SS-31 (Elamipretide) — Research Summary

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1. What It Is

SS-31 (elamipretide, also known as Bendavia or MTP-131) is a synthetic mitochondria-targeted tetrapeptide with the sequence D-Arg-Dmt-Lys-Phe-NH2 (Dmt = 2’,6’-dimethyltyrosine, an unusual amino acid critical to its mitochondrial targeting). It was developed by Hazel Szeto and Peter Bhatt at Weill Cornell Medical College and by Stealth BioTherapeutics.

SS-31 selectively concentrates in the inner mitochondrial membrane at concentrations reported over 1,000-fold higher than in the cytoplasm, where it binds and stabilizes cardiolipin — a phospholipid essential for organizing electron transport chain complexes.

Regulatory status: SS-31 has the strongest human clinical trial dataset of any mitochondria-targeted research peptide. It received FDA approval in September 2025 for Barth syndrome, under the brand name FORZINITY. Research-peptide and compounded forms for other uses remain unapproved by the FDA.

FORZINITY is the FDA-approved pharmaceutical form. This RUO product is not that drug, has not been reviewed by the FDA, and no equivalence is claimed or implied.

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2. Reported Effects in Research Literature

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- **Barth syndrome (FDA-approved indication):** Multiple Phase 2/3 trials (the TAZPOWER program) reported that long exposure (48 weeks) resulted in significant improvement on the 6-Minute Walk Test and the Barth Syndrome Symptom Assessment Scale, along with improved cardiac stroke volumes.
- **Primary mitochondrial myopathy:** The MMPOWER trial series (Phase 2 and Phase 3) evaluated elamipretide in this population, contributing multi-month controlled adverse-event and efficacy data.
- **Mechanism research:** Reported to bind directly to the mitochondrial ADP transporter (adenine nucleotide translocator, ANT) and improve ADP sensitivity in aged mitochondria, rescuing physiological function in aging models.
- **Cardiac/renal/neurodegenerative research:** Investigated in additional trial contexts including heart failure and Friedreich’s ataxia (FRDA); received FDA Rare Pediatric Disease designation for Barth syndrome specifically.
- **Safety:** Across Phase 2/3 trials, injection-site reactions were the dominant reported adverse event (approximately 40–60% of treated participants in some trial reports) — more frequent than typically seen with most research peptides. GI symptoms, headache, and transient fatigue followed at lower frequencies. ECG monitoring, vital signs, and serum chemistry showed no clinically significant changes attributable to elamipretide across trials.

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3. Clinical & Preclinical Study References

- Karaa A, et al. TAZPOWER trial (Barth syndrome). PMID: 30587518
- Reid Thompson W, et al. Barth syndrome trial data. PMID: 34192522
- Mechanism paper: cardiolipin binding characterization. PMID: 32554501
- Pharaoh G, Kamat V, Kannan S, et al. “Elamipretide Improves ADP Sensitivity in Aged Mitochondria

by Increasing Uptake through the Adenine Nucleotide Translocator (ANT).” PMID: 36778398
- Nature Scientific Reports: “SS-31 treatment ameliorates cardiac mitochondrial morphology and defective mitophagy in a murine model of Barth syndrome.” Full text

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4. Reconstitution Process

For research/laboratory handling purposes only.

Keep out of reach of children. Not for use by pregnant or nursing individuals. For laboratory research use by qualified personnel only.

1. **Materials needed:** lyophilized (freeze-dried) SS-31 powder, bacteriostatic water, alcohol swabs, syringe with needle.
2. **Bring the vial to room temperature** before reconstitution.
3. **Sanitize** the rubber stopper of both vials with an alcohol swab.
4. **Add the water slowly** down the *inside wall* of the vial, to reduce shear/foaming.
5. **Do not shake.** Gently swirl or roll between palms until fully dissolved.
6. **Inspect the solution** — should be clear and free of particulates.
7. **Label the vial** with reconstitution date and concentration.
8. **Storage:** refrigerate (2–8°C); avoid freeze-thaw cycles.

Reference: Bacteriostatic Water Volume by Vial Size

Vial Size	BAC Water Added	Resulting Concentration
5 mg	1 mL	5 mg/mL
5 mg	2 mL	2.5 mg/mL
5 mg	5 mL	1 mg/mL
10 mg	1 mL	10 mg/mL
10 mg	2 mL	5 mg/mL
10 mg	4 mL	2.5 mg/mL
10 mg	5 mL	2 mg/mL
10 mg	10 mL	1 mg/mL
50 mg	10 mL	5 mg/mL
50 mg	20 mL	2.5 mg/mL

Notes: Your order sheet also carries a 50mg SS-31 vial size, included above. Higher water volume = more dilute solution; lower volume = more concentrated. Always use bacteriostatic water (0.9% benzyl alcohol) for multi-draw vials; sterile water without preservative should be discarded within 24 hours.

Document created: July 16, 2026. **Revision 1:** July 29, 2026. Regulatory status (FDA compounding lists, WADA lists) is actively shifting; re-verify against current sources before any customer-facing use.

This document is intended for research and internal reference use only. It does not constitute medical advice, dosing guidance, or an endorsement of unsupervised human use. SS-31/elamipretide is FDA-approved (as FORZINITY) only for Barth syndrome under physician prescription; RUO material is not the approved pharmaceutical product and carries no such approval.