国立研究開発法人
国立がん研究センター
National Cancer Center Japan

First drug approved for unresectable thymic carcinoma

Responding to unmet medical needs with an investigator-initiated clinical trial

March 23, 2021

National Cancer Center

Key points

- The results of the nationwide investigator-initiated clinical trial conducted at eight medical institutions led by the National Cancer Center Hospital resulted in the world's first approved drug in Japan for unresectable thymic carcinoma patients.
- The annual incidence of thymic carcinoma is 0.15 per 100,000 persons, and unresectable thymic carcinoma has poor prognoses. Thus, this is a "rare cancer" for which the research and development of therapeutic drugs are much needed.
- In this investigator-initiated clinical trial, the efficacy of lenvatinib for unresectable thymic carcinoma was significantly greater than the pre-defined threshold.
- The small number of patients with rare cancers leads to difficulty in the development of pharmacotherapy and discourages industry-initiated clinical trials. This “REMORA study” is a successful example of academia meeting unmet medical needs by leading a clinical trial to evaluate the efficacy and safety of lenvatinib for thymic carcinoma.

Overview

In 2017, the National Cancer Center Hospital (Director: Kazuaki Shimada), initiated an investigator-initiated clinical trial to evaluate the efficacy and safety of lenvatinib in unresectable thymic carcinoma, a rare cancer for which no approved drug had been available. Lenvatinib is an anticancer drug that has already been approved for thyroid cancer and hepatocellular carcinoma in Japan. The result of this study named “REMORA study” demonstrated 38.1% (16 of the 42 patients) in response rate for refractory thymic carcinoma. The safety was also shown as those previously observed in thyroid cancer and hepatocellular carcinoma.

Based on the results of the REMORA study, Eisai Co., Ltd., which developed and distributes lenvatinib, submitted a marketing authorization application for an additional indication for lenvatinib for thymic carcinoma, and the Ministry of Health, Labour and Welfare approved it as a new efficacy drug on March 23, 2021. It is the first indication for thymic carcinoma.

The National Cancer Center Hospital has been actively involved in clinical trials for developing effective treatments for unmet medical needs including rare cancers, which are difficult for industries to address. This is a successful example in which the efficacy and safety of an anticancer agent were demonstrated in an investigator-initiated clinical trial, leading to the approval for a label in Japan.

The results of the "REMORA study" were published in one of the top international journals, "The Lancet Oncology."

Refer to:

Journal: The Lancet Oncology
Title: Lenvatinib in patients with advanced or metastatic thymic carcinoma (REMORA): a multicentre, phase 2 trial
Author: Sato J, et al.
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<Contact information>

Inquiries about investigator-initiated clinical trials
National Cancer Center Hospital
Clinical Research Support Office, Research Management Division, Clinical Trial Managemnt Section
E-mail: NCCH1508_office@ml.res.ncc.go.jp

Inquiries related to the press
National Cancer Center
Office of Public Relations, Strategic Planning Bureau
E-mail: ncc-admin@ncc.go.jp