

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

Anti-CD20 Monoclonal Antibody “RITUXAN[®],” Approved for Additional Indication of CD20-Positive Chronic Lymphocytic Leukemia

TOKYO, March 26, 2019 -- [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[®] injection 100 mg and 500 mg [generic name: rituximab (genetical recombination)] (hereafter, “RITUXAN”), which was co-developed by the two companies for an additional indication of CD20-positive chronic lymphocytic leukemia (CLL). RITUXIAN 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 and plasma cells, which attacks B cells as targets with the immune system in the body. RITUXAN is used in combination with other antineoplastic drugs for the treatment of CD20-positive CLL, the additional indication approved this time.

CLL is a disease in which small mature B lymphocytes proliferate monoclonally and proliferate in peripheral blood, bone marrow, lymph nodes and spleen, many of which progress slowly. This rare disease is mostly prevalent in elderly people, and considered as difficult to cure with current treatments while many patients often experience recurrence and progression repeatedly. The number of patients in Japan is small, reportedly about 0.3 to 100,000 people per year. The age of onset is typically over 50 years, and rarely seen in people under 30 years of age. In patients with CLL, the ratio of males to females is higher at about 1.5 or 2 to 1*.

Zenyaku and Chugai will continue to work closely together to make RITUXAN contribute to the treatment of CD20-positive CLL.

* Center for Cancer Control and Information Services. Chronic Lymphocytic Leukemia / Small Lymphocytic Lymphoma

<https://ganjoho.jp/public/cancer/CLL/index.html> (Japanese only)

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