astellas
Leading Light for Life

European Medicines Agency
Product and Application Business Support (PA-BUS)
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

[redacted]

Date 24 October 2024

CONFIDENTIAL/COMMERCIALLY RESTRICTED

RE: Withdrawal of Izelvay, (Avacincaptad Pegol), 20 mg/mL, solution for injection - EMEA/H/C/006153/0000

Dear CHMP Chair, Co-Chair,

For the withdrawal of initial marketing authorisation applications
I would like to inform you that, at this point of time, Astellas Pharma Europe B.V. has taken the decision to withdraw the application for Marketing Authorisation of Izelvay, (Avacincaptad Pegol), 20 mg/mL, solution for injection, which was intended to be used for the treatment of adults with geographic atrophy (GA) secondary to age related macular degeneration (AMD).

This withdrawal is based on the following reasons:

Feedback from the CHMP indicates that despite the promising data shown for Izelvay in slowing GA lesion growth, their uncertainties of this efficacy endpoint translating into clinically relevant treatment benefit, do not allow the Committee to conclude on a positive benefit risk balance at the present time based on the data provided.

Astellas maintains that the clinically meaningful benefit in slowing the GA lesion growth demonstrated by Izelvay outweighs the risks.

This withdrawal does not have any impact on ongoing clinical trials with Izelvay.

We remain fully committed to the development of Izelvay in GA and reserve the right to make further Marketing Authorisation Application submissions at a future date in this or other therapeutic indication(s).

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

Yours sincerely,