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Mosunetuzumab Achieved Primary Endpoint in Expansion Cohort of Japanese Phase I study for Relapsed and Refractory Follicular Lymphoma

- Mosunetuzumab demonstrated clinically meaningful complete response rates in patients with relapsed or refractory follicular lymphoma who have received two or more prior systemic therapies
- Chugai will file a new drug application in Japan based on these study results and the overseas Phase I/II clinical studies conducted by Roche

TOKYO, February 9, 2024 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that anti-CD20/CD3 bispecific antibody mosunetuzumab achieved the primary endpoint of complete response rate (CRR) in an expansion cohort of the Japanese Phase I study evaluating the efficacy and safety in patients with relapsed or refractory (R/R) follicular lymphoma (FL) who have received two or more prior systemic therapies. The safety profile was consistent with previous overseas studies.

“R/R FL is a disease that repeatedly recurs and is difficult to cure, and new treatment strategies are required. We are very pleased that bispecific antibody mosunetuzumab achieved CRR and showed promising results for remission. We will continue efforts to apply for the approval of mosunetuzumab in Japan to deliver this drug as a new treatment option for patients as quickly as possible,” said Dr. Osamu Okuda, Chugai’s President and CEO.

Chugai will file a new drug application in Japan based on these study results and the overseas Phase I/II clinical studies conducted by Roche in the same patient population.

About Japanese Phase I study for mosunetuzumab

This study is a Japanese phase I clinical study to evaluate the efficacy and safety of mosunetuzumab in a dose-escalation cohort and in 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 CRR. Key secondary endpoints included overall response rate, progression-free survival, and duration of response.

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 expressed 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.

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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 expected. In Japan, approximately 5,000 people reportedly become afflicted with FL each year[2,3].

Sources

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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: February 2024

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