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Chugai Files for Additional Indication of Polivy for Previously Untreated Diffuse Large B-cell Lymphoma

- Polivy plus R-CHP significantly improved outcomes in previously untreated diffuse large B-cell lymphoma (DLBCL) compared to the standard of care for the first time in 20 years
- Filing is based on the results from Phase III POLARIX study in people with previously untreated DLBCL

TOKYO, December 10, 2021 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it filed a regulatory application with the Ministry of Health, Labour and Welfare for approval of an additional indication for an anticancer agent/antimicrotubule binding anti-CD79b monoclonal antibody Polivy® intravenous infusion 30 mg and 140 mg [generic name: polatuzumab vedotin (genetical recombination)] for previously untreated diffuse large B-cell lymphoma (DLBCL).

“While DLBCL is the most common type of non-Hodgkin Lymphomas which accounts for 30% of the disease, no new treatment has emerged for 20 years after the introduction of R-CHOP treatment,” said Chugai’s President and CEO Dr. Osamu Okuda. “We believe that Polivy plus R-CHP can transform the treatment paradigm for previously untreated DLBCL given the fact that the treatment showed prolonged survival without disease progression compared to the standard of care. We will continue working toward obtaining approval to deliver this new treatment regimen to patients as soon as possible.”

The filing is based on the result from Phase III POLARIX study (GO39943) evaluating the efficacy, safety and pharmacokinetics of Polivy plus R-CHP versus R-CHOP in people with previously untreated DLBCL. Chugai joins the POLARIX study.

As a leading company in the field of oncology in Japan, Chugai is committed to contribute to patients and medical professionals through offering innovative drug to fulfill unmet medical needs in cancer treatment.

[Reference information]
Phase III study shows Roche's Polivy plus R-CHP is the first regimen in 20 years to significantly improve outcomes in previously untreated aggressive form of lymphoma compared to standard of care (Press release issued by Roche on August 9, 2021)
https://www.roche.com/media/releases/med-cor-2021-08-09.htm

About POLARIX study
POLARIX (NCT03274492) is an international phase III, randomized, double-blind, placebo-controlled study evaluating the efficacy, safety and pharmacokinetics of Polivy plus Rituxan® (rituximab), cyclophosphamide, doxorubicin and prednisone (R-CHP) versus Rituxan, cyclophosphamide, doxorubicin, vincristine and prednisone (R-CHOP) in people with previously untreated diffuse large B-cell lymphoma

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(DLBCL). 879 patients were randomized 1:1 to receive either Polivy plus R-CHP plus a vincristine placebo for six cycles, followed by Rituxan for two cycles; or R-CHOP plus a Polivy placebo for six cycles, followed by two cycles of Rituxan. The primary outcome measure is progression-free survival as assessed by the investigator using the Lugano Response Criteria for malignant lymphoma. POLARIX is being conducted in collaboration with The Lymphoma Study Association (LYSA) and The Lymphoma Academic Research Organisation (LYSARC).

About the LYSA and the LYSARC

The Lymphoma Study Association, or LYSA, is the internationally leading cooperative group for lymphoma research in Europe, conducting clinical studies ranging from the first tests of new medicines in humans to the establishment of reference therapeutic strategies. LYSA includes in its network more than 120 care centers distributed throughout three countries (France, Belgium, Portugal), and collaborates with many scientific teams at the international level.

The Lymphoma Academic Research Organisation, or LYSARC, is the LYSA operational structure that conducts clinical research projects on lymphomas at the international level.

About Polivy (polatuzumab vedotin)

Polatuzumab vedotin was developed by Roche using Seagens' 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 the most common form of non-Hodgkin lymphoma (NHL), accounting for about one in three cases of NHL.[5] DLBCL is an aggressive type of NHL.[6] While it is generally responsive to treatment in the frontline, as many as 40% of patients will relapse or have refractory disease, at which time salvage therapy options are limited and survival is short.[6] Approximately 150,000 people worldwide are estimated to be diagnosed with DLBCL each year.[7]

Salvage therapy: 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[8] are generally used.

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