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LEQEMBI to launch in Japan for Alzheimer's disease on December 20

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Swedish firm BioArctic AB's partner Eisai has announced that LEQEMBI (lecanemab) will be launched in Japan on December 20, following its scheduled inclusion in the price listing on the Japan National Health Insurance (NHI) drug price list.

LEQEMBI obtained manufacturing and marketing approval for the indication of slowing progression of mild cognitive impairment (MCI) and mild dementia due to Alzheimer's disease (AD) in Japan on September 25, 2023.

In addition to inclusion in Japan's NHI drug price list, the products Optimal Clinical Use Guidelines were agreed at a general meeting of the Central Social Insurance Medical Council, an advisory body of the Japanese Ministry of Heath, Labour and Welfare, held today. The launch, planned for December 20, will make Japan the second country to have the product on the market, following the US.

LEQEMBI selectively binds to soluble amyloid-beta (A?) aggregates (protofibrils), as well as insoluble A? aggregates (fibrils) which are a major component of A? plaques, 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.

Eisai will conduct a post-marketing special use results survey in all patients who are administered LEQEMBI (all-case surveillance) until data from a certain number of patients are accumulated, in accordance with an approval condition imposed by the Ministry of Health, Labour and Welfare.

Japanese pharma company 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. BioArctic has the right to commercialise lecanemab in the Nordic region, pending European approval, and currently Eisai and BioArctic are preparing for a joint commercialisation in the region.