

Lundbeck wins Japan approval for Vyepti in migraine prevention

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The MHLW authorisation makes eptinezumab the only intravenous CGRP-targeted preventive treatment approved for adult migraine prevention in Japan.



Lundbeck has received marketing authorisation from Japan's Ministry of Health, Labour and Welfare for Vyepti, or eptinezumab, for the prevention of migraine attacks in adults.

Eptinezumab is an intravenous monoclonal antibody targeting calcitonin gene-related peptide, or CGRP.

According to Lundbeck, it is the only intravenous CGRP-targeted preventive treatment approved for adult migraine prevention and has been launched in more than 30 countries worldwide.

The Japanese authorisation is supported by data from the Phase III SUNRISE study and the SUNSET long-term extension study conducted in Japanese patients.

Migraine is a neurological disorder characterised by recurrent headache attacks and associated symptoms that can significantly affect daily functioning and quality of life.

CGRP has emerged as a major therapeutic target in migraine because of its role in pain signalling and migraine pathophysiology.

Vyepti is administered intravenously and is designed as a preventive treatment rather than an acute therapy.

The approval expands treatment options for Japanese patients who require preventive migraine therapy.

It also marks a commercial milestone for Lundbeck in Japan.

The company said the authorisation paves the way for its first product launch in Japan as the Marketing Authorisation holder, allowing Lundbeck to operate independently in the market.

The milestone builds on the company's 25-year presence in brain health in Japan.

Lundbeck will now prepare for the commercial launch of Vyepti as it continues expanding its neurological and psychiatric portfolio across Asia.

The approval also adds Japan to the growing number of markets where CGRP-targeted therapies are becoming integrated into migraine prevention.