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PRESS RELEASE

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Potassium-Competitive Acid Blocker Patent Allowance in China

RaQualia Pharma Inc. (RaQualia) today announced that the company has received an allowance* for a potassium-competitive acid blocker (P-CAB)* use patent in China (Application number: 201610246787.9).

This patent allowance grants P-CAB the right of use for improving diseases or symptoms associated with gastrointestinal motility reduction such as abdominal bloating, discomfort and constipation with the occurrence of the phase III interdigestive migrating contraction (IMC)*. The scope of this patent includes tegoprazan (Compound code: RQ-00000004) discovered by RaQualia as well as vonoprazan and revaprazan.

P-CAB is a class of drugs used for gastric acid secretion-related diseases with a new mechanism of action, also called acid pump antagonist, attracting attention in the field of gastrointestinal diseases. With a different mechanism of action, P-CAB suppresses gastric acid secretion more rapidly and constantly than proton pump inhibitor (PPI), the first-line therapeutic for the treatment of gastroesophageal reflux disease (GERD)*. Furthermore, this invention adds the use of P-CAB as a gastrointestinal function regulator or gastrointestinal motility activator. RaQualia expects that P-CAB will be effective for patients whose symptoms are not sufficiently improved by PPI.

In September 2010, RaQualia signed an exclusive license agreement including rights to sublicense with CJ CheilJedang Corp. to develop, sell and manufacture P-CAB (including tegoprazan) for the East Asian territory. CJ CheilJedang Corp. became independent as CJ Healthcare Corp. in April 2014 and changed its name to HK inno.N Corp. in April 2020 (Headquarters: Seoul, Korea, Representative Director: Seok-Hee Kang; hereinafter “HK inno.N”).

Launched in March 2019 as Korea’s first P-CAB (K-CAB[®]), tegoprazan is steadily expanding its sales in various medical settings in Korea. As for China, HK inno.N signed a sub-licensing agreement for tegoprazan with Shandong Luoxin Pharmaceutical Group Stock Co., Ltd. (hereinafter “Luoxin”). Since then, Luoxin has conducted clinical development of tegoprazan in China and a New Drug Application (NDA) was filed earlier this year. In addition, HK inno.N is promoting the development of tegoprazan in Southeast Asia, Latin America and the United States.

RaQualia will continue to focus on strengthening its intellectual properties. In collaboration with HK inno.N to maximize the value of tegoprazan, RaQualia will expand the treatment options for gastrointestinal diseases by delivering new drugs, aiming to improve the quality of life (QOL) of patients around the world.

The financial forecasts for the fiscal year 2021 (Jan. 1, 2021 – Dec. 31, 2021) will not be affected by this announcement.

References:

About Potassium-Competitive Acid Blocker (P-CAB):

Potassium-competitive acid blocker (P-CAB) is a next-generation gastric acid secretion inhibitor that blocks H⁺/K⁺-ATPase (proton pump) in a K⁺-competitive manner at the final step of gastric acid secretion. P-CABs are expected to take a large share against PPIs or H₂ blockers in the gastric acid secretion inhibitor market, which amounts to 2.5 trillion yen globally. Currently, vonoprazan is available in Japan, and tegoprazan and revaprazan are on the market in Korea.

About interdigestive migrating contractions (IMC):

Interdigestive migrating contractions (IMC) are coordinated gastrointestinal motility contractions consisting of four phases (phase I to phase IV) that propagate from the stomach to the anus during the normal fasting period. Of the four phases of IMC, phase III contraction is the strongest rhythmic contractile motion phase.

About gastroesophageal reflux disease (GERD):

Gastroesophageal reflux disease (GERD) includes reflux esophagitis (RE) with esophageal mucosal damage and non-erosive reflux disease (NERD) with no esophageal mucosal damage.

About patent allowance:

Patent allowance is issued by each country's patent office to recognize an applied invention as "an invention worthy of a patent." After the patent fee is paid, the patent will be registered in the relevant country.