ONO PHARMACEUTICAL CO.,LTD.

March 18, 2016

ONO Receives Approval for PROEMEND® for Intravenous Infusion 150 mg for Treatment of Chemotherapy-Induced Nausea and Vomiting for a Partial Change in Approved Items for Additional Application to Pediatric Patients

ONO PHARMACEUTICAL CO., LTD. (Osaka, Japan; President, Representative Director, Gyo Sagara; "ONO") announced that it has received approval for a partial change in approved items of the manufacturing and marketing authorization of PROEMEND® for Intravenous Infusion 150 mg ("PROEMEND"), antiemetic drug, a selective Neurokinin-1 receptor antagonist in additional application (use) for infants more than 6 months old and pediatric patients less than 12 years old.

Before marketing PROEMEND, ONO launched EMEND® Capsules ("EMEND"), an oral formulation for the treatment of chemotherapy-induced nausea and vomiting (CINV) in December 2009 and then received an approval of EMEND for additional application (use) for pediatric patients more than 12 years old in June 2012, in order to meet the requests from medical sites. However, EMEND is not indicated for pediatric patients less than 12 years old, and there are lots of patients who have a difficulty in taking oral (capsule) formulation among pediatric patients. Under such circumstances, requests for the development of PROEMEND, an infusion formulation, in use in pediatric patients have been made from medical sites.
In order to meet the requests from medical sites, ONO has been committed to the development of PROEMEND for additional application in pediatric patients for the treatment of CINV, and submitted supplemental application for additional application (use) in infants more than 6 months old and pediatric patients less than 12 years old on May 27, 2015.

In accordance with an approval for additional application, we are very pleased that PROEMEND will be more wildly used not only in adult patients and pediatric patients more than 12 years old, but in infants more than 6 months old and pediatric patients less than 12 years old suffering from CINV.

PROEMEND has been exclusively developed by ONO in Japan, under the license agreement concluded between ONO and Merck & Co., Inc., Kenilworth, N.J., U.S.A. in November 2004 and launched in December 2011. Currently, PROEMEND has been approved and launched in over 77 countries around the world, including Japan, US and Europe. It is recommended to use PROEMEND as a prophylactic drug for CINV in adult patients in the guideline on proper use for antiemetic drugs prepared by the Japan Society of Clinical Oncology and overseas guidelines*[1].

＊1: Guidelines in American Society of Clinical Oncology (ASCO), Multinational Association of Supportive Care in Cancer (MASCC), National Comprehensive Cancer Network (NCCN), etc.

Summary of approved items:

Product name	PROEMEND® for Intravenous Infusion 150mg
Generic name (JAN)	Fosaprepitant Meglumine
Indication	Digestive symptoms (nausea, vomiting) resulting from the administration of antineoplastic agents (cisplatin, etc.) (including the delayed phase)
Dosage and administration	・ Adults and pediatric patients more than 12 years old Usually, for adults and pediatric patients more than 12 years old, infuse intravenously at 150 mg of fosaprepitant once, in combination with other antiemetic drugs on Day 1 of administration of an antineoplastic drug. ・ Infants more than 6 months old and pediatric patients less than 12 years old Usually, for Infants more than 6 months old and pediatric patients less than 12 years old, infuse intravenously at 3.0 mg/kg of fosaprepitant once in combination with other antiemetic drugs on Day 1 of administration of an antineoplastic drug. It should not exceed 150 mg of fosaprepitant.
Conditions for approval	Design and appropriately implement a Risk Management Plan.

The underline shows revised parts in accordance with additional approval this time.

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