Eisai starts rolling submission for injectable version of Alzheimer's drug with US FDA

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London: Eisai and partner Biogen said on Tuesday that the Japanese drugmaker has begun submitting data on a rolling basis to the US health regulator for a marketing application of a subcutaneous form of their Alzheimer's disease drug Leqembi.

The companies are seeking the Food and Drug Administration's (FDA) approval of a weekly dose of Leqembi to be given as an under-the-skin injection.

Under a rolling submission the regulator assesses the data as and when it becomes available, and the process continues until there is enough data for a formal marketing application.

Eisai in April delayed filing for marketing approval of the subcutaneous form of Leqembi, as the FDA had requested for additional three-month immunogenicity data.

If approved, the injectable version of the drug could be given to patients at home or at medical facilities as the process requires less time than the intravenous formulation, the companies said.

Under the weekly maintenance regimen, patients who have completed the bi-weekly intravenous version would receive weekly 360 milligram doses of the drug as an under-the-skin injection.

The intravenous formulation of Leqembi, which received standard approval last year, has requirements such as additional diagnostic tests, twice-monthly infusions and regular brain scans which have contributed to a slower adoption of the drug than markets were expecting.

Leqembi is an antibody designed to remove sticky deposits of a protein called amyloid beta from the brains of Alzheimer's patients.

Leqembi's sales are projected to grow 13-fold to 56.5 billion yen ($361.28 million) in fiscal 2024 from the year ended in March, Eisai said in its annual results on Wednesday.

Eisai expects most of the sales growth to come from the US market, with plans to launch the drug in China in July. ($1 = 156.3900 yen)

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