27 June 2024
EMA/CHMP/287484/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Tauvid

flortaucipir (^{18}F)

On 27 June 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Tauvid, intended for the diagnosis of Alzheimer's disease. The applicant for this medicinal product is Eli Lilly Nederland B.V.

Tauvid will be available as a solution for injection (800 MBq/ml and 1900 MBq/ml). The active substance of Tauvid is flortaucipir (^{18}F), a diagnostic radiopharmaceutical for the central nervous system (ATC code: V09AX07). Flortaucipir binds to aggregated tau protein enabling brain positron emission tomography (PET) imaging.

The benefit of Tauvid is its potential to improve the diagnosis of Alzheimer's disease, as supported by a histopathology study. The most common side effects are headache, injection site pain and increased blood pressure.

The full indication is:

> This medicinal product is for diagnostic use only.
>
> Flortaucipir (^{18}F) is a radiopharmaceutical indicated for positron emission tomography (PET) imaging of the brain to assess the neocortical distribution of aggregated tau neurofibrillary tangles (NFTs) in adult patients with cognitive impairment who are being evaluated for Alzheimer's disease (AD). Flortaucipir (^{18}F) is an adjunct to clinical and other diagnostic evaluations.
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> For limitations of use, see sections 4.4 and 5.1.

A PET scan with flortaucipir (^{18}F) should be requested by physicians skilled in the clinical management of neurodegenerative disorders. Tauvid images should only be interpreted by readers trained in the interpretation of PET images with flortaucipir (^{18}F).

Detailed recommendations for the use of this product will be described in the summary of product

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.