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Eisai Co., Ltd.

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

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that the U.S. District Court for the District of New Jersey has ruled in favor of Helsinn Healthcare S.A. (Headquarters: Lugano, Switzerland, CEO: Riccardo Braglia, "Helsinn") in the patent infringement lawsuit for antiemetic agent ALOXI® (palonosetron hydrochloride) brought by Helsinn together with Roche Palo Alto LLC (Roche) against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively "Teva") in the United States, where it was determined that certain formulation patent claims for ALOXI are valid and infringed.

Since 2011, Helsinn and Roche filed patent infringement lawsuits in the U.S. District Court for the District of New Jersey, against Dr. Reddy's Laboratories, Ltd., Dr. Reddy's Laboratories, Inc. (collectively "Dr. Reddy's"), Sandoz Inc. (Sandoz) and Teva, who were the first to submit Abbreviated New Drug Applications (ANDAs) for ALOXI. Of these companies, Helsinn has already made settlements with Sandoz and Dr. Reddy's, and under the conditions of the settlements, in principle, neither Sandoz nor Dr. Reddy's is allowed to launch a generic version of palonosetron hydrochloride via an ANDA prior to September 30, 2018, except under certain circumstances.

In this decision which concerns Teva, the court ruled that the patent claims at issue are valid and are infringed. The term of these formulation patent rights plus pediatric exclusivity currently provides coverage for ALOXI through to July 30, 2024, subject to any appeal.

In addition, patent infringement lawsuits were brought by Helsinn and Roche against several other companies who subsequently filed ANDAs or 505(b)(2) applications for ALOXI after Dr. Reddy's, Sandoz and Teva. Some of these lawsuits have been settled while the remaining lawsuits are currently being disputed in U.S. District Courts. Helsinn and Roche continue to aggressively litigate these cases, and the outcome of those litigations and any resolutions reached by the parties will ultimately determine the date of generic entry.

Eisai's U.S. subsidiary Eisai Inc. gained exclusive marketing rights to ALOXI in the United States and Canada from Helsinn. 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.

Upon obtaining this ruling, there will be no changes at the present time to Eisai's full-year consolidated financial results forecasts for the year ending March 31, 2016 as announced on May 14, 2015. Should a revision to the financial results forecasts become necessary in the future, the company will make an announcement as soon as possible.

Media Inquiries:
Public Relations Department,
Eisai Co., Ltd.
+81-(0)3-3817-5120

[Notes to editors]

1. About the Helsinn Group

Helsinn is a family run, privately owned pharmaceutical group focused on building quality cancer care with a large portfolio of products. Founded in 1976 with headquarters in Lugano, Switzerland, Helsinn also has operating subsidiaries in Ireland, the United States and a representative office in China. Helsinn's business model is focused on the licensing of pharmaceuticals, medical devices and nutritional supplement products in the therapeutic area of cancer care.

Helsinn Group in-licenses early-to-late stage new chemical entities, completing their development by performing preclinical and clinical studies and associated manufacturing activities. Helsinn then prepares necessary regulatory filings in order to achieve marketing approvals worldwide. Helsinn's products are out-licensed to its global network of marketing and commercial partners that have been selected for their local market knowledge. Helsinn supports these partners by providing a full range of product and scientific management services, including commercial, regulatory, and medical marketing advice. In March 2013, Helsinn established a new commercial organization within its subsidiary, Helsinn Therapeutics U.S. Inc., in order to conduct direct sales and marketing activities within the U.S. market. Helsinn’s products are manufactured according to the highest quality, safety, and environmental standards at Helsinn's GMP facilities in Switzerland and Ireland from where they are then supplied worldwide to customers.

Further information on Helsinn Group is available at: 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.

3. About 505(b)2 Applications

As established in section 505(b)(2) of the U.S. Federal Food, Drug and Cosmetic Act, a 505(b)(2) application is one of the U.S. Food and Drug Administration (FDA) drug approval pathways. A 505(b)(2) application contains full safety and effectiveness reports, but allows at least some of the required information, such as safety and efficacy information on the active ingredient, to come from studies not conducted by or for the applicant. As an example, a 505(b)(2) application might be submitted for an already approved injectable medicine using a different formulation design.