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RaQualia Pharma Inc.

Marketing Approval of Tegoprazan in Colombia

Nagoya, Japan, September 2, 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 Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA) of tegoprazan, an acid suppressant (“tegoprazan”), which was licensed through HK inno.N Corporation (headquartered in Seoul, South Korea; “HK inno.N”).

Tegoprazan is a potassium-competitive acid blocker (P-CAB), a new-generation acid suppressant. 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 Latin America, HK inno.N has concluded license agreements with two companies, including Carnot, and activities for the development and marketing of tegoprazan are being carried out in 18 countries. With the approval of tegoprazan by INVIMA, Carnot has now obtained marketing approval in nine countries of Latin America: Mexico, Peru, Chile, the Dominican Republic, Honduras, Nicaragua, Guatemala, El Salvador and Colombia. Of these countries where the product has already been approved, sales of the product under the brand name “Ki-CAB®” began in Mexico and Peru in 2023, and the product has also been launched in Chile. Carnot expects to launch the product in the remaining six countries by the end of the year.

The anti-ulcer drug market in the 17 countries of Latin America is estimated to be worth 574 billion Korean won and HK inno. N and Carnot have been actively promoting tegoprazan in the region since last year, holding academic conferences for medical professionals. In Mexico, these activities have attracted considerable attention, and just seven months after its launch, Ki-CAB® entered the top 10 of the anti-ulcer drug market in Mexico, and it is expected to enter the top 5 this year. In addition, the Mexican Society of Gastroenterology recently announced new clinical guidelines recommending the prescription of P-CABs for first-line treatment of gastroesophageal reflux disease, and it is expected that the market for tegoprazan in the anti-ulcer drug market in Latin America will continue to expand.

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, 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 announced on February 14, 2024. At this time, RaQualia will not revise the forecast for the consolidated business results for the current fiscal year. Still, if it becomes necessary to revise the business results forecast, we will promptly announce it as soon as it is determined.

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.

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