Anavex Germany GmbH
[redacted]

Date: 26 March 2026

To: European Medicines Agency
Professor Bruno Sepodes, Committee for Human Medicinal Products
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: Withdrawal of Marketing Authorisation Application for Blarcamesine Anavex, (blarcamesine), 10 mg, capsule - EMEA/H/C/006475

Dear Professor Sepodes,

I would like to inform you that, at this time, Anavex Germany GmbH has taken the decision to withdraw the application for Marketing Authorisation for Blarcamesine Anavex (blarcamesine), 10 mg, capsule, which was intended to be used as add-on therapy for the treatment of early Alzheimer's disease in adults with mild cognitive impairment (MCI) due to Alzheimer's disease or early-stage mild dementia due to Alzheimer's disease, in patients with SIGMAR1 wild-type genotype.

This withdrawal is based on the feedback received from the CHMP indicating that the Committee will not be able to conclude that the benefits outweigh the risks on the basis of the data provided.

Anavex respectfully disagrees with this assessment. The company remains fully committed to the continued development of blarcamesine to address the unmet medical needs of patients with Alzheimer's disease and will focus on gathering additional data and conducting further analyses to address the questions raised by the CHMP.

This withdrawal does not have any impact on ongoing clinical trials with blarcamesine or compassionate use programmes. Anavex remains fully dedicated to the development of blarcamesine and reserves the right to make further submissions at a future date in this or other therapeutic indication(s).

Anavex would like to thank the Rapporteurs, the CHMP and the EMA for the time dedicated to the assessment of this application and for the valuable feedback we have received from them on our application.

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

Yours sincerely,

[redacted]

Anavex Germany GmbH

[redacted]