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ONO PHARMACEUTICAL CO., LTD.

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Application Filed in Japan for an Intravenous Antiemetic Selective Neurokinin-1 (NK_1) Receptor Antagonist, Fosaprepitant

Ono Pharmaceutical Co., Ltd. (Osaka, Japan) announced that a marketing authorization application for fosaprepitant dimeglumine, a selective neurokinin-1 (NK_1) receptor antagonist, was submitted to Pharmaceuticals and Medical Devices Agency of Japan today. It is the prodrug of an antiemetic drug, EMEND® Capsule and has been developed for the prophylactic indication of "chemotherapy-induced nausea and vomiting".

Fosaprepitant dimeglumine has been developed exclusively by Ono in Japan under the license granted by Merck Sharp & Dohme Corp., an affiliate of Merck & Co., Inc., Whitehouse Station, N.J., U.S.A., in November 2004. The new drug application for fosaprepitant dimeglumine was filed worldwide including in the U.S. and EU member states by Merck Sharp & Dohme Corp. last year, and have already been approved in 27 EU countries, and Norway and Iceland.

Ono launched "EMEND® Capsule" (INN: aprepitant), a drug for the prevention of chemotherapy-induced nausea and vomiting, in December 2009. Since then EMEND® Capsule has been widely used in patients receiving chemotherapy. 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.

Fosaprepitant dimeglumine is a prodrug of oral aprepitant and is rapidly metabolized to aprepitant by phosphatases in the body after intravenous administration. In the Phase 3 study in Japan, fosaprepitant dimeglumine has proven to be effective in the prevention of nausea and vomiting in acute[1)] as well as delayed phases[2)] after administration of cancer chemotherapy and was well tolerated, and thus, the drug is expected to provide a new treatment option for prevention of chemotherapy-induced nausea and vomiting.

EMEND® Capsule has been approved and marketed in more than 70 countries worldwide including Japan, the U.S. and EU member states, and is recommended as a prophylactic use for nausea and vomiting caused by cancer therapy in antiemetic guidelines issued by Japan Society of Clinical Oncology (JSCO) and overseas guidelines[3)].

1) Acute phase: within 24 hours after administration of cancer chemotherapy
2) Delayed phase: after 24 hours after administration of cancer chemotherapy
3) Overseas guidelines: Antiemetic guidelines issued by major cancer associations including as the American Society of Clinical Oncology (ASCO), the Multinational Association of Supportive Care in Cancer (MASCC), the National Comprehensive Cancer Network (NCCN), etc.