

# Press Release



## **Regarding “Japan Agency for Medical Research and Development (AMED)”’s decision on “Cyclic Innovation for Clinical Empowerment” (CiCLE)**

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**TOKYO, December 06th, 2019** - The development of “pyridoxamine for patients with premenstrual syndrome/menstrual dysphoric disorder with psychiatric symptoms” by Renascience Inc. (Head Office: Chuo-Ku, Tokyo, President: Atsushi Tanase, hereinafter "Renascience") has been accepted to the 4th public request for “Cyclic Innovation for Clinical Empowerment” (CiCLE) by the “Japan Agency for Medical Research and Development” (AMED).

The development above by Renascience together with ASKA Pharmaceutical Co., Ltd. (Head Office: Minato-ku, Tokyo, President: Takashi Yamaguchi, hereinafter "ASKA"), and Kinki University (Head Office: Higashi-Osaka City, President: Yoshihiko Hosoi, hereinafter "Kinki University") with other medical institutions are collaborating to develop new medications for Premenstrual syndrome and Premenstrual dysphoric disorder (hereinafter “PMS/PMDD”) in Japan.

PMS/PMDD is a condition characterized by premenstrual emotional instability, anger, depressive moods, and anxiety, etc.... In severe cases, it may have a great impact on social life and since social recognition is low, it is considered to be one of the major factors that hinder women's social success.

Up to now, there has not been a medication with insurance coverage in Japan for the above indications, and the development of a new therapeutic drug that is effective and safe for PMS/PMDD has been eagerly desired by healthcare professionals and patients.

Through basic science and clinical research, Tohoku University, Kinki University, along with Renascience have confirmed that “pyridoxamine”, a derivative of vitamin B6, may have the potential to treat the above conditions. With the support of AMED, a Phase II investigator initiated clinical trials in collaboration with ASKA along with multiple medical institutions in Japan, is scheduled to start in August 2020 after receiving approval from the PMDA (Pharmaceuticals and Medical Devices Agency).

The practical application of this potential drug is expected to improve women's QOL(Quality Of Life).

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