

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

Tokyo, February 21, 2013 --- [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) jointly announced today that *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) has been approved by Japan’s Ministry of Health, Labour and Welfare. 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 histological chronic gastritis caused by the chronic 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, the approved indications required for the reimbursement under National Health Insurance (NHI) for eradication of *H. pylori* have been limited to gastric and duodenal ulcers, gastric MALT lymphoma, idiopathic thrombocytopenic purpura, and the stomach after endoscopic resection of early stage gastric cancer to date. In response to this situations, the Japanese Society of Gastroenterology, the Japan Gastroenterological Endoscopy Society and the Japanese Society for Helicobacter Research jointly submitted a letter to the Minister of Health, Labour and Welfare in December 2011 requesting the subsequent coverage by NHI of *H. pylori* gastritis as an additional indication for the eradication of *H. pylori* by concomitant therapy. Following this letter, the companies* submitted the joint application for the additional indication for each drug based on the medical and pharmaceutical knowledge in the public domain in August 2012.

Kyowa Hakko Kirin and Astellas Pharma expect that, 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., Ltd., Shionogi & Co., Ltd. and Taisho Pharmaceutical Co., Ltd.
Mylan Inc., Ohara Pharmaceutical Co., Ltd. and TAKATA SEIYAKU Co., Ltd. submitted the application for the

additional indication of their drugs in December 2012.

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)>
- Omeprazole Tablets “Mylan” 10mg and 20mg (omeprazole) <Mylan Inc.>
- Rabeprazole Na Tablets ”Ohara” 10mg (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 200mg <ABBOTT JAPAN Co., LTD.>
- Clarithromycin Tablets “Mylan” 200mg <Mylan Inc.>
- Clarithromycin Tablets “Takata” 200mg <TAKATA SEIYAKU 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>

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