



October 8, 2026

Dear SMA Europe,

Today, Scholar Rock is excited to share with you that following collaborative engagement with the European Medicines Agency (EMA), we have resubmitted the Marketing Authorisation Application (MAA) for apitegromab.

As we communicated in August, Scholar Rock, in alignment with EMA guidance, withdrew the MAA for apitegromab for the treatment of children and adults with spinal muscular atrophy (SMA). This action followed Official Action Indicated (OAI) inspection classification by the U.S. FDA at our third-party fill-finish manufacturing facility.

Our commitment to you upon that announcement was to work with urgency to resubmit with an alternate fill-finish facility to facilitate the most expeditious path to Committee for Medicinal Products for Human Use (CHMP) opinion.

Following the successful approval in the United States, this resubmission is an important milestone in our mission to bring the first muscle-targeted treatment to the SMA community in Europe which is the second step in our goal to bring apitegromab to more than 50 countries across the globe. We will continue to keep you updated as the regulatory review process progresses.

We remain grateful for your continued collaboration and support.

You can find our press release announcing the MAA resubmission [here](#).

With respect and gratitude,

Your Scholar Rock Patient Advocacy Team

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