Tokyo, January 5, 2012 – Astellas Pharma Inc. (Tokyo:4503, “Astellas”) announces that it will halt exports of Gaster-D 20mg tablets to Korea for a period of three months in accordance with a directive issued by the Korea Food and Drug Administration (KFDA) due to the usage of active ingredients produced by Gedeon Richter Plc., which were not listed on the KFDA approval document.

In addition, Astellas Pharma Korea, Inc. and Dong-A Pharmaceutical Co., Ltd., a consigned marketing partner, implemented a voluntary recall of the relevant products on November 17.

Details of the KFDA directive are listed below:

(Import Halt Directive)
Product: Gaster-D 20mg Tablets
Period: To March 30, 2012 from December 31, 2011

The active ingredients manufactured by Gedeon Richter Plc. used in the above mentioned have been found to have the same quality, efficacy, and safety as the active ingredients manufactured by the Takahagi Technology Center of Astellas Pharma Tech Co., Ltd. and Astellas Ireland Co, Ltd. which have been approved by the KFDA.

Astellas will implement strict management of its active ingredients to prevent a reoccurrence of this issue.

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