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PRESS RELEASE

Zeria Pharmaceutical Co., Ltd.
10-11 Nihonbashi-Kobunacho,
Chuo-ku, Tokyo
103-8351

Conclusion of Co-Development and Co-Marketing Agreement on Z-338 for Functional Dyspepsia in Japan with Astellas Pharma Inc.

We would like to announce that Zeria and Astellas Pharma Inc., (Astellas Pharma; Headquarters: Chuo-ku, Tokyo; President and CEO: Masafumi Nogimori) concluded the agreement for the co-development and co-marketing of Z-338 (generic name: acotiamide hydrochloride) for the treatment of functional dyspepsia in Japan. Based on this agreement, Zeria will obtain marketing approval, and both companies will co-market the product under the same brand name.

Acotiamide hydrochloride is a novel compound originated by Zeria and being developed in Europe, North America and Japan as the first therapeutic drug in the world for the treatment of Functional Dyspepsia (FD). In the North America, Zeria has granted to Astellas Pharma exclusive rights for development and commercialization, and co-development of P IIb for “Z-338/YM443” is underway. Upon this conclusion of the agreement in Japan, Zeria and Astellas Pharma will commence co-development of P III. In Europe, Zeria retains rights to develop it and P IIb study is ongoing.

According to the Rome III, which is the latest version of the international classification and diagnostic criteria for functional gastrointestinal disorders, FD is a gastrointestinal disease that comprises subjective symptoms such as postprandial fullness, early satiation and epigastric pain without any structural abnormality on gastrointestinal tract. The etiology of FD is still unclear, but it has been shown that delayed gastric emptying is closely associated with FD.

Acetylcholine is an important neurotransmitter for gastrointestinal motility, and it has been considered that acotiamide hydrochloride inhibits peripheral acetylcholinesterase activities, and results in improvement of delayed gastric emptying, and consequently the symptoms of FD.

Recent studies indicate that one fourth of adult population in Japan suffers from FD, and FD is a disease with a high incidence rate. To date, there has been no product that demonstrated the efficacy in patients with FD nor obtained marketing approval. Acotiamide hydrochloride is expected to be the first therapeutic drug in the world for FD.

Zeria is focusing on the marketing of pharmaceuticals for digestive diseases such as H₂ antagonist Acinon[®] Tablets 75mg/150mg, Promac[®] Granule 15%/D Tablets 75 containing zinc for gastric ulcer, Marzulene[®]-S Granule/ES Tablets for gastric ulcer and gastritis, Visiclear[®] Tablets for colon cleansing prior to colonoscopy and New Lecicarbon[®] Suppository for constipation.

Furthermore, in the same area, Z-206 for inflammatory bowel disease, Z-360 for pancreatic cancer and Z-208 for hepatocellular carcinoma are under development.