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Eisai Co., Ltd.

PATENT INFRINGEMENT LITIGATION FOR ANTIEMETIC AGENT ALOXI® IN THE UNITED STATES

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") has announced today that the United States Court of Appeals for the Federal Circuit ("Federal Circuit"), in the patent infringement lawsuit for antiemetic agent ALOXI® (palonosetron hydrochloride) injection brought by Helsinn Healthcare S.A. (Headquarters: Lugano, Switzerland, CEO: Riccardo Braglia, "Helsinn") against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively "Teva") in the United States, has denied Helsinn's petition for rehearing en banc, which if granted would have allowed the full court to review a panel decision issued in May 2017, that certain formulation patent claims covering ALOXI are not valid and are therefore not infringed by Teva's generic palonosetron product.

On May 1, 2017, a panel of the Federal Circuit issued a decision that reversed the opinion of the District Court for the District of New Jersey and held that the asserted claims for the ALOXI formulation patents are not valid and therefore not infringed by Teva's generic palonosetron product. In response to this decision, Helsinn filed a petition for rehearing en banc, asking for a review of the panel decision by all eligible judges. During this process, amicus briefs (opinions from third parties) supporting the position of Helsinn and Eisai were submitted to the Federal Circuit by Congressman Lamar Smith, who co-drafted the America Invents Act, the Pharmaceutical Research and Manufacturers of America (PhRMA), the American Intellectual Property Law Association (AIPLA), the Biotechnology Innovation Organization (BIO), the Boston Patent Law Association (BPLA) and the Intellectual Property Owners Association (IPO). However, Helsinn's petition was denied. Helsinn will file for a stay of the mandate at the Federal Circuit and, if necessary, at the Supreme Court. Furthermore, Helsinn will continue to explore all legal options available to protect the ALOXI patents, including requesting review by the US Supreme Court. Additional patents covering the product exist, which were not included in the Federal Circuit's prior decision and which will continue to be litigated at the New Jersey District Court.

Teva will not be able to launch a generic version of ALOXI until additional steps are taken by the Federal Circuit, the District Court for the District of New Jersey and the Food & Drug Administration (FDA) allowing such a launch.

Helsinn and Eisai are disappointed with the court's ruling. Protecting intellectual property is vital to a company's ability to continue developing innovative medicines. Helsinn and Eisai maintain their position that the patents protecting ALOXI are valid and will pursue further legal options to protect and enforce such patents.

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[Notes to editors]

1. About the Helsinn Group

Helsinn is a privately owned pharmaceutical group with an extensive portfolio of marketed cancer care products and a robust drug development pipeline. Since 1976, Helsinn has been improving the everyday lives of patients, guided by core family values of respect, integrity and quality. The Group works across pharmaceuticals, biotechnology, medical devices and nutritional supplements and has expertise in research, development, manufacture and the commercialization of therapeutic and supportive care products for cancer, pain and inflammation and gastroenterology. In 2016, Helsinn created the Helsinn Investment Fund to support early-stage investment opportunities in areas of unmet patient need. The company is headquartered in Lugano, Switzerland, with operating subsidiaries in Switzerland, Ireland, and the U.S., and China, as well as a product presence in approximately 190 countries globally.
To learn more about Helsinn Group please visit www.helsinn.com

2. About Eisai and the Helsinn Group

Eisai Inc. gained exclusive marketing rights to ALOXI in the United States and Canada from Helsinn Healthcare S.A. through its acquisition of MGI Pharma, Inc. in 2008. Under the terms of the agreement, Helsinn Healthcare S.A. is responsible for conducting all development activities (Chemistry and Manufacturing Controls [CMC], preclinical and clinical), obtaining regulatory approvals and holding the New Drug Application (NDA). ALOXI is co-promoted in the United States by Eisai Inc. and Helsinn Therapeutics U.S. Inc., while sales of the product in the United States are booked by Eisai Inc.