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24 June 2026

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

Subject: Withdrawal of IMFINZI (durvalumab), 50 mg/mL, concentrate for solution for infusion – EMA/VR/0000289524

[redacted],

I would like to inform you that, at this point of time, AstraZeneca AB has taken the decision to withdraw the Type II variation application to extend the indications for IMFINZI (durvalumab) to include its use in combination with Bacillus Calmette-Guérin (BCG) for the treatment of adults with BCG-naive, high-risk non-muscle-invasive bladder cancer (NMIBC).

This withdrawal is based on CHMP feedback indicating that the Committee would not be able to conclude, on the basis of the data provided, that the benefits outweigh the risks.

This withdrawal does not have any impact on ongoing clinical trials with durvalumab or on the use of durvalumab in its approved indications.

AstraZeneca is committed to exploring opportunities to bring this new treatment regimen to patients with high-risk NMIBC in Europe and reserves the right to make further applications in support of this or other therapeutic indication(s).

We would like to sincerely 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.

Yours sincerely,

[redacted]