

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

Anti-CD20 Monoclonal Antibody Rituxan Approved for Additional Indications of Refractory Pemphigus Vulgaris and Pemphigus Foliaceus

TOKYO, December 24, 2021 -- [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”) for additional indications of refractory pemphigus vulgaris and pemphigus foliaceus. Rituxan is co-marketed by the two companies in Japan.

Rituxan is an anti-CD20 monoclonal antibody that specifically binds to CD20 antigen, a protein expressed on B 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 clinical trial in Japan in patients with pemphigus inadequately responding to steroidal treatment (KCTR-D006 study) led by Keio University Hospital, and an overseas phase III clinical trial (PEMPHIX study) conducted by Roche.

Pemphigus is an autoimmune bullous disease that affects the skin and mucous membranes. Pemphigus vulgaris is the most common subtype in Japan, followed by pemphigus foliaceus. The male-to-female ratio is 1:1.5, more often in female, and the peak age of onset is 50 to 69. The main clinical features are painful and intractable erosions and ulcers in the oral mucosa, which may result in poor feeding in severe cases. Also, stratified squamous epithelium, including lips, pharynx, larynx, esophageal, palpebral conjunctiva, and vagina may be damaged, which can cause flaccid blisters and erosions in the skin in about half of the cases.¹⁾ Approximately 3,000 patients with pemphigus are reported in Japan²⁾, among which about 500 patients are with refractory pemphigus and eligible for Rituxan.³⁾ Pemphigus has been designated as an intractable disease by the Ministry of Health, Labour and Welfare (designated intractable disease 35).⁴⁾

Zenyaku and Chugai will continue working closely together so that Rituxan may contribute to the treatment of refractory pemphigus vulgaris and pemphigus foliaceus.

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Sources

- 1) Masayuki Amagai, Akiko Tanikawa, Tomoko Shimizu, et al. Japanese guidelines for the management of pemphigus. The Japanese Journal of Dermatology. 2010;120(7): 1443-1460
- 2) Japan Intractable Diseases Information Center. Number of holders of specific medical expenses (designated intractable disease) beneficiary certificate (as of the end of the first fiscal year of Reiwa. <https://www.nanbyou.or.jp/entry/5354>. Accessed December 2021 (Japanese only)
- 3) 4th round development request for unapproved drugs/indications with high medical need (Request No. IV-7). <https://www.mhlw.go.jp/file/06-Seisakujouhou-11120000-iyakushokuhinkyoku/0000112749.pdf>. Accessed December 2021 (Japanese only)
- 4) Japan Intractable Diseases Information Center. Pemphigus (designated intractable disease 35) <https://www.nanbyou.or.jp/entry/153>. Accessed December 2021 (Japanese only)

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