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Singapore: Kyowa Hakko Kirin and Astellas Pharma have submitted a joint application to Japan's Ministry of Health, Labor and Welfare seeking approval of Helicobacter pylori gastritis as an additional indication for H. pylori eradication by triple therapy, including amoxicillin hydrate. This concomitant therapy consists of a proton pump inhibitor, amoxicillin hydrate and either clarithromycin or metronidazole.

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, Labor 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.

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, amoxicillin hydrate, clarithromycin and metronidazole: Takeda Pharmaceutical, AstraZeneca, Mitsubishi Tanabe, Eisai, Kyowa Hakko Kirin, Astellas Pharma, Abbott Japan, Shionogi and Taisho Pharmaceutical.