ZENYAKU KOGYO CO.,LTD.
6-15,Otsuka5-chome,Bunkyo-Ku,Tokyo,Japan

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CHUGAI PHARMACEUTICAL CO., LTD.
Roche Group

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

Anti-CD20 Monoclonal Antibody "Rituxan®," Approved for Additional Indication of Acquired Thrombotic Thrombocytopenic Purpura

TOKYO, February 21, 2020 -- 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 acquired thrombotic thrombocytopenic purpura. Rituxian is co-marketed by the two companies in Japan.

The Review Committee on Unapproved Drugs and Indications with High Medical Needs held on May 29, 2019, concluded that public knowledge-based application should be applicable for Rituxan for acquired thrombotic thrombocytopenic purpura. On August 1, 2019, the First Committee on New Drugs, Pharmaceutical Affairs and Food Sanitation Council made a decision that filing through the "public knowledge-based application" was reasonable. The Japanese Society of Hematology had requested development of this additional indication.

Thrombotic thrombocytopenic purpura (TTP) is a disease complicated with thrombosis in several organs (including cerebral infarction and myocardial infarction), caused by facilitated platelet aggregation due to reduced activity of a disintegrin-like and metalloprotease with thrombospondin type 1 motif 13 (ADAMTS13), an *in vivo* macromolecular cleavage enzyme. TTP can be classified into congenital TTP resulting from genetic abnormality in ADAMTS13, and acquired TTP which is caused by autoantibody production against ADAMTS13. In Japan and other countries, Rituxan is listed in the guidelines as one of the treatment options to be considered for patients with treatment failure with plasmapheresis that is the first-line therapy for acquired TTP, or for those with early relapse.[1, 2)] In Japan, TTP is estimated to affect approximately 500 people annually.[3)] Considering that 95% of patients with TTP are reported to have acquired TTP[4)], total patients with acquired TTP are estimated to be less than 450.

Zenyaku and Chugai will continue to work closely together to make Rituxan contribute to the treatment of acquired thrombotic thrombocytopenic purpura.

Sources

1 Matsumoto M, et al. Consensus report on the diagnosis and management of thrombotic thrombocytopenic purpura 2017. Jpn J Clin Hematol. 2017; 58(4): 271-281

2 Scully M, et al. Guidelines on the diagnosis and management of thrombotic thrombocytopenic purpura and other thrombotic microangiopathies. British Journal of Haematology 2012; 158(3): 323-335

3 Japan Intractable Diseases Information Center: Available from: https://www.nanbyou.or.jp/. Accessed February 2020 (Japanese only)

4 Morishita E. Diagnosis and treatment of microangiopathic hemolytic anemia. Jpn J Clin Hematol. 2015; 56(7): 795-806

Contact:	
Zenyaku Kogyo Co., Ltd. Tel: +81-3-3946-1111	Chugai Pharmaceutical Co., Ltd., Corporate Communications Dept., Media Relations Group Tel: +81-3-3273-0881 Investor Relations Group Tel: +81-3-3273-0554