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Date: 26 February 2025

Prof. Bruno Sepodes
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: Amyvid®, Florbetapir (18F), 800 MBq/mL and 1900 MBq/mL solution for injection
Withdrawal of Type II Variation
EMEA/H/C/002422/II/0046

Dear Dr. Sepodes,

I would like to inform you that, at this point of time, Eli Lilly Nederland B.V. has taken the decision to withdraw the Type II Variation application submitted for Amyvid on 10 October 2023, procedure number EMEA/H/C/002422/II/0046. The application proposed extension of indication to include monitoring response to therapy for AMYVID, based on supporting literature.

This withdrawal is based on the following reasons:

- The MAH could not fully address the 25 April 2024 list of requests for supplementary information (RSI) before expiration of the clock stop

The withdrawal of this Type II Variation will have no consequences for ongoing clinical trials or compassionate use programmes.

The MAH reserves the right to submit a future Type II Variation to extend the marketing authorisation for this indication.

I agree for this letter to be published on the EMA website.

Yours sincerely,

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