

FORXIGA[®] launches in Japan for the treatment of Type 2 diabetes

Ono Pharmaceutical Co., Ltd.
AstraZeneca K.K.

May 23, 2014

AstraZeneca K.K. (Osaka, President and Representative Director: Gabriel Baertschi) and Ono Pharmaceutical Co., Ltd. (Osaka, Japan, President, Representative Director, and CEO: Gyo Sagara) today announced that sales of FORXIGA[®] 5mg, 10mg Tablet (generic name: dapagliflozin), an inhibitor of sodium-glucose co-transporter 2 (SGLT2), as a once-daily oral treatment of type 2 diabetes started today in Japan.

FORXIGA[®] is a highly selective and reversible inhibitor of sodium-glucose co-transporter 2 (SGLT2) that works independently of insulin to help remove excess glucose from the body. Currently approved in 45 countries globally (as of May 2014), FORXIGA[®] was the first SGLT2 inhibitor in the world to gain regulatory approval to treat type 2 diabetes when it was approved in the EU by the European Commission in November 2012. It was approved in the US (brand name in the US: FARXIGA[™]) by the Food and Drug Administration on January 8, 2014 for the treatment of adults with type 2 diabetes, supported by a robust clinical development program comprising of 24 clinical studies evaluating safety and efficacy. The studies enrolled more than 11,000 adults with type 2 diabetes, including more than 6,000 patients treated with dapagliflozin. The ongoing clinical development program also includes a cardiovascular outcomes trial which aims to enroll over 17,000 patients.

【Feature of FORXIGA[®] Tablet】

- It was the first SGLT2 inhibitor launched in the world, and is now approved in 45 countries .
- It showed excellent HbA1c lowering effect in clinical experience both in and outside of Japan.
- Two-year overseas clinical data in patients from studies with various background medication have been reported and published in multiple papers.
- It shows high selectivity for SGLT2.
- It can be administered at any time of day irrespective of meals.
- It has been studied in combination with all classes of oral hypoglycemia agents (or oral anti-diabetic drugs) as well as GLP-1 receptor agonists

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Product name	FORXIGA [®] 5mg, 10mg Tablet
General name	Dapagliflozin
Indication or usage	Type 2 diabetes
Dosage and Administration	Usually, dapagliflozin is administered orally once a day 5mg in adult patients. In the case of patients that effects are insufficient, it can be increased to once a day 10mg while observing sufficiently elapsed.
NHI Price	FORXIGA [®] 5mg Tablet: 205.50 yen/tablet FORXIGA [®] 10mg Tablet: 308.30 yen/tablet
Approval date for production/distribution	March 24, 2014
NHI Price listed date	May 23, 2014
Launch date	May 23, 2014
Marketing Authorization holder:	Bristol-Myers K.K.
Co-promoted by:	AstraZeneca K.K.
Distributed and co-promoted by:	Ono Pharmaceutical Co., Ltd.

About Ono Pharmaceutical Co., Ltd.

Ono Pharmaceutical Co., Ltd. is a R&D-oriented pharmaceutical company specialized in creating innovative medicines in specific areas and is headquartered in Osaka, Japan, putting focus in the area of diabetes and oncology. For more information about Ono, visit the company's website at <http://www.ono.co.jp/eng/index.html>

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business engaged in the discovery, development and commercialisation of prescription medicines. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information, please visit: <http://www.astrazeneca.com>

In Japan, we aspire to further contribute to patients health and healthcare advancement with primary focus on oncology, cardiovascular, gastrointestinal, respiratory, diabetic, and neuroscience disease areas. For more information about us, please visit <http://www.astrazeneca.co.jp>

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