

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

Anti-CD20 Monoclonal Antibody Rituxan Approved for Additional Indication of Systemic Sclerosis

TOKYO, September 27, 2021 -- [Zenyaku Kogyo Co., Ltd.](#) (Japanese-only website) and [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) announced today that Zenyaku obtained approval from the Ministry of Health, Labour and Welfare (MHLW), for an anti-CD20 monoclonal antibody, Rituxan® injection 100 mg and 500 mg [generic name: rituximab (genetical recombination)] (hereafter, “Rituxan”) for an additional indication of systemic sclerosis (SSc). Rituxan is co-marketed by the two companies in Japan.

Rituxan is an anti-CD20 monoclonal antibody that specifically binds to CD20, a protein expressed on B cells other than stem cells and plasma cells, and attacks target B cells along with the body's immune system. Clinical development of Rituxan for systemic sclerosis was conducted as an investigator-initiated phase II clinical trial (IDEC-C2B, coordinating investigator: Dr. Ayumi Yoshizaki, Department of Dermatology, The University of Tokyo Hospital), under the Practical Research Project for Rare / Intractable Diseases (fiscal 2017) by the Japan Agency for Medical Research and Development (AMED). Based on the findings of this study, Rituxan was approved for the additional indication.

Systemic sclerosis is a chronic disease characterized by changes that make the skin and internal organs stiff. However, it is important to note that the degree of sclerosis, progression, etc. may vary among patients. Major symptoms include Raynaud's symptoms (pale to purple fingers when touching cold objects), skin induration, and pulmonary fibrosis. In Japan, there are more than 20,000 patients, and the male-to-female ratio is 1:12. It has been found that the disease is more common in women in their 30-50s. The disease has been designated as an intractable disease by the Ministry of Health, Labour and Welfare (designated intractable disease 51)¹⁾.

Zenyaku and Chugai will continue working closely together to make Rituxan contribute to the treatment of systemic sclerosis.

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Sources

- 1) Japan Intractable Diseases Research Foundation/Japan Intractable Diseases Information Centre Available from: <https://www.nanbyou.or.jp/entry/4026>. Accessed September 2021 (Japanese only)

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