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

cc. [redacted] *EMA Product Lead*

Date: 23 July 2025

Subject: Withdrawal of plitidepsin (Aplidin) 2 mg, power for solution for infusion
PROCEDURE: EMEA/H/C/004354
APPLICANT: PHARMA MAR, S.A.

Dear CHMP Chairman,

I would like to inform you that, at this point of time, PharmaMar S.A. has taken the decision to withdraw the application for Marketing Authorisation of Aplidin (plitidepsin), 2 mg, power for solution for infusion, which was indicated in combination with dexamethasone, which was intended to be used for the treatment of adult patients aged < 75 years with relapsed/refractory multiple myeloma (MM) who have received at least three prior regimens including both a proteasome inhibitor and an immunomodulatory agent and have demonstrated disease progression on the last therapy.

This withdrawal is based on a change to the company's marketing strategy.

PharmaMar confirms there are no consequences of the withdrawal on ongoing clinical trials with plitidepsin.

We reserve the right to make further 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,

[redacted]