Scholar Rock

13th August 2026

Dr Bruno Sepodes

Chairman CHMP, European Medicines Agency

Domenico Scarlattilaan 6

1083 HS Amsterdam

The Netherlands

Subject: Withdrawal of ISEMBYLD (apitegromab) 50mg/ml concentrate for solution for infusion

EMEA/H/C/005909

Dear Dr Sepodes,

I would like to inform you that, at this point of time, Scholar Rock Netherlands B.V. has taken the decision to withdraw the application for Marketing Authorisation of Isembyld (apitegromab) 50mg/ml , concentrate for solution for infusion which was intended to be used for the treatment of muscular atrophy in patients with Spinal Muscular Atrophy (SMA)

This withdrawal is based on the following reason:

- lack of GMP compliance for the Catalent Indiana Drug Product manufacturing site

This withdrawal has no consequences in relation to ongoing clinical trials or compassionate use programs.

Scholar Rock remains committed to the development of Apitegromab in the SMA patient group.

We reserve the right to make further Marketing Authorisation Application submissions at a future date in this or other therapeutic indications

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

Senior Director, Regulatory Strategy, Europe

Scholar Rock Netherlands B.V.