1 (NCT02268214) and DEPICT-2 (NCT02460978). DEPICT-1 and DEPICT-2 are 24-week, randomised, double-blinded, 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 were evaluated at week 24 and after a 28-week extension (52 weeks in total). Forxiga 10mg has not been approved for the treatment of T1D.

About Forxiga

Forxiga (dapagliflozin) is a first-in-class, oral once-daily selective inhibitor of human sodium-glucose co-transporter 2 (SGLT2) indicated as both monotherapy and as part of combination therapy to improve glycaemic control, with the additional benefits of weight loss and blood pressure reduction, as an adjunct to diet and exercise in adults with T2D. Forxiga has a robust clinical trial programme of more than 35 completed and ongoing Phase IIb/III trials in over 35,000 patients, as well as more than 1.8 million patient-years' experience.

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
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AstraZeneca PLC

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Endocrinol. 2017:5;846-17
2. Mathieu C, Dandona, P, Gillard, P, et al. Efficacy and Safety of Dapagliflozin in Patients With Inadequately Controlled Type 1 Diabetes (the DEPICT-2 Study): 24-Week Results From a Randomized Controlled Trial. Diabetes Care 2018;41:1938-1946
3. Dandona P, Mathieu C, Phillip M, et al. Efficacy and safety of dapagliflozin in patients with inadequately controlled type 1 diabetes: The Depict-1 52 week study. Diabetes Care 2018 Dec; 41(12): 2552-2559
4. "Diabetes Home." Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 15 Aug. 2018, www.cdc.gov/diabetes/basics/type1.html.
5. Type 1 Diabetes." Mayo Clinic, Mayo Foundation for Medical Education and Research, 7 Aug. 2017, www.mayoclinic.org/diseases-conditions/type-1-diabetes/symptoms-causes/syc-20353011.

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: 25 March 2019

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