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CHUGAI PHARMACEUTICAL CO., LTD.
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Zenyaku Kogyo Co., Ltd.
Chugai Pharmaceutical Co., Ltd.

Anti-CD20 Monoclonal Antibody Rituxan Approved for the Prevention of Recurrence of Neuromyelitis Optica Spectrum Disorder

TOKYO, June 20, 2022 -- 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 the prevention of recurrence of neuromyelitis optica spectrum disorder (including neuromyelitis optica). Rituxan obtained orphan drug designation for this indication in June 2020, and Zenyaku filed the application for regulatory approval in October 2021.

Rituxan is an anti-CD20 monoclonal antibody that specifically binds to CD20, a protein expressed on B cells, excluding stem cells and plasma cells. It attacks target B cells using the immune system equipped with the human body, and damages cells.

This approval is based on the results of an investigator-initiated phase II/III clinical study (RIN-1 study)[1] which evaluated Rituxan for the reduction of relapse in Japanese patients with neuromyelitis optica (NMO) or neuromyelitis optica spectrum disorder (NMOSD). This study was conducted at eight hospitals in Japan, mainly led by Dr. Tahara, Chief of the Clinical Research Center, Dr. Oeda, Director of Clinical Research Center and Dr. Sawada, Vice President, of the National Hospital Organization Utano National Hospital, and was funded by the Japan Agency for Medical Research and Development.

NMOSD is an inflammatory disease of the central nervous system, characterized by severe optic neuritis and transverse myelitis.[2,3,4] The disease can lead to continual and significant decrease in quality of life due to permanent neurological disability. It is a designated intractable disease with the prevalence of 5.3 per 100,000 people in Japan.[5] About 90% of NMOSD patients are female,[2,6] and the onset peaks in the late 30s to early 40s.[6,7] If not treated, the frequency of recurrence is reported as an average of 1 to 1.5 times per year, with the level of disability progressively worsening due to repeated recurrences.[8] A major factor in the pathogenesis of NMOSD is thought to be cell injury caused by autoantibodies against aquaporin-4, which is expressed on astrocytes in the central nervous system.[9] Rituxan prevents recurrence of NMOSD by eliminating CD20-positive B cells in the blood, thereby suppressing the production of new autoantibodies.

Zenyaku and Chugai will continue working closely together so that Rituxan may contribute to the

treatment of NMOSD (including NMO).

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Sources

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