Innovation all for the patients

CHUGAI

Roche A member of the Roche group

Chugai Obtains Regulatory Approval for "LUNSUMIO for Intravenous Infusion" for Relapsed or Refractory Follicular Lymphoma in Japan

- For patients with relapsed or refractory (R/R) follicular lymphoma (FL) after receiving two or more prior standard therapies, LUNSUMIO monotherapy is expected to become a new treatment option with high response rates and the potential for durable remission
- With a predetermined treatment duration based on the patient's response to therapy, LUNSUMIO is expected to reduce the burden of treatment on patients

TOKYO, December 27, 2024 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it has obtained regulatory approval from the Ministry of Health, Labour and Welfare (MHLW) for "LUNSUMIO® for intravenous infusion 1mg" and "LUNSUMIO® for intravenous infusion 30mg" (generic name: mosunetuzumab (genetical recombination)) (hereafter, LUNSUMIO), antineoplastic agent / anti-CD20/CD3 bispecific antibody for the treatment of patients with relapsed or refractory (R/R) follicular lymphoma (FL) who have received two or more prior standard therapies. LUNSUMIO is a T-cell engaging bispecific antibody targeting CD20/CD3, offering a new treatment option with high response rates and the potential for durable remission. The treatment duration is set at approximately six months or one year, depending on the patient's response to treatment.

"R/R FL is a difficult-to-cure disease that repeatedly relapses, and there is 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 are proceeding with preparations for the launch to make this drug available for treatment as soon as possible," said Dr. Osamu Okuda, Chugai's President and CEO.

This approval is based on the results of a Japanese Phase I study with an expansion cohort (FLMOON-1 study) conducted in patients with R/R FL 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.

The FLMOON-1 study was conducted on 19 Japanese patients with R/R FL who had previously received two or more prior standard therapies. The complete response rate (CRR), which was the primary endpoint as assessed by an independent review facility (IRF), was 68.4% (90% confidence interval: 47.0-85.3%). The most frequent adverse reactions were lymphocyte count decrease, cytokine release syndrome, alanine aminotransferase increase, neutrophil count decrease, aspartate aminotransferase increase, and infusion-related reactions.

CHUGAI PHARMACEUTICAL CO., LTD. Corporate Communications Dept.
1-1, Nihonbashi-Muromachi 2-chome, Chuo-ku Tokyo, 103-8324 Japan
Media Relations Group TEL:+81-(0)3-3273-0881 E-mail:pr@chugai-pharm.co.jp
Investor Relations Group TEL:+81-(0)3-3273-0554 E-mail:ir@chugai-pharm.co.jp

The overseas Phase I/II study was conducted on 90 patients with R/R FL who had previously received two or more standard therapies. The primary endpoint, CRR as assessed by an IRF, was 57.8% (95% confidence interval: 46.9-68.1%). The most frequent adverse reactions were cytokine release syndrome, fever, fatigue, pruritus, neutropenia, and hypophosphatemia.

[Approval Information]

Product name: "LUNSUMIO® for intravenous infusion 1mg" and "LUNSUMIO® for intravenous infusion 30mg"
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.

[Reference]

Chugai Files New Drug Application in Japan for Mosunetuzumab for Relapsed or Refractory Follicular Lymphoma (Press release issued on March 14, 2024)
https://www.chugai-pharm.co.jp/english/news/detail/20240314150001_1055.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 with intravenous and subcutaneous formulations for the treatment of R/R FL and R/R aggressive B-cell non-Hodgkin lymphoma.

About follicular lymphoma

FL 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 FL 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: December 2024

###