AstraZeneca K.K.
Daiichi Sankyo Company Limited

Nexium® 10 mg and 20 mg Capsules received additional approval of paediatric dosage and administration, and marketing approval of Nexium® 10 mg and 20 mg Granules for Suspension, Sachet in Japan

— First paediatric dosage and administration as a proton pump inhibitor and an additional formulation provide new treatment options for a wide range of patients —

Osaka and Tokyo, Japan, January 19, 2018 --- AstraZeneca K.K. (based in Kita-ku, Osaka, Japan; Stefan Woxström, President; hereinafter, AstraZeneca) and Daiichi Sankyo Company Limited (based in Chuo-ku, Tokyo, Japan; Sunao Manabe, President; hereinafter, Daiichi Sankyo) today announced that the Japanese Ministry of Health, Labour and Welfare granted approval of a partial registration change in terms of additional dosage and administration for children aged 1 year and older for Nexium® 10 mg and 20 mg Capsules as a proton pump inhibitor (PPI) (generic name: esomeprazole magnesium hydrate) indicated for gastric ulcer, duodenal ulcer, anastomotic ulcer, reflux esophagitis (initial treatment), nonerosive reflux disease*, and Zollinger-Ellison syndrome as well as marketing approval for Nexium® 10 mg and 20 mg Granules for Suspension, Sachet with the same indications.

The number of patients with acid-related diseases such as reflux esophagitis is presumably increasing in Japan. Although the number of paediatric patients is smaller than adult patients, paediatric patients still require treatment because a server form of the disease possibly causes esophagitis, poor body weight gain, recurrent pneumonia and asthma. However, none of the traditional PPIs, which are commonly used as a treatment for adult patients, have been approved for paediatric dosage and administration. A strong medical need for a PPI indicated for paediatric use exists as requested by the Japanese Society of Pediatric Gastroenterology, Hepatology and Nutrition.

The approval of the paediatric dosage and administration is based on results from a Japanese phase I/III study (D961TC00002) in children aged 1 to 14 years, and a Japanese phase I clinical pharmacology study (D961TC00004) that examined bioequivalence of the 20mg capsule formulation and 20 mg granules for suspension. Nexium has been approved and marketed in more than 75 countries**as a therapeutic agent with established paediatric dosage and administration. In Japan, it is the first PPI approved with paediatric dosage and administration.

The new formulation Nexium® 10 mg and 20 mg Granules for Suspension, Sachet, which is suspended in water for oral use, allows administration to younger children. This dosage form may also improve drug adherence in patients with difficulty swallowing such as elderly patients. Providing a dosage form option that meets the needs of a wider range of patients is expected to enhance the clinical value of Nexium and help patients receiving better treatment.

Daiichi Sankyo and AstraZeneca will extend the co-promotion partnership to Nexium® 10 mg and 20 mg Granules for Suspension, Sachet, as with their Nexium® Capsules. With the current

approval, Daiichi Sankyo and AstraZeneca are determined to continue their strong collaboration for contributing to the needs of patients with acid-related diseases in Japan.

* 10mg only
** As of December 2017

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About *Nexium*® (esomeprazole magnesium hydrate)
Nexium® (esomeprazole magnesium hydrate) selectively inhibits the proton pump that is responsible for the final process of gastric acid secretion to suppress acid secretion and thereby produce excellent clinical effects in acid related disease.

Nexium® has been approved and marketed in more than 125 countries. In Japan, it was approved in July 2011 for the following indications in adults: gastric ulcer, duodenal ulcer, anastomotic ulcer, reflux esophagitis, nonerosive reflux disease, Zollinger-Ellison syndrome, risk reduction of NSAID-related gastric or duodenal ulcer recurrence, and supplemental *H. pylori* eradication in the stomach after endoscopic therapy for gastric ulcer, duodenal ulcer, gastric MALT lymphoma, idiopathic thrombocytopenic purpura, and early gastric cancer. *Nexium*® has been marketed jointly by AstraZeneca and Daiichi Sankyo since September 15, 2011. Additional indications of “risk reduction of low-dose aspirin-related duodenal or gastric ulcer recurrence” and “supplemental *H. pylori* eradication in *H. pylori* enteritis” were approved in June 2012 and February 2013, respectively. Since its first launch, *Nexium*® has been widely used and demonstrated favourable performance in clinical practice.

About Daiichi Sankyo
Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address diversified, unmet medical needs of patients in both mature and emerging markets. With over 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 15,000 employees around the world draw upon a rich legacy of innovation and a robust pipeline of promising new medicines to help people. In addition to a strong portfolio of medicines for hypertension and thrombotic disorders, under the Group’s 2025 Vision to become a “Global Pharma Innovator with Competitive Advantage in Oncology,” Daiichi Sankyo research and development is primarily focused on bringing forth novel therapies in oncology, including immuno-oncology, with additional focus on new horizon areas, such as pain management, neurodegenerative diseases, heart and kidney diseases, and other rare diseases. For more information, please visit: www.daiichisankyo.com.

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 main therapy areas - Oncology, Cardiovascular & Metabolic Diseases 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.

In Japan, we focus on three therapy areas, Oncology, Cardiovascular and Metabolic Diseases/Gastrointestinal, and Respiratory, to contribute to patients’ health and healthcare advancements. For more information, please visit: https://www.astrazeneca.co.jp/

News Release

Media Inquiries to	
DAIICHI SANKYO COMPANY, LIMITED Corporate Communications Department Phone：+81-3-6225-1126 http://www.daiichisankyo.com	AstraZeneca K.K. Ikei and Sugimoto at Corporate Affairs Phone： +81-3-6268-2800 JPN.Ex.Comm@astrazeneca.com