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Japan grants Sakigake designation to Eisai’s novel FGFR

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The SAKIGAKE Designation System promotes R&D in Japan aiming at early practical applications for innovative new medicines and other products

Eisai Co., Ltd. is a leading global research and development-based pharmaceutical company headquartered in Japan. The company has announced that its in-house discovered fibroblast growth factor receptor (FGFR) tyrosine kinase inhibitor E7090 has been granted the SAKIGAKE designation by Japan's Ministry of Health, Labour and Welfare for the treatment of unresectable biliary tract cancer with FGFR2 gene fusion. E7090 selectively inhibits FGFR1, FGFR2 and FGFR3, and is currently under development as a novel orally available anticancer agent.

The SAKIGAKE Designation System promotes R&D in Japan aiming at early practical applications for innovative new medicines and other products. Under this system, in principle the designated product must have the potential for prominent effectiveness based on a different mechanism of action from already approved products. Designated products are eligible for prioritized consultation services and reviews for regulatory authorizations.

FGFRs with genetic aberrations are known to play an important role in the proliferation, survival and migration of cancer cells as well as tumor angiogenesis and drug resistance. These genetic aberrations in FGFRs have been observed in various types of cancers; therefore, FGFRs are gaining attention as a promising target for cancer therapy. By selectively inhibiting FGFR1, 2 and 3, and blocking those signals, E7090 has the potential to become a new molecular targeted therapy for cancers with FGFR genetic aberrations.

In Japan, E7090 is currently being investigated in a First in Human study (Phase I clinical study) targeting patients with solid tumors including cholangiocarcinoma harboring FGFR2 gene fusion.

Eisai positions oncology as a key therapeutic area and is aiming to discover revolutionary new medicines with the potentialto cure cancer. Eisai is committed to exploring the potential clinical benefits of E7090 as it seeks to contribute further to addressing the diverse needs of, and increasing the benefits provided to patients with cancer, their families, and healthcare

providers.