The European Commission has granted marketing authorisation for Itvisma (intrathecal formulation of onasemnogene abeparvovec, developed by Novartis) for the treatment of adults and children aged 2 years and older living with 5q spinal muscular atrophy (SMA).

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SUMMARY: The European Commission has granted marketing authorisation for Itvisma (intrathecal formulation of onasemnogene abeparvovec, developed by Novartis) for the treatment of adults and children aged 2 years and older living with 5q spinal muscular atrophy (SMA).

The European Commission's decision follows the positive opinion adopted by the Committee for Medicinal Products for Human Use (CHMP) in April 2026.

Unlike Zolgensma, which is administered intravenously, Itvisma is delivered through a single intrathecal injection into the cerebrospinal fluid surrounding the spinal cord. Intrathecal route enables the therapy to be delivered directly to the central nervous system while a lower vector dose and without requiring weight-based dosing. This approach has enabled the therapy to be studied in older children, adolescents, and adults, leading to its approval for this broader age group.

For the SMA community, the European Commission's decision represents a milestone in the regulatory process. The next steps will be national pricing, reimbursement, and access decisions, which determine when and how people can receive the treatment in each country.

Nicole Gusset, CEO of SMA Europe states:

> "Every new treatment represents progress for the SMA community and brings renewed hope to people living with SMA and their families. We welcome the decision of the European Commission and, together with our members, will continue advocating for timely and equitable access across Europe, so that everyone who may benefit has the opportunity to do so."

SMA Europe continues working with its members, healthcare professionals, industry partners, and decision-makers to support timely and equitable access to approved treatments across Europe. We will continue sharing updates as national implementation progresses and more information becomes available on our Access Hub website. In addition, SMA Europe is considering organising an informational webinar and developing a Q&A document to support the community as further information becomes available.

Additional information:
Novartis Press Release: Novartis receives European Commission approval for Itvisma® for spinal muscular atrophy (SMA) | Novartis
CHMP summary of opinion from 23 April 2026: Itvisma, INN-onasemnogene abeparvovec

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