RaQualia Pharma Inc.
December 15, 2023

Tegoprazan has been filed in China for Helicobacter pylori eradication therapy

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 filed an application for 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 for adjunctive therapy for the treatment of Helicobacter pylori ("H. pylori") infection ("H. pylori eradication therapy").

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.

Luoxin announced that its application for the indication of H. pylori eradication therapy had been accepted by the National Medical Products Administration (NMPA). In addition, Luoxin reported that in a Phase III clinical trial with the primary efficacy endpoint of a 14-day eradication rate in Chinese patients with H. pylori infection, a quadruplet therapy containing tegoprazan and bismuth showed statistically significant higher eradication rates than the control group of a quadruplet therapy containing esomeprazole[1] and bismuth.
In H. pylori eradication therapy, it is crucial to maintain a high pH level in the stomach to prevent a decrease in the activity of antimicrobial agents, and P-CAB has advantages over PPIs in this respect. According to epidemiological studies, the H. pylori infection rate in China is 40% to 60%[2]. H. pylori has been implicated in the development of various diseases, including peptic ulcers and gastric cancer. In China and internationally, guidelines and consensus recommend that H. pylori eradication therapy be performed when H. pylori infection is confirmed.

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. In South Korea, H. pylori eradication therapy was approved in March 2020, and tegoprazan has been prescribed to many patients.

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.

Upon approval of the application, tegoprazan will be approved in China for three indications: erosive esophagitis, duodenal ulcers, and H. pylori eradication therapy. In addition, the development of injectable formulations is underway in China. These are expected to expand tegoprazan sales in China in the future.

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 addition of tegoprazan's approved indications 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.

Notes:
1) Esomeprazole: one of typical PPIs
2) Information source: Luoxin's corporate website (https://www.luoxin.cn/)