

News Release

FORXIGA[®] (dapagliflozin) receives regulatory approval in Japan for the treatment of Type 2 diabetes

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

March 24, 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 the Japanese Ministry of Health, Labour and Welfare (MHLW) approved 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. The application of FORXIGA[®] for the manufacture and marketing was submitted to the MHLW by Bristol Myers K.K. (Tokyo, Japan, Representative Director and President: Davide Piras).

AstraZeneca and Ono entered into an agreement to co-promote FORXIGA[®] on December 3, 2013.

FORXIGA[®] is a highly selective and reversible inhibitor of SGLT2 that works independently of insulin to help remove excess glucose from the body. Currently approved in over 40 countries globally, 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 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.

FORXIGA[®] has the potential to benefit many of the estimated 9.5 million people with strongly suspected type 2 diabetes in Japan.

*1: According to the National Health and Nutrition Survey made in 2012 by the Ministry of Health, Labor and Welfare, those strongly suspected of having diabetes are approximately 9.5 million people.

News Release

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.
Approval date for production/distribution	March 24, 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>

CONTACTS

Yukio Tani, Ono Pharmaceutical Co., Ltd., +81-6-6263-5670, y.tani@ono.co.jp
Takako Mitsui, AstraZeneca K.K., +81-6-6453-8011,
Takako.Mitsui@astrazeneca.com (Japan)