20 April 2022

Dr. Harald Enzmann
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

**Subject:** **Withdrawal of Aduhelm (aducanumab) 100 mg/mL concentrate for solution for infusion, EMEA/H/C/005558**

Dear Dr. Enzmann,

We would like to inform you that, at this point of time, Biogen Netherlands B.V. has taken the decision to withdraw the application for Marketing Authorisation of Aduhelm (aducanumab) 100 mg/mL concentrate for solution for infusion, which was intended to be used as a disease modifying treatment in adult patients with Alzheimer's disease at the mild cognitive impairment (MCI) or mild dementia stage.

This withdrawal is based on interactions with the CHMP indicating that the data provided thus far would not be sufficient to support a positive opinion on the marketing authorization of Aduhelm (aducanumab).

Biogen confirms there are no consequences of the withdrawal on ongoing clinical trials with Aduhelm.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

Biogen agrees for this letter to be published on the EMA website.

Yours sincerely,

Biogen Netherlands B.V.

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