CHMP Chair
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Date: 07 November 2025

Subject: Withdrawal of Nurzigma (pridopidine), 45mg, hard capsules - **EMEA/H/C/006261**

Dear CHMP Chair

I would like to inform you that, at this point of time, Prilenia Therapeutics B.V. has taken the decision to withdraw the application for Marketing Authorisation of Nurzigma (pridopidine) 45mg hard capsules, which was intended to be used for the treatment of early Huntington´s disease (HD) in adults who are not treated with antidopaminergic medicinal products.

The withdrawal is based on the need to collect additional clinical data to fully address the questions raised by the CHMP.

The withdrawal has no impact on planned clinical trials and ongoing post-trial access and compassionate use programmes with pridopidine in any indication under development.

Prilenia remains fully committed to the development of pridopidine and we reserve the right to make further Marketing Authorisation Application submissions at a future date in HD or other therapeutic indications.

Prilenia thanks the Rapporteur teams, the EMA and the CHMP members for their thorough review of this application.

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

Yours sincerely,

Prilenia Therapeutics B.V.
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