

Holbaek, 22.07.2026

[REDACTED]
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: Withdrawal of Zinmyleo, (trilaciclib), 300 mg, powder for concentrate for solution for infusion - EMEA/H/C/006709

Dear [REDACTED],

I am writing on behalf of Pharmacosmos A/S to formally notify you that, at this point of time, Pharmacosmos A/S has taken the decision to withdraw the application for Marketing Authorisation of Zinmyleo, (trilaciclib), 300 mg, powder for concentrate for solution for infusion, which was intended to be used for reduction of chemotherapy-induced myelosuppression in extensive stage small cell lung cancer patients.

This withdrawal reflects Pharmacosmos A/S' decision to allow further maturation and generation of data, taking into account the CHMP feedback that, while the available data support the continued evaluation of trilaciclib, the current data package does not yet provide a sufficient basis for approval.

This withdrawal will not have any consequences on any ongoing clinical trials and additional data will continue to be generated on the effects of trilaciclib in small cell lung cancer.

We reserve the right to make further Marketing Authorisation Application submissions at a future date in this or other therapeutic indications.

Yours sincerely,

[REDACTED]
[REDACTED]
Pharmacosmos A/S