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Immunosuppressant “CellCept®” Obtained Approval for Additional Indication of “Lupus Nephritis”

TOKYO, May 13, 2016 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it obtained a supplemental approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) on May 13, 2016, for “CellCept® Capsules 250” and “CellCept® Powder for Oral Suspension 31.8%” (generic name: mycophenolate mofetil) for the indication of “Lupus Nephritis.” CellCept 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 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 became formally entitled to use a public knowledge-based application at the “First Committee on New Drugs, Pharmaceutical Affairs and Food Sanitation Council” held on July 31. Chugai filed an application for this additional indication on August 24, and thus obtained a supplemental approval.

"With this additional Indication, we believe that the treatment of lupus nephritis in Japan will be greatly advanced and we can contribute to patients who have been waiting for this approval,” said Chugai’s Director and Executive Vice President, Dr. Yutaka Tanaka. “We will make efforts to ensure appropriate use of the drug in cooperation with related academic societies by providing accurate risk/benefit information to healthcare professionals.”

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 designated as one of the 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 the U.S. and EU. Meanwhile, CellCept is known to have teratogenic effects and in some cases, it has been reported as the cause of congenital anomaly and natural abortion in Japan and overseas. Given this situation, notice on consideration for the use of CellCept has been issued from the Pharmaceutical and Food Safety Bureau, MHLW.

For overseas market, Roche is marketing CellCept.

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