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Translation

Filing of Public Knowledge-Based Application for Immunosuppressant "CellCept®" for Additional Indication of Lupus Nephritis

August 24, 2015 - Chugai Pharmaceutical Co., Ltd. [Head Office: Chuo-ku Tokyo; Chairman & CEO: Osamu Nagayama] (hereafter, "Chugai") announced today that it has filed public knowledge-based applications for "CellCept® Capsules 250" (generic name: mycophenolate mofetil) (hereafter, "CellCept Capsule") and "CellCept® Powder for Oral Suspension 31.8%" (hereafter, "CellCept Powder for Oral Suspension") for the additional indication of lupus nephritis with the Ministry of Health, Labour and Welfare (MHLW). CellCept Capsule has been marketed with 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." As regarding CellCept Powder for Oral Suspension, Chugai obtained an approval on August 17 and is waiting for listing in the National Health Insurance (NHI) drug price list.

As a result of the evaluation by the "Review Committee on Unapproved Drugs and Indications with High Medical Needs" held on July 10, 2015, CellCept was recognized to be entitled to file a public knowledge-based application for the indication of lupus nephritis. With this evaluation, CellCept was formally allowed to use of a public knowledge-based application at the "First Committee on New Drugs, Pharmaceutical Affairs and Food Sanitation Council" held on July 31, and Chugai filed an application for this additional indication.

Lupus nephritis is a refractory disease associated with an autoimmune disease, systemic lupus erythematosus (SLE) and the estimated number of patients count to 30,000. SLE is one of the designated refractory diseases in the "Act on medical treatment for patients with refractory diseases," effective on January 2015.

CellCept is recommended as the standard therapy for lupus nephritis in the treatment guideline in US and EU. Meanwhile, CellCept has teratogenic effect and it has been reported cases of congenital anomaly and natural abortion due to congenital anomaly in patients who administered the drug in Japan and overseas. For this reason, the notices on consideration for the use of CellCept are released from the Pharmaceutical and Food Safety Bureau, MHLW.

Based on the fact, Chugai will make efforts to ensure appropriate use of the drug in cooperation with related academic societies by providing the information for benefit and risk of the drug administration and the necessity of birth control etc. to medical professionals and

patients. Also, Chugai will make effort to obtain early approval of CellCept as the drug for lupus nephritis with high unmet medical needs. For overseas market, F. Hoffmann-La Roche, Ltd. [Head Office: Basel, Switzerland / CEO: Severin Schwan] is marketing CellCept.