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Chugai Files New Drug Application in Japan for Mosunetuzumab for Relapsed or Refractory Follicular Lymphoma

- Mosunetuzumab monotherapy showed promising results in achieving remission for patients with relapsed or refractory (R/R) follicular lymphoma (FL)
- This application is an important step in making mosunetuzumab a new treatment option for patients with R/R FL

TOKYO, March 14, 2024 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it filed regulatory applications with the Ministry of Health, Labour and Welfare for the anti-CD20xCD3 bispecific antibody mosunetuzumab for the treatment of patients with R/R FL who have received two or more prior systemic therapies.

“Mosunetuzumab has shown promising results in clinical trials as monotherapy for achieving durable remissions. In addition, unlike previous treatments that require long-term continuous administration and hospitalization, the treatment period is predetermined, so it is expected to reduce the burden of hospital visits associated with treatment. We will continue working with the authorities to deliver this drug, which has the potential to change patients' prognosis and social life, for patients as quickly as possible,” said Dr. Osamu Okuda, Chugai’s President and CEO.

The application is based on the results of the Japanese phase I study and overseas Phase I/II study conducted by Roche in patients with R/R FL who had previously received two or more prior systemic therapies.

[Reference]

Mosunetuzumab Achieved Primary Endpoint in Expansion Cohort of Japanese Phase I study for Relapsed or Refractory Follicular Lymphoma (Press release issued on Feb 9, 2023)
https://www.chugai-pharm.co.jp/english/news/detail/20240209113000_1042.html

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

About Japanese Phase I study for mosunetuzumab

Japanese phase I clinical study to evaluate the efficacy and safety of mosunetuzumab includes a dose-escalation cohort and an expansion cohort for patients with R/R FL who have previously received two or more systemic therapies. 19 patients were enrolled in the expansion cohort. The primary endpoint was complete response rate (CRR). The key secondary endpoints included overall response rate, progression-free survival, and duration of response. Details of the study results will be announced at future academic conferences.

About overseas Phase I/II study for mosunetuzumab

Overseas Phase I/II clinical study conducted by Roche is a multicenter, open-label, dose-escalation and expansion study evaluating the safety, efficacy and pharmacokinetics of mosunetuzumab in patients with R/R B-cell non-Hodgkin's lymphoma. The primary endpoint of the expansion cohort is CRR. The key secondary endpoints included response rate, duration of response, progression-free survival, safety and tolerability.

About mosunetuzumab

Mosunetuzumab is a CD20xCD3 T cell-engaging bispecific antibody designed to target CD20 on B cells and CD3 on T cells. Mosunetuzumab is expected to activate the immune system through cytotoxic T cells and have antitumor effects on CD20 expressing tumor cells. Mosunetuzumab 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 5,000 people reportedly become afflicted with FL each year[2,3].

Sources

1. Japanese Society of Hematology. Practical Guidelines for Hematological Malignancies 2023 edition. Kanehara & Co., Ltd.
2. Chihara D, Ito H, Matsuda T, Shibata A, et al. Differences in incidence and trends of haematological malignancies in Japan and the United States. Br J Haematol. 2014;164(4):536-45.
3. "Cancer Statistics in Japan" in Cancer information service of National Cancer Center (National Cancer Registry), National Cancer Incidence Data (2016-2019). Available from: https://ganjoho.jp/reg_stat/statistics/data/dl/excel/cancer_incidenceNCR(2016-2019).xls Access date: March 2024

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