

# News Release

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

## **Approval of Additional Indications for *Helicobacter pylori* Eradication by Concomitant Therapy with Proton Pump Inhibitors**

**Osaka and Tokyo, Japan, June 18, 2010** --- Takeda Pharmaceutical Company Limited (Osaka, President and CEO: 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 that they have received approval from the Japanese Ministry of Health, Labor and Welfare 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<sup>(\*)1</sup>, idiopathic thrombocytopenic purpura<sup>(\*)2</sup> ("ITP") and the stomach after endoscopic resection of early stage gastric cancer.

The approved indications for eradication of *H. pylori* were 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, Labor and Welfare in December 2008, requesting the earliest possible approval of the additional indications based on the abundant clinical evidence already published to date. In response to this, the relevant companies<sup>(\*)3</sup> submitted joint applications on September 30, 2009 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 providing the proton pump inhibitors expect that these additional indications will significantly contribute to improving the quality of life (QOL) and prognosis of a wider range of patients.

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- (<sup>\*1</sup>) Gastric MALT lymphoma is a B-cell lymphoma derived from Mucosa-Associated Lymphoid Tissue (“MALT”) in the stomach.
- (<sup>\*2</sup>) 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.
- (<sup>\*3</sup>) Takeda Pharmaceutical Company Limited, AstraZeneca K.K., Mitsubishi Tanabe Pharma Corporation, Eisai Co., Ltd., Kyowa Hakko Kirin Co., Ltd., Astellas Pharma Inc., Taisho Pharmaceutical Co., Ltd., ABBOTT JAPAN Co., LTD., and Shionogi & Co., Ltd.

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

#### **2. Amoxicillin hydrates**

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

#### **3. Clarithromycin products**

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

#### **4. Metronidazole products**

- Flagyl<sup>®</sup> Oral Tablets < Shionogi & Co., Ltd.>

#### **5. Combination package**

- Lansap<sup>®</sup> 400 and 800 <Takeda Pharmaceutical Company Limited>

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