NOVARTIS

[redacted]

Date: 23 Mar 2026

Dr. Bruno Sepodes
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

[redacted]

Subject: Withdrawal of Type II variation application for Pluvicto® (lutetium (^{177}Lu) vipivotide tetraxetan), 1 000 MBq/mL solution for injection/infusion - Procedure No. EMA/VR/0000288073

Dear Dr. Sepodes,

I would like to inform you that, at this point of time, Novartis Europharm Ltd has taken the decision to withdraw the Type II variation (Scope C.I.6.a) to add a new therapeutic indication for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who are asymptomatic or mildly symptomatic after having progressed on androgen receptor pathway inhibitor (ARPI) and for whom chemotherapy is not yet clinically indicated for Pluvicto® (lutetium (^{177}Lu) vipivotide tetraxetan), 1 000 MBq/mL solution for injection/infusion.

This withdrawal is based on the following reasons:

Feedback from the CHMP indicates that Committee will not be able to conclude that the benefits outweigh the risks on the basis of the data provided.

This withdrawal is not related to the product's quality, efficacy or safety.

This withdrawal does not have any impact on clinical trials with Pluvicto or on the use of Pluvicto in its approved indication.

Novartis Europharm Ltd remains fully committed to further advancing the treatment of patients with Prostate Cancer and reserves the right to make further applications to vary the terms of this Marketing Authorisation at a future date.

We would like to thank the Rapporteurs, the EMA and the CHMP and PRAC members for the time dedicated to reviewing this application and the support provided during the procedure.

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