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Eisai's LEQEMBI receives approval in South Korea for treatment of Alzheimer’s Disease

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Eisai Korea Inc. will distribute the product and conduct information provision activities

Japan-headquartered pharmaceutical firm Eisai Co. and US-based Biogen Inc. have announced that the Ministry of Food and Drug Safety (MFDS) in South Korea has approved humanised anti-soluble aggregated amyloid-beta (A?) monoclonal antibody LEQEMBI (lecanemab) for treatment in adult patients with mild cognitive impairment due to Alzheimer’s disease (AD) or mild AD (early AD).

LEQEMBI selectively binds to soluble A? aggregates (protofibrils), as well as insoluble A? aggregates (fibrils) which are a major component of A? plaques in AD, thereby reducing both A? protofibrils and A? plaques in the brain.

LEQEMBI is the first and only approved treatment shown to reduce the rate of disease progression and to slow cognitive and functional decline through this mechanism. South Korea is the fourth country to grant approval, following approvals in the US, Japan, and China.

It is estimated there were approximately 900,000 dementia patients in South Korea in 2021, with one in ten people over the age of 65 suffering from dementia, and one in five from mild cognitive impairment (MCI). The average annual nursing care and medical costs per dementia patient is estimated to be 21.1 million KRW, while the cost for patients with severe dementia reaches 33.1 million KRW.

Eisai serves as the lead of LEQEMBI development and regulatory submissions globally with both Eisai and Biogen co-commercialising and co-promoting the product and Eisai having final decision-making authority. In South Korea, Eisai Korea Inc. will distribute the product and conduct information provision activities.