13 January 2026

Dear SMA Europe,

In response to your request, we are pleased to share that the European Commission (EC) has granted extension of the marketing authorisation for a high dose regimen of SPINRAZA™ (nusinersen) (09 January 2026) which is comprised of 50 mg and 28 mg doses for the treatment of spinal muscular atrophy (SMA) in the European Union (EU).

This approval follows the positive opinion issued by the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) dated, 13 November 2025 and is based on data from the three-part, Phase 2/3 DEVOTE study and interim data from its ongoing long-term extension study, ONWARD.

The new high dose regimen comprises a more rapid loading phase, two 50 mg/5 mL loading doses administered 14 days apart, and 28 mg/5 mL maintenance dose injections every four months thereafter.

Over the past decade, advances in treatment have redefined what's possible for people living with SMA. With each milestone, we move closer to addressing the evolving needs of the SMA community and delivering therapies that make a real and lasting difference.

We are sincerely grateful to the SMA community for their partnership and advocacy. Together, we share a commitment to ensuring that every innovation brings meaningful benefit to those impacted by SMA around the world.

Kind regards,

Daniela Cohen

Biogen International