

Pasetocin[®] and Sawacillin[®]: Joint Application Seeking Approval for Additional Indication for *Helicobacter pylori* Eradication by Triple Therapy with Proton Pump Inhibitors and either Clarithromycin or Metronidazole

Tokyo, August 31, 2012 - [Kyowa Hakko Kirin Co., Ltd.](#) (“Kyowa Hakko Kirin”; Tokyo:4151; President and CEO: Nobuo Hanai) and [Astellas Pharma Inc.](#) (“Astellas Pharma”; Tokyo:4503; President and CEO: Yoshihiko Hatanaka) 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 triple therapy including amoxicillin hydrate (generic name; brand names: “Pasetocin[®] Capsules 125 and 250; Pasetocin[®] Tablets 250”, “Sawacillin[®] Capsules 125 and 250; Sawacillin[®] Tablets 250” and one other brand). This concomitant therapy consists of a proton pump inhibitor (lansoprazole, omeprazole, rabeprazole sodium and esomeprazole magnesium hydrate, generic name; marketed under five brand names), amoxicillin hydrate, 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.

Kyowa Hakko Kirin and Astellas Pharma 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 include nine companies marketing proton pump inhibitors (lansoprazole, omeprazole, rabeprazole sodium and esomeprazole magnesium hydrate), amoxicillin hydrate, clarithromycin and metronidazole: Takeda Pharmaceutical Company Limited, AstraZeneca K.K., Mitsubishi Tanabe

Pharma Corporation, Eisai Co., Ltd., 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>
The products manufactured by Kyowa Hakko Kirin or Astellas Pharma are underlined.

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)>

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 200mg <ABBOTT JAPAN Co., LTD.>

4. Metronidazole products

- Flagyl[®] Oral Tablets 250 mg <Shionogi & Co., Ltd.>

5. Combination package

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

###

For inquiries or additional information
Kyowa Hakko Kirin Co., Ltd. Corporate Communications Department TEL: +81-3-3282-0009 Astellas Pharma Inc. Corporate Communications TEL: +81-3-3244-3201