

News Release

Takeda Pharmaceutical Company Limited
AstraZeneca K.K.
Mitsubishi Tanabe Pharma Corporation
Eisai Co., Ltd.

Application Submitted for Additional Indications for *Helicobacter pylori* Eradication by Concomitant Therapy with Proton Pump Inhibitors

Osaka and Tokyo, Japan, October 1, 2009 --- Takeda Pharmaceutical Company Limited (Osaka, President: Yasuchika Hasegawa), AstraZeneca K.K. (Osaka, President and CEO: Masahiro Kato), Mitsubishi Tanabe Pharma Corporation (Osaka; President and CEO: Michihiro Tsuchiya), and Eisai Co., Ltd. (Tokyo; President and CEO: Haruo Naito) jointly announced today the submission of an application^(*1) for additional indications for *Helicobacter pylori* (“*H. pylori*”) eradication by concomitant therapy with three proton pump inhibitors, lansoprazole, omeprazole, and rabeprazole sodium, marketed in Japan under four brand names. This concomitant therapy consists of a proton pump inhibitor, amoxicillin hydrate, and either clarithromycin or metronidazole and is indicated for the eradication of *H. pylori* in gastric MALT lymphoma^(*2), the stomach after endoscopic resection of early stage gastric cancer, and idiopathic thrombocytopenic purpura^(*3) (“ITP”).

Under the Japanese National Health Insurance system, the approved indications for eradication of *H. pylori* are currently limited to gastric and duodenal ulcers. While recent findings have revealed that the *H. pylori* plays a central role in the cause and pathology of a variety of diseases including gastric cancer, the Japanese Society for Helicobacter Research submitted a letter to the Minister of Health, Labour and Welfare in December 2008, requesting for the earliest possible approval of the additional indications based on the abundance of clinical evidence already published to date. In response to this, the relevant companies submitted joint applications based on the said published evidence in accordance with the "Handling of Ethical Drugs for Off-label Use", Notification No. 4 of the Research and Development Division / Notification No. 104 of the Evaluation and Licensing Division, dated February 1, 1999.

The four companies expect that, once approved, these additional indications will significantly contribute to improving the quality of life (QOL) and prognosis of the patients with the said three diseases.

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- (*1) The joint applicants of the additional indications include five other companies marketing amoxicillin hydrate, clarithromycin and metronidazole; Kyowa Hakko Kirin Co., Ltd., Astellas Pharma Inc., Taisho Pharmaceutical Co., Ltd., ABBOTT JAPAN Co., LTD., and Shionogi & Co., Ltd.
- (*2) Gastric MALT lymphoma is a B-cell lymphoma derived from Mucosa-Associated Lymphoid Tissue (“MALT”) in the stomach.
- (*3) Idiopathic thrombocytopenic purpura is characterized by decrease in platelets, leading to a variety of bleeding symptoms for which causes, such as underlying disease or medicinal treatment, are unknown.

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Notes for Editors

Products included in the application are as follows: (Generic name) and <name of manufacturer>

1. Proton Pump Inhibitors

- Takepron[®] Capsules 15 and 30; Takepron[®] OD Tablets 15 and 30 (lansoprazole) <Takeda Pharmaceutical Company Limited>
- Omepral[®] Tablets 10 and 20 (omeprazole) <AstraZeneca K.K.>
- Omeprazon[®] Tablets 10 mg and 20 mg (omeprazole) <Mitsubishi Tanabe Pharma Corporation>
- Pariet[®] Tablets 10 mg (rabeprazole sodium) <Eisai Co., Ltd.>

2. Amoxicillin hydrates

- Pasetocin[®] Capsules 125 and 250; Pasetocin[®] Tablets 250 < Kyowa Hakko Kirin Co., Ltd.>
- Sawacillin[®] Capsules; Sawacillin[®] Tablets 250 < Astellas Pharma Inc.>
- Amolin[®] Capsules 125 and 250; Amolin[®] Granules 10% <Takeda Pharmaceutical Company Limited>

3. Clarithromycin products

- Clarith[®] Tablets < Taisho Pharmaceutical Co., Ltd.>
- Klaricid[®] Tablets < ABBOTT JAPAN Co., LTD.>

4. Metronidazole products

- Flagyl[®] Oral Tablets < Shionogi & Co., Ltd.>

5. Combination package

- Lansap[®] 400; Lansap[®] 800 <Takeda Pharmaceutical Company Limited>

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