ASTRAZENECA PLC
Form 6-K
June 29, 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 June 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-_____

INDEX TO EXHIBITS

1.
Bydureon receives positive CHMP opinion for BCise

29 June 2018 15:00 BST

Bydureon receives positive EU CHMP opinion for new BCise device for patients with type-2 diabetes

New formulation of once-weekly Bydureon in a pre-filled device recommended to help improve glycaemic control

AstraZeneca today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion, recommending inclusion of Bydureon (2mg prolonged-release suspension for injection) BCise device as a new formulation within the marketing authorisation for Bydureon (exenatide extended-release) for the treatment of type-2 diabetes.

The new formulation of once-weekly Bydureon is an improved single-dose, pre-filled pen device which, in combination with other glucose-lowering medicines including basal insulin, aims 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.

The CHMP recommendation is based on the 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 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 administered once weekly via the BCise device 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.

This new formulation of once-weekly Bydureon (2mg prolonged-release suspension for injection) for the BCise device is approved by the US FDA.

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.

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; M&A	+44 7881 615 764
Henry Wheeler	Oncology	+44 203 749 5797
Mitchell Chan	Oncology; Other	+1 240 477 3771
Christer Gruvris	Brilinta; Diabetes	+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: 29 June 2018

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