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Eisai Co., Ltd.

EISAI ANNOUNCES MOVE TO SOLO DEVELOPMENT AND COMMERCIALIZATION OF FARLETUZUMAB ECTERIBULIN (FZEC) ANTIBODY DRUG CONJUGATE (ADC)

Strategic collaboration with Bristol Myers Squibb ended

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that it has agreed to end its global strategic collaboration with Bristol Myers Squibb for the co-development and co-commercialization of farletuzumab ecteribulin (FZEC), formerly known as MORAb-202, a folate receptor alpha (FR α)-targeting antibody drug conjugate (ADC) due to ongoing portfolio prioritization efforts within Bristol Myers Squibb. Based on the agreement, Eisai now owns all rights to FZEC and will solely conduct the global development and commercialization of the agent. Eisai will accelerate the development of the agent as a high priority with the hope to deliver it to patients as early as possible. Eisai plans to refund a part of the unused portion of the \$200 million payment it received towards research and development expenses from Bristol Myers Squibb under the collaboration agreement and record the remaining as other income.

FZEC is Eisai's first ADC and is composed of Eisai's in-house developed farletuzumab, a humanized IgG1 monoclonal antibody that binds to the FR α , and Eisai's in-house developed anticancer agent eribulin, using an enzymatically cleavable linker. Currently, three clinical studies are ongoing: Eisai's Phase 1/2 study for solid tumors ([NCT04300556](#)), and Bristol Myers Squibb's Phase 2 studies for ovarian, peritoneal and fallopian tube cancers ([NCT05613088](#)) and non-small cell lung cancer ([NCT05577715](#)).

Eisai positions oncology as a key franchise area and aims to contribute toward the cure of cancers by exploring the depths of human biology. FZEC development for refractory cancers is a testament of our dedication to addressing the unmet medical needs of patients with cancer. Eisai will make continuous efforts to increase the benefits provided to patients with cancer and their families.

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[Notes to editors]

1. Farletuzumab eribulin (FZEC, formerly known as MORAb-202)

FZEC is Eisai's first antibody drug conjugate (ADC) and that is composed of Eisai's in-house developed farletuzumab, a humanized IgG1 monoclonal antibody that binds to the folate receptor alpha (FR α), and Eisai's in-house developed anticancer agent eribulin, using an enzymatically cleavable linker. After FZEC enters the target FR α -positive cancer cells, it is thought that the linker is enzymatically cleaved, releasing eribulin from the antibody leading to its antitumor activity. When the anticancer agent and antibody components of an ADC are separated inside a targeted antigen-positive cancer cell, it is theorized that the released anticancer agent also has a bystander effect on neighboring antigen-negative cancer cells and the component cells of the tumor microenvironment. In pre-clinical studies, FZEC demonstrated a bystander effect*, with antitumor activity on the FR α -negative cancer cells surrounding the FR α -positive cancer cells.

The payload eribulin was the first in the halichondrin class of microtubule dynamics inhibitor. Structurally, eribulin is a simplified and synthetically produced version of halichondrin B, a natural product isolated from the marine sponge *Halichondria okadai*, and functions by inhibiting the growth phase of microtubule dynamics which prevents cell division. Eribulin has been approved in countries including Japan, the United States, China, in Europe and in Asia for use in the treatment of advanced breast cancer and liposarcoma (soft tissue sarcoma in Japan).

*Bystander effect: When the anticancer agent and antibody parts of an ADC are separated inside a targeted antigen-positive cancer cell, the released anticancer agent also affects neighboring antigen-negative cancer cells and the component cells of the cancer microenvironment.