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PRESS RELEASE

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New Drug Application for Tegoprazan in China

February 1, 2021 --- RaQualia Pharma Inc. (RaQualia) was informed that a new drug application (NDA) for tegoprazan (Korean registered trademark: K-CAB[®], hereinafter called “tegoprazan”), a novel drug for the treatment of gastroesophageal reflux disease, which RaQualia licensed to HK inno.N Corporation (Representative Director: Seok-Hee Kang, headquarters: Seoul, Korea and hereinafter called “HK inno.N”) and was sublicensed to Shandong Luoxin Pharmaceutical Group Stock Co., Ltd. (China and hereinafter called “Luoxin”), has been accepted by the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) of China. There will be no milestones associated with this matter.

RaQualia’s tegoprazan is a gastric acid secretion inhibitor with a new mechanism of action called potassium-competitive acid blocker (P-CAB). P-CAB has a different mechanism from proton pump inhibitor (PPI), the first-line drug for the treatment of gastroesophageal reflux disease. Since it suppresses gastric acid secretion more rapidly and continuously than PPI, it is expected to be a new therapeutic agent for acid-related diseases as an alternative to PPI.

In September 2020, RaQualia signed an exclusive license agreement with HK inno.N, which includes rights to sublicense, develop and commercialize tegoprazan for the East Asian territories. Having developed tegoprazan in Korea, HK inno.N launched it as the 30th new pharmaceutical of Korea in March 2019. Furthermore, HK inno.N has sublicensed tegoprazan to certain leading companies in China, Southeast Asia and Latin America to cultivate markets in sequence.

As for China, HK inno.N signed a sub-licensing agreement for tegoprazan with Luoxin in October 2015. Since then, Luoxin has been conducting clinical development in China. Luoxin announced in December 2019 that it had achieved its primary endpoint in a Phase III clinical trial of tegoprazan for erosive gastroesophageal reflux disease in China. Given the current development status, RaQualia anticipates that tegoprazan will be launched in China in 2022.

RaQualia will continue to support the clinical development and sub-licensing transactions of HK inno.N, aiming to earn milestone revenue and post-sales royalties. Furthermore, RaQualia will proceed with discussions with HK inno.N to seek potential licensees to spur the development of tegoprazan in Japan.

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