

16 October 2026

Subject: Salanersen clinical trial program in SMA update

Dear SMA Europe,

In response to your request regarding an update on the salanersen clinical trial program, we are pleased to share that the Phase 3 salanersen studies are all open for enrollment. As of October 2026, STELLAR-1 study has enrolled its first participants in the United States and Japan.

For more details on the ***salanersen Phase 3 Clinical Development Program***:

Salanersen is being evaluated in three global Phase 3 studies designed to assess the efficacy and safety of once-yearly dosing in a broad range of individuals living with SMA. These studies will follow participants for up to 5 years to evaluate long-term outcomes. Data will be evaluated at multiple timepoints throughout the studies, with key analyses occurring before the completion of the full follow-up period. Salanersen remains investigational and has not been approved for use outside of clinical trials.

Currently, there are three global studies enrolling, with sites opening on a rolling basis:

- **STELLAR-1**, an open-label study, will evaluate salanersen in very young (under 6 weeks of age), treatment-naïve and clinically presymptomatic infants with a genetic diagnosis of SMA. Approximately 40 sites are planned globally.
- **STELLAR-2**, a randomized, double-blind, sham-controlled study, will evaluate salanersen when initiated in infants with SMA approximately 6 months after receiving onasemnogene abeparvovec-xioi presymptotically at 6 weeks of age or younger. Approximately 35 sites are planned globally.
- **SOLAR**, an open-label study, will evaluate salanersen in teens and older adults with SMA (aged 15–60 years) who are either treatment-naïve or previously treated with risdiplam. Approximately 50 sites are planned globally.

For the most up-to-date information on study status, locations and other trial details, please visit ClinicalTrials.gov.

We are grateful to the SMA community, clinical trial participants, families and patient advocacy leaders for their continued contributions to SMA research.

Regards,



Daniela Cohen
Biogen International

Note: This letter has been prepared by Biogen for use with SMA Patient Organizations and is intended solely for informational purposes. The information contained herein is accurate as of the date of this letter and may be subject to change.