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Eisai Co., Ltd.

EISAI WITHDRAWS NEW DRUG APPLICATION FOR MECOBALAMIN ULTRA-HIGH DOSE PREPARATION AS TREATMENT FOR AMYOTROPHIC LATERAL SCLEROSIS

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) announced today that it has withdrawn its new drug application for ultra-high dose mecobalamin (development code: E0302) as a treatment for amyotrophic lateral sclerosis (ALS) in Japan.

On May 27, 2015, Eisai submitted a new drug application for mecobalamin seeking approval as a treatment for ALS. As a result of meetings with the Pharmaceuticals and Medical Devices Agency (PMDA), the application package submitted was not sufficient for approval, and therefore Eisai has withdrawn the application. Eisai will carefully reconsider the future development strategy for mecobalamin after consultation with the regulatory authority.

ALS is an intractable, progressive, neurodegenerative disease that causes severe muscle atrophy and weakness in the muscles. With treatment options currently limited, this is a disease with significant unmet medical need. Eisai considers neurology a therapeutic area of focus and is committed to new drug development in this field in order to fulfill unmet medical needs in neurology and further contribute to increasing the benefit for patients and their families.

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