News Release

Chugai Launches "LUNSUMIO for Intravenous Infusion," a Bispecific Antibody for Relapsed or Refractory Follicular Lymphoma in Japan

- Launched as a treatment for patients with follicular lymphoma who have failed to respond to or have relapsed after two or more standard therapies
- LUNSUMIO monotherapy is expected to become a new treatment option with high complete response rates and the potential for durable remission
- LUNSUMIO is a fixed-duration treatment based on the patient's response to therapy, and is expected to reduce the burden of treatment on patients

TOKYO, March 19, 2025 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it launched "LUNSUMIO® for intravenous infusion 1 mg" and "LUNSUMIO® for intravenous infusion 30 mg" (generic name: mosunetuzumab (genetical recombination)) (hereafter, LUNSUMIO), antineoplastic agent / anti-CD20/CD3 humanized bispecific antibody for the treatment of patients with relapsed or refractory follicular lymphoma who have received two or more prior standard therapies. LUNSUMIO had been approved by the Ministry of Health, Labour and Welfare (MHLW) on December 27, 2024 and was listed on the national health insurance (NHI) reimbursement price list today.

"Relapsed or refractory follicular lymphoma is a difficult-to-cure disease that repeatedly relapses, and therefore there was a need for new treatment options. LUNSUMIO is expected to provide durable remission with monotherapy, and with a predetermined treatment duration based on each patient's response to therapy, which can help reduce the burden of treatment on patients. We will strive to promote proper use in order to deliver new value to patients, their families, and healthcare professionals," said Chugai's President and CEO, Dr. Osamu Okuda.

This approval is based on the results of a Japanese Phase I study with an expansion cohort (FLMOON-1 study) conducted in patients with relapsed or refractory follicular lymphoma who had received two or more prior standard therapies, as well as an overseas Phase I/II clinical trial conducted by Roche in the same patient population. In both studies, the efficacy and safety of this drug were evaluated as a monotherapy. Furthermore, four-year

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follow-up data from the overseas Phase I/II clinical trial was presented at the 66th Annual Meeting of the American Society of Hematology (ASH).

Approval Information

Product name: "LUNSUMIO® for intravenous infusion 1 mg" and "LUNSUMIO® for intravenous infusion 30 mg"
Generic name: mosunetuzumab (genetical recombination)
Indications: relapsed or refractory follicular lymphoma
Precautions concerning indications:

- Treatment with this drug should be targeted at patients who have failed to respond to or have relapsed after two or more standard therapies, including an anti-CD20 monoclonal antibody product.
- This drug should be administered to patients diagnosed with Grade 1-3A by a pathologist with sufficient experience.

Dosage and administration:
For adults, the usual dosage of mosunetuzumab (genetically modified) is administered as an intravenous infusion in 21-day cycles as follows:
Cycle 1: 1 mg on Day 1, 2 mg on Day 8, and 60 mg on Day 15
Cycle 2: 60 mg on Day 1
Cycles 3-8: 30 mg on Day 1 of each cycle
After 8 cycles, treatment should be discontinued for patients who achieve a complete response. For patients with stable disease or partial response, treatment may be continued for up to a total of 17 cycles.
Date of approval: December 27, 2024
Date of NHI reimbursement price listing: March 19, 2025
Date of launch: March 19, 2025
Drug price:

LUNSUMIO for intravenous infusion 1 mg	JPY 83,717 / bottle
LUNSUMIO for intravenous infusion 30 mg	JPY 2,393,055 / bottle

Reference

Chugai Obtains Regulatory Approval for "LUNSUMIO for Intravenous Infusion" for Relapsed or Refractory Follicular Lymphoma in Japan (Press release December 27, 2024)
https://www.chugai-pharm.co.jp/english/news/detail/20241227153000_1124.html

About LUNSUMIO

LUNSUMIO is a CD20/CD3 T cell-engaging bispecific antibody designed to target CD20 on B cells and CD3 on T cells. LUNSUMIO is expected to activate the immune system through cytotoxic T cells and have antitumor effects on CD20 expressing tumor cells. LUNSUMIO has been approved in 61 countries worldwide. LUNSUMIO is currently being developed for the treatment of follicular lymphoma (second-line treatment and previously untreated) and relapsed or refractory aggressive B-cell non-Hodgkin's lymphoma.

About follicular lymphoma

Follicular lymphoma is a type of lymphoma that occurs when B lymphocytes, a type of white blood cell, become cancerous. At diagnosis, 70-85% of patients reach an advanced stage[1]. Generally, the progression is slow, and chemotherapy is initially effective, but recurrences occur repeatedly in many cases. Repeated recurrences can make it difficult for existing treatments to be effective, and new highly effective treatments are needed. In Japan, approximately 9,000 people reportedly become afflicted with follicular lymphoma each year[2].

Sources

1. Japanese Society of Hematology. Practical Guidelines for Hematological Malignancies 2023 edition. Kanehara & Co., Ltd.
2. “Cancer Statistics in Japan” in Cancer information service of National Cancer Center (National Cancer Registry), National Cancer Incidence Data (2016-2020).
   Available from: https://ganjoho.jp/public/cancer/follicular_lymphoma/index.html
   Access date: March 2025

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