

# News Release

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

## **Companies Submit Joint Application Seeking Approval for Additional Indication for *Helicobacter pylori* Eradication by Concomitant Therapy with Proton Pump Inhibitors, Amoxicillin Hydrate and either Clarithromycin or Metronidazole**

**Osaka and Tokyo, Japan, August 31, 2012** --- Takeda Pharmaceutical Company Limited (Headquarters: Osaka, President: Yasuchika Hasegawa), AstraZeneca K.K. (Headquarters: Osaka, President: Paul Hudson), Mitsubishi Tanabe Pharma Corporation (Headquarters: Osaka; President: Michihiro Tsuchiya), and Eisai Co., Ltd. (Headquarters: Tokyo; President and CEO: Haruo Naito) announced today that they have submitted a joint application\* to Japan's Ministry of Health, Labour and Welfare seeking approval of *Helicobacter pylori* ("*H. pylori*") gastritis as an additional indication for *H. pylori* eradication by concomitant therapy with four proton pump inhibitors—lansoprazole, omeprazole, rabeprazole sodium and esomeprazole magnesium hydrate—manufactured and marketed by the four companies in Japan under five brand names. This concomitant therapy consists of a proton pump inhibitor, amoxicillin hydrate (generic name; marketed under two brand names), and either clarithromycin (generic name; marketed under two brand names) or metronidazole (generic name; marketed under one brand name).

*H. pylori* gastritis is also known as chronic active gastritis due to the fact that it causes histological gastric mucosal injury as a result of the persistent infiltration of inflammatory cells in the gastric mucosa due to *H. pylori* infection, and is believed to be associated with the development of various *H. pylori*-related diseases such as gastric and duodenal ulcers. However, under the Japanese National Health Insurance (NHI) system, the approved indications for eradication of *H. pylori* are currently limited to gastric and duodenal ulcers, gastric MALT lymphoma, idiopathic thrombocytopenic purpura, and the stomach after endoscopic resection of early stage gastric cancer. Against this backdrop, the Japanese Society of Gastroenterology, the Japan Gastroenterological Endoscopy Society and the Japanese Society for Helicobacter Research submitted a letter to the Minister of Health, Labour and Welfare in December 2011 requesting the earliest possible approval and subsequent coverage under NHI of *H. pylori* gastritis as an additional indication for the eradication of *H. pylori* by concomitant therapy based on the abundance of clinical evidence already published to date. In response to this, the companies submitted the latest joint application 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, this additional indication will significantly contribute to the prevention and treatment of diseases related to *H. pylori*.

\* The joint applicants of the additional indication also include five other companies marketing amoxicillin hydrate, clarithromycin and metronidazole: Kyowa Hakko Kirin Co., Ltd., Astellas Pharma Inc., ABBOTT JAPAN Co., LTD., Shionogi & Co., Ltd. and Taisho Pharmaceutical Co., Ltd.

## **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.>
- Nexium<sup>®</sup> Capsules 10 mg and 20 mg (esomeprazole magnesium hydrate) <AstraZeneca K.K (sales and distribution by Daiichi Sankyo 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 125 and 250; 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 200 <Taisho Pharmaceutical Co., Ltd. (Marketed by: Taisho Toyama Pharmaceutical Co. Ltd.)>
- Klaricid<sup>®</sup> Tablets 200mg <ABBOTT JAPAN Co., LTD.>

### **4. Metronidazole products**

- Flagyl<sup>®</sup> Oral Tablets 250 mg <Shionogi & Co., Ltd.>

### **5. Combination package**

- Lansap<sup>®</sup> 400; Lansap<sup>®</sup> 800 <Takeda Pharmaceutical Company Limited>
- Lampion<sup>®</sup> Pack <Takeda Pharmaceutical Company Limited>

## **Media Contacts:**

### **Takeda Pharmaceutical Company Limited**

Corporate Communications Department TEL: +81-3-3278-2037

### **AstraZeneca K.K.**

Corporate Communications, Corporate Affairs TEL: +81-6-6453-8011

### **Mitsubishi Tanabe Pharma Corporation**

Corporate Communications Department TEL: +81-6-6205-5211

### **Eisai Co., Ltd.**

Public Relations Department TEL: +81-3-3817-5120

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