ASTRAZENECA PLC
Form 6-K
October 23, 2017

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 2017

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-_____

23 October 2017 07:00 BST

US FDA APPROVES NEW EASY-TO-USE, ONCE-WEEKLY BYDUREON BCISE INJECTABLE MEDICINE FOR PATIENTS WITH TYPE-2 DIABETES

New formulation of once-weekly exenatide in an improved device provides significant HbA1c reduction with added benefit of weight loss

AstraZeneca today announced that the US Food and Drug Administration (FDA) has approved Bydureon BCise (exenatide extended-release) injectable suspension, a new formulation of Bydureon in an improved once-weekly, single-dose autoinjector device for adults with type-2 diabetes whose blood sugar remains uncontrolled on one or more oral medicines in addition to diet and exercise, to improve glycaemic control.

Unlike other glucagon-like peptide-1 (GLP-1) receptor agonists, Bydureon BCise has a unique, continuous-release microsphere delivery system designed to provide consistent therapeutic levels of the active ingredient, exenatide, to help patients reach and maintain steady state. The new formulation in the innovative Bydureon BCise device is proven to reduce blood sugar levels, with the added benefit of weight loss.

Across two clinical trials, average HbA1c reductions of up to 1.4% and average weight loss of up to 3.1 pounds (1.4 kilograms) were achieved when used as monotherapy or as an add-on to metformin, a sulfonylurea, a thiazolidinedione, or any combination of two of these oral anti-diabetic medicines at 28 weeks. The most common adverse reactions reported in ≥5% of patients in clinical trials were nausea (8.2%) and adverse events associated with injection-site nodules (10.5%).

Ruud Dobber, President, AstraZeneca US and Executive Vice President, North America, said: "We know that physicians have established long-standing confidence in the significant HbA1c reduction Bydureon provides their patients to help achieve consistent control, with the added benefit of weight loss. With the approval of Bydureon BCise, we're now introducing a new formulation in an improved, easy-to-use device that will help enhance the patient experience."

Bydureon BCise will be available for patients in the US in the first quarter of 2018. A regulatory application for the new autoinjector device has also been accepted by the European Medicines Agency.

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. As a main 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, 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 products to help more patients achieve treatment success earlier in their disease.

About AstraZeneca in Cardiovascular, Renal & Metabolic Diseases (CVMD)
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 CVMDs and even regenerate organs and restore function, by continuing to deliver transformative science that improves treatment practices and CVMD 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 & Metabolic Diseases 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: 23 October 2017

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