11 November 2026

Subject: Update on the nusinersen ThecaFlex DRx System clinical development program

Dear SMA Europe,

Thank you for your interest in the nusinersen ThecaFlex DRx™ System clinical development program. In response to your request, we would like to share an update on the ongoing PIERRE and PIERRE-PK studies.

ThecaFlex DRx System is an investigational implantable port and catheter device being evaluated for the intrathecal delivery of nusinersen (via the ThecaFlex DRx System) in people living with spinal muscular atrophy (SMA).

The clinical development program currently includes two studies:

- **PIERRE** is evaluating the safety profile and performance of ThecaFlex DRx System for the delivery of nusinersen in people living with SMA (who meet the study eligibility criteria).
- **PIERRE-PK** is a Phase 1 study evaluating how the body processes nusinersen when administered through ThecaFlex DRx System compared with administration via lumbar puncture.

Both studies are currently recruiting. For the most current information on study eligibility, recruitment status and participating study locations, please visit ClinicalTrials.gov

We are grateful to the SMA community for your continued interest and engagement in SMA research, and we look forward to providing further updates on the clinical development program as appropriate.

Regards,

Daniela Cohen

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