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

**Subject: Withdrawal of Zumrad (sasanlimab) 300 mg/2 mL, solution for injection
EMA/H/C/006641/0000**

Dear Professor Sepodes,

I would like to inform you that, at this time, Pfizer Europe MA EEIG has taken the decision to withdraw the application for Marketing Authorisation of **Zumrad (sasanlimab) 300 mg/2 mL, solution for injection**, which was intended to be used for the treatment of adult patients with BCG -naïve, high-risk, non-muscle invasive bladder cancer (NMIBC).

This withdrawal is to allow for additional data collection and analyses to address the questions raised by the Committee for Medicinal Products for Human Use (CHMP).

This withdrawal does not have any impact on ongoing clinical trials with sasanlimab.

Pfizer Europe MA EEIG reserves the right to make a further Marketing Authorisation application submission at a future date in this or other therapeutic indication(s). Pfizer would like to sincerely thank the Rapporteurs, EMA, PRAC and CHMP 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,

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