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For Immediate Release

AstraZeneca K.K.
Daiichi Sankyo Company, Limited

NEXIUM receives first regulatory approval in Japan for the treatment of acid-related disease

TOKYO, Japan (July 1, 2011) – Daiichi Sankyo Co., Ltd. (hereafter, Daiichi Sankyo) and AstraZeneca KK today announced that AstraZeneca has received approval from the Japanese Ministry of Health, Labour and Welfare for the manufacture and marketing of the proton pump inhibitor, NEXIUM[®] Capsule (esomeprazole magnesium) 10mg and NEXIUM[®] Capsule 20mg.

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 disease.

NEXIUM[®] Capsules received an indication for prevention of recurrence of gastric ulcer and duodenal ulcer in patients treated with non-steroidal anti-inflammatory drugs (NSAIDs), in addition to other therapeutic indications Omepral[®] has already received in Japan, including reflux esophagitis and non-erosive reflux disease (NERD).

NEXIUM[®] Capsules has been globally approved and is currently sold in more than 120 countries and regions backed up by rich and robust clinical evidence/experience. In the phase III clinical studies for reflux esophagitis patients in Japan, NEXIUM[®] Capsules demonstrated a quick relief of symptoms, endoscopic healing, patient tolerability and a good safety profile.

Under the terms of this agreement AstraZeneca and Daiichi Sankyo will co-promote this product in Japan. AstraZeneca will manufacture and develop the product and Daiichi Sankyo will be responsible for its sales and distribution.

Daiichi Sankyo and AstraZeneca are determined to contribute to the needs of patients with acid related disease in Japan by maximizing the value of NEXIUM[®] Capsules through their strong collaboration.

Product outline

Product name	NEXIUM [®] Capsules 10mg, NEXIUM [®] Capsules 20mg
Generic name (JAN)	Esomeprazole magnesium
Indications	<ul style="list-style-type: none"> ○Gastric ulcer, duodenal ulcer, anastomotic ulcer, reflux esophagitis, non-erosive reflux disease (NEXIUM[®] Capsules 10mg only), Zollinger-Ellison syndrome, and prevention of recurrence of gastric ulcer and duodenal ulcer in patients treated with non-steroidal anti-inflammatory drugs ○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
Dosage	<ul style="list-style-type: none"> ○Gastric ulcer, duodenal ulcer, anastomotic ulcer and Zollinger-Ellison syndrome The usual adult dosage is 20 mg of esomeprazole given orally once daily. The usual duration of administration is up to 8 weeks for gastric and anastomotic ulcers, and up to 6 weeks for duodenal ulcer. ○Reflux esophagitis Usually the adult dosage is 20 mg of esomeprazole given orally once daily. The usual duration of administration is up to 8 weeks. The dosage for maintenance therapy of repeatedly recurring or relapsing reflux esophagitis is 10 - 20 mg given orally once daily. ○Non-erosive reflux disease Usually the adult dosage is 10 mg of esomeprazole given orally once daily. The usual duration of administration is up to 4 weeks. ○Prevention of recurrence of gastric ulcer and duodenal ulcer in patients treated with non-steroidal anti-inflammatory drugs Usually the adult dosage is 20 mg of esomeprazole given orally once daily. ○Adjunct for eradication of Helicobacter pylori Usually to adults, 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. If the triple therapy with proton pump inhibitor, amoxicillin hydrate and clarithromycin for eradication of Helicobacter pylori failed, usually to adults, 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.
Approval for manufacture and marketing	July 1, 2011
Manufacture and marketing	AstraZeneca KK
Sales and distribution	DAIICHI SANKYO Co., Ltd.

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