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ASIA EDITION

Malaysia gives nod to RaQualia's Tegoprazan for gastroesophageal reflux disease treatment

September 27, 2024 | News

Tegoprazan is a potassium-competitive acid blocker (P-CAB), a new-generation acid suppressant



Japan-based RaQualia Pharma Inc. has announced that one of its licensees, HK inno.N Corporation's business partner, Pharmaniaga Logistics Sdn Bhd has received marketing approval from the National Pharmaceutical Regulatory Agency (NPRA) forthe gastric acid secretion inhibitor tegoprazan.

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 its business partners worldwide have been conducting business activities for tegoprazan.

Currently, tegoprazan products are marketed in nine countries, including South Korea, Mongolia, China, the Philippines, Indonesia, Singapore, Mexico, Peru, and Chile, and preparations for launch, approval reviews and clinical trials are underway in 37 countries, including the United States.

In Malaysia, in 2021, HK inno.N entered into an agreement for finished product supply with Pharmaniaga, and since then, Pharmaniaga has been working to obtain marketing approval. Approved indications include erosive gastroesophageal reflux disease, non-erosive gastroesophageal reflux disease, gastric ulcer, and Helicobacter pylori eradication.

The market size for peptic ulcer drugs in Southeast Asia is $520 million, and further growth is expected. Tegoprazan is already marketed in the Philippines, Singapore, and Indonesia, as well as Malaysia, where approval has been now obtained, and is also in the process of regulatory review for approval in Thailand and Vietnam, steadily expanding its foothold in the top six countries in terms of economic scale in Southeast Asia.

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, RaQualia believes

expanding the number of countries where tegoprazan is marketed will contribute to the improvement of our business revenue and corporate value in the medium to long term.