

July 13, 2009

DATA ON GASTER[®] SHOW PREVENTION OF PEPTIC ULCERS IN USERS OF LOW-DOSE ASPIRINE

- "FAMOUS trial" reported in The Lancet -

Tokyo, Japan, July 13, 2009 - Astellas Pharma Inc. ("Astellas"; Headquarters: Tokyo; President and CEO: Masafumi Nogimori) today announced that the FAMOUS (**Fam**otidine for the Prevention of Peptic **U**lcers in Users of Low-Dose Aspirin) trial in which Gaster[®] (famotidine) was effective on the prevention of peptic ulcers in uses of low-dose aspirin was observed was reported in the leading medical journal "The Lancet" published on July 11, 2009 (local time).

"Thanks to low-dose aspirin, the mortality rate resulting from myocardial infarction and stroke is steadily dropping. How we control severe complications such as gastrointestinal haemorrhage and perforation holds the key to continuing to provide effective treatment safely" said Dr. Ali S Taha, the investigator and the first author of FAMOUS trial, Clinical Director of Crosshouse Hospital, Kilmarnock, UK and Consultant and Senior Lecturer in Medicine and Gastroenterology of University of Glasgow, UK. "The results of FAMOUS study demonstrated that famotidine can inhibit gastrointestinal disorders in patients with cardiovascular diseases, cerebrovascular diseases or diabetes who are taking low-dose aspirin. I also think the fact that famotidine was effective without affecting other concomitant medications (especially clopidogrel) has enormous significance. I am very pleased that the FAMOUS study could present a new treatment option to the patients not only in Scotland but also around the world."

Gaster was launched as the first H₂ receptor blocker originated in Japan in July 1985. Gaster is indicated for gastric ulcers, duodenal ulcers and gastric mucosal lesions associated with acute gastritis and chronic gastritis and now prescribed in 1.2 million patients daily. Astellas is committed to contribute to gastrointestinal therapy in Japanese patients by enhancing product value, including making effort on creating high-quality evidence such as FAMOUS trial.

About FAMOUS trial

FAMOUS trial is 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.

FAMOUS trial was carried to investigate incidences of gastric ulcer after 12 weeks of treatment.

After 12 weeks of treatment, incidence of duodenal ulcer and gastric ulcer in patients taking Gaster showed significant difference ($p=0.00021$ and 0.0045 , respectively) in this trial (3.4% and 0.5% in patients taking Gaster, and 15.0% and 8.5% in patients taking placebo, respectively).

<Reference>

The title and authors of the article reported in The Lancet published on July 11, 2009 (local time) are as follows:

Title: Famotidine for the prevention of peptic ulcers and oesophagitis in patients taking low-dose aspirin (FAMOUS):

Page: Lancet 2009; 374: 119-125

Authors: Ali S Taha et al

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Contacts for inquiries or additional information
Astellas Pharma Inc. Corporate Communications Tel: +81-3-3244-3201 Fax: +81-3-5201-7473 http://www.astellas.com