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Chugai Receives Orphan Drug Designation for Polatuzumab vedotin in Diffuse Large B-Cell Lymphoma from the MHLW

- Diffuse large B-cell lymphoma is an aggressive lymphoma that accounts for about one third of non-Hodgkin's lymphoma
- Orphan drug designation was granted based on the results from overseas phase Ib/II clinical studies

TOKYO, November 20, 2019 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that polatuzumab vedotin, an anti-CD79b antibody-drug conjugate under development, received orphan drug designation by the Ministry of Health, Labour and Welfare (MHLW) for diffuse large B-cell lymphoma (DLBCL). This designation is based on the results of overseas phase Ib/II clinical studies (GO29044 study and GO29365 study) in patients with untreated DLBCL and relapsed or refractory DLBCL.

"While the standard therapy for untreated DLBCL is a combination of Rituxan and chemotherapy, the disease recurs in about 40 percent of the patients. There are high unmet medical needs in treating such recurrent DLBCL because many of those patients inadequately respond to subsequent autologous stem cell transplantation," said Dr. Yasushi Ito, Chugai's Executive Vice President, Co-Head of Project & Lifecycle Management Unit. "We continue to work on preparing for the regulatory submission so that we can provide polatuzumab vedotin as one of the new treatment options to patients as soon as possible."

About polatuzumab vedotin

Polatuzumab vedotin is a first-in-class anti-CD79b antibody-drug conjugate (ADC), comprising the anti-CD79b humanized monoclonal antibody and a tubulin polymerization inhibitor attached together using a linker. The CD79b protein is expressed specifically in the majority of B-cells, making it a promising target for the development of new therapies[1, 2]. Polatuzumab vedotin binds to CD79b and destroys these B-cells through the delivery of an anti-cancer agent, which is thought to suppress the effects on normal cells[3, 4]. Polatuzumab vedotin is being developed by Roche using Seattle Genetics ADC technology and is currently being investigated for the treatment of several types of non-Hodgkin's lymphoma.

About diffuse large B-cell lymphoma (DLBCL)

DLBCL is one of the histologic subtypes of non-Hodgkin's lymphoma (NHL), which is categorized as aggressive disease that progresses on a monthly basis. DLBCL is the most common form of NHL, accounting for 30-40 percent of NHL[5-7]. DLBCL frequently occurs in middle-aged and older people, mainly in their 60's[8]. The median age at diagnosis has been reported to be 64[9].

The combination of Rituxan and chemotherapy is the standard therapy for untreated DLBCL; however, recurrence has been observed in about 40% of the patients due to insufficient therapeutic effect[10]. In addition, although autologous stem cell transplantation (ASCT) is recommended in eligible patients with

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recurrent or refractory DLBCL, ASCT cannot be performed in about half of these patients due to failure of salvage chemotherapy prior to ASCT[11]. Furthermore, no standard therapy has been established for patients ineligible for ASCT due to reasons including age or complications[12].

Salvage chemotherapy: A therapy mainly used in patients with hematologic malignancy who experienced no therapeutic effects (refractory), or recurrence/relapse of the disease is referred to as a salvage chemotherapy or salvage therapy. Applicable treatment may vary depending on the type of cancer, most of which will be combination therapies consisting of multiple drugs including anticancer agents[13].

About orphan drugs

Based on Pharmaceuticals and Medical Devices Law, orphan drugs are designated by the Minister of Health, Labour and Welfare and granted priority review. The designation criteria are as follows: The number of patients who may use the drug is less than 50,000 in Japan; The drug is indicated for the treatment of serious diseases and there is a significant medical value such as no alternative appropriate drug or treatment, or high efficacy or safety expected compared to existing products; there is a theoretical rationale for using the product for the targeted disease and the development plan is reasonable.

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