

Translation

Drug Application Filed for Additional Form of Immunosuppressant, “CellCept® Powder for Oral Suspension 32%”

August 22, 2013 - Chugai Pharmaceutical Co., Ltd. [Head Office: Chuo-ku Tokyo; Chairman & CEO: Osamu Nagayama] (hereafter, “Chugai”) today announced that it has filed a new drug application to the Ministry of Health, Labour and Welfare (MHLW) for additional form of “CellCept® Powder for Oral Suspension 32%” with regard to mycophenolate mofetil (brand name: “CellCept® Capsules 250”, hereafter referred to as “CellCept® Capsules”), an immunosuppressant which has been sold as the indications of “Treatment of refractory rejections after kidney transplant” and “Suppression of rejections after the following organ transplants: kidney, heart, liver, lung and pancreas transplants”.

This time, Chugai decided to file a powdered drug application for suspension so that each patient can select different forms of mycophenolate mofetil formulations according to their own situations considering the approval of pediatric dosage and administration for “Suppression of rejections after kidney transplants” as the indication of “CellCept® Capsules” on September 16, 2011, the availability of the powder formulation for suspension in other countries in addition to the capsule formulation, and the need for future transplantation therapy in Japan due to the development of transplantation technology.

Chugai will make efforts toward an early approval to achieve the prompt provision of “CellCept® Powder for Oral Suspension 32%” to patients.