

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 Gruvis	<i>Brilinta</i> ; 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

This information is provided by RNS, the news service of the London Stock Exchange. RNS is approved by the Financial Conduct Authority to act as a Primary Information Provider in the United Kingdom. Terms and conditions relating to the use and distribution of this information may apply. For further

information, please contact ms@seg.com or visit www.ms.com.