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PRESS RELEASE

Eisai to Present Clinical Trial and Biomarker Exploration Results of E7386, Co-Created with PRISM BioLab, at the ESMO Annual Congress

TOKYO, Japan, October 17, 2025: -- PRISM BioLab, Co. Ltd. (“PRISM”) announces that Eisai Co., Ltd. ((Head Office: Bunkyo-ku, Tokyo, hereinafter “Eisai”),; hereinafter “Eisai”) will present clinical trial results and biomarker exploration data for E7386 (*1), co-created by PRISM BioLab and Eisai, in combination with lenvatinib mesylate (*2), at the European Society for Medical Oncology (ESMO) Congress 2025, held in Berlin, Germany from October 17 to 22, 2025. The abstract of the study has been disclosed today.

Title:
Clinical and biomarker results from E7386 study 102: Global dose-expansion cohort of E7386 + lenvatinib (LEN) in patients (pts) with advanced/recurrent endometrial cancer (aEC) that progressed on platinum-based chemotherapy (PBC) and an anti−PD-(L)1 immunotherapy (IO)

Eisai will report preliminary analysis and biomarker exploration from the ongoing open-label Phase Ib clinical trial (NCT04008797 *4) evaluating the combination therapy of E7386 and lenvatinib.
In this cohort, the combination therapy of E7386 and lenvatinib has shown promising antitumor activity and manageable safety in patients with advanced endometrial cancer who have undergone platinum-based chemotherapy and anti-PD-(L)1 immunotherapy. Based on these results, dose optimization trials are currently underway.

(*1) E7386
E7386 is an orally available small molecule CBP/ β-catenin inhibitor that inhibits protein-protein interactions between the transcription factor CBP and β-catenin, and regulates the Wnt signaling. E7386 achieved clinical POC (Proof of concept) in October 2021 and following clinical studies are ongoing including phase I for solid tumors as monotherapy, Phase Ib/II for solid tumors in combination with tyrosine kinase inhibitor Lenvatinib, both conducted by Eisai.

(*2) Lenvatinib
Lenvatinib is a multi-kinase inhibitor, discovered by Eisai and being co-developed and co-commercialized under a collaboration agreement with Merck & Co., Inc., Rahway, NJ, USA, which inhibits vascular endothelial growth factor receptors (VEGFRs),VEGFR1, VEGR2, VEGFR3 and fibroblast growth factor receptors (FGFRs), FGFR1, FGFR2, FGFR3, FGFR4, and other receptor tyrosine kinases, PDGFR-alpha, KIT, RET.

Lenvatinib have been approved for thyroid cancer, hepatocellular carcinoma, thymic caner and renal cell carcinoma (in combination with Everolimus or pembrolizumab, the anti-PD-1 antibody from Merck & Co., Inc., Rahway, NJ, USA.). Lenvatinib is also approved for endometrium cancer in combination with pembrolizumab.

(*3) Biomarkers
Biomarkers are indicators within the body that reflect disease states such as cancer. They can be detected from blood, urine, etc., and include circulating tumor DNA (ctDNA), microRNA (miRNA), proteins, metabolites, DNA methylation patterns, and circulating tumor cells (CTCs). Selecting and measuring appropriate biomarkers enables analysis of cancer characteristics, accurate diagnosis, prediction of treatment efficacy, patient selection, drug efficacy evaluation, and optimization of dosage and schedule.

(*4) NCT04008797
NCT04008797 is an open-label Phase Ib study of E7386 in combination with other anticancer drug, Lenvatinib for the patients with solid tumors. The study has been implemented by Eisai to determine the safety and the recommended phase 2 dose (RP2D) and also to see the pharmacokinetics and efficacy of E7386 + Lenvatinib. Enrolment of each cohort of hepatic, colon, endometrial cancers are ongoing.
For clinical trial results in endometrial cancer patients, please refer to Eisai's announcement and PRISM BioLab's press release:
https://contents.xj-storage.jp/xcontents/AS09340/a2567c40/1707/42b7/90a3/2474e875f091/140120250521560456.pdf

About PRISM BioLab
PRISM BioLab is a discovery and development biotechnology company utilizing proprietary PepMetics® technology to discover orally available small molecule inhibitors of protein-protein interaction (PPI) targets and transform lives of patients suffering from cancer, autoimmune, fibrosis and other diseases. PepMetics® are a unique class of small molecules that mimic three-dimensional structures of alpha-helix and beta-turn, the peptide structures commonly found in intracellular PPI interphases and receptor-ligand interactions. By combining proprietary chemistry, know-how around PPI targets and AI-supported design, PepMetics® technology can deliver inhibitors of challenging PPI targets. The technology holds promise to expand the field of drug discovery by turning previously undruggable PPIs into targets readily druggable with small molecules and by generating oral small molecule alternatives for injectable biologics.

PRISM BioLab is collaborating on new PPI targets with global and Japanese pharmaceutical companies. PepMetics® targeting CBP/beta-catenin PPIs licensed to Eisai Co., Ltd. and Ohara Pharmaceuticals Co., Ltd. are in clinical development for cancer and liver disease, respectively.

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