February 20, 2025

Mr. Bruno Sepodes
European Medicines Agency,
Domenico Scarlattilaan 6,
1083 HS Amsterdam,
The Netherlands

Subject: Withdrawal of Pelgraz Paediatric (Pegfilgrastim) 1.5 mg/0.15 mL, 2.5 mg/0.25 mL and 4.0 mg/0.4 mL solution for injection in pre-filled syringe
EMEA/H/C/006348/0000

Dear Mr. Bruno Sepodes,

I would like to inform you that, at this point of time, Accord Healthcare S.L.U. has taken the decision to withdraw the application for Marketing Authorisation of Pelgraz Paediatric (Pegfilgrastim) 1.5 mg/0.15 mL, 2.5 mg/0.25 mL and 4.0 mg/0.4 mL solution for injection in pre-filled syringe which was intended to be used for the reduction in the duration of neutropenia and the incidence of febrile neutropenia in paediatric patients treated with cytotoxic chemotherapy for malignancy.

This withdrawal is based on the following reasons:

- Identification of major multidisciplinary and clinical issues.

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

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

Yours sincerely,

[Redacted Name]
Senior Director
Head of [Redacted Title]
Tel. [Redacted Number]
Mob. [Redacted Number]
E-Mail: [Redacted Email]