sanofi

Product and Application Business Support (PA-BUS)
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

To the attention of:
[redacted]
- All CHMP Members
- All PRAC Members

Gentilly, 14 February 2025

Subject: Dupixent (dupilumab) solution for injection – withdrawal of application EMEA/H/C/004390/II/0083 to extend the therapeutic indication

Dear Madam, Dear Sir,

I would like to inform that the Applicant has taken the decision to withdraw the application EMEA/H/C/004390/II/0083 to add a therapeutic indication to the Dupixent marketing authorization, for the treatment of chronic spontaneous urticaria in patients aged 12 years and older who are symptomatic despite treatment with H1-antihistamines and who are intolerant or inadequately controlled by anti-IgE therapy.

This withdrawal is based on the following reason:

The Applicant is planning to submit a new application with a revised therapeutic indication based on additional data that have been generated.

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

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

Yours sincerely,

[redacted]