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Roche Group

Translation

Immunosuppressive Agent, CellCept® Filed for Pediatric Dosage and Administration for Prevention of Organ Rejection in Renal Transplant by "Application Based on Evidence in the Public Domain"

May 16, 2011 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Main Office: Chuo-ku, Tokyo. President: Osamu Nagayama (hereafter, "Chugai")] announced today that on May 16, it filed an "application based on evidence in the public domain" with the Japanese Ministry of Health, Labour and Welfare, seeking approval for the "additional dosage and administration for pediatric patients for the prevention of organ rejection in renal transplant" for the immunosuppressive agent mycophenolate mofetil capsule (brand name: CellCept® Capsules 250, hereafter, "CellCept®"). In Japan, CellCept® is currently marketed with indications for the "treatment of refractory organ rejection receiving kidney transplants," and "the prophylaxis of organ rejection in patients receiving kidney, heart, liver, lung or pancreas transplants."

As a result of the evaluation by the "Review Committee on Unapproved Drugs and Indications with High Medical Needs*" held on April 18, an "application based on evidence in the public domain" is applicable when filing for this dosage and administration. 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 April 27, which confirmed that filing through the application based on evidence in the public domain was reasonable for the "additional dosage and administration of CellCept® for pediatric patients for the prophylaxis of organ rejection in renal transplant."

CellCept®, marketed by Chugai in Japan, has been already approved in Europe and the United States with the indication for the prophylaxis of organ rejection receiving renal transplant in pediatric patients and has been used as one of the standard therapies.

Chugai will make efforts toward an early approval so that CellCept® can be provided to pediatric patients as a treatment to prevent organ rejection who receive renal transplants, in where high unmet medical need exist.

* 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."