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

\textit{Helicobacter pylori Gastritis Approved as Additional Indication in Japan for Helicobacter pylori Eradication by Triple Therapy with Proton Pump Inhibitor}

\textbf{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 \textit{Helicobacter pylori} (“\textit{H. pylori}”) gastritis has been approved by Japan’s Ministry of Health, Labour and Welfare as an additional indication for \textit{H. pylori} eradication by triple therapy with proton pump inhibitors. This therapy consists of a proton pump inhibitor\(^1\), amoxicillin hydrate\(^1\), and either clarithromycin\(^1\) or metronidazole\(^1\).

\textit{H. pylori} gastritis is a histological gastric mucosal injury caused by the persistent infiltration of inflammatory cells in the gastric mucosa due to \textit{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 \textit{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 \textit{H. pylori} gastritis as an additional indication for \textit{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\(^2\) 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 \textit{H. pylori}.

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\(^1\) For a full list of products, please refer to “Notes for Editors” below.

\(^2\) 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® 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.>
   - Nexium® 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® Capsules 125 and 250; Pasetocin® Tablets 250 <Kyowa Hakko Kirin Co., Ltd.>
   - Sawacillin® Capsules 125 and 250; Sawacillin® Tablets 250 <Astellas Pharma Inc.>
   - Amolin® Capsules 125 and 250; Amolin® Granules 10% <Takeda Pharmaceutical Company Limited>

3. Clarithromycin Products
   - Clarith® Tablets 200 <Taisho Pharmaceutical Co., Ltd. (Marketed by: Taisho Toyama Pharmaceutical Co. Ltd.))>
   - Klaricid® 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® Oral Tablets 250 mg <Shionogi & Co., Ltd.>

5. Combination Packages
   - Lansap® 400; Lansap® 800 <Takeda Pharmaceutical Company Limited>
   - Lampion® Pack <Takeda Pharmaceutical Company Limited>

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