

## Translation

Antiemetic Agent, Kytril®  
Filed for Additional Indication By  
“Application Based on Evidence in the Public Domain”

August 10, 2011 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Main Office: Chuo-ku, Tokyo. President: Osamu Nagayama (hereafter, “Chugai”)] announced today that on August 10, it filed an “application based on evidence in the public domain” with the Japanese Ministry of Health, Labour and Welfare, seeking approval for the indication “gastrointestinal symptoms (nausea and vomiting) associated with antineoplastic agents (cisplatin, etc.) administration and radiotherapy,” for Kytril®. Kytril® is the antiemetic 5-HT<sub>3</sub> receptor antagonist granisetron hydrochloride, with brand names: “Kytril® Tablet 1mg,” “Kytril® Tablet 2mg,” “Kytril® Fine Granule 0.4%,” “Kytril® Injection 1mg,” “Kytril® 3mg,” “Kytril® Intravenous Bag 3mg/50mL” and “Kytril® 3mg/100mL.” In Japan, Kytril® is currently approved for the indications of “gastrointestinal symptoms (nausea and vomiting) associated with antineoplastic agents (cisplatin, etc.) administration” for oral administration, and “gastrointestinal symptoms (nausea and vomiting) associated with antineoplastic agents (cisplatin, etc.) administration and pretreatment with total body irradiation (TBI) for hemopoietic stem cell transplantation” for intravenous injection administration.

As a result of the evaluation by the “Review Committee on Unapproved Drugs and Indications with High Medical Needs\*” held on June 29, an “application based on evidence in the public domain” is applicable when filing for this indication. The filing was made based on the decision at the meeting of the First Committee on New Drugs, Pharmaceutical Affairs and Food Sanitation Council, held on July 29, which confirmed that filing through the “application based on evidence in the public domain” was reasonable for this additional indication.

Kytril®, marketed by Chugai in Japan, was first launched overseas on February 1991 as the antiemetic agent of 5-HT<sub>3</sub> receptor antagonist. In Japan, injection formulation was launched in 1992, and oral formulation was launched in 1995. Kytril® is being positioned as a standard therapy in several guidelines including that of World Health Organization for treating gastrointestinal symptoms (nausea and vomiting) associated with antineoplastic agent administration and radiotherapy. It is.

Nausea and vomiting associated with antineoplastic agent administration and radiotherapy entail pain on the part of the patients. They not only impair their QOL; but also make continuation of treatment itself difficult.

Chugai is convinced that Kytril® will provide opportunity for better care to these patients, and will continue to make efforts toward its early approval.

\* The “Review Committee on Unapproved Drugs and Indications with High Medical Needs” was established for the purpose of “enhancing development by the pharmaceutical companies of drugs and indications that have been approved for use in western countries but not yet approved in Japan, through activities such as evaluating medical needs and confirming the applicability of “application based on evidence in the public domain” and investigating the need for studies that should be additionally conducted.”