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Chugai Pharmaceutical Co., Ltd.
Nippon Shinyaku Co., Ltd.

Humanized Anti-CD20 Monoclonal Antibody, "GAZYVA[®] Intravenous Infusion 1000 mg," Approved for the Treatment of CD20-Positive Follicular Lymphoma

TOKYO, July 2, 2018 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) and [Nippon Shinyaku Co., Ltd.](#) (TOKYO: 4516) announced today that Chugai obtained approval from the Ministry of Health, Labour and Welfare (MHLW), for glycoengineered type II anti-CD20 monoclonal antibody GAZYVA[®] Intravenous Infusion 1000 mg [generic name; obinutuzumab (genetical recombination)], which was co-developed by the two companies for the treatment of "CD20-positive follicular lymphoma" in Japan.

"This approval of GAZYVA will add a new treatment option for CD20-positive follicular lymphoma" said Dr. Yasushi Ito, Chugai's Executive Vice President, Co-Head of Project & Lifecycle Management Unit. "GAZYVA has been confirmed to be more efficacious than RITUXAN[®] in combination with chemotherapy which is the standard therapy. Based on our experiences in the field of blood cancer cultivated over many years, we will prepare a system for providing information of proper use so that GAZYVA will be prescribed appropriately."

Shouzou Sano, Nippon Shinyaku's Director, General Manager of Sales and Marketing Div. said "I am very glad that manufacturing and marketing approval for our co-developed product, GAZYVA, was granted. By adding this new product to our lineup in the area of hematologic malignancies, on which we are focusing, we will make utmost efforts to meet the demands in the clinical setting and contribute to the treatment of patients."

Identical to RITUXAN which is recommended as a treatment of non-Hodgkin's lymphoma in treatment guidelines in Japan and overseas, GAZYVA is a glycoengineered type II anti-CD20 monoclonal antibody designed to attach to CD20, a protein expressed on certain B cells, but not on stem cells or plasma cells. GAZYVA is designed to attack and destroy targeted B cells both directly and together with the body's immune system.

Follicular lymphoma is a type of non-Hodgkin's lymphoma, and the number of patients are seven to fifteen percent of non-Hodgkin's lymphoma¹⁾. In Japan, the prevalence of malignant lymphoma was reported to be approximately 27,000 and the number of deaths due to the disease was reported to be approximately 11,000, both in 2012^{2, 3)}. Since the cases of Hodgkin's lymphoma is reported to account for approximately eight to ten percent of the cases of malignant lymphoma in

Japan¹⁾, the prevalence of non-Hodgkin's lymphoma is estimated to be approximately 24,000 and the number of deaths from this condition is estimated to be approximately 10,000. The prevalence and deaths from malignant lymphoma tend to increase in recent years^{2, 3)}, and a same tendency is seen in patients with non-Hodgkin's lymphoma.

Chugai and Nippon Shinyaku will work closely to make GAZYVA contribute to the treatment of CD20-positive follicular lymphoma.

1. Japanese Society of Hematology. Guidelines on Treatment of Hematopoietic Tumors (2013) Version 1.2. (<http://www.jshem.or.jp/gui-hemali/table.html>, Japanese only)
2. Center for Cancer Control and Information Services, National Cancer Center. National estimates of cancer incidence based on cancer registries in Japan (1975-2012) (<http://ganjoho.jp/en/>)
3. Center for Cancer Control and Information Services, National Cancer Center. Cancer mortality from Vital Statistics in Japan (1958-2015) (<http://ganjoho.jp/en/>)

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