



Xenpozyme in Saudi Arabia

The SFDA named-patient coordination pathway — indicative 2026

RARE DISEASE · ASMD (NON-CNS MANIFESTATIONS)

The clinical situation

Xenpozyme (olipudase alfa-rpcp) is a recombinant human acid sphingomyelinase enzyme replacement therapy FDA-approved for the non-CNS manifestations of acid sphingomyelinase deficiency (ASMD, Niemann-Pick types A/B and B) in paediatric and adult patients. Manufactured by Sanofi. Administration uses a weight-based dose-escalation schedule over several weeks to the 3 mg/kg every-two-week maintenance dose, mitigating the cytokine-mediated infusion-related reaction signal. Pre-treatment workup covers SMPD1 genetic confirmation, LFTs, ferritin, organomegaly imaging, and pulmonary function per FDA labelling.

The pathway, 5 steps

- 1 Consultation & clinical rationale.** Your metabolic-genetics physician documents ASMD diagnosis, SMPD1 genotype, organ involvement, and Xenpozyme rationale.
- 2 Baseline workup.** LFTs, ferritin, spleen/liver imaging, PFTs, infusion-site plan per FDA labelling.
- 3 SFDA named-patient application.** Physician or hospital pharmacy files clinical rationale, patient reference, dose-escalation schedule, and chain-of-custody commitment.
- 4 US-side sourcing & logistics.** Reserve Meds coordinates product through our US-licensed DSCSA-compliant specialty wholesale partner with cold-chain 2–8°C shipment.
- 5 Arrival & first dose.** Dispensing pharmacy releases the first escalation vials; first infusion scheduled at the treating centre with premedication.

Indicative economics

Reference US cash-pay range: USD 700,000–800,000 per year of Xenpozyme (drug-only reference; Reserve Meds provides a transparent delivered quote at intake).

Indicative first-dose timing

7–14 days from a complete SFDA application to first dispensation, once cohort intake opens. Indicative — not guaranteed.

Reserve Meds's role

Sourcing. US-licensed specialty wholesale partner, DSCSA chain-of-custody from Sanofi authorised distribution.

Documentation. Physician kit tailored to SFDA review, with ASMD diagnostic confirmation and dose-escalation IRR-prevention annex. **Logistics.** Cold-chain 2–8°C internationally tracked shipment with temperature excursion log. **Concierge case lead.** Named point of contact for family and physician through escalation and every two-week maintenance infusion cycle. **We are a coordinator** — not the prescriber, not the dispensing pharmacy. All clinical decisions remain with your treating physician.

COMPOSITE EXAMPLE · PRE-LAUNCH WAITLIST

Join the Xenpozyme × Saudi Arabia first-cohort waitlist. *Our concierge reaches out as we open intake.*

reservemed.com/access-guides/xenpozyme-saudi-arabia.html



SCAN TO JOIN

Reserve Meds · US-based concierge for cross-border specialty medicine. We are a coordinator; we are not the prescriber and not the dispensing pharmacy. All clinical decisions remain with the treating physician. Not medical advice.

Reserve Meds is in pre-launch. Service availability is limited to our first cohort; all timelines published are indicative, not guarantees. Composite case examples only.

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