

June 2, 2009

## NEWLY PRESENTED DATA ON GASTER<sup>®</sup> SHOW PREVENTION OF PEPTIC ULCERS IN USERS OF LOW-DOSE ASPIRINE

- "FAMOUS trial" presented at the AGA -

Japan, June 2, 2009 - Astellas Pharma Inc. (Headquarters: Tokyo; President and CEO: Masafumi Nogimori, hereinafter "Astellas") today announced that the prevention of peptic ulcers in uses of low-dose aspirin was showed when they were treated with Gaster<sup>®</sup> (famotidine), according to a new trial presented at the American Gastroenterology Association (AGA), held in Chicago, the US, from May 30 to June 4.

The effectiveness of low-dose Aspirin, which is well-known to inhibit platelet aggregation, against arterial diseases and cardiovascular diseases including myocardial infarction and cerebral infarction has been shown in many studies and is widely prescribed in those patients. On the other hand, those patients who take low-dose aspirin are also known to have possible risk to experience gastrointestinal injury. Now that a challenge is to prevent the episode of gastrointestinal injury, given that termination of low-dose Aspirin is preferable for those who experience gastrointestinal injury but at the same time, the termination may raise risk to recurrent primary disease.

FAMOUS trial showed that the combination therapy of low-dose aspirin and Gaster is effective on antiplatelet therapy and is well tolerated. Given that the number of patients who take low-dose aspirin increases in Japan, they may enjoy some good news on this finding.

## About FAMOUS trial

FAMOUS (**Famo**tidine for the Prevention of Peptic <u>Ulcers</u> in Users of Low-Dose Aspirin) trial was a randomized, double-blind, placebo-controlled, multicenter study in patients taking low-dose aspirin (75-325 mg daily) (n=404) carried in the UK and Scotland. After 12 weeks of treatment, incidence of all lesions diagnosed with endoscope in patients taking Gaster showed significant difference (p<0.00001) in this trial (5.9% in patients taking Gaster 20-mg twice daily and 33.0% in patients taking placebo). It is also featured its protocol was under clinical condition in which patients took aspirin with or without latest antiplatelet therapy clopidogrel are also recruited. Moreover, Gaster is the first drug to show effectiveness on prevention of gastrointestinal injury attributed by low-dose aspirin among those approved in Japan.

## **About Gaster**

Gaster is for gastric ulcers, duodenal ulcers and gastric mucosal lesions associated with acute gastritis and chronic gastritis. Gaster was launched as the first  $H_2$  receptor blocker originated in Japan in July 1985 and now prescribed in 1.2 million patients daily.

Astellas is committed to contribute to gastrointestinal therapy in Japanese patients with the mainstay product Gaster.

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