

## **US Court of Appeals for Federal Circuit Rejects Petition by Helsinn for Rehearing En Banc of Federal Circuit Panel Ruling That Certain Patents Covering Aloxi® in the US Market Are Invalid**

**Lugano, Switzerland, and Woodcliff Lake, N.J., January 17, 2018** – In the patent infringement lawsuit for antiemetic agent ALOXI® (palonosetron hydrochloride) injection brought by Helsinn Healthcare S.A. against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively “Teva”), the United States Court of Appeals for the Federal Circuit yesterday denied a petition by Helsinn for a rehearing en banc to review the panel decision issued on May 1<sup>st</sup>, 2017 by the Federal Circuit holding that certain patent claims covering Aloxi® (palonosetron hydrochloride) injection are not valid and therefore not infringed by Teva’s generic palonosetron product.

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 is currently not able to launch a generic version of Aloxi® until additional steps are taken by the Federal Circuit, the New Jersey District Court and the Food & Drug Administration (“FDA”) to allow such a launch.

Helsinn Group and Eisai Inc. are disappointed with the Court’s ruling. Protecting intellectual property is critical to a company’s ability to continue developing medicines that will make a difference in the lives of patients. Helsinn and Eisai maintain their position that the patents protecting Aloxi® are valid and will continue to pursue available options to protect and enforce these patents.

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### **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](http://www.helsinn.com)

### **About Eisai Inc.**

At Eisai Inc., *human health care (hhc)* is our goal. We give our first thoughts to patients and their families, and helping to increase the benefits health care provides. As the U.S. pharmaceutical subsidiary of Tokyo-based Eisai Co., Ltd., we have a passionate commitment to patient care that is the driving force behind our efforts to discover and develop innovative therapies to help address unmet medical needs.

Eisai is a fully integrated pharmaceutical business that operates in two global business groups: oncology and neurology (dementia-related diseases and neurodegenerative diseases). Each group functions as an end-to-end global business with discovery, development, and marketing capabilities. Our U.S. headquarters, commercial and clinical development organizations are located in New Jersey; our discovery labs are in Massachusetts and Pennsylvania; and our global demand chain organization resides in Maryland and North Carolina.

To learn more about Eisai Inc., please visit us at [www.eisai.com/US](http://www.eisai.com/US)

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