

Regarding Discontinuation of Administration of “Tazverik® Tablets 200mg” (tazemetostat hydrobromide)

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) announced today that the administration of the anticancer agent EZH2 inhibitor “Tazverik® Tablets 200 mg” (generic name: tazemetostat hydrobromide), which is manufactured and marketed in Japan by Eisai should be discontinued. We plan to discontinue sales of this product once we have confirmed that it is no longer being administered to any patients.

Following the announced voluntarily withdrawal of this product in the United States and other countries, Eisai has been collecting and reviewing safety data, including from the overseas clinical trials including SYMPHONY-1*¹ and postmarketing data both domestic and from overseas. Based on the review of the available safety data, multiple cases of secondary hematologic malignancies have occurred on both combination and monotherapy treatment with tazemetostat.

After a comprehensive evaluation of these findings, we concluded that it is necessary to give the fullest possible consideration to the risk of secondary hematologic malignancies occurring even under the approved conditions of use in Japan.

Prioritizing patient safety, we are communicating with medical institutions in Japan where the drug is prescribed to consider discontinuing Tazverik immediately for patients currently receiving it, and to refrain from initiating any new administration.

Eisai will continue to make every effort to provide timely and appropriate information to healthcare professionals to prevent any confusion or disruption for medical institutions or patients.

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*1. Regarding the SYMPHONY-1 trial

The SYMPHONY - 1 study is a phase 1b/3 trial evaluating whether adding tazemetostat to rituximab plus lenalidomide (R² therapy), the standard second - line treatment, prolongs progression - free survival (PFS) in patients with relapsed/refractory follicular lymphoma who have received at least one prior chemotherapy regimen*².

The phase 1b portion is a single - arm dose - finding study. In the phase III trial, eligible patients will be randomized 1:1; the experimental group will receive R² therapy plus tazemetostat for 12 months, followed by up to 2 years of tazemetostat monotherapy. The control group will receive a placebo instead of tazemetostat.

The primary endpoint is PFS; secondary endpoints are objective response rate (ORR), overall survival (OS), duration of response (DOR), health-related quality of life (HR-QOL), and safety. This trial is being conducted under Ipsen's

leadership as the confirmatory trial required for the accelerated approval of Tazverik for follicular lymphoma in the United States and China, and is being carried out at 229 sites in 15 countries, including the United States, the European Union, and China (no sites in Japan are participating).

*2. The indication approved for Tazverik in Japan is monotherapy for "relapsed or refractory EZH2 mutation–positive follicular lymphoma (limited to cases where standard treatment is difficult)."

[Notes to editors]

1. About tazemetostat hydrobromide (generic name, product name “Tazverik Tablets 200 mg”)

Tazemetostat is a first-in-class, oral small molecule inhibitor that targets EZH2 that was jointly researched and developed under the alliance agreement between Eisai and Epizyme, Inc., an Ipsen company, utilizing Epizyme, Inc.'s proprietary product platform. This agent selectively inhibits EZH2 in a competitive manner with S-adenosylmethionine (a methyl group donor) to suppress methylation of H3K27. Eisai was granted exclusive rights for development and commercialization of this agent in Japan.