



## **PRESS RELEASE**

### **Approval in Japan for Treating Functional Dyspepsia with Acofide<sup>®</sup>**

**Tokyo, March 25, 2013** - Zeria Pharmaceutical Co., Ltd. (Tokyo: 4559; “Zeria”) and Astellas Pharma Inc. (Tokyo: 4503; “Astellas”) announced today that as of March 25, Zeria has obtained the marketing approval of Acofide<sup>®</sup> Tablets 100mg (nonproprietary name: acotiamide hydrochloride hydrate; “Acofide”; Zeria’s development code: “Z-338”; Astellas’s development code: “YM443”) for the treatment of functional dyspepsia (FD) from the Ministry of Health, Labour and Welfare in Japan. Acofide has been co-developed by both companies.

Acotiamide hydrochloride hydrate 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, Acofide improves the impaired gastric motility and delayed gastric emptying, and consequently the subjective symptoms of FD such as postprandial fullness, upper abdominal bloating, and early satiation.

Acofide, the world first FD treatment which demonstrated efficacy in the patients with FD diagnosed by the Rome III, will be launched in Japan ahead of the rest of the world.

Also, since Acofide will be the first treatment with FD indication, Zeria and Astellas will co-promote Acofide for the sake of the increase of disease awareness of FD, the prompt market penetration, and the maximization of product potential.

In March 2008, Zeria and Astellas concluded the agreement for the co-development and co-marketing of Acofide and, subsequently conducted the co-development. In September 2010, Zeria submitted the application for marketing approval to the Ministry of Health, Labour and Welfare in Japan.

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

Summary of Approval

Product name: Acofide® Tablets 100mg  
Nonproprietary name: Acotiamide hydrochloride hydrate  
Formulation: Tablet  
Indication: Postprandial fullness, upper abdominal bloating, and early satiation due to functional dyspepsia  
Dosage regimen: Normally in adults, 100mg of acotiamide hydrochloride hydrate is taken orally three times per day before a meal.

About Functional Dyspepsia (FD)

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.

For inquiries or additional information
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