dbv technologies

CHMP chair
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Montrouge, 17 December 2021

Subject: Withdrawal of Marketing Authorisation Application for ABYLQIS - Peanut Allergen Extract, 250 mcg cutaneous patch – EMEA/H/C/004810

Dear Dr. Enzmann,

I would like to inform you that DBV Technologies has taken the decision to withdraw the application for Marketing Authorisation of **ABYLQIS, Peanut Allergen Extract**, which was intended to be used for the treatment of peanut allergy in children 4 to 11 years of age at the time of treatment initiation.

The decision to withdraw was based on the Day 180 feedback received and subsequent discussions with the CHMP indicating that the data available from a single pivotal study were not sufficient to preclude a Day 180 Major Objection, which focused on limitations of the data, including the clinical relevance and effect size. DBV Technologies believes that generating data from a new, Phase 3 pivotal trial will support a more robust path to licensure for ABYLQIS in the European Union.

The withdrawal does not have any impact on ongoing clinical trials.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

We would like to take this opportunity to thank the (Co)-Rapporteurs and EMA for their time reviewing this application and the guidance provided during the procedure.

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

Yours sincerely,

[redacted]