

FOR IMMEDIATE RELEASE

September 24, 2025

Listed Company Name:	Eisai Co., Ltd.
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Securities Code:	4523
Stock Exchange Listings:	Prime Market of the Tokyo Stock Exchange
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Notice of the Settlement of Patent Infringement Litigation Related to Lenvatinib in the U.S.

Eisai Co., Ltd. ("the Company") announced today that the Company had entered into a settlement agreement ("the Settlement") with generic drug manufacturers Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively "Dr. Reddy's"), on September 22, 2025 regarding a lawsuit filed in the U.S. District Court for the District of New Jersey for infringement of patents relating to Lenvima® (generic name: lenvatinib), an orally available multiple receptor tyrosine kinase inhibitor discovered by the Company (U.S. Patent Nos. 10,407,393 and 11,186,547; collectively "the Patents"). Dr. Reddy's had submitted an Abbreviated New Drug Application ("ANDA") for a generic version of Lenvima. Under the settlement agreement, Dr. Reddy's will be permitted to launch its generic lenvatinib product in the United States as of July 1, 2030, unless certain defined contingencies occur earlier than that date. The settlement will be effective after the Consent Judgement is entered by the Court.

The Patents are directed to highly pure lenvatinib and have been asserted in other patent infringement litigations. Previously, the Company settled a prior patent infringement lawsuit against SUN Pharmaceutical Industries Ltd. and SUN Pharmaceutical Industries Inc. (collectively "SUN Pharma") for their ANDA submission on March 21, 2024. Under the settlement agreement, SUN Pharma will be permitted to launch its generic lenvatinib product in the United States as of July 1, 2030, unless certain defined contingencies occur earlier than that date.

Additionally, the Company received a favorable decision on May 28, 2025, against generic drug manufacturer Shilpa Medicare Limited ("Shilpa") in the lawsuit filed in the U.S. District Court for the District of New Jersey. Based on that decision, Shilpa is not able to receive approval from the U.S. Food and Drug Administration ("FDA") to sell its generic lenvatinib product until after the '547 Patent and related exclusivity expires in February 2036.¹

An additional patent infringement litigation against Torrent Pharmaceuticals Ltd., another generic drug manufacturer, is currently ongoing in the U.S. District Court for the District of New Jersey.

Sales revenue of Lenvima in the U.S. for the fiscal year ended March 31, 2025 was 229.6 billion yen (US\$1,505 million). The Settlement should not have any impact on the consolidated financial forecasts for the fiscal year ending March 31, 2026.

¹ Shilpa has appealed this decision to U.S. Court of Appeals for the Federal Circuit.

* Please note that actual business results may change due to several factors since the above-mentioned forecasts were made based on information available as of today.