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Eisai Co., Ltd.

MHLW APPROVES PARTIAL LABEL CHANGE FOR EGG-WHITE LYSOZYME PREPARATION NEUZYM®

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that its partial label change application to remove chronic sinusitis as an approved indication for egg-white lysozyme preparation Neuzym® (lysozyme hydrochloride, "lysozyme") has been approved by the Japanese Ministry of Health, Labour and Welfare (MHLW). With the approval of the partial label change, Neuzym will no longer able to be used for the indication of "chronic sinusitis."

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%). Neuzym is manufactured by Eisai's pharmaceutical manufacturing and marketing subsidiary Sannova Co., Ltd. (Headquarters: Gunma Prefecture, President: Toru Takekawa, "Sannova") and marketed by Eisai.

After receiving a designation to reevaluate lysozyme preparations including Neuzym in January 2012, Eisai, Sannova and three other companies* handling lysozyme have been jointly carrying out post-marketing clinical studies (double blind, placebo-controlled comparative studies) to verify efficacy of these drugs for chronic sinusitis, bronchitis, bronchial asthma, and bronchiectasis.

Among these studies, in the study on chronic sinusitis, the efficacy of lysozyme as an add-on to the current standard treatment could not be verified, and therefore an application for a partial label change was submitted to remove the indication of chronic sinusitis for Neuzym on May 29, 2015.

Meanwhile, 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 the studies, an application for reevaluation of efficacy was submitted on the same day and is currently under review by the regulatory authority.

Eisai and Sannova will strive to ensure that information is provided to healthcare professionals in order to avoid confusion either in the medical setting or amongst patients taking Neuzym.

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

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[Notes to editors]

1. Changes to the Neuzym label (underlined parts have been deleted)

1) Neuzym Tablets 10 mg, Neuzym Tablets 30 mg, Neuzym Tablets 90 mg, Neuzym Granules 10%, Neuzym Fine Granules 20%

Label Prior to Revision	Revised Label
【Indications】 Remission of swelling in the following diseases: Chronic sinusitis Difficulty of expectoration in the following diseases with hard-to-eliminate sputum and frequent expectoration: Bronchitis, bronchial asthma and bronchiectasis	【Indications】 Difficulty of expectoration in the following diseases with hard-to-eliminate sputum and frequent expectoration: Bronchitis, bronchial asthma and bronchiectasis

2) Neuzym Syrup 0.5%

Label Prior to Revision	Revised Label
【Indications】 Difficulty of expectoration in the following diseases with hard-to-eliminate sputum and frequent expectoration: Bronchitis, bronchial asthma and bronchiectasis Remission of swelling in the following diseases: Chronic sinusitis	【Indications】 Difficulty of expectoration in the following diseases with hard-to-eliminate sputum and frequent expectoration: Bronchitis, bronchial asthma and bronchiectasis