

NOTICE REGARDING DISCONTINUATION OF SALES AND VOLUNTARY RECALL OF EGG WHITE LYSOZYME PREPARATION NEUZYM[®]

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that its pharmaceutical manufacturing and marketing subsidiary Sannova Co., Ltd. (Headquarters: Gunma Prefecture, President: Toru Takekawa, "Sannova") has been informed the results of deliberation of the Committee on Reevaluation of the Pharmaceutical Affairs and Food Sanitation Council's ("Committee") meeting held on March 17 regarding the egg white lysozyme preparation Neuzym[®] (lysozyme hydrochloride, "lysozyme") which had been submitted for reevaluation. The Committee's opinion was that "the medical usefulness of lysozyme in the present medical environment is thought to have decreased, and its usefulness cannot be confirmed at this point in time." As such, sales of the product have been discontinued, and a voluntary recall is being conducted as of today. Regarding safety of the products, no unusual issues have been observed since launch, and there were no issues observed in these post-marketing clinical studies as well.

The Neuzym series consists of six products — Neuzym Tablets (10 mg, 30 mg, 90 mg), Neuzym Granules (10%), Neuzym Fine Granules (20%) and Neuzym Syrup (0.5%). While Sannova is the manufacturing and marketing authorization holder of Neuzym, Eisai is responsible for marketing the products. Since the approval and launch of Neuzym Tablets 10 mg in 1964, Neuzym has been used by many patients and healthcare professionals. However, given advancements in medical and pharmaceutical science, lysozyme preparations including Neuzym received a designation for reevaluation from Japan's Ministry of Health, Labour and Welfare (MHLW) in January 2012 in an effort to verify the efficacy of the products in line with the present medical environment. In response, Eisai, Sannova and three other companies¹ handling lysozyme jointly carried out post-marketing clinical studies (double blind, placebo-controlled comparative studies) to verify efficacy of lysozyme in chronic sinusitis, bronchitis, bronchial asthma, and bronchiectasis.

In the studies on bronchitis, bronchial asthma and bronchiectasis, the efficacy of lysozyme as an add-on to standard treatment in patients with chronic obstructive pulmonary disease (COPD) was considered. Based on the results of these studies, the companies submitted an application for reevaluation of efficacy on May 29, 2015. Regarding chronic sinusitis, an application for a partial label change to remove the indication of chronic sinusitis for Neuzym was submitted on May 29, 2015, and was approved (indication removed) on December 11, 2015.

Eisai and Sannova will strive to ensure that information is provided to healthcare professionals in order to avoid confusion regarding the voluntary recall of Neuzym products.

At present, this matter is expected to not have a major impact on the Eisai Group's consolidated financial performance in fiscal 2015.

¹ ASKA Pharmaceutical Co., Ltd., Nippon Shinyaku Co., Ltd., Sioe Pharmaceutical Co., Ltd.

*Reevaluation System: The reevaluation of drugs is a system whereby the quality, efficacy and safety of a drug, which has already been approved, is reconsidered on the basis of the current status of medical and pharmaceutical sciences.

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