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PRESS RELEASE

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Announcement of the results from Phase II study of Z-338 for functional dyspepsia conducted in Europe

We would like to announce the results of the European P II study for our original product Z-338 (acotiamide hydrochloride hydrate; “acotiamide”) for the treatment of functional dyspepsia (FD).

This study was a multicenter, randomized, double-blind, parallel-group, placebo-controlled study to evaluate the efficacy and safety of acotiamide 100 mg or 300 mg three times a day for 12 weeks in patients with FD. A total of 473 FD patients from 76 medical institutions in 8 European countries were enrolled in this study (randomized: 295 patients). The results have shown that acotiamide is effective compared to placebo, and has no particular concern in safety.

Based on the above positive findings, Zeria plans to conduct a consultation with the European Medicines Agency to initiate P III studies. To speed up the next phase of the development, Zeria is going to select a suitable partner.

Acotiamide 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 FD. In North America, Zeria has granted exclusive rights for development and commercialization to Astellas Pharma, and co-development of P IIb for “Z-338/YM443” is underway. Also in Japan, Zeria and Astellas Pharma are jointly conducting P III studies under the co-development and co-marketing agreement.

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 organic 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 inhibits peripheral acetylcholinesterase activities, resulting in improvement of delayed gastric emptying and consequently the symptoms of FD.

Recent studies indicate that one fourth of the adult population in Japan suffers from FD, and FD is a disease with a high prevalence rate. To date, there has been no product that demonstrated the efficacy in patients with FD nor obtained marketing approval. Acotiamide 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 (Asacol[®]) for inflammatory bowel disease, Z-360 for pancreatic cancer and Z-208 for hepatocellular carcinoma are under development.