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

NEXIUM receives approval in Japan for prevention of recurrence of gastric ulcer and duodenal ulcer in patients treated with aspirin at low doses

TOKYO, Japan (June 22, 2012) − Daiichi Sankyo Co., Ltd. (hereafter, Daiichi Sankyo) and AstraZeneca KK (hereafter, AstraZeneca) today announced that AstraZeneca has received approval from the Japanese Ministry of Health, Labour and Welfare for a supplemental New Drug Application (sNDA) 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 acetylsalicylic acid (ASA) 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 ASA (commonly known as 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 and the rapidly increasing number of patients with so called *lifestyle related diseases*, such as high blood pressure, diabetes and hyperlipidemia. However, the long-term administration of ASA is known to be associated with a risk of peptic ulcers. Because low-dose ASA 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, Asian Phase 3 clinical trials using NEXIUM® Capsules were conducted jointly in Japan, South Korea, and Taiwan on patients who are receiving long-term administration of low-dose ASA. NEXIUM capsule 20mg once daily demonstrated statistically

significantly superior gastric ulcer/duodenal ulcer preventive effect over placebo, and was found to be safe and well tolerated. Based on the positive results of the trials, AstraZeneca submitted an application for the additional indication.

Through their strong collaboration, Daiichi Sankyo and AstraZeneca are determined to contribute to the needs of patients with acid-related conditions.

For further inquiries:

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Product outline

<table>
<tr><td>Product name</td><td>NEXIUM® Capsules 10mg, NEXIUM® Capsules 20mg</td></tr>
<tr><td>Generic name (JAN)</td><td>Esomeprazole magnesium</td></tr>
<tr><td>Indications</td><td>● Gastric ulcer, duodenal ulcer, anastomotic ulcer, reflux esophagitis, non-erosive reflux disease (NEXIUM® Capsules 10mg only), Zollinger-Ellison syndrome, prevention of recurrence of gastric ulcer and duodenal ulcer in patients treated with non-steroidal anti-inflammatory drugs, and prevention of recurrence of gastric ulcer and duodenal ulcer in patients treated with aspirin at low doses
● Adjunct for eradication of Helicobacter pylori in the following diseases
Gastric ulcer, duodenal ulcer, gastric MALT lymphoma, idiopathic thrombocytopenic purpura and metachronous development of gastric cancer after endoscopic resection of early gastric cancer</td></tr>
<tr><td>Dosage (to adults)</td><td>
<table>
<tr><th rowspan="2">indications</th><th colspan="2">NEXIUM®</th><th rowspan="2">daily dose</th><th rowspan="2">notes</th></tr>
<tr><th>10mg</th><th>20mg</th></tr>
<tr><td>Gastric ulcer, anastomotic ulcer</td><td></td><td>○</td><td>1</td><td>up to 8 weeks</td></tr>
<tr><td>duodenal ulcer</td><td></td><td>○</td><td>1</td><td>up to 6 weeks</td></tr>
<tr><td>Zollinger-Ellison syndrome</td><td></td><td>○</td><td>1</td><td></td></tr>
<tr><td>Reflux esophagitis (primary therapy)</td><td></td><td>○</td><td>1</td><td>up to 8 weeks</td></tr>
<tr><td>Reflux esophagitis (maintenance therapy)</td><td>○</td><td>○</td><td>1</td><td>For maintenance therapy of repeatedly recurrent/relapsing reflux esophagitis</td></tr>
<tr><td>Non-erosive reflux disease</td><td>○</td><td></td><td>1</td><td>up to 4 weeks</td></tr>
<tr><td>Prevention of recurrence of gastric ulcer and duodenal ulcer in patients treated with non-steroidal anti-inflammatory drug</td><td></td><td>○</td><td>1</td><td></td></tr>
<tr><td>Prevention of recurrence of gastric ulcer and duodenal ulcer in patients treated with aspirin at low doses</td><td></td><td>○</td><td>1</td><td></td></tr>
<tr><td>Adjunct for eradication of Helicobacter pylori in the following diseases
Gastric ulcer, duodenal ulcer, gastric MALT lymphoma, idiopathic thrombocytopenic purpura and metachronous development of gastric cancer after endoscopic resection of early gastric cancer</td><td></td><td>○</td><td>2</td><td>*1</td></tr>
</table>
*1
① 20 mg of esomeprazole, 750 mg (potency) of amoxicillin hydrate and 200 mg (potency) of clarithromycin should be given concomitantly via oral route all twice a day for 7 days, provided that the dose of clarithromycin can be increased up to 400 mg (potency) twice a day according to the need.
② If ① failed, 20 mg of esomeprazole, 750 mg (potency) of amoxicillin hydrate and 250 mg of metronidazole should be given concomitantly via oral route all twice a day for 7 days as an alternative therapy.</td></tr>
<tr><td>Approval for manufacture and marketing</td><td>July 1, 2011</td></tr>
<tr><td>NHI drug price listing</td><td>September 12, 2011</td></tr>
<tr><td>Product launch</td><td>September 15, 2011</td></tr>
<tr><td>Manufacture and marketing</td><td>AstraZeneca KK</td></tr>
<tr><td>Sales and distribution</td><td>Daiichi Sankyo Co., Ltd.</td></tr>
</table>

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