sanofi

Gentilly, 24 June 2026

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

Subject: Withdrawal of Dupixent (dupilumab) solution for injection – EMA/VR/0000248778 to extend the therapeutic indication to the treatment of bullous pemphigoid (BP)

Dear [redacted],

I would like to inform you that, at this point of time, the Applicant has taken the decision to withdraw the application EMA/VR/0000248778 to add a new therapeutic indication to the Dupixent Marketing Authorisation, for the treatment of bullous pemphigoid.

The Applicant reluctantly withdraws this application following divergence with the CHMP on the data sufficiency to support the extension of Dupixent indication in the European Union (EU) for the treatment of bullous pemphigoid, a disease with urgent and substantial unmet medical need for which current standard of care (oral corticosteroids) is associated with significant adverse effects.

The Applicant would like to thank the Rapporteur, the EMA and the CHMP members for the time dedicated to reviewing this application.

We reserve the right to make further variation application for this therapeutic indication for this Marketing Authorisation at a future date.

The Applicant agrees for this letter to be published on the EMA website.

Yours sincerely,

[redacted]

[redacted]