News Release

Chugai Obtains Regulatory Approval for Lunsumio and Polivy Combination Therapy for Additional Indication of Relapsed or Refractory Large B-cell Lymphoma

- A new treatment option that has demonstrated a high response rate and suppression of disease progression in patients with relapsed or refractory large B-cell lymphoma has been approved for the first time in the world
- In the global Phase III SUNMO study, the Lunsumio and Polivy combination demonstrated an objective response rate (ORR) of 69.7% and reduced the risk of disease progression or death by 59% compared with the regimen of rituximab, gemcitabine, and oxaliplatin (R-GemOx; not approved in Japan)

TOKYO, March 23, 2026 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it obtained regulatory approval from the Ministry of Health, Labour and Welfare (MHLW) for the additional indication of the combination therapy of anti-cancer agent / anti-CD20/CD3 humanized bispecific monoclonal antibody Lunsumio® subcutaneous injection 5mg and 45mg [generic name: mosunetuzumab (genetical recombination)] (hereafter, Lunsumio) and anti-cancer agent/antimicrotubule-binding anti-CD79b monoclonal antibody Polivy® intravenous infusion 30 mg and 140 mg [generic name: polatuzumab vedotin (genetical recombination)] (hereafter, Polivy) for the treatment of relapsed or refractory large B-cell lymphoma. This marks the first approval in the world for the combination therapy of Lunsumio and Polivy for this indication.

“For patients with relapsed or refractory large B-cell lymphoma, treatment options remain limited and unmet medical needs persist. The Lunsumio and Polivy combination therapy achieved responses in approximately 70% of patients and showed a 59% reduction in the risk of disease progression or death compared to the chemotherapy control arm. We are committed to delivering this treatment to patients as quickly as possible by providing timely information to healthcare professionals and promoting appropriate use,” said Dr. Osamu Okuda, Chugai’s President and CEO.

This approval is based on the results of the global, multi-center, randomized Phase III SUNMO study evaluating the efficacy and safety of the combination therapy compared to

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the regimen of rituximab, gemcitabine, and oxaliplatin (R-GemOx; not approved in Japan) in patients with relapsed or refractory large B-cell lymphoma who are not eligible for autologous hematopoietic stem cell transplantation.

In the interim analysis of the study, the objective response rate (ORR), a primary endpoint assessed by an independent review committee, was 69.7% (95% CI: 60.7–77.8) in the Lunsumio and Polivy combination therapy group and 44.1% (95% CI: 31.2–57.6) in the R-GemOx group, with a between-group difference of 25.7% (97.5% CI: 7.4–43.9). At the time of the primary analysis, the progression-free survival (PFS), also a primary endpoint assessed by an independent review committee, was 11.5 months (95% CI: 5.6–18) in the Lunsumio and Polivy combination therapy group and 3.8 months (95% CI: 2.9–4.1) in the R-GemOx group, demonstrating a 59% reduction in the risk of disease progression or death.

The safety profile of the combination therapy of Lunsumio and Polivy was consistent with the known profiles of each agent in their respective individual studies. Adverse events were observed in 131 of 135 patients (97.0%) in the Lunsumio and Polivy combination therapy group and in 61 of 64 patients (95.3%) in the R-GemOx group. The main adverse events in the Lunsumio and Polivy combination therapy group included injection site reactions in 71 patients (52.6%), neutropenia in 62 patients (45.9%), anemia in 41 patients (30.4%), and cytokine release syndrome in 35 patients (25.9%), among others[1].

**Approval Information (Lunsumio) ***Relevant sections only, with modifications underlined
Product name: “LUNSUMIO® subcutaneous injection 5mg” and “LUNSUMIO® subcutaneous injection 45mg”
Generic name: mosunetuzumab (genetical recombination)

Indications:
<u>The following relapsed or refractory large B-cell lymphomas:</u>
<u>Diffuse large B-cell lymphoma</u>

High-grade B-cell lymphoma
Relapsed or refractory follicular lymphoma

Dosage and administration:
〈Relapsed or refractory large B-cell lymphoma (diffuse large B-cell lymphoma, high-grade B-cell lymphoma) and relapsed or refractory follicular lymphoma (Grade 3B)〉
In combination with polatuzumab vedotin (genetical recombination), mosunetuzumab (genetical recombination) is administered subcutaneously to adults in 21-day cycles.
In the first cycle, 5 mg is administered on Day 1, followed by 45 mg on Days 8 and 15, and from the second cycle onward, 45 mg is administered on Day 1 for up to 8 cycles.

**Approval Information (Polivy) ***Relevant sections only, with modifications underlined
Product name: “Polivy® intravenous infusion 30 mg” and “Polivy® intravenous infusion 140 mg”
Generic name: polatuzumab vedotin (genetical recombination)

Indications:
The following large B-cell lymphomas:
Diffuse large B-cell lymphoma
High-grade B-cell lymphoma
Relapsed or refractory follicular lymphoma

Precautions concerning indications:
<Relapsed or Refractory Follicular Lymphoma>
This drug should be administered to patients diagnosed with Grade 3B by a pathologist with sufficient experience.

Dosage and administration:
In combination with other anti-cancer agents, polatuzumab vedotin (genetical recombination) is usually administered to adults as an intravenous infusion at a dose of

1.8 mg/kg (body weight) once every three weeks for a total of six doses. The initial dose is infused over 90 minutes, and if tolerated well, the infusion time for subsequent doses may be shortened to 30 minutes. The dose may be reduced as appropriate depending on the patient's condition.

[Reference]
Roche's Lunsumio and Polivy combination significantly prolongs remission for people with relapsed or refractory large B-cell lymphoma (Press release from Roche issued on June 20, 2025)
https://www.roche.com/media/releases/med-cor-2025-06-20

About the SUNMO study

The SUNMO [NCT05171647] study is a multinational, multicenter, randomized Phase III trial that targets patients with relapsed or refractory large B-cell lymphoma who are not eligible for autologous hematopoietic stem cell transplantation, and evaluates the combination therapy of subcutaneously administered Lunsumio (mosunetuzumab) and intravenously administered Polivy (polatuzumab vedotin) in comparison with the R-GemOx regimen [Rituxan (rituximab), gemcitabine, and oxaliplatin]. The primary endpoints are progression-free survival and objective response rate, and the secondary endpoints include overall survival, duration of objective response, complete response rate, duration of complete response, safety and tolerability, and patient-reported outcomes (PROs: Patient Reported Outcomes).

About Lunsumio® (mosunetuzumab)

Lunsumio is a T-cell-engaging bispecific antibody designed to target CD3 on T cells and CD20 on B cells. Lunsumio is expected to activate immunity mediated by cytotoxic T cells and exert antitumor effects against tumor cells expressing CD20. Lunsumio has been approved in 65 countries worldwide. Clinical studies are currently underway in follicular lymphoma (second line and untreated settings). In December 2025, in addition to the intravenous formulation, Lunsumio obtained manufacturing and marketing approval for a new subcutaneous formulation.

About Polivy® (polatuzumab vedotin)

Polivy is a first-in-class anti-CD79b antibody-drug conjugate (ADC). The CD79b protein is expressed in the majority of B cells, an immune cell impacted in some types of non-Hodgkin lymphoma (NHL), making it a promising target for the development of new therapies. Polivy binds to cancer cells such as those expressing CD79b and destroys these B cells through the delivery of an anti-cancer agent, which is thought to minimize the effects on normal cells. Polivy is being developed by Roche and is currently being investigated for the treatment of several types of NHL.

About Large B-cell lymphoma (LBCL)

LBCL consists primarily of diffuse large B-cell lymphoma (DLBCL), which is the most common subtype of non-Hodgkin lymphoma (NHL) affecting B-cell lymphocytes, a type of white blood cell. DLBCL is the most common form of aggressive NHL and accounts for approximately 80%[2] of LBCL cases. LBCL also includes high-grade B-cell lymphoma (HGBL), which is considered to be even more aggressive and to have a poorer prognosis than DLBCL. Although patients generally respond to frontline therapy, up to 40%[3]experience relapse or become refractory, and in such cases, treatment options for salvage therapy are limited.

Sources

1. Lihua E. Budde, et al. Mosunetuzumab Plus Polatuzumab Vedotin in Transplant-Ineligible Refractory/Relapsed Large B-Cell Lymphoma: Primary Results of the Phase III SUNMO Trial. J Clin Oncol 43, 3799-3811(2025)
2. Masashi Nakagawa. Diffuse large B-cell lymphoma: Recent advances in diagnosis and therapy. Osaka General Medical Journal. 2023;45:3–12. Available from: https://www.gh.opho.jp/pdf/medicaljournal_045_001.pdf (accessed March 2026) (Japanese only)

3. Fabbri N, et al. Second-line treatment of diffuse large B-cell lymphoma: Evolution of options. Semin Hematol 2023; 60(5): 305–312.

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