

# News Release

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

## ***Helicobacter pylori* Gastritis Approved as Additional Indication in Japan for *Helicobacter pylori* Eradication by Triple Therapy with Proton Pump Inhibitor**

**Osaka and Tokyo, Japan, February 21, 2013** --- Takeda Pharmaceutical Company Limited (Headquarters: Osaka, President & CEO: 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) jointly announced today that *Helicobacter pylori* (“*H. pylori*”) gastritis has been approved by Japan’s Ministry of Health, Labour and Welfare as an additional indication for *H. pylori* eradication by triple therapy with proton pump inhibitors. This therapy consists of a proton pump inhibitor<sup>\*1</sup>, amoxicillin hydrate<sup>\*1</sup>, and either clarithromycin<sup>\*1</sup> or metronidazole<sup>\*1</sup>.

*H. pylori* gastritis is a histological gastric mucosal injury caused by 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 diseases such as gastric and duodenal ulcers. Existing indications approved for reimbursement under Japan’s National Health Insurance (NHI) for *H. pylori* eradication were 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 respective presidents of the Japanese Society of Gastroenterology, the Japan Gastroenterological Endoscopy Society, and the Japanese Society for Helicobacter Research submitted a joint letter to the Minister of Health, Labour and Welfare in December 2011 requesting the subsequent coverage under NHI of *H. pylori* gastritis as an additional indication for *H. pylori* eradication by triple therapy. In response to this, the four companies submitted a joint application in August 2012 based on the clinical evidence already published to date, together with five other companies<sup>\*2</sup> also seeking additional indication approval for each drug.

The four companies expect the approval of this additional indication to significantly contribute to the prevention and treatment of diseases related to *H. pylori*.

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<sup>\*1</sup> For a full list of products, please refer to “Notes for Editors” below.

<sup>\*2</sup> 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. Mylan Inc., Ohara Pharmaceutical Co., Ltd. and Takata Seiyaku Co., Ltd. submitted their respective applications for the additional indication of their drugs in December 2012.

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## Notes for Editors

The approved 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.)>
- Omeprazole Tablets “Mylan” 10 mg and 20 mg (omeprazole) <Mylan Inc.>
- Rabeprazole Na Tablets “Ohara” 10 mg (rabeprazole sodium) <Ohara Pharmaceutical 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 200 mg <Abbott Japan Co., Ltd.>
- Clarithromycin Tablets “Mylan” 200 mg <Mylan Inc.>
- Clarithromycin Tablets “Takata” 200 mg < Takata Seiyaku Co., Ltd. >

### **4. Metronidazole Products**

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

### **5. Combination Packages**

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

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