



## Direct Healthcare Professional Communication (DHPC):

### **Lecanemab, LEQEMBI® 100 mg/mL concentrate for solution for infusion – Risk of ARIA-E and updated MRI monitoring requirements.**

02-Nov- 2025

Dear Healthcare Professional,

Following the registration of Lecanemab (Leqembi®) in Saudi Arabia after thorough evaluation of its efficacy, safety, quality, and compliance with regulatory standards. Eisai Kingdom of Saudi Arabia (EKS) in agreement with the Saudi Food and Drug authority (SFDA) would like to inform you of important safety information regarding Lecanemab and updates to the magnetic resonance imaging (MRI) monitoring schedule:

#### **Summary**

- Cases of Amyloid-Related Imaging Abnormalities with Edema (ARIA-E) early during treatment have been reported in patients treated with Lecanemab. Although ARIA-E usually occurs early in treatment and is usually asymptomatic, serious and life-threatening events, including seizure and status epilepticus, rarely can occur. ARIA-E can be fatal.
- The initial SPC recommended that MRI scans be carried out before starting treatment and before the 5<sup>th</sup>, 7<sup>th</sup>, and 14<sup>th</sup> infusions. The MRI schedule for Lecanemab has now been updated to **add an MRI scan before the 3<sup>rd</sup> infusion.**
- **Lecanemab HCPs guide** is available for prescribing HCPs which provide information about the risk and the management of Amyloid Related Imaging Abnormalities (ARIA) and Intracerebral Haemorrhage for patients receiving Lecanemab.
- Patients should be provided with **Lecanemab patient alert cards** as well.

#### **Background on the Safety Concern**

Lecanemab is indicated for the treatment of adult patients with a clinical diagnosis of mild cognitive impairment and mild dementia due to Alzheimer's disease (early Alzheimer's disease) who are apolipoprotein E ε4 (ApoE ε4) non-carriers or heterozygotes with confirmed amyloid pathology.

Lecanemab can cause amyloid-related imaging abnormalities (ARIA), characterized as ARIA with edema (ARIA-E) and ARIA with hemosiderin deposits (ARIA-H). ARIA can also occur spontaneously in patients with Alzheimer's disease. ARIA usually occurs early in treatment and is usually asymptomatic; however, serious and life-threatening events can occur and it can be fatal. Enhanced clinical vigilance for ARIA is therefore recommended during the first 14 weeks of treatment with lecanemab. The initial lecanemab SPC recommends MRI scans before starting treatment and before the 5<sup>th</sup>, 7<sup>th</sup>, and 14<sup>th</sup> infusions.

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA



An assessment of post-marketing data from outside the EU shows that serious and fatal ARIA-E events can occur early in the treatment course. Some events were reported before the 5<sup>th</sup> infusion of lecanemab. Therefore, an additional monitoring MRI scan prior to the 3<sup>rd</sup> infusion of lecanemab is recommended to identify ARIA-E at an early stage. In line with the current SPC recommendations to mitigate serious and, in a few cases, fatal events, healthcare professionals may decide to suspend or discontinue lecanemab treatment in patients found to have ARIA-E.

in general, the MRI should be performed within approximately one week before the scheduled infusion of Lecanemab and reviewed prior to proceeding with the infusion.

The SPC, patient information leaflet and Eisai educational materials (healthcare professional (HCP) guide and patient card) are/will be updated to reflect this change.

### **Call for reporting**

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions.

Please report any adverse event through the following:

National Pharmacovigilance Centre (NPC) at Saudi Food and Drug Authority (SFDA):

Call Center: 19999

E-mail: [npc.drug@sFDA.gov.sa](mailto:npc.drug@sFDA.gov.sa)

Website: <http://ade.sFDA.gov.sa/>



Eisai Kingdom of Saudi Arabia (EKS) – Safety and pharmacovigilance department:

Jude Center, 4328 Salah Ad Din Al Ayyubi Rd,

4328, 8042, Riyadh

12233, building 3

Email: [ME\\_Safety@eisai.net](mailto:ME_Safety@eisai.net)

Phone: +966 55 628 5221

Yours sincerely,

Norah Alsalem

LSO (local safety officer), on behalf of Eisai Kingdome of Saudi Arabia (EKS)