September 26, 2011

ONO PHARMACEUTICAL CO., LTD.

President and Representative Director: Gyo Sagara,
Code No.:4528 at the 1st section of Tokyo / Osaka Stock Exchange
INQUIRIES: Kinya Morimoto, Executive Officer, Director, Corporate Communications

Approval received for an Intravenous Antiemetic Selective Neurokinin-1 (NK1) Receptor Antagonist, "PROEMEND® Intravenous Infusion 150mg"

Ono Pharmaceutical Co., Ltd. (Osaka, Japan) today announced that an application filed in September 2010 for an intravenous antiemetic selective neurokinin-1 (NK_1) receptor antagonist, "PROEMEND® Intravenous Infusion 150mg" (INN: fosaprepitant meglumine) was approved on September 26, 2011.

The drug has been exclusively developed by Ono in Japan under the license granted by Merck Sharp & Dohme Corp., (MSD, known as Merck inside the United States and Canada), in November 2004. "PROEMEND® Intravenous Infusion 150mg" has been approved and marketed in more than 30 countries worldwide including the US and EU countries. It is recommended in National Comprehensive Cancer Network (NCCN) guideline as preventive agent for nausea and vomiting induced by highly emetic anticancer agent such as cisplatin.

Ono launched "EMEND® Capsule" (INN: aprepitant), a drug for the prevention of chemotherapy-induced nausea and vomiting, in December 2009 and it has been widely used in adult patients who suffer chemotherapy-induced nausea and vomiting. However, because physicians and patients like choices in their anti-emetics and the majority of anticancer agents are administered intravenously, the injectable form of the antiemetic treatment will potentially allow more patients to receive appropriate prevention from chemotherapy-induced nausea and vomiting in this more convenient, single-day dosing formulation. Ono had therefore developed fosaprepitant dimeglumine actively in order to meet such clinical needs.

"PROEMEND® Intravenous Infusion 150mg" is a prodrug of "EMEND® Capsule" and rapidly metabolized to aprepitant by phosphatase in the body after the intravenous

administration.
We expect that the approval of "PROEMEND® Intravenous Infusion 150mg" will provide a new therapeutic option for medical practice in addition to existing oral form, and it will meet the needs of the patients and medical professionals more than ever.

"EMEND® Capsule" has been approved and marketed in more than 70 countries worldwide including Japan, the U.S. and EU member countries. The drug is recommended as a prophylactic use of nausea and vomiting caused by cancer therapy in antiemetic guidelines issued by Japan Society of Clinical Oncology and overseas guidelines[1)].

PRODUCT SUMMARY:

Trade Name	PROEMEND® Intravenous Infusion 150mg
Generic Name (INN)	fosaprepitant
Indications	Digestive symptoms (nausea, vomiting) resulting from the administration of antineoplastic agents (cisplatin, etc) (including the delayed phase)
Dosage and Administration	For intravenous infusion, the usual adult dosage of fosaprepitant, in combination with other antiemetic agents, is 150mg once on Day 1 of administration of an antineoplastic agent.

(Reference)

1) Overseas guideline: Guidelines of ASCO: American Society of Clinical Oncology, MASCC: Multinational Association of Supportive Care in Cancer, and NCCN: National Comprehensive Cancer Network.