This press release is an English-language translation of the original Japanese-language version. To the extent that there are discrepancies between this translation and the original version, the original version shall be definitive.

For Immediate Release

AstraZeneca K.K.
Daiichi Sankyo Company, Limited

Application Submitted in Japan for Additional Indication for NEXIUM® 10mg and 20mg Capsules

TOKYO, Japan (October 24, 2011) – Daiichi Sankyo Co., Ltd. (hereafter, Daiichi Sankyo) and AstraZeneca KK (hereafter, AstraZeneca) today announced that an application has been submitted to the Ministry of Health, Labor and Welfare in Japan by AstraZeneca seeking an additional indication for the proton pump inhibitor, NEXIUM® Capsule (esomeprazole magnesium) 10mg and NEXIUM® Capsule 20mg (Product launch: September 15, 2011) for the “prevention of recurrence of gastric ulcer and duodenal ulcer in patients treated with aspirin at low doses”.

The active ingredient in NEXIUM® Capsules, esomeprazole magnesium, is one of the two isomers in omeprazole, the active substance in Omepral®. Esomeprazole selectively inhibits the activity of the enzyme H⁺/K⁺-ATPase, the acid pump. Esomeprazole thus inhibits the final step in the regulation of acid secretion and thereby provides effective control of acid-related conditions.

By preventing the formation of blood clots, low-dose aspirin has been a mainstay in the prevention of myocardial infarction and ischemic stroke in Japan in recent years against the backdrop of a steadily graying population. However, the long-term administration of aspirin is known to be associated with a risk of peptic ulcers.

Because low-dose aspirin is used to control the blocking of blood vessels and the formation of blood clots, in most cases discontinuing administration is not a viable option. Consequently, there is a need for an appropriate measure for the advance prevention of serious complications in the upper digestive tract.

Based on this unmet medical need, phase three clinical trials using NEXIUM® Capsules were conducted on patients who are receiving long-term administration of low-dose aspirin, and AstraZeneca submitted an application for the additional indication based on the positive results of the trials.

Daiichi Sankyo and AstraZeneca are determined to contribute to the needs of patients with acid-related conditions in Japan, such as reflux esophagitis and non-erosive reflux disease, by maximizing the value of
NEXIUM® Capsules through their strong collaboration.

For further inquiries:

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