Phase III Clinical Trial in the Chinese Gastroesophageal Reflux Drug Tegoprazan Meets Primary Endpoint

December 27,2019---Today, RaQualia announced that tegoprazan (RQ-00000004/CJ-12420/ Korean Brand Name: K-CAB® and LXI-15028, hereafter “tegoprazan”), which RaQualia derived to CJ Healthcare Co., Ltd. (Headquarters: Seoul, South Korea, Co-Representative: Seok-Hee Kang, Sang-Hyun Yoon, Inc. hereafter “CJ”), achieved the primary endpoint in a phase 3 clinical trial in China (Phase 3 study, hereafter referred to as "this study") from Shandong Luoxin Pharmaceutical Group Stock Co., Ltd., a sub-licensee in China.

This study was a multi-center, randomized, double-blinded, active-control parallel-group study in which 261 patients with erosive gastroesophageal reflux in China were randomly assigned to tegoprazan 50 mg and esomeprazole 40 mg (control) groups at a 1:1 ratio. The results showed that the endoscopic cure rate in tegoprazan group was not inferior to that in esomeprazole group 8 weeks after administration.

Based on the results of this study, as the next step, Luoxin will conduct a detailed analysis of all the data in this study and submit an NDA in China.

Erosive gastroesophageal reflux is one of the major conditions in GERD. This drug has a major impact on the quality of life of patients with gastroesophageal reflux because it is characterized by acid swallowing, heart burn, and other diseases that can cause barrett esophagus, esophageal ulcer, esophageal stricture, and gastrointestinal cancer.Approximately 10 to 15% of patients fail to achieve clinical cure after the current standard of care, and 30% of patients continue to have residual symptoms such as heartburn.

Tegoprazan is a gastric acid secreation inhibitor with a new mechanism of action called potassium-competitive acid blocker (P-CAB) that was created by RaQualia. P-CAB has a different mechanism from proton pumping inhibitors (PPI), which are the first drug of choice for the treatment of gastroesophageal reflux, and is expected to become a new

therapeutic agent for acid-related diseases that replaces PPI because it suppresses gastric acid secretion more quickly and continuously than PPI.

We will continue to strengthen our collaboration with CJ and further strengthen our collaboration toward the launch of tegoprazan in China.

End

For more information, please refer to Luoxin's presentation. (External Link)
https://www.luoxin.cn/page.aspx?node=53&id=10915