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PRESS RELEASE

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

Astellas Pharma Inc.
2-3-11 Nihonbashi-Honcho,
Chuo-ku, Tokyo 103-8411

Announcement of the NDA submission of Z-338 /YM443 for functional dyspepsia in Japan

Zeria Pharmaceutical Co., Ltd. (Headquarters: Chuo-ku, Tokyo; President and CEO: Sachiaki Ibe; "Zeria") and Astellas Pharma Inc. (Headquarters: Chuo-ku, Tokyo; President and CEO: Masafumi Nogimori; "Astellas Pharma") announced today that Zeria had submitted the application for marketing approval of the therapeutic agent (nonproprietary name: acotiamide hydrochloride hydrate; "acotiamide"; Zeria's development code: "Z-338"; Astellas Pharma's development code: "YM443") for the treatment of functional dyspepsia (FD) to the Ministry of Health, Labour and Welfare in Japan. Acotiamide was discovered by Zeria, and has been co-developed by both companies.

Acotiamide is a new chemical entity originated by Zeria, and inhibits peripheral acetylcholinesterase activities. Acetylcholine is an important neurotransmitter to regulate gastrointestinal motility, and through the inhibition of degradation of acetylcholine, acotiamide produces the improvement of impaired gastric motility and delayed gastric emptying, and consequently the symptoms of FD.

In the Phase-III clinical trial, a multicenter, randomized, double-blind, parallel-group, placebo-controlled study, acotiamide was statistically significantly effective when compared to placebo in both of two primary endpoints ("general impression" and "elimination rate of 3 symptoms (post-prandial fullness, upper abdominal bloating and early satiety)"). Significant improvements were observed also in several secondary endpoints including QOL. The findings definitively demonstrated that acotiamide alleviated the symptoms of FD patients. Furthermore, no statistical difference in adverse drug reactions was noted between the Acotiamide and Placebo groups.

Zeria will obtain marketing authorization and thereafter both companies will co-market acotiamide in Japan with a single brand name.

To date, no product has obtained marketing approval which demonstrated efficacy for treatment of patients with FD diagnosed by the Rome III, which is the latest version of the international classification and diagnostic criteria for functional gastrointestinal disorders. Acotiamide is expected to be the first-in-class for FD, and will be launched in Japan ahead of the rest of the world.

According to the Rome III, FD is a gastrointestinal disease comprised of subjective symptoms including 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.
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.

We believe that acotiamide will contribute to alleviate the symptoms and improve QOL of patients with FD.