December 8, 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

Launch of 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 (NK1) receptor antagonist, "PROEMEND® Intravenous Infusion 150mg" (INN: fosaprepitant) will be launched in Japan on December 9, 2011.

The drug has been exclusively developed by Ono in Japan under the license granted by Merck Sharp & Dohme Corp., (known as Merck inside the United States and Canada), in November 2004, and was approved for marketing on September 26, 2011. "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 American Society of Clinical Oncology (ASCO) guideline and 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 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)].

(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.

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.
Product Characteristics	1. This compound is a phosphorylated prodrug, which solubility in water was increased, of aprepitant, an antiemetic selective substance P/neurokinin-1 (NK1) receptor antagonist. 2. Antiemetic effect on digestive symptoms (nausea, vomiting) resulting from the administration of antineoplastic agents (cisplatin, etc) (including the delayed phase) was observed in combination with a dexamethazone and a 5-HT3 receptor antagonist. 3. In a double-blind comparative Clinical Phase III Study conducted in Japan, adverse reactions to PROEMEND®, including abnormal laboratory test values, were observed in 46 (26.4%) of 174 patients evaluated for analysis of adverse reactions. The major adverse reactions were constipation in 16 cases (9.2%), increased ALT (GPT) in 12 cases (6.9%), hiccups in 10 cases (5.7%), infusion site pain/instillation site pain in 9 cases (5.2%), increased AST (GOT) in 8 cases (4.6%), increased γ-GTP in 6 cases (3.4%), protein urine in 5 cases (2.9%), and infusion site erythema in 4 cases (2.3%), etc.
Packaging:	PROEMEND® Intravenous Infusion 150mg: 5 vials
NHI reimbursement prices:	JPY 14,919
Date of NHI price listed:	November 25, 2011
Date of launch:	December 9, 2011