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Sovicille (Siena), 24 June 2025

To: **Prof. Bruno Sepodes**

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: Withdrawal of Nidlegy (bifikafusp alfa/onfekafusp alfa), 2.17 mg + 0.40 mg solution for injection – EMEA/H/C/5651.

Dear Professor Bruno Sepodes,

We would like to inform you that, at this point of time, Philogen S.p.A. has taken the decision to withdraw the application for Marketing Authorisation of Nidlegy (bifikafusp alfa/onfekafusp alfa, 2.17 mg + 0.40 mg solution for injection) submitted in June 2024, which was intended to be used for the following indication: *"Nidlegy is indicated for the neoadjuvant treatment of adult patients with locally advanced fully resectable melanoma"*.

The company's decision to withdraw the Marketing Authorisation Application was due to the timing of the availability of Chemistry Manufacturing and Controls (CMC) and additional clinical data to better characterize the benefit:risk profile in patients with locally advanced resectable melanoma. Provision of the CMC and clinical data were unlikely to be completed within the current allowed timeframe.

This withdrawal does not have any impact on ongoing clinical trials with Nidlegy. Philogen S.p.A. remains fully committed to the development of Nidlegy in melanoma (as recommended in the ESMO 2024 guidelines) and in non-melanoma skin cancer. Both indications represent unmet medical needs.

Philogen S.p.A. reserves the right to make further Marketing Authorisation Application submissions at a future date in the same or in other therapeutic indication(s).

Philogen S.p.A. would like to take this opportunity to thank the (Co-)Rapporteurs, CHMP and EMA for their time and consideration for this application.

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

Your sincerely,

[redacted]