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# Anti-CD20 Monoclonal Antibody Rituxan® Approved for Lupus Nephritis that has Not Responded Sufficiently to Existing Therapies

TOKYO, August 23, 2023 -- Zenyaku Kogyo Co., Ltd. (Japanese-only website) and Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that Zenyaku obtained regulatory approval from the Ministry of Health, Labour and Welfare (MHLW), for an anti-CD20 monoclonal antibody Rituxan® intravenous injection 100 mg and 500 mg [generic name: rituximab (genetical recombination)] (hereafter, “Rituxan”) for “lupus nephritis that has not responded sufficiently to existing therapies.”

Rituxan is an anti-CD20 monoclonal antibody that specifically binds to CD20, a protein expressed on B cells, excluding hematopoietic stem cells and plasma cells. It attacks target B cells using the immune system equipped with the human body, and damages cells.

The addition of the indication of Rituxan for "lupus nephritis that has not responded sufficiently to existing therapies" requested by the Japan college of rheumatology (chairman: Dr. Yoshiya Tanaka) was evaluated as a public knowledge-based application at the “54th evaluation committee on unapproved or off-labeled drugs with high medical needs” held on February 15, 2023.
After that, it was officially decided that a public knowledge-based application was appropriate for this additional indication at the first committee on drugs of pharmaceutical affairs and food sanitation council held on March 3, 2023. In response to these decisions, Zenyaku and Chugai submitted regulatory application on March 31, and obtained approval.

Lupus nephritis is a kidney lesions associated with systemic lupus erythematosus (SLE). It occurs frequently among major organ lesions and is one of the organ complications that affect the prognosis of SLE[1]. SLE is a nationally designated intractable disease, and the number of patients in Japan is estimated to be approximately 60,000 to 100,000, of which the incidence of lupus nephritis is reported to be 45 to 86%[2]. Lupus nephritis is thought to be caused by abnormalities in the immunoregulatory mechanism, resulting in persistent impairment of the immune response and renal damage[3]. Rituxan improves renal symptoms by damaging B cells involved in autoantibody production and immune complex formation, which are central to the pathogenesis of lupus nephritis.

Japan College of Rheumatology, Japanese Society of Nephrology, Pediatric Rheumatology Association in Japan and The Japanese Society of Pediatric Nephrology conducted a survey on the actual use of Rituxan for lupus nephritis at 47 facilities in Japan[4]. Based on the survey

results, the “Statement on the use of rituximab (genetical recombination) for lupus nephritis[5]” has been published.

Zenyaku and Chugai will continue working closely together so that Rituxan may contribute to the treatment of lupus nephritis that has not responded sufficiently to existing therapies.



Sources

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2. Yokoyama H, Okuyama H, Yamaya H. Clinicopathological insights into lupus glomerulonephritis in Japanese and Asians. Clin Exp Nephrol 2011; 15(3): 321-330.
3. Hahn BH, McMahon MA, Wilkinson A, et al. American College of Rheumatology guidelines for screening, treatment, and management of lupus nephritis. Arthritis Care Res (Hoboken) 2012; 64(6): 797-808.
4. Tanaka Y, et al. Rituximab in the Real-World Treatment of Lupus Nephritis: A Retrospective Cohort Study in Japan. Mod Rheumatol 2023; 33(1): 145-153.
5. Japan College of Rheumatology, Japanese Society of Nephrology, Pediatric Rheumatology Association in Japan and The Japanese Society of Pediatric Nephrology. Statement on the Use of Rituximab (genetical recombination) for Lupus Nephritis (February 18, 2022 Version 1). (Japanese only)



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