

Community Updates

Dear SMA Community,

It has been a little over than 10 years since Biogen and the SMA community embarked on the original Phase 3 clinical trials of SPINRAZA® (nusinersen); ENDEAR and CHERISH. Since then, we have continued to strive to understand what more may be possible. In 2019 we launched DEVOTE, a Phase 2/3 trial, to explore the potential of an investigational higher dose of nusinersen.

As we reflect on the start of 2023, we have been thrilled to see community members attending the Cure SMA Summits of Strength and the MDA Clinical & Scientific Conference already this year. And, with the Cure SMA Annual Conference just around the corner, we are proud to be a returning Presenting Sponsor.

– The Biogen Team



Individual results may vary based on several factors, including severity of disease, initiation of treatment, and duration of therapy.

In case you missed it, since our last update we launched SPINRAZA TikTok videos, added an additional brochure focused on infants, and additional patient videos to SPINRAZA.com. Be sure to also check out information about STEP events happening online or near you. This year we plan to offer events, such as:

- SPINRAZA Pivotal Trials & Observational Data in Adults
 - Understanding Intrathecal Injection
- Patient Transition of Care: Adult and Pediatric
 - Advocating for Optimal SMA Care
- Multidisciplinary Care: Pediatric and Adult
 - Assessing Motor Function in SMA
 - Physical Assessment – Pediatric
- Navigating Insurance: Adult and Pediatric

Biogen is committed to building on our culture of inclusion and belonging that reflects the communities we serve. To uphold this commitment and promote transparency, we have translated our SPINRAZA materials including the SPINRAZA adult and pediatric brochures, treatment overviews and welcome kits into Spanish.

Clinical Trial Updates*^

DEVOTE: Phase 2/3, Part B; enrolling at 7 US sites:

- Stanford Hospital and Clinics (CA)
- Children's Hospital Colorado (CO)
- Ann & Robert H. Lurie Children's Hospital of Chicago (IL)
- The Johns Hopkins Hospital (MD)
- Boston's Children's Hospital (MA)
- St. Jude Children's Research Hospital (TN)
- The University of Texas Southwestern Medical Center (TX)

RESPOND: Phase 4; enrolling at 13 US sites:

- Arkansas Children's Hospital (AR)
- Boston Children's Hospital (MA)
- Stanford Neuromuscular Research (CA)
- Children's Hospital Colorado (CO)
- Nemours Children's Hospital (FL)
- Rare Disease Research, LLC (GA)
- Ann & Robert H. Lurie Children's Hospital of Chicago (IL)
- Gillette Children's Specialty Healthcare (MN)
- Oregon Health & Science University (OHSU) (OR)
- Children's Hospital Philadelphia - Neurology (PA)
- Cook Children's Medical Center (TX)
- University of Utah (UT)
- Children's Hospital of The King's Daughters (VA)

ASCEND: Phase 3b; enrolling at 11 US sites:

- Arkansas Children's Hospital (AR)
- Stanford Neuromuscular Research (CA)
- Rare Disease Research, LLC (GA)
- University of Iowa Children's Hospital (IA)
- Ann & Robert H. Lurie Children's Hospital of Chicago (IL)
- Boston Children's Hospital (MA)
- Wake Forest University (NC)
- Columbia University (NY)
- University of Pennsylvania (PA)
- The University of Texas Health Science Center at Houston (TX)
- Children's Hospital of The King's Daughters (VA)

*As of April 6, 2023

^For more information please visit www.clinicaltrials.gov

INDICATION

SPINRAZA® (nusinersen) is a prescription medicine used to treat spinal muscular atrophy (SMA) in pediatric and adult patients.

IMPORTANT SAFETY INFORMATION

Increased risk of bleeding complications has been observed after administration of similar medicines. Your healthcare provider should perform blood tests before you start treatment with SPINRAZA and before each dose to monitor for signs of these risks. Seek medical attention if unexpected bleeding occurs.

Increased risk of kidney damage, including potentially fatal acute inflammation of the kidney, has been observed after administration of similar medicines. Your healthcare provider should perform urine testing before you start treatment with SPINRAZA and before each dose to monitor for signs of this risk.

The most common side effects of SPINRAZA include lower respiratory infection, fever, constipation, headache, vomiting, back pain, and post-lumbar puncture syndrome.

These are not all of the possible side effects of SPINRAZA. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Before taking SPINRAZA, tell your healthcare provider if you are pregnant or plan to become pregnant.

Click here to access full [Prescribing Information](#).

This information is not intended to replace discussions with your healthcare provider.