RaQualia Pharma Inc.

Marketing Approval of Tegoprazan in Chile

Nagoya, Japan, February 20, 2024 – 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 Agencia Nacional de Medicamentos (ANAMED) 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 in Chile.

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. Chile is the ninth country to approve the sale of tegoprazan products, following South Korea, Mongolia, China, the Philippines, Indonesia, Singapore, Mexico, and Peru. In South Korea, where tegoprazan was first launched in 2019 by HK inno.N under the trade name K-CAB®, the product achieved domestic sales in 2023 on an outpatient prescription basis reaching 158.2 billion Korean won (approximately 17.4 billion yen / 1 Korean won = 0.11 yen). The cumulative sales from 2019 to 2023 reached 508.5 billion won (approximately 55.9 billion yen / 1 Korean won = 0.11 yen), and sales are steadily increasing.

Regarding Chile, in 2018, HK inno. N and Carnot entered into a license agreement for 17 Latin American countries, including Chile, and since then, Carnot has been working to obtain marketing approval. The regulatory review by ANAMED 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 Chile, is worth 574 billion Korean won (approximately 63.1 billion yen / 1 Korean won = 0.11 yen). We expect more product launches in other Latin American countries following Mexico and Chile.

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 first quarter of the fiscal year ending December 31, 2024. The impact on the consolidated financial results for the fiscal year ending December 31, 2024, has already been incorporated in the consolidated earnings forecast for the current fiscal year stated in the financial results for the fiscal year ended December 31, 2023, which were disclosed on February 14, 2024.

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.