Chugai Files a New Drug Application for Polatuzumab Vedotin for the Treatment of Relapsed or Refractory Diffuse Large B-cell Lymphoma

- This application is an essential step for polatuzumab vedotin to become a new treatment option for diffuse large B-cell lymphoma
- Confirmed usefulness in Japanese and overseas clinical studies for relapsed or refractory diffuse large B-cell lymphoma


“About 40% of patients with untreated DLBCL experience relapse of the disease after standard therapy and subsequent treatment options are limited. In many cases, therapeutic effects on relapsed or refractory DLBCL are insufficient, and there is a high unmet medical need” said Dr. Osamu Okuda, Chugai’s President and COO. “Polatuzumab vedotin is a therapeutic antibody which bolsters Chugai’s blood cancer franchise following Rituxan® and Gazyva®. We will continue our efforts to deliver polatuzumab vedotin, an antibody-drug conjugate with a novel mechanism of action, to patients as early as possible and contribute to the realization of better treatment.”

This application is based on the results from a multicenter, single-arm Japanese phase II study (JO40762/P-DRIVE study) that evaluated the efficacy and safety of the combination therapy of polatuzumab vedotin with bendamustine and rituximab (BR therapy) in relapsed or refractory DLBCL, and a multicenter overseas phase Ib/II clinical study (GO29365) comparing the efficacy and safety of polatuzumab vedotin in combination with BR therapy to BR therapy. A double-blind, placebo-controlled global phase III study (GO39942/POLARIX study) is ongoing for untreated DLBCL to compare the efficacy and safety of polatuzumab vedotin in combination with rituximab plus cyclophosphamide, doxorubicin, prednisolone (R-CHP) to rituximab plus cyclophosphamide, doxorubicin, vincristine, prednisolone (R-CHOP).

[Reference information]
Polatuzumab Vedotin Achieved Primary Endpoint in the Japanese Phase II study for Relapsed or Refractory Diffuse Large B-cell Lymphoma (Press release issued by Chugai on February 13, 2020)

European Commission approves Roche’s Policy for people with previously treated aggressive lymphoma
(Press release issued by Roche on January 21, 2020)

Chugai Receives Orphan Drug Designation for Polatuzumab vedotin in Diffuse Large B-Cell Lymphoma from the MHLW (Press release issued by Chugai on November 20, 2019)

About polatuzumab vedotin
Polatuzumab vedotin was developed by Roche using Seattle Genetics' ADC technology. It 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 therapies1, 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 cells3, 4). Polatuzumab vedotin was granted accelerated approval in the US in June 2019 and conditional marketing authorization in the EU in January 2020, respectively.

About diffuse large B-cell lymphoma (DLBCL)
DLBCL is one of the histologic subtypes of non-Hodgkin’s lymphoma (NHL), which is categorized as an aggressive disease that progresses on a monthly basis. DLBCL is the most common form of NHL, accounting for 30-40 percent of NHL5-7). DLBCL frequently occurs in middle-aged and older people, mainly in their 60’s8). The median age at diagnosis has been reported to be 649).

The combination of rituximab and chemotherapy is the standard therapy for untreated DLBCL; however, recurrence has been observed in about 40% of the patients due to insufficient therapeutic effect10). In addition, although autologous stem cell transplantation (ASCT) is recommended in eligible patients with recurrent or refractory DLBCL, ASCT cannot be performed in about half of these patients due to failure of salvage chemotherapy prior to ASCT11). Furthermore, no standard therapy has been established for patients ineligible for ASCT due to reasons including age or complications12). Therefore, more useful new treatment options for relapsed or refractory DLBCL are in great need.

Sources


Japanese Society of Hematology. Practical Guidelines for Hematological Malignancies, 2018, Kanehara & Co., Ltd. (Japanese only)

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