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PRESS RELEASE

Phase 1 clinical research results of E7386, Jointly Created by PRISM BioLab and Eisai, Published in *ESMO OPEN*

TOKYO, Japan, January 21, 2026: -- PRISM BioLab, Co. Ltd. ("PRISM") announces that a paper reporting the results of a domestic Phase I clinical trial on E7386 (*1), jointly created with Eisai Co., Ltd. (Head Office: Bunkyo-ku, Tokyo, hereinafter "Eisai"), has been published in the *ESMO OPEN*, the open access medical journal issued by the European Society for Medical Oncology (ESMO). Please find an overview of the paper and the link to the publication below.

Paper Overview
Title: E7386 in patients with advanced solid tumors: results from the dose-escalation part and an expansion part of a phase I study
DOI: https://doi.org/10.1016/j.esmoop.2025.105893

Abstract
Background: E7386 is an orally active inhibitor reported to block the CBP/ß-catenin interaction. We present data from the dose-escalation and expansion part 1 of Study 103 (NCT03833700 (*2): phase I of NCT04008797(*3)) of E7386 in patients with advanced, unresectable, or recurrent (A/U/R) solid tumors. Fifty-five enrolled patients (dose-escalation: *n* = 36; expansion: *n* = 19) received one or more dose of E7386.
Patients and methods: This open-label study was conducted in Japan. In dose-escalation, eligible patients aged ≥20 years were diagnosed with A/U/R solid tumors with no alternative standard/effective therapies. In the expansion part, eligible patients were diagnosed with A/U/R colorectal cancer (two or more prior systemic anticancer therapies) or other gastrointestinal tumors (one or more prior systemic anticancer therapy). The primary objective was assessment of safety and tolerability. Secondary objectives were assessment of pharmacokinetic (PK) and antitumor activity.
Results: The recommended dose was 120 mg b.i.d. Most patients (dose-escalation/expansion) experienced treatment-emergent adverse events (TEAEs): the most frequent TEAEs were nausea and vomiting. These were primarily low-grade in severity and well managed with antiemetics in patients receiving up to 120 mg b.i.d. No patients died due to TEAEs.
In dose-escalation, two patients achieved PR: one with small bowel carcinoma (APC/KRAS/TP53 mutations); one with a desmoid tumor (APC mutation). No PRs were observed in the expansion part.

PK exposure increased with doses (range: 10-160 mg b.i.d.) following single and repeat-dose administrations, although large inter-subject variability was observed.
Conclusion: In heavily pretreated patients with advanced solid tumors, E7386 demonstrated a manageable safety profile and a dose-dependent PK profile. PRs were noted in patients with small bowel carcinoma (*APC*/*KRAS*/*TP53* mutations) or desmoid tumor (*APC* mutation).

(*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. 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 other anticancer drug(s), both conducted by Eisai.

(*2) NCT03833700
The NCT03833700 is an open-label Phase I trial designed to evaluate the safety and tolerability of E7386 monotherapy in patients with solid tumors. For details of the NCT03833700 study, please refer to ClinicalTrials.gov.
https://clinicaltrials.gov/study/NCT03833700

(*3) NCT04008797
NCT04008797 is an open-label Phase Ib study of E7386 in combination with other anticancer drug(s) in subjects with solid tumors. For details of the NCT04008797 study, please refer to ClinicalTrials.gov.
https://clinicaltrials.gov/study/NCT04008797

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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