Reactive statement: TGA initial decision for lecanemab

Eisai is aware that the Therapeutic Goods Administration (TGA) has issued a public statement about the initial decision regarding the registration of lecanemab in Australia. The outcome of the initial stage of an evaluation is not routinely communicated to the public whilst the TGA review process is ongoing, as it has been with lecanemab. Typically, the TGA publish a detailed summary of this decision via an Australian Public Assessment Report when the review period is complete.

Bringing new medicines to the Australian market is a complex process, and therefore it is important that both the TGA and Eisai have sufficient time to review all points raised as part of the established TGA evaluation process, before a final decision is made.

While we have received an initial decision from the TGA, Eisai will request a review of this decision under Section 60 of the Therapeutic Goods Act. The positive clinical trial results, with gold standard validated endpoints which were discussed with health authorities at the design of the trial, provide confidence for our ongoing efforts to secure approval for the medicine in Australia.

Eisai will refrain from commenting on the details of closed meetings with the TGA. We do not wish to influence the outcome for lecanemab or influence other external stakeholders during the ongoing evaluation of the medicine.

Lecanemab has been approved for use in the United States, Japan, China, South Korea, Israel, Hong Kong, the United Arab Emirates and Great Britain. Ongoing evaluations are taking place in countries that include the EU, Switzerland, Canada, Singapore, Taiwan, Brazil, Russia, Saudi Arabia and India.

Eisai Australia remains committed to working with the TGA so that suitable Australians have access to a treatment option that can make a difference to those living with early Alzheimer's disease.