



RaQualia Pharma Inc.
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Tegoprazan Received Regulatory Approval for the Treatment of Duodenal Ulcers in China

Nagoya, Japan – RaQualia Pharma Inc. (headquartered in Nagoya; President & CEO: Hirobumi Takeuchi, “RaQualia”) announced today that one of its sublicensees, Shandong Luoxin Pharmaceutical Group Stock Co., Ltd. (China, “Luoxin”), has received an approval for manufacturing and marketing tegoprazan, a gastric acid suppressant (Chinese trade name Taixinzan, “tegoprazan”), which was licensed through HK inno.N Corporation (headquartered in Osong, South Korea; “HK inno.N”), for the treatment of duodenal ulcers.

Tegoprazan is a potassium-competitive acid blocker (P-CAB), a new-generation treatment for gastroesophageal reflux disease. P-CABs have a different mechanism of action from proton pump inhibitors (PPIs), the first-line therapy for gastroesophageal reflux disease, and suppress gastric acid secretion more rapidly and persistently than PPIs. RaQualia and HK inno.N entered into an exclusive license agreement for developing, marketing, and manufacturing tegoprazan with sublicensing rights. HK inno.N and sublicensees worldwide have been conducting business activities for tegoprazan. In South Korea, where tegoprazan was first launched in 2019 by HK inno.N under the trade name K-CAB[®], the product has maintained the No. 1 market share, with domestic sales in 2022 on an outpatient prescription basis reaching 132.1 billion won (approximately 13.2 billion yen / 1 Korean won = 0.10 yen). The cumulative sales from January to September this year reached 114 billion won (approximately 11.4 billion yen / 1 Korean won = 0.10 yen), and sales are steadily increasing.

Regarding China, in 2021, HK inno. N entered into a license agreement with Luoxin for tegoprazan in China. Since then, Luoxin has been working on the development, manufacturing, and marketing of tegoprazan in China. In April 2022, Luoxin received a Class 1 approval, an indication for innovative medicines for the treatment of erosive esophagitis, and has been marketing tegoprazan products through major hospitals, retail pharmacies, and the Internet since that month. Tegoprazan became listed in the National Catalog of Basic Medical Insurance, Work Accident Insurance, and Maternity Insurance Drugs (2022) (NRDL) and has been reimbursed by public medical insurance since March this year.

With this regulatory approval, tegoprazan is now approved for manufacturing and marketing in China for two indications: erosive esophagitis and duodenal ulcers. Duodenal ulcers are one of the most common and frequent chronic diseases in China, accounting for approximately 70% of all peptic ulcers. In China, phase 3 clinical trials have been completed for *Helicobacter pylori* eradication adjuvant therapy, and the development of injectable formulations is underway.

Under the license agreement with HK inno.N, RaQualia has the right to receive a portion of the revenues earned by HK inno.N from sublicensees. Although RaQualia will receive no lump-sum payment due to this regulatory approval, and there will be no impact on the consolidated financial results for the fiscal year ending December 31, 2023 (January 1, 2023 to December 31, 2023), RaQualia believes that the expansion of tegoprazan’s indication will increase the sales in China, which will contribute to enhancing RaQualia’s business earnings and corporate value over the medium to long term.

RaQualia will continue to strengthen its partnership with HK inno.N, providing continuous support for the development and sublicensing to expand the options for gastric acid-related diseases, thereby making further contributions to improving patients' quality of life.