

Translation

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

Co-Development and Co-Marketing Agreement for the Glycoengineered Type II Anti-CD20 Monoclonal Antibody, “GA101 (obinutuzumab)”

November 27, 2012 (Tokyo) - Chugai Pharmaceutical Co., Ltd. (“Chugai”) [Head Office: Chuo-ku, Tokyo; Chairman & CEO: Osamu Nagayama] and Nippon Shinyaku Co., Ltd. (“Nippon Shinyaku”) [Head Office: Kyoto-shi, Kyoto; President: Shigenobu Maekawa] announced today that they have entered into an agreement to co-develop and co-market “GA101” (generic name: obinutuzumab), the first glycoengineered, type II anti-CD20 monoclonal antibody which Chugai has licensed-in from GlycArt AG (current Roche Glycart AG, a 100% subsidiary of Roche) and started the development for the expected indication of indolent and aggressive non-Hodgkin’s lymphoma (NHL) since October 2008 in Japan. Chugai will receive an upfront fee and milestone payments from Nippon Shinyaku.

GA101 is a glycoengineered type II anti-CD20 monoclonal antibody created by GlycArt AG and is a compound that selectively targets the CD20 protein on B-cells, same as rituximab (recombinant) which is recommended as a treatment of non-Hodgkin’s lymphoma in treatment guidelines in Japan and overseas. GA101 has been designed for increased Antibody-Dependent Cellular Cytotoxicity (ADCC) activity and Direct Cell Death induction compared to rituximab.

In Japan, approximately 14,000 patients are newly diagnosed as NHL every year. While various effective drugs are available for the treatment of NHL, many patients suffer relapse or develop treatment resistance; therefore there is a need to develop safe and effective treatment that enable to prolong duration of remission and improve survival. Chugai and Nippon Shinyaku expect further improvement of the outcomes of patients with NHL, by demonstrating that GA101 is more effective than and as tolerable as rituximab.

Currently, Chugai is participating in two Phase III multinational studies, GALLIUM study in patients with indolent NHL and GOYA study in patients with aggressive NHL, conducted by Roche and Genentech.

Through the joint effort to develop and market GA101, Chugai and Nippon Shinyaku hope to provide another effective treatment option for NHL to as many patients as possible.

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