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Innovation all for the patients
CHUGAI PHARMACEUTICAL CO., LTD.
Roche Group

Zenyaku Kogyo Co., Ltd.
Chugai Pharmaceutical Co., Ltd.

Anti-CD20 Monoclonal Antibody Rituxan® Approved for Treatment of Refractory Steroid-Resistant Nephrotic Syndrome

TOKYO, September 24, 2024 -- 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 “refractory steroid-resistant nephrotic syndrome[*1].”

Nephrotic syndrome is a general term for a condition in which damage to the glomerular slit membrane in the nephrons that make up the kidneys results in severe proteinuria and hypoalbuminemia, leading to generalized edema[1)]. Nephrotic syndrome that develops in childhood is the most common chronic kidney disease in children[2)] and is a designated intractable disease of unknown cause. Approximately 10% to 20% are classified as "steroid-resistant nephrotic syndrome," in which complete remission cannot be achieved with steroid treatment, which is the first-choice drug[3)]. Steroid pulse therapy or remission induction therapy using immunosuppressants are recommended for "steroid-resistant nephrotic syndrome," but in cases of "refractory steroid-resistant nephrotic syndrome" where remission cannot be achieved even with these treatments, there is a high risk of developing end-stage renal failure and the prognosis is poor[3)].

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. It has been suggested that B cells may be involved in the pathogenesis and disease activity of nephrotic syndrome[4) 5) 6)], and it is expected that removing B cells with Rituxan will have a therapeutic effect on nephrotic syndrome.

Rituxan was approved in August 2014 for the treatment of childhood-onset "refractory nephrotic syndrome (frequently relapsing or steroid-dependent)." In the development of Rituxan for "refractory steroid-resistant nephrotic syndrome," the primary endpoint (reduction rate from baseline in urinary protein creatinine ratio at 169 days) was achieved[7) 8)] in an investigator-initiated clinical trial[*2] targeting patients with childhood-onset refractory steroid-resistant nephrotic syndrome. Zenyaku filed an application for partial changes to the manufacturing and sales approval items on December 22, 2023, which led to the current approval.

Zenyaku and Chugai will continue working closely together so that Rituxan can further contribute to the treatment of refractory nephrotic syndrome.

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*1 Approved indication or effect
- Refractory nephrotic syndrome (frequently relapsing, steroid-dependent or steroid-resistant)
  Rituxan was approved for the treatment of refractory nephrotic syndrome (frequently relapsing or steroid-dependent) in August 2014, and obtained additional approval for the treatment of refractory steroid-resistant nephrotic syndrome.

*2 Multicenter single-armed clinical trial of combination therapy with IDEC-C2B8 and steroid pulse therapy for childhood-onset refractory steroid-resistant nephrotic syndrome (JSKDC11)

Sources

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