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

Anti-CD20 Monoclonal Antibody Rituxan® Approved for Treatment of Autoimmune Hemolytic Anemia

TOKYO, February 19, 2026 -- Zenyaku Kogyo Co., Ltd. (website in Japanese only) 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 additional indication of an anti-CD20 monoclonal antibody Rituxan® intravenous injection 100 mg and 500 mg [generic name: rituximab (genetical recombination)] (hereafter “Rituxan”), which is co-marketed by both companies, for the treatment of autoimmune hemolytic anemia.

The Japanese Society of Hematology and the Japanese Society of Pediatric Hematology/Oncology submitted development requests for an additional indication for Rituxan for autoimmune hemolytic anemia (hereafter “AIHA”). The request was evaluated and deemed to qualify for a public knowledge-based application at the “64th Evaluation Committee on unapproved or off-label drugs with high medical needs” held on July 4, 2025. It was officially decided that a public knowledge-based application could be submitted at the “Pharmaceutical Affairs Council's First Committee on Drugs” held on July 31, 2025. In response to this, Zenyaku submitted a public knowledge-based application on August 29, 2025, and has now obtained approval.

AIHA is a collective term for immune hemolytic anemia caused by the acquired production of autoantibodies that react with antigens on red blood cell membranes, resulting in the destruction (hemolysis) of red blood cells through antigen-antibody reactions and a markedly shortened red blood cell lifespan[1)]. It is designated as an intractable disease by the Japanese government (designated intractable disease No. 61). AIHA is broadly classified into warm AIHA, where autoantibodies react near body temperature (37°C), and cold AIHA [cold agglutinin disease (hereafter "CAD") and paroxysmal cold hemoglobinuria (hereafter "PCH")], which react at temperatures below body temperature[1)]. In all types, factors such as infection, immunodeficiency, immune system dysregulation, hormonal environment, drugs, and tumors are considered to be involved in the etiology of AIHA[1)].

In the treatment of AIHA, approximately 80% of warm AIHA patients show improvement with adrenocortical steroids; however, recurrence is common and long-term administration is necessary, and for relapsed or refractory cases, splenectomy has been performed[1)]. In CAD patients, maintaining warmth is the most basic treatment, but severe

symptoms such as anemia, transfusion dependence, and peripheral circulatory disorders may occur[1)2)]. Japanese and international clinical practice guidelines[1)2)] recommend Rituxan therapy as one of the treatment options for such patients. PCH is a rare type, mainly observed in young children following viral infections, and is generally treated with warmth maintenance and adrenocortical steroids. Nonetheless, reports suggest the efficacy of Rituxan in chronic patients or in patients who are refractory to adrenocortical steroid therapy[1)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 and damages target B cells by leveraging the human body's own immune system. B cells ultimately differentiate into antibody-producing plasma cells, but in diseases involving autoantibodies, it is believed that autoreactive B cells are activated and differentiated for some reason, leading to the proliferation of plasma cells that produce autoantibodies[4)5)]. Although the etiology leading to the activation of autoreactive B cells and the appearance of autoantibodies in AIHA has not been fully elucidated, the common presence of autoantibodies in both warm and cold AIHA[1)] suggests that therapeutic effects through B cell depletion by Rituxan can be expected.

Zenyaku and Chugai are committed to working closely together to ensure that Rituxan can further contribute to the treatment of patients with autoimmune hemolytic anemia.

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Sources

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4. Browning JL. B cells move to centre stage: novel opportunities for autoimmune disease treatment. Nat Rev Drug Discov 2006; 5(7): 564-576.
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