

November 26, 2019

Company Name: RaQualia Pharma Inc.  
Representative's Name: President & CEO Naoki Tani  
(Ticker code number: 4579)  
Inquiries: Director & Executive Vice President Kiichiro Kawada  
(Tel. +81-52-446-6100)

### **Announcement about an expansion of the strategic alliance with CJ HealthCare Corp.**

RaQualia Pharma is pleased to announce that at our board of directors meeting held today we decided to expand our global partnership with CJ HealthCare Corp. (headquarters: Seoul, South Korea; joint representative directors: Seok-Hee Kang and Sang-Hyun Yoon; hereinafter referred to as "CJ"). We have concluded collaboration agreement (hereinafter referred to as the "Agreement") with CJ targeting North America and Europe for Tegoprazan\*<sup>1</sup> that was invented by our company (RQ-00000004 / CJ-12420 / Korea brand name (Korean registered trademark): K-CAB®, hereinafter referred to as "Tegoprazan").

#### 1. Reasons for concluding this Agreement

In June 2010, RaQualia Pharma started a strategic alliance with CJ in the field of digestive system diseases. In September of the year, we granted to CJ a license in the East Asian region for gastric acid secretion inhibitors, including Tegoprazan, and have deepened the relationship between the two companies. CJ subsequently developed Tegoprazan in South Korea and succeeded in launching it as the 30th new drug in Korea in March 2019. In September, a basic agreement was reached between the two companies to expand the global partnership. Detailed discussions and negotiations were conducted to conclude collaboration agreement for Tegoprazan in North America and Europe. Now that we have agreed on the terms and conditions, we have executed a definitive agreement.

#### 2. Details of the Agreement, etc.

Under this Agreement, RaQualia Pharma grants an exclusive license to CJ with sublicensing rights for exclusive development, sales and manufacturing of Tegoprazan in North America and Europe. Together with receiving a contract lump-sum payment as compensation, RaQualia Pharma has the right to receive milestones according to the progress, and the right to receive royalties according to the sales amount. Under the contract, the specific achievement conditions and amounts, etc., will not be disclosed.

Regarding the development of Tegoprazan in the U.S., we made an application with the U.S. Food and Drug Administration (FDA) to conduct a clinical trial for a new drug (IND: investigational new drug) in 2010. A Phase I clinical trial of the drug was conducted. In addition to examining safety, tolerability and pharmacokinetics, we confirmed that it has an excellent effect in inhibiting gastric-acid secretions\*<sup>2</sup>. Following this Agreement, CJ will take over the IND of RaQualia Pharma and will resume development in the U.S. during FY12/2020. With regards to the business development of Tegoprazan in Japan, we will retain licenses related to development, sales and manufacturing, and intend to select the most suitable partners.

RaQualia Pharma and CJ will further strengthen cooperation, and by delivering the drug to many patients

around the world we will expand options for treating digestive system diseases, and will strengthen our intent to contribute to improve the quality of life (QOL) of patients.

### 3. Outline of the contracting partner

(1) Name	CJ HealthCare Corporation	
(2) Address	100, Eulji-ro, Jung-gu, Seoul, Republic of Korea	
(3) Names of the representatives	Joint Representative Directors Seok-Hee Kang & Sang Hyun Yoon	
(4) Business details	Research, development, manufacturing and sales of medicinal drugs, pharmaceutical raw materials, and health & beauty products	
(5) Date of establishment	1984	
(6) Major shareholders and shareholding ratio	Kolmar Korea Co., Ltd.100%	
(7) Relationship between the listed company and the relevant company	Capital ties	Not applicable
	Human relationship	Not applicable
	Business relationship	Strategic alliance and license agreement in the field of digestive system diseases, including Tegoprazan
	Relevant status for the related parties	Not applicable

\*CJ HealthCare is an operating company of Kolmar, and capital, operating results and financial information are not listed since it is an unlisted company.

### 4. Schedule

(1) Date of the board meeting resolution	November 26, 2019
(2) Date the agreement was signed	November 26, 2019

### 5. Future outlook

With this Agreement, RaQualia Pharma will receive a contract lump-sum payment, and this will be recorded as business income in the fourth quarter of FY12/2019. Regarding the impact of this matter on the full-year FY12/2019 results, there are no changes to the consolidated forecast for the full-year FY12/2019 (January 1, 2019 to December 31, 2019) that was announced on September 6, 2019. RaQualia Pharma believes that the global expansion of Tegoprazan will contribute not only to short-term results, but also to the sustainable growth and enhanced corporate value of the corporate group.

#### [Reference]

\*1 <About Tegoprazan>

Tegoprazan is a gastric acid secretion inhibitor with a new mechanism called potassium-competitive acid blocker (P-CAB) that was created by RaQualia Pharma. P-CAB has a different mechanism from proton pump inhibitors (PPI), which are the first drug of choice for the treatment of gastroesophageal reflux disease (GERD). Since it inhibits gastric-acid secretion more quickly and continuously than PPI, it is expected to be a new therapeutic medication for acid-related diseases that replaces PPI. In September 2010, RaQualia Pharma granted CJ a license for P-CAB, including Tegoprazan, in the East Asian region, including South Korea and China. We concluded agreements granting exclusive licenses with sublicensing rights for development, sales and manufacturing in the Southeast Asian region in November 2014, and the rest of the world (ROW) in December 2017 that included Latin America, Russia, Eastern Europe and the Middle East. On the other hand,

CJ has granted Tegoprazan sublicensing rights to leading companies in China, Vietnam, Latin America, Indonesia and Thailand, and is gradually developing the market.

\*<sup>2</sup> <About the Phase I clinical trial of Tegoprazan in the U.S.>

In order to measure pH in the stomach (hydrogen ion concentration), which is considered to be one of the indicators of the effectiveness of GERD therapeutic drugs, a tube that can detect pH in the stomach was passed through the nose into the stomach and the change was measured over 24 hours. A single dose of 3 mg to 300 mg of the drug was administered to healthy male volunteers. In addition to safety, tolerability and pharmacokinetics, we examined the effect of Tegoprazan on gastric-acid secretions using the pH level in the stomach as a biomarker. As a result, for the doses used in this trial, the safety and tolerability of Tegoprazan and a dose-dependent increase in the blood level were confirmed. Furthermore, with regards to the effect of Tegoprazan on gastric-acid secretions, for doses of 30mg or more, it was confirmed that pH inside the stomach reached to 6 or more in about one hour after administration, that the gastric pH increased in a dose-dependent manner, and that nighttime gastric pH levels were maintained almost over 4 until the next morning following an evening administration