

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

Anti-CD20 Monoclonal Antibody “RITUXAN®,” Application for Approval of Additional Indication of CD20-Positive Chronic Lymphocytic Leukemia

TOKYO, August 3, 2018 -- [Zenyaku Kogyo Co., Ltd.](#) (Japanese-only website) and [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) announced today that Zenyaku filed an application for approval with the Ministry of Health, Labour and Welfare for the anti-CD20 monoclonal antibody RITUXAN® injection 100 mg and 500 mg [generic name: rituximab (genetical recombination)] for the treatment of “CD20-positive chronic lymphocytic leukemia (CLL). RITUXAN is co-marketed by the two companies in Japan.

Zenyaku received a request from the MHLW to develop RITUXAN for the treatment of CD20-positive CLL issued on April 6, 2012, as a result of the evaluation by the “11th Review Committee on Unapproved Drugs and Indications with High Medical Needs” held on March 23, 2012, and has been preparing to file for the addition of this indication. On March 20, 2018, the orphan drug designation was granted for RITUXAN for CD20-positive CLL as the estimated number of newly diagnosed CLL patient per year is about 400.

CLL is a disease in which small mature B lymphocytes proliferate monotonally 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 females to males is higher at about 1.5 or 2 to 1*.

Zenyaku and Chugai will continue to work for the early approval of the product to provide RITUXAN for CLL patients and medical professionals who are waiting for a new treatment option.

* 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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