18 November 2025

Dear SMA Europe,

In response to your request, we are pleased to share that the European Medicine Agency's Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending by consensus the approval of the high dose regimen (50mg/28mg) of SPINRAZA™ (nusinersen) for the treatment of Spinal Muscular Atrophy (SMA).

The CHMP's positive opinion for the high dose regimen of nusinersen will now be reviewed by the European Commission with a final decision expected in January 2026.

The positive opinion is based on data from the Phase 2/3 DEVOTE study evaluating the investigational high dose regimen of nusinersen. The high dose regimen comprises of a loading regimen of two 50 mg doses 14 days apart, and a maintenance regimen of 28 mg every four months.

We are committed to continuing to work with regulatory and reimbursement authorities to secure appropriate access for the high dose regimen for people living with SMA in the EU.

We also sincerely thank the SMA community for years of partnership and advocacy in supporting those living with the condition.

Kind regards,

Daniela Cohen

Biogen International