RaQualia
innovators for life

RaQualia Pharma Inc.
July 24, 2023

Marketing Approval of Tegoprazan in Peru

Nagoya, Japan – RaQualia Pharma Inc. (headquartered in Nagoya; President & CEO: Hirobumi Takeuchi, "RaQualia") announced today that one of its sublicensees, Laboratorios Carnot (Headquarters: Mexico City, Mexico; "Carnot"), received marketing approval from the Dirección General de Medicamentos Insumos y Drogas (DIGEMID) of tegoprazan, a drug for gastroesophageal reflux disease ("tegoprazan"), which was licensed through HK inno.N Corporation (headquartered in Seoul, South Korea; "HK inno.N"), for the treatment of four indications, including erosive esophagitis.

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. Peru is the eighth country to approve the sale of tegoprazan products, following Korea, Mongolia, China, the Philippines, Indonesia, Singapore, and Mexico. In 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 for three consecutive years since its launch, with domestic sales in 2022 on an outpatient prescription basis reaching 132.1 billion won (approximately 13.2 billion yen / 1 won = 0.10 yen). The cumulative sales from January to June this year reached 74.1 billion won (approximately 7.4 billion yen / 1 Korean won = 0.10 yen), and sales are steadily increasing.

Regarding Peru, in 2019, HK inno. N and Carnot entered into a license agreement for 17 Latin American countries, including Peru, and since then, Carnot has been working to obtain marketing approval. The regulatory review by DIGEMID has been completed, and Carnot received the marketing approval for four indications, including erosive esophagitis, non-erosive gastroesophageal reflux disease, gastric ulcer, and adjuvant Helicobacter pylori eradication. The anti-ulcer drug market in 17 Latin American countries, including Peru, is worth approximately 57 billion yen. In May of this year, sales began in Mexico, Latin America's second-largest pharmaceutical market. We expect more product launches in other Latin American countries following Mexico and Peru.

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. As a result of the product launch, RaQualia will receive a lump-sum payment from HK inno.N, which will be recorded as business income for the third quarter of the fiscal year ending December 31, 2023. The impact on the consolidated financial results for the fiscal year ending December 31, 2023 (January 1, 2023 to December 31, 2023) will be immaterial.

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.