24 August 2026
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EMEA/H/C/006709

Withdrawal of application for the marketing authorisation of Zinmyleo (trilaciclib)

Pharmacosmos A/S withdrew its application for a marketing authorisation of Zinmyleo, a medicine for reducing myelosuppression (damage to the bone marrow) caused by chemotherapy in patients undergoing certain treatment for extensive-stage small-cell lung cancer.

The company withdrew the application on 22 July 2026.

What is Zinmyleo and what was it intended to be used for?

Zinmyleo was developed as a medicine to reduce myelosuppression caused by chemotherapy in patients having treatment for extensive-stage small-cell lung cancer.

It was to be given before chemotherapy that included a combination of a platinum-based medicine with etoposide, or topotecan.

Zinmyleo contains the active substance trilaciclib and was to be available as a powder for making a concentrate for a solution to be given by infusion (drip) into a vein.

How does Zinmyleo work?

The active substance in Zinmyleo, trilaciclib, blocks the activity of proteins known as cyclin-dependent kinases (CDK) 4 and 6. These proteins are necessary for blood-forming cells to grow and multiply in the bone marrow. Because chemotherapy mainly affects cells that are actively dividing, stopping the activity of these proteins was expected to help protect bone marrow cells from damage caused by chemotherapy medicines.

What did the company present to support its application?

The applicant provided data from a main study involving 107 patients with newly-diagnosed extensive-stage small-cell lung cancer who were undergoing platinum-based chemotherapy with etoposide and another medicine, atezolizumab.

The study, which compared Zinmyleo with placebo (a dummy treatment), evaluated the damage to the bone marrow by assessing the duration and occurrence of severe neutropenia (low levels of white blood cells known as neutrophils).

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How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the information from the company and prepared questions for the company. After the Agency had assessed the company's responses to the last round of questions, there were still some unresolved issues.

What did the Agency recommend at that time?

Based on the review of the data and the company's response to the Agency's questions, at the time of the withdrawal, the Agency had some concerns and its provisional opinion was that Zinmyleo could not have been authorised for reducing myelosuppression caused by chemotherapy in patients undergoing treatment for extensive-stage small-cell lung cancer.

The Agency considered that at this time there is insufficient evidence that it reduces myelosuppression in a meaningful way. In addition, available data does not yet provide sufficient reassurance that Zinmyleo would not interfere with the anti-cancer activity of chemotherapy.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of the application, the company stated that the withdrawal will allow it to generate further data.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that the 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.

If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.

PHARMACOSMOS

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