ASTRAZENECA PLC
Form 6-K
August 30, 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 August 2018

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-_____

AstraZeneca PLC

INDEX TO EXHIBITS

1.
EC approves Bydureon BCise device for T2 diabetes

30 August 2018 07:00 BST

European Commission approves new easy-to-use, once-weekly Bydureon BCise device for patients with type-2 diabetes

AstraZeneca today announced that the European Commission (EC) has approved Bydureon BCise (exenatide 2mg prolonged-release suspension for injection in pre-filled pen) as a new formulation within the marketing authorisation for Bydureon (exenatide extended release) for the treatment of patients with type-2 diabetes.

The new formulation of once-weekly Bydureon is an improved single-dose, pre-filled pen device that requires no titration and is approved for use in combination with other glucose-lowering medicines, including basal insulin, to help improve glycaemic control in adults with type-2 diabetes whose blood sugar levels are inadequately controlled by other glucose-lowering medicines together with diet and exercise.

This approval is supported by data from two clinical trials, DURATION-NEO-1 and NEO-2. DURATION-NEO-1 is a 28-week, randomised, open-label, comparator-controlled trial (n=375), which showed that once-weekly Bydureon BCise demonstrated an HbA1c reduction of 1.4% vs. 1.0% for twice-daily Byetta (exenatide) injection at 28 weeks (baseline HbA1c 8.5% and 8.4%, respectively). Additionally, Bydureon BCise demonstrated a mean weight reduction of -1.5 Kg as monotherapy vs. -1.9 Kg (baseline was 97 Kg) when combined with certain oral antidiabetic medicines.

Elisabeth Björk, Vice President, Head of Cardiovascular, Renal and Metabolism, Global Medicines Development at AstraZeneca, said: "Building on the already well-established efficacy and safety profile of once-weekly Bydureon, today's approval of Bydureon BCise will enable us to offer an additional treatment option for patients with type-2 diabetes whose blood sugar levels are inadequately controlled by other glucose-lowering medicines together with diet and exercise."

This new formulation of once-weekly Bydureon BCise was approved by the US Food and Drug Administration (FDA) in October 2017.

About AstraZeneca in Cardiovascular, Renal & Metabolism (CVRM)
Cardiovascular, renal and metabolism together forms one of AstraZeneca's main therapy areas and key growth drivers. 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 www.astrazeneca.com and follow us on Twitter @AstraZeneca.

Media Relations		
Karen Birmingham	UK/Global	+44 203 749 5634
Rob Skelding	UK/Global	+44 203 749 5821
Matt Kent	UK/Global	+44 203 749 5906
Gonzalo Viña	UK/Global	+44 203 749 5916
Jacob Lund	Sweden	+46 8 553 260 20
Michele Meixell	US	+1 302 885 2677

Investor Relations		
Thomas Kudsk Larsen		+44 203 749 5712
Josie Afolabi		+44 203 749 5631
Craig Marks	Finance; Fixed Income	+44 7881 615 764
Henry Wheeler	Oncology	+44 203 749 5797
Mitchell Chan	Oncology; Other	+1 240 477 3771
Christer Gruvris	Cardiovascular; Metabolism	+44 203 749 5711
Nick Stone	Respiratory; Renal	+44 203 749 5716
Jennifer Kretzmann	Retail Investors	+44 203 749 5824
US toll-free		+1 866 381 7277

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: 30 August 2018

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