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Eisai Co., Ltd.

EISAI CONFIRMS THERAPEUTIC EFFECTS OF LENVATINIB IN PATIENTS WITH MELANOMA IN STRATEGIC COLLABORATION WITH QUINTILES TO DEVELOP EISAI ANTICANCER COMPOUNDS

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that the therapeutic effects of lenvatinib (generic name; VEGF receptor tyrosine kinase inhibitor and multi-kinase inhibitor discovered in-house) on melanoma have been confirmed in one of a series of joint development programs being conducted as part of the company's strategic collaboration with Quintiles (Headquarters: North Carolina, the United States; CEO: Thomas Pike, "Quintiles"). The finding has provided the basis for the first proof of concept (POC) to be achieved under the partnership.

The collaboration agreement was initiated in October 2009 as a new business model aimed at expediting POC achievements by conducting multiple programs in parallel to clinically develop Eisai-owned oncology candidate compounds. As part of the collaboration, Quintiles played a critical role in the execution of the program that led to the POC.

The program focused on lenvatinib in patients with melanoma, including BRAF wild-type melanoma. During the program, a randomized open-label Phase II study was conducted in Stage IV chemotherapy-naive melanoma patients to compare lenvatinib and dacarbazine to dacarbazine alone, which is one of the standard first-line treatment agents in patients with melanoma. The results demonstrated a statistically significant 2.7-fold increase (p=0.0033) in progression-free survival (PFS) in patients given the combination of lenvatinib and dacarbazine versus dacarbazine alone (median PFS: 19.1 weeks versus 7.0 weeks respectively). Furthermore, a statistically significant 3.9-fold increase in PFS (p=0.0306) was observed in a BRAF wild-type subgroup of patients given the combination of lenvatinib and dacarbazine versus dacarbazine alone (median PFS: 23.9 weeks versus 6.1 weeks respectively). The finding has also been confirmed to meet the POC criteria agreed upon by both companies in the initial terms of the agreement.

Eisai will now begin further clinical study preparations aimed at gaining regulatory approval for lenvatinib in light of the finding while continuing to discuss related developments with relevant health authorities in various countries. The company remains committed in its collaboration with Quintiles to expediting the early and steady development of novel anticancer compounds in order to further contribute to addressing the unmet medical needs of, and increasing the benefits provided to, patients living with cancer.

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