September 6, 2019

PRESS RELEASE

Company: RaQualia Pharma Inc.
(Ticker Code # : 4579)
Representative: Representative Director Naoki Tani
Inquiries: Executive Vice President Kiichiro Kawada
(TEL : +81-52-446-6100)

RaQualia Announces Top-Line Results of Phase III clinical trial of Ziprasidone Conducted by Meiji Seika Pharma in Patients with Schizophrenia in Japan

Tokyo, Japan, September 6, 2019-- RaQualia Pharma Inc (RaQualia) announced today that the Phase III clinical trial to assess the safety and efficacy of ziprasidone for the treatment of patients with acute schizophrenia in Japan did not meet its primary endpoint. Treatment with ziprasidone did not result in a statistically significant change in the Positive and Negative Symptoms Scale (PANSS) a medical scale commonly used for measuring symptom severity of patients with schizophrenia.

In 2011, RaQualia and Meiji Seika Pharma signed a licensing agreement through which Meiji Seika Pharma gained the exclusive rights to develop and commercialize ziprasidone in Japan. Effect of this issue on consolidated earnings forecast of the fiscal year 2019 was estimated in separate report which has been released today.

Meiji is conducting an in-depth, detailed analysis of the results observed in the study, including additional data on efficacy endpoints in order to determine the future development plans of ziprasidone.

About the Study:
This Phase III study design of this clinical trial was placebo-controlled, randomized, multicenter, double-blind comparative study in Japanese patients with acute exacerbation of schizophrenia. The primary endpoint was the mean change in Positive and Negative Symptoms Scale (PANSS) total score in 6-week treatment. The results of the trial showed no statistically-significant difference with ziprasidone versus placebo in the primary endpoint. There was a greater variation in PANSS score reduction from baseline in placebo group in this Phase III study of patients in Japan than expected, [i.e., a large placebo effect]. No new safety issues were observed among ziprasidone treatment groups during the course of this study.

About Ziprasidone:
Ziprasidone is an atypical, second generation antipsychotic agent for treatment of schizophrenia developed by Pfizer Inc. Its antischizophrenic effect is believed to be mediated via antagonism of dopamine D_2 and serotonin 5-HT_{2A} receptor with lower incidence of body weight gain and blood sugar elevation.

Ziprasidone has a well-established benefit risk profile globally supported by 21 years of clinical and post-marketing experience. Ziprasidone has been shown to be an effective treatment for schizophrenia and bipolar disorder and has been studied extensively in more than 20,000 patients resulting in 3 million patient-years of exposure.

About Schizophrenia:
Schizophrenia is one of severe mental disorder, characterized by profound disruptions in thinking, affecting language, perception, and the sense of self. It often includes psychotic experiences, such as hearing voices or delusions.

<Reference>
Meiji's press release is available below.
https://www.meiji-seika-pharma.co.jp/index.html