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PRESS RELEASE

Phase 1 Clinical Pharmacology Results of E7386, Jointly Created by PRISM BioLab and Eisai, Published in *The Journal of Clinical Pharmacology*

TOKYO, Japan, July 2, 2026: -- PRISM BioLab Co., Ltd. ("PRISM BioLab") today announced that results from a clinical pharmacology study evaluating the pharmacokinetics (PK) and absorption, metabolism, and excretion (AME) characteristics of E7386 (*1), a molecule jointly created by PRISM BioLab and Eisai Co., Ltd. ("Eisai"), have been published in *The Journal of Clinical Pharmacology*, a peer-reviewed scientific journal in the field of clinical pharmacology.

The study design using concomitant dosing routes, IV [¹⁴C] microtracer technology, and oral [¹⁴C] radiolabeling successfully characterized the absolute bioavailability and AME profile of E7386 in healthy adults. Please refer to the details below.

This study enabled a quantitative understanding of the pharmacokinetic and overall disposition characteristics of E7386, and provide insights to support ongoing clinical development.

Paper Overview

Journal: *The Journal of Clinical Pharmacology* 2026; 66(5): e70202

Title: A Phase 1 Oral Mass Balance and Combined Intravenous [¹⁴C] Microtracer Study to Characterize the Absorption, Metabolism, Excretion, and Pharmacokinetics of Antitumor Drug E7386 in Humans

DOI: <https://doi.org/10.1002/jcph.70202>

Summary

This Phase 1 clinical pharmacology study was conducted in healthy volunteers to evaluate the absolute bioavailability (*5) and AME characteristics of E7386.

The study employed a combined design of oral radiolabeled dosing and intravenous [¹⁴C] microtracer administration, allowing detailed characterization of the drug's pharmacokinetic properties.

The geometric mean (CV%) of absolute bioavailability was 23.6% (34.6), reflecting pharmacokinetic characteristics influenced by absorption, first-pass, and systemic metabolism. 87.9% of administered radioactivity was recovered, with the majority (85.1%) excreted in feces.

In addition, unchanged drug was identified as the major circulating component in plasma, and no major metabolites were observed.

These findings provided a quantitative characterization of the absorption, metabolism, and excretion profile of E7386. Overall, IV and oral administration of a single E7386 dose was tolerable in healthy participants, and adverse events were manageable.

E7386 is currently under clinical evaluation as a monotherapy (NCT03264664, NCT03833700) and in combination with other anticancer drug(s) (NCT04008797).

(*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 3 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) About the Microtracer Approach

The microtracer approach involves administering an ultra-low dose (microdose) of a radiolabeled drug to enable highly sensitive and quantitative analysis of pharmacokinetics and AME characteristics in humans.

Because the dose is far below pharmacologically active levels, it has minimal impact on safety.

This technique is widely used in clinical pharmacology to precisely evaluate bioavailability and drug disposition.

(*3) About Bioavailability

Bioavailability refers to the fraction of an administered drug that reaches systemic circulation.

Absolute bioavailability compares the fraction reaching the bloodstream after oral administration with that following intravenous administration.

For oral drugs, it reflects the effects of absorption and first-pass metabolism and is an important parameter for evaluating drug availability in the body.

About PRISM BioLab

PRISM BioLab is a discovery and development biotechnology company utilizing proprietary PepMetrics® 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.

PepMetrics® 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, PepMetrics® 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. PepMetrics® 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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