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Chugai Launches Polivy Intravenous Infusion for the Treatment of Diffuse Large B-cell Lymphoma

- Launched Polivy as a first-in-class anti-CD79b antibody-drug conjugate for the treatment of relapsed or refractory diffuse large B-cell lymphoma

TOKYO, May 19, 2021 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it launched an anticancer agent/antimicrotubule binding anti-CD79b monoclonal antibody Polivy® intravenous infusion 30 mg and 140 mg [generic name: polatuzumab vedotin (genetical recombination)] for the treatment of relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL). Polivy had been approved by the Ministry of Health, Labour and Welfare (MHLW) on March 23, 2021 and was listed on the national health insurance (NHI) reimbursement price list today.

"We are very pleased to launch Polivy as a new treatment for relapsed or refractory DLBCL," said Chugai's President and CEO Dr. Osamu Okuda. "R/R DLBCL represents a high unmet medical need given the limited treatment options. We are committed to providing information in order to promote appropriate use of this first-in-class anti-CD79b antibody-drug conjugate (ADC) so that we may contribute to better treatment for patients."

The approval is based on data including the results from a multicenter overseas phase Ib/II clinical study (GO29365) that evaluated the efficacy and safety of Polivy in combination with bendamustine and rituximab (BR therapy) compared to BR therapy alone, and a multicenter, single-arm Japanese phase II study (JO40762/P-DRIVE study) that evaluated the efficacy and safety of Polivy in combination with BR therapy in R/R DLBCL.

A double-blind, placebo-controlled global phase III study (GO39942/POLARIX study) is ongoing for untreated DLBCL to examine the efficacy and safety of Polivy in combination with rituximab plus cyclophosphamide, doxorubicin, prednisolone (R-CHP) compared to rituximab plus cyclophosphamide, doxorubicin, vincristine, prednisolone (R-CHOP).

[Reference information]
Chugai Obtains Approval for Polivy for the Treatment of Relapsed or Refractory Diffuse Large B-cell Lymphoma (Press release issued by Chugai on March 23, 2021)
https://www.chugai-pharm.co.jp/english/news/detail/20210323170005_810.html

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)
https://www.chugai-pharm.co.jp/english/news/detail/20200213150000_697.html

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Approval information

Product name:	Polivy® Intravenous Infusion 30 mg Polivy® Intravenous Infusion 140 mg	
Generic name:	polatuzumab vedotin (genetical recombination)	
Intended uses or indications:	Relapsed or refractory diffuse large B-cell lymphoma	
Dosage and administration:	The usual adult dosage is 1.8 mg/kg (body weight) polatuzumab vedotin (genetical recombination) administered by intravenous infusion every 3 weeks for 6 doses, in combination with bendamustine hydrochloride and rituximab (genetical recombination). If the first infusion is well tolerated after 90 minutes, subsequent infusions may be administered over a shorter time of at least 30 minutes. Reduce the dose as necessary in accordance with the patient's condition.	
Date of approval:	March 23, 2021	
Date of NHI reimbursement price listing:	May 19, 2021	
Date of launch:	May 19, 2021	
Drug price:	Polivy® Intravenous Infusion 30 mg Polivy® Intravenous Infusion 140 mg	JPY 298,825/vial JPY 1,364,330/vial

About GO29365 study[1)]

GO29365 is a global, phase Ib/II study evaluating the safety and tolerability of Polivy in combination with bendamustine and rituximab (BR therapy) or obinutuzumab (BG therapy) in R/R follicular lymphoma or DLBCL. In the phase II randomized part of the study with 80 DLBCL patients, the efficacy and safety of Polivy in combination with BR therapy were studied compared to BR therapy alone. The primary endpoint was complete response at the point of primary response assessment as evaluated by an independent assessment committee using PET-CT. Patients received six cycles of treatment, spaced three weeks apart.

About JO40762 (P-DRIVE) study

JO40762 (P-DRIVE) is an open label, single-arm study investigating Polivy in combination with BR therapy in 35 patients with R/R DLBCL. Primary endpoint is investigator's assessment of CRR by PET-CT at the timing of primary response assessment. Patients received six cycles of treatment, spaced three weeks apart.

About Polivy

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 therapies[2, 3)]. 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[4, 5)]. 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 NHL, which is equivalent to about 23,000-32,000 patients[6-10]. DLBCL frequently occurs in middle-aged and older people, mainly in their 60's[11]. The median age at diagnosis has been reported to be 64[12].

The combination of rituximab and chemotherapy is the standard therapy for untreated DLBCL; however, recurrence has been observed in about 40% of patients due to insufficient therapeutic effect[13]. In addition, although autologous stem cell transplantation (ASCT) is recommended for 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 ASCT[14]. Furthermore, no standard therapy has been established for patients ineligible for ASCT due to reasons including age or complications[15]. Therefore, more useful new treatment options for relapsed or refractory DLBCL are in great need.

Salvage chemotherapy: Salvage chemotherapy or salvage therapy is used to treat patients with hematologic malignancy who experienced no therapeutic effects (refractory), or recurrence/relapse of the disease. Applicable treatment may vary depending on the type of cancer. Combination therapies of multiple drugs including anticancer agents[16] are generally used.

Sources

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