June 22, 2012

ONO PHARMACEUTICAL CO., LTD.
Corporate Communications
Phone: +81-6-6263-5670
Fax: +81-6-6263-2950

Approval for Additional Indication of "EMEND® Capsule", an Antiemetic Selective Neurokinin-1 (NK1) Receptor Antagonist, for Pediatric Patients Aged 12 and older

Ono Pharmaceutical Co., Ltd. (Osaka, Japan, President and Representative Director: Gyo Sagara, hereinafter referred to as "Ono") announced today that an additional application filed in September 2011 for pediatric patients aged 12 years and older for "EMEND® Capsule" (INN: aprepitant), an antiemetic selective neurokinin-1 (NK1) receptor antagonist, was approved on June 22, 2012.

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.

Ono launched "EMEND® Capsule", a drug for the prevention of chemotherapy-induced nausea and vomiting, in December 2009. Since then EMEND® Capsule has been widely used in adult patients who suffer from chemotherapy-induced nausea and vomiting. Meanwhile, an additional indication of EMEND® Capsule for pediatric patients is strongly desired in clinical practice, and "the Japanese Society of Pediatric Hematology" and "Japanese Society of Pediatric Oncology" have submitted requests to Ministry of Health, Labor and Welfare. To respond to such requests in clinical practice, Ono has therefore advanced development of EMEND® Capsule to expand the indication of chemotherapy-induced nausea and vomiting for pediatric patients.

Now that EMEND® Capsule received approval for this additional indication, we are truly delighted that the drug can be widely used in many pediatric patients aged 12 years and older as well as adult patients who suffer from chemotherapy-induced nausea and vomiting. Ono will also consider development for the use in pediatric patients under 12 years of age to meet clinical needs.

"EMEND® Capsule" has been approved and marketed in more 78 countries worldwide including Japan, the U.S. and Europe. The drug is recommended as a prophylactic use in adult patients with nausea and vomiting caused by cancer therapy in antiemetic guidelines issued by Japan Society of Clinical Oncology and overseas guidelines[1)].

PRODUCT SUMMARY:

(Newly approved part of Dosage and Administration is shown in bold underlined type.)

Trade Name	EMEND® Capsule 125 mg, EMEND® Capsule 80 mg, EMEND® Capsule Set
Generic Name (INN)	aprepitant
Indications	Digestive symptoms (nausea, vomiting) resulting from the administration of antineoplastic agents (cisplatin, etc) (including the delayed phase)
Dosage and Administration	For oral administration, the usual adult **and pediatrics aged 12 years or older** dosage of aprepitant, in combination with other antiemetic agents, is 125 mg on Day 1 of administration of an antineoplastic agent, followed by a daily dose of 80mg from Day 2 on.

(Reference)

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