

RaQualia Pharma Inc. May 25, 2023

Launch of Tegoprazan in Mexico for the Treatment of Gastroesophageal Reflux Disease in Mexico

Nagoya – 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"), started the product sales in Mexico 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").

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. Tegoprazan has been marketed in South Korea by HK inno.N under the tradename "K-CAB[®]" since 2019. Korean domestic sales in 2022 on an outpatient prescription basis reached 132.1 billion won (approximately 13.2 billion yen; 1 won = 0.10 yen).

Regarding Mexico, in 2019, HK inno.N entered into a sublicensing agreement with Carnot for 17 Latin American countries, including Mexico. In February 2023, Carnot received marketing approval from the Mexican regulatory authority (Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS)) for four indications, including erosive esophagitis. Since then, Carnot has been preparing for the product launch, which began on May 11 under the trade name Ki-CAB[®]. With the launch of tegoprazan in Mexico, tegoprazan is now available in five countries: South Korea, China, Mongolia, the Philippines, and Mexico.

The market for gastric acid suppressants in 17 Latin American countries, including Mexico, is worth approximately 57 billion yen, and according to Carnot, more than 40 million people in Mexico suffer from gastritis, heartburn, and acid reflux. Tegoprazan is effective within 30 minutes after the first dose, and is also effective for nighttime symptoms because it shows sustained effect taken once daily.

Carnot is the leading pharmaceutical company in Mexico's peptic ulcer treatment market, and RaQualia expects that Carnot will gain market share through its excellent sales force. Under the license agreement with HK inno.N, RaQualia retains the right to receive a certain percentage of HK inno. N's revenue from Carnot.

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.

Additional resource:

P-CAB website (in Spanish): <u>https://www.vidasinreflujo.com.mx/</u>