EISAI SUBMITS APPLICATIONS FOR REEVALUATION OF EFFICACY AND PARTIAL CHANGE TO LABEL OF EGG WHITE LYSOZYME PREPARATION NEUZYM® BASED ON RESULTS OF REEVALUATION STUDIES

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 submitted an application for reevaluation of the indication of bronchitis, bronchial asthma and bronchiectasis for egg white lysozyme preparation Neuzym® (lysozyme hydrochloride, "lysozyme"). At the same time, Sannova has also submitted an application for a partial label change to remove chronic sinusitis as an approved indication for Neuzym. 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.

After receiving a designation to reevaluate lysozyme preparations including Neuzym in January 2012, Eisai, Sannova and three other companies[1] 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 the studies on the lower respiratory tract diseases bronchitis, bronchial asthma and bronchiectasis, the clinical pharmacology study on chronic obstructive pulmonary disease (COPD)[2] and asthma with sputum symptom (Study LYS-003) suggested that lysozyme has efficacy as an add-on to standard treatment in patients with COPD. In the study to assess

[Notes to editors]

1. Proposed changes to the Neuzym® label (application seeks to remove underlined parts)

  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 (Proposed)
Indications	