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RaQualia Pharma Inc.

Marketing Approval of Tegoprazan in China for Helicobacter pylori Eradication Therapy

Nagoya, Japan, October 22, 2024 – RaQualia Pharma Inc. (headquartered in Nagoya; President & CEO: Hirobumi Takeuchi, "RaQualia") announced today that one of its sublicensees, Shandong Luoxin Pharmaceutical Group Stock Co., Ltd. (China, "Luoxin"), has received marketing approval from the National Medical Products Administration (NMPA) for adjunctive therapy for the treatment of Helicobacter pylori ("H. pylori") infection ("H. pylori eradication therapy").

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.

The H. pylori infection rate in China ranges from 40% to 60% of the population[1]. H. pylori has been implicated in the development of various diseases, including peptic ulcers and gastric cancer. In China and internationally, guidelines and consensus recommend that H. pylori eradication therapy be performed when H. pylori infection is confirmed. In H. pylori eradication therapy, it is crucial to maintain a high pH level in the stomach to prevent a decrease in the activity of antimicrobial agents, and P-CAB has advantages over PPIs in this respect. In a phase III clinical trial conducted by Luoxin in China, the eradication rate for the quadruplet therapy containing tegoprazan and bismuth was 93.5%, significantly higher than the 86.4% eradication rate for the control group who received the quadruplet therapy containing esomeprazole[2] and bismuth.

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 where phase III clinical trials are in progress. In China, Luoxin first developed oral formulations, and the tegoprazan products have been marketed since April 2022. With this approval, there are now three approved indications in China: erosive esophagitis, duodenal ulcer, and H. pylori eradication therapy. In addition, the development of injectable formulations is underway in China.

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, and there will be no impact on the consolidated financial results for the fiscal year ending December 31, 2024 (January 1, 2024 to December 31, 2024), RaQualia believes that the addition of tegoprazan's approved indications will increase the sales in China, which will contribute to enhancing RaQualia's business earnings and corporate value over the medium to long term.

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.

Notes:
1) Information source: Luoxin's corporate website (https://www.luoxin.cn/)
2) Esomeprazole: one of typical PPIs

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RaQualia Pharma, Inc. Media Contact:
RaQualia Pharma, Inc.
8F Meieki Southside Square, 1-21-19 Meieki Minami Nakamura-ku, Nagoya 450-0003, Japan
Tel: +81-446-6100
Email: ask@raqualia.com