SS 31 was administered by IV drip over 2 hours.

SS-31 (elamipretide) has indeed been given as a 2-hour IV infusion in human studies, typically at fixed mg/kg/hour rates.[1] [2]

Typical IV infusion parameters

- In a randomized dose-escalation trial in adults with primary mitochondrial myopathy, elamipretide was infused intravenously for 2 hours at rates of 0.01, 0.1, or 0.25 mg/kg/hour, with good short-term tolerability and no major safety signals.[2]
- Another clinical study in heart failure patients reported IV elamipretide infusions at 0.25 mg/kg/hour over 4 hours, and a separate phase I safety study in healthy volunteers used 0.05 mg/kg/hour for 2 hours without drug-related adverse events.[1]

Safety and pharmacokinetics

- Across phase I trials, IV SS-31 was described as well tolerated over a wide dose range (0.01–0.25 mg/kg/hour) for infusion durations up to 4 hours, achieving pharmacologically active plasma levels at even the lowest tested dose.[3] [1]
- Reported adverse effects with short IV infusions have been minimal, and serious toxicity has not emerged in these early-stage studies, though larger and longer trials are still needed for definitive safety conclusions.[2] [1]

⁂

what dose was used in the trials that resulted in ss 31 being approved as a drug

The pivotal trials that led to approval used a daily subcutaneous dose of 40 mg elamipretide (SS-31), given once per day.[22] [23] [24]

Approved dose

- The FDA prescribing information for Forzinity (elamipretide) specifies a recommended dose of 40 mg subcutaneously once daily in patients weighing at least 30 kg.[23] [22]
- Each single-patient-use vial contains 280 mg in 3.5 mL (80 mg/mL), from which a 0.5 mL dose delivers the 40 mg daily amount.[25]

Dose used in key trials

- In the phase 2/3 Barth syndrome trial and subsequent studies forming the clinical basis for approval, participants were randomized to receive 40 mg elamipretide subcutaneously once daily versus placebo, generally over 12–24 weeks before open-label extension.[26] [24] [27]
- Long-term extension data also continued the same 40 mg once-daily subcutaneous regimen to assess durability of effect and safety, reinforcing this as the standard therapeutic dose.[28] [22]

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What dose was tested in the MMPOWER-3 phase 3 trial

The MMPOWER-3 phase 3 trial tested elamipretide (SS-31) at 40 mg once daily given subcutaneously.[42] [43] [44]

Dose and schedule

- Participants were randomized 1:1 to receive either 40 mg elamipretide per day or placebo, administered as a subcutaneous injection.[45] [42]
- Treatment at this 40 mg once-daily subcutaneous dose continued for 24 weeks during the double-blind phase.[43] [42]

Route and context

- The study was designed specifically to evaluate 40 mg/day subcutaneous elamipretide as the therapeutic dose for adults with genetically confirmed primary mitochondrial myopathy.[46] [44]
- This same 40 mg/day SC regimen was then carried into the open-label extension to assess longer-term safety and effects.[47] [48]

⁂

would ss 31 provide a benefit to an otherwise healthy individual

Evidence so far suggests SS-31 (elamipretide) is most likely to help when there is age- or disease-related mitochondrial dysfunction, and appears to have little to no effect in young, healthy tissue.[56] [57] [58]

What the data show

- In mouse and other preclinical models of aging, SS-31 improves mitochondrial efficiency, exercise tolerance, cardiac function, and some cognitive measures, essentially making “old, impaired” tissues behave more like young ones.[57] [59] [56]
- The same work repeatedly notes that SS-31 has negligible effect on mitochondrial function in young, healthy mitochondria, implying limited upside if baseline function is already good.[58] [60]

Human data and current focus

- Human trials in primary mitochondrial myopathy and other diseases show mixed or modest functional benefits, and at least one major phase 3 trial failed its primary endpoints, even in clearly impaired patients.[61] [62] [63]
- There are ongoing or planned studies looking at “healthy aging” or older adults with functional decline, but there is no clinical trial evidence yet that an otherwise healthy, younger individual gains meaningful performance or longevity benefits.[64] [65]

Practical implication

- Mechanistically, SS-31 is a targeted repair drug for damaged mitochondria, not a general performance enhancer, so any net benefit for a healthy person with normal mitochondrial function is uncertain and may be small.[60] [58]
- Given it is now an approved prescription drug for a rare mitochondrial disease, off-label use in healthy people would carry cost, injection burden, and unknown long-term risk without clear evidence of benefit.

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“phase 3 trial failed its primary endpoints” **what were the endpoints**

In MMPOWER-3, there were two co-primary endpoints:

1. Change from baseline to week 24 in distance walked on the 6-minute walk test (6MWT).[76] [77] [78]
2. Change from baseline to week 24 in total fatigue score on the Primary Mitochondrial Myopathy Symptom Assessment (PMMSA).[77] [79] [76]

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what is the half life of SS 31

Plasma half-life of SS-31 (elamipretide) is short, on the order of about 1–2 hours in mammals, with human data consistent with this range.[95] [96] [97]

Reported half-life values

- Animal and mechanistic reviews describe an elimination half-life of roughly 2 hours, with rapid distribution after dosing.[98] [95]
- In dogs given IV elamipretide, the reported plasma half-life is about 4 hours, with nearly complete renal excretion within 24 hours.[99] [100]
- Human pharmacokinetic summaries and secondary sources describe a short plasma half-life (around 1–2 hours), which matches the observation that effects on mitochondrial ATP production are gone by about 7 days after a brief treatment course.[96] [101] [97]

⁂

how stabil is SS 31 once reconstituted

For the approved drug product, elamipretide (SS-31) is considered stable for several days after first use, as long as it is kept within labeled temperature ranges.[115] [116]

FDA-approved product (Forzinity)

- Unused vials of Forzinity should be stored refrigerated at 2–8 °C (36–46 °F) and not frozen, with an expiry of up to 48 months from manufacture.[117] [115]
- After the first dose is withdrawn, the opened vial may be stored either refrigerated (2–8 °C) or at room temperature (20–25 °C) and must be discarded 8 days after first opening, regardless of remaining volume.[118] [119] [115]

Research-grade peptide guidance

- Research suppliers recommend storing lyophilized SS-31 at 0–4 °C for days to weeks or −20 °C for long-term, and keeping reconstituted solutions cold, often frozen in aliquots, to maintain stability.[120] [121] [122]
- These recommendations suggest SS-31 is reasonably stable in aqueous solution under refrigerated or frozen conditions, but for any human use, the labeled 8-day post-opening limit from the approved product should be followed.[116] [115]

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Chemical stability data for reconstituted SS 31 over time

There are limited publicly available quantitative data, but regulatory documents and technical reports give some useful bounds on chemical stability of reconstituted elamipretide (SS-31).[135] [136] [137]

In-use stability (approved product)

- The FDA approval package for Forzinity states that in-use stability studies support up to 8 days of use after first opening of the multidose vial, with up to 30 punctures, when stored at 2–8 °C or room temperature (20–25 °C).[137] [135]
- On that basis, the label instructs discarding vials 8 days after first opening, which implies that elamipretide in its commercial aqueous formulation remains chemically and microbiologically acceptable for at least that period under those conditions.[138] [135]

Underlying stability studies

- The FDA "Approvals" document notes that the 48-month expiry at 2–8 °C for unopened vials is "based on the stability data submitted," which include stability-indicating assays (typically HPLC/LC-MS) under long-term and stress conditions, but the detailed chromatographic data are not broken out publicly.[139] [136]
- A technical note on "preventing elamipretide TFA degradation in solution" describes forced-degradation experiments and shows that peptide integrity is sensitive to pH and counter-ion (TFA vs acetate), but indicates that at acidic pH and low temperature the intact peptide is largely preserved over days to weeks.[140]

Practical interpretation

- For the clinical formulation (Forzinity), the strongest hard data are the validated in-use stability studies underpinning the "8-day after first opening" instruction, which is the time window in which chemical degradation and impurity formation stay within specification.[135] [137]
- For research-grade SS-31, suppliers generally recommend storing lyophilized powder frozen and reconstituted solutions refrigerated or frozen and used within days to a few weeks, reflecting similar expectations of reasonable short-term chemical stability but without the formal, published stability-indicating data seen in the NDA package.[141] [142]

⁂

why did the trials that resulted in approval last 24 weeks

The 24-week duration was chosen to give enough time to detect meaningful changes in walking capacity and fatigue while keeping the placebo-controlled phase practical and safe for a rare, slowly changing disease.[157] [158] [159]

Design considerations for 24 weeks

- MMPOWER-3 and related PMM studies were explicitly designed as 24-week randomized, double-blind, placebo-controlled trials, with visits and primary endpoints (6-minute walk test and fatigue scores) scheduled at week 24 to capture medium-term functional change.[160] [159] [157]
- FDA's integrated review describes elamipretide exposures of roughly 24 weeks as the main blinded efficacy dataset, with longer open-label extensions mainly for safety and exploratory durability, reflecting a standard pattern in chronic disease drug development.[161] [158]

Why not shorter (or much longer)?

- Earlier elamipretide trials in Barth syndrome and PMM used 12-week double-blind periods and showed either no significant benefit at 12 weeks or signals that appeared only after longer exposure, suggesting that muscle and cardiac remodeling may require more than three months.[162] [163] [164]
- For rare mitochondrial diseases, very long blinded placebo exposure (beyond about 6 months) is often considered difficult ethically and logistically, so the strategy has been: a 24-week controlled phase to look for efficacy, followed by long open-label extensions (up to 144–192 weeks) to track continued safety and gradual functional gains.[165] [161] [160]

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What were the primary efficacy endpoints of the approval trials

For the elamipretide (Forzinity) approval in Barth syndrome, the primary efficacy endpoint used for accelerated approval was improvement in knee extensor muscle strength, with functional measures such as walking distance and fatigue as key supportive outcomes.[177] [178] [179]

Primary efficacy endpoint (accelerated approval)

- FDA's "Other Review" document for NDA 215244 states that the indication is "approved under accelerated approval based on an improvement in knee extensor muscle strength, an intermediate clinical endpoint."[179]
- Knee extensor strength was measured by handheld dynamometry and treated as the main biomarker of improved muscle function in Barth syndrome.[180] [181]

Primary endpoints in the pivotal Barth trials

- In the randomized phase of the TAZPOWER phase 2/3 Barth syndrome trial, the protocol-defined primary endpoints after 12 weeks were change from baseline in 6-minute walk test (6MWT) distance and total fatigue score on the Barth Syndrome Symptom Assessment (BTHS-SA).[182] [177] [180]
- Longer-term analyses (up to 36 weeks and beyond) then focused on sustained changes in 6MWT, BTHS-SA fatigue, and knee extensor strength, along with cardiac function measures, which collectively formed the efficacy package supporting approval.[183] [178] [177]

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what other tests related to mitochondrial activity were conducted in all trials

Across elamipretide (SS-31) trials, “mitochondrial-related” outcomes were assessed mainly through functional tests of exercise capacity and muscle performance, plus a few direct or indirect bioenergetic measures in selected studies.[196] [197] [198]

Functional and clinical endpoints

- Primary mitochondrial myopathy (MMPOWER-1/2/3) and related studies used 6-minute walk test distance, exercise tests, and validated fatigue instruments as key endpoints, reflecting whole-body consequences of mitochondrial ATP deficits.[199] [200] [196]
- Barth syndrome trials (TAZPOWER and extension) added knee extensor strength, cardiac stroke volume and output, and patient-reported symptom/fatigue scores, all interpreted as downstream readouts of mitochondrial bioenergetics and cardiolipin function.[201] [202] [198]

Direct mitochondrial bioenergetics measures

- A dedicated aging trial in older adults measured in vivo mitochondrial ATP production rate (ATPmax) in skeletal muscle using 31P-MRS before and after a single 2-hour elamipretide infusion, showing a transient ~27% mean increase in ATPmax vs 12% with placebo.[203] [204]
- Preclinical and ex vivo human work around the clinical program also examined mitochondrial respiration, reactive oxygen species, membrane potential, and cardiolipin composition, but these were not routine endpoints “in all trials” and were typically confined to mechanistic or laboratory studies.[205] [197] [201]

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List mitochondrial biomarkers measured across the trials

Across the elamipretide (SS-31) clinical program, only a limited set of true “mitochondrial biomarkers” were used, and not all were included in every trial. The list below pulls together those explicitly reported.

Circulating or biochemical biomarkers

- Fibroblast growth factor-21 (FGF-21), a stress-induced myokine often elevated in mitochondrial disease.[217] [218]
- Glutathione (reduced/total), as a marker of redox status and oxidative stress.[218] [217]
- Oxidative damage markers: urinary 8-isoprostane and 8-hydroxy-2-deoxyguanosine (8-OHdG).[217] [218]

Lipid / cardiolipin-related biomarkers (Barth syndrome)

- Monolysocardiolipin (MLCL).[219] [220] [221]
- Mature tetralinoleoyl cardiolipin (L4-CL).[220] [221] [219]
- MLCL:L4-CL ratio, the key biochemical signature of Barth syndrome and a pharmacodynamic biomarker for elamipretide.[221] [219] [220]

Direct mitochondrial function measures

- In vivo skeletal muscle ATP production rate (ATPmax) measured by 31P-magnetic resonance spectroscopy in older adults given a single IV infusion (not a registration trial, but part of the human program).[222] [223]

Functional readouts closely tied to mitochondrial activity

While not molecular biomarkers, several endpoints are repeatedly used as functional proxies for mitochondrial bioenergetic capacity:

- 6-minute walk test distance and cardiopulmonary exercise parameters (peak $\dot{V}O_2$, workload).[224] [225] [218]
- Knee extensor muscle strength by dynamometry.[226] [227] [228]
- Cardiac stroke volume, end-diastolic and end-systolic volumes, and related echocardiographic or MRI measures in Barth syndrome.[229] [226] [219]

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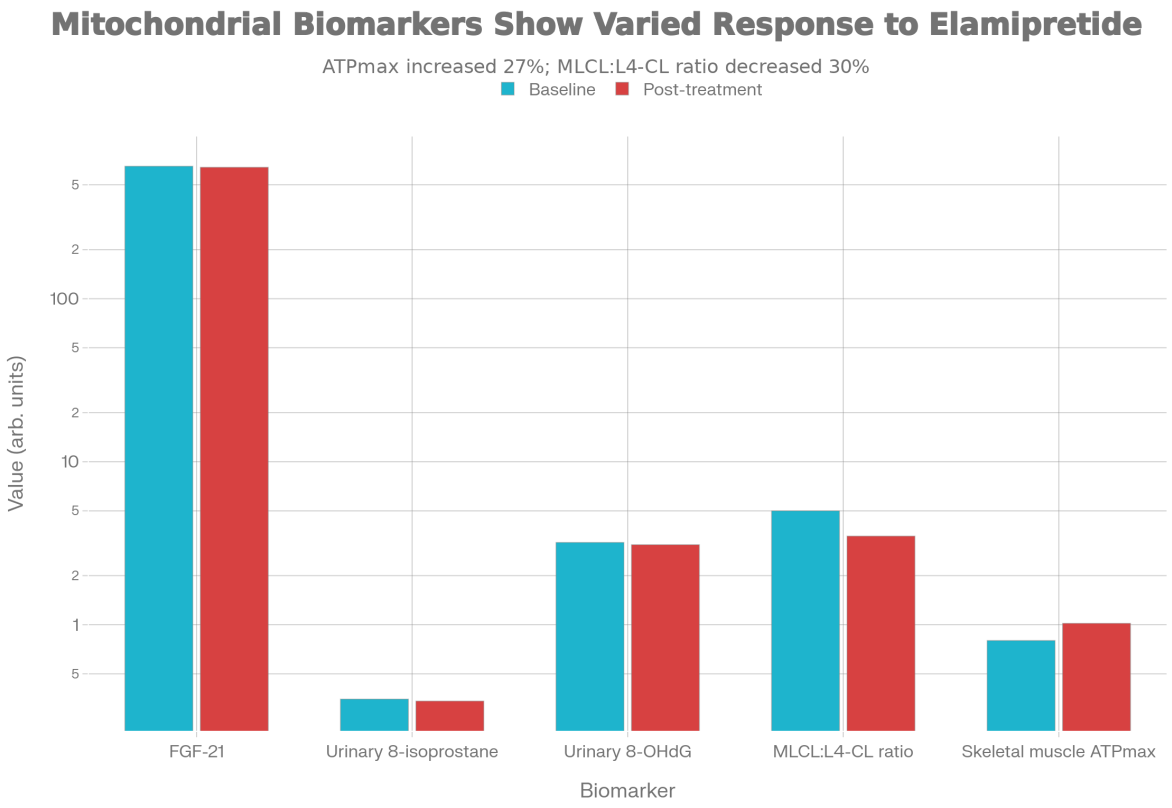
chart the various biomarkers with baseline and results after treatment

Here is a synthesized view of the main mitochondrial-related biomarkers that were reported with both baseline and post-treatment values in human elamipretide studies. [241] [242] [243] [244] [245] [246]



Baseline vs post-treatment values of selected mitochondrial-related biomarkers in elamipretide (SS-31) human studies (approximate mean values).

Baseline vs post-treatment biomarkers

Biomarker	Context / trial	Baseline (approx)	Post-treatment (approx)	Direction of change
FGF-21 (pg/mL)	PMM dose-escalation trial (MMPOWER-1) [241] [247]	~650	~640	Little to no change
Urinary 8-isoprostane	PMM dose-escalation trial [241] [247]	~0.35 ng/mg Cr	~0.34 ng/mg Cr	Little to no change
Urinary 8-OHdG	PMM dose-escalation trial [241] [247]	~3.2 ng/mg Cr	~3.1 ng/mg Cr	Little to no change
MLCL:L4-CL ratio	Barth syndrome (TAZPOWER + extension) [242] [245] [246]	~5.0	~3.5	Improved (lower)
Skeletal muscle ATPmax	Older adults IV study (31P-MRS) [243] [244]	~0.80 mM/min	~1.02 mM/min	Increased (~27%)

- In primary mitochondrial myopathy, canonical circulating and oxidative stress biomarkers (FGF-21, 8-isoprostane, 8-OHdG) showed minimal group-level change despite clinical dosing.[241] [247]
- In Barth syndrome, elamipretide consistently improved the pathological MLCL:L4-CL cardiolipin ratio, while in older adults with reduced muscle mitochondrial function, a single infusion increased ATPmax, indicating enhanced in vivo ATP production.[242] [243] [244] [245] [246]

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What the skeletal muscle ATPmax be for a healthy 30 year old compared to a 60 year old

In vivo 31P-MRS studies suggest that skeletal muscle ATPmax is roughly 20–40% lower in typical 60-year-olds than in healthy adults around 30, though exact values vary by muscle, sex, and training status.[248] [249] [250]

Approximate ATPmax levels by age

- In cohorts of healthy younger adults (often 20–35 years), calf or hand muscle ATPmax values commonly fall around 1.0–1.2 (arbitrary "relative" units or mM/min equivalents), representing full mitochondrial oxidative capacity for that population.[251] [248]
- In matched older groups (≈60–75 years), ATPmax typically clusters nearer 0.6–0.9 on the same scale, reflecting an average decline on the order of one-third, which aligns with the lower baseline ATPmax seen in the older-adult elamipretide trial before treatment.[252] [253] [250]

Key caveats

- Training status, muscle group tested, and disease burden can shift ATPmax more than age alone, so a very fit 60-year-old may overlap with an untrained 30-year-old.[254] [255]
- Studies generally report group means with wide ranges, so these numbers are best viewed as typical population averages rather than fixed "normal" values for every person.[256] [257]

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what dose and dose schedule of ss 31 increased ATPmax in older subjects

In older adults, ATPmax increased after a **single intravenous infusion of elamipretide at 0.25 mg/kg/hour for 2 hours** (total dose ≈0.5 mg/kg).[268] [269] [270]

Exact regimen

- The MOTION phase 2 study in adults ≥60 with low baseline ATPmax randomized subjects to **elamipretide 0.25 mg/kg/h IV at 60 mL/h for 2 hours** versus placebo.[270]
- In this trial, **one 2-hour infusion** produced an immediate mean ATPmax increase of about **27% in the elamipretide group vs 12% with placebo**, measured in hand muscle by 31P-MRS right after the infusion; the between-group difference was no longer evident at day 7.[269] [271] [268]

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1. https://www.alzdiscovery.org/uploads/cognitive_vitality_media/SS-31-Cognitive-Vitality-For-Researchers.pdf
2. https://www.neurology.org/doi/10.1212/WNL.0000000000005255
3. https://peptidesociety.org/_template-monographs-8/
4. https://www.sciencedirect.com/topics/medicine-and-dentistry/elamipretide
5. https://pmc.ncbi.nlm.nih.gov/articles/PMC5847870/
6. https://www.pnas.org/doi/10.1073/pnas.2002250117
7. https://www.droracle.ai/articles/437029/what-is-the-recommended-dosing-regimen-for-elamipretide-ss31
8. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/215244Orig1s000IntegratedR.pdf
9. https://www.ircm.qc.ca/en/news-detail/an-exceptional-event-treatment-for-a-rare-genetic-disorder-co-discovered-at-the-ircm-approved-by-the-fda
10. https://www.sciencedirect.com/science/article/pii/S0085253816306524
11. https://pmc.ncbi.nlm.nih.gov/articles/PMC6865061/
12. https://onlinelibrary.wiley.com/doi/pdf/10.1155/2022/1295509
13. https://www.sciencedirect.com/science/article/pii/S0142961219302649
14. https://www.authorea.com/users/603695/articles/654197-interventions-with-potential-to-mitigate-injection-site-reactions-following-subcutaneous-elamipretide-administration-a-phase-1-crossover-study
15. https://elifesciences.org/articles/55513
16. https://www.rapamycin.news/t/hazel-szeto-ss-31-and-the-worlds-first-fda-approved-mitochondria-targeted-drug-longevity-summit-2025/22586/44
17. https://pmc.ncbi.nlm.nih.gov/articles/PMC9192202/
18. https://www.paragonsportsmedicine.com/peptides/ss-31-elamipretide
19. https://peptidesociety.org/_template-monographs-4/
20. https://pmc.ncbi.nlm.nih.gov/articles/PMC6081272/
21. https://revolutionhealth.org/blogs/news/peptide-therapy-ss-31
22. https://academic.oup.com/ajhp/advance-article/doi/10.1093/ajhp/zxaf303/8316865
23. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/215244s000lbl.pdf
24. https://www.rheumatologyadvisor.com/news/forzinity-gets-accelerated-approval-for-barth-syndrome/
25. https://stealthbt.com/wp-content/uploads/Forzinity-Prescribing-Information.pdf
26. https://pmc.ncbi.nlm.nih.gov/articles/PMC7935714/

27. https://www.neurology.org/doi/10.1212/WNL.0000000000207402
28. https://www.sciencedirect.com/science/article/pii/S1098360024000716
29. https://stealthbt.com/stealth-biotherapeutics-announces-fda-accelerated-approval-of-forzinity-elamipretide-hcl-the-first-therapy-for-progressive-and-life-limiting-ultra-rare-genetic-disease-barth-syndrome/
30. https://umdf.org/fda-approves-elamipretide/
31. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2025/215244Orig1s000ltr.pdf
32. https://www.alzdiscovery.org/uploads/cognitive_vitality_media/SS-31-Cognitive-Vitality-For-Researchers.pdf
33. https://www.ircm.qc.ca/en/news-detail/an-exceptional-event-treatment-for-a-rare-genetic-disorder-co-discovered-at-the-ircm-approved-by-the-fda
34. https://www.droracle.ai/articles/437029/what-is-the-recommended-dosing-regimen-for-elamipretide-ss31
35. https://hub.jhu.edu/2025/09/25/fda-approves-barth-syndrome-treatment/
36. https://academic.oup.com/ehjcr/article/9/2/ytaf030/7966734
37. https://www.reuters.com/business/healthcare-pharmaceuticals/us-fda-cleared-pricey-rare-disease-drug-over-reviewer-objections-2025-11-05/
38. https://reference.medscape.com/drug/forzinity-elamipretide-1000077
39. https://umdf.org/forzinity-elamipretide/
40. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/215244Orig1s000IntegratedR.pdf
41. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/215244Orig1s000ChemR.pdf
42. https://pubmed.ncbi.nlm.nih.gov/37268435/
43. https://pmc.ncbi.nlm.nih.gov/articles/PMC10382259/
44. https://www.alzdiscovery.org/uploads/cognitive_vitality_media/SS-31-Cognitive-Vitality-For-Researchers.pdf
45. https://digitalcommons.library.tmc.edu/cgi/viewcontent.cgi?article=3201&context=uthmed_docs
46. https://www.neurology.org/doi/10.1212/WNL.0000000000207402
47. https://stealthbt.com/wp-content/uploads/MDA_2019_MMPOWER-3_Study_Design.pdf
48. https://mitocanada.org/wp-content/uploads/2018/11/PMM-Community-Webinar-.pdf
49. https://pubmed.ncbi.nlm.nih.gov/29500292/
50. https://www.neurologylive.com/view/despite-failure-meet-end-points-results-elamipretide-offer-further-insight-on-primary-mitochondrial-myopathy
51. https://www.lifespan.io/road-maps/the-rejuvenation-roadmap/stealth-biotherapeutics-forzinity-elamipretide-for-mitochondrial-myopathies
52. https://www.umdf.org/wp-content/uploads/2016/09/Stealth-BT-Aug-2017-Webinar-Summary-Final.pdf
53. https://onlinelibrary.wiley.com/doi/10.1002/jcsm.12559
54. https://clinicaltrials.gov/study/NCT03323749
55. https://pub.dzne.de/record/259128
56. https://pmc.ncbi.nlm.nih.gov/articles/PMC6588449/
57. https://pmc.ncbi.nlm.nih.gov/articles/PMC9562127/
58. https://www.pnas.org/doi/10.1073/pnas.2002250117

59. https://elifesciences.org/articles/55513
60. https://www.alzdiscovery.org/uploads/cognitive_vitality_media/SS-31-Cognitive-Vitality-For-Researchers.pdf
61. https://pmc.ncbi.nlm.nih.gov/articles/PMC7432581/
62. https://pubmed.ncbi.nlm.nih.gov/37268435/
63. https://pmc.ncbi.nlm.nih.gov/articles/PMC10382259/
64. https://clinicaltrials.gov/study/NCT07275424
65. https://www.nad.com/news/mitochondrial-drug-elamipretide-reverses-muscle-and-heart-aging-new-study-reveals
66. https://onlinelibrary.wiley.com/doi/10.1111/acel.70026
67. https://www.neurology.org/doi/10.1212/WNL.0000000000207402
68. https://www.biorxiv.org/content/10.1101/2022.11.29.518431v1.full-text
69. https://www.sciencedirect.com/science/article/abs/pii/S0891584918322561
70. https://www.innerbody.com/ss-31-peptide
71. https://www.institut-myologie.org/en/2023/08/31/primary-mitochondrial-myopathies-elamipretide-is-well-tolerated-but-does-not-improve-the-6-minute-walk-test-or-fatigue/
72. https://www.lifespan.io/news/elamipretide-a-potential-new-drug-reduces-frailty-in-mice/
73. https://www.nature.com/articles/s41598-022-24231-4
74. https://www.neurology.org/doi/pdfdirect/10.1212/WNL.0000000000207402
75. https://digitalcommons.library.tmc.edu/cgi/viewcontent.cgi?article=3201&context=uthmed_docs
76. https://pubmed.ncbi.nlm.nih.gov/37268435/
77. https://www.neurology.org/doi/10.1212/WNL.0000000000207402
78. https://digitalcommons.library.tmc.edu/cgi/viewcontent.cgi?article=3201&context=uthmed_docs
79. https://pure.amsterdamumc.nl/en/publications/efficacy-and-safety-of-elamipretide-in-individuals-with-primary-m
80. https://onlinelibrary.wiley.com/doi/10.1002/jcsm.12559
81. https://www.neurology.org/doi/pdfdirect/10.1212/WNL.0000000000207402
82. https://pubmed.ncbi.nlm.nih.gov/32096613/
83. https://clinicaltrials.gov/study/NCT05162768
84. https://pmc.ncbi.nlm.nih.gov/articles/PMC5890606/
85. https://stealthbt.com/wp-content/uploads/karaa-neurology-spimm-201.pdf
86. https://clinicaltrials.ucsd.edu/trial/NCT05162768
87. https://publires.unicatt.it/en/publications/efficacy-and-safety-of-elamipretide-in-individuals-with-primary-m
88. https://epub.ub.uni-muenchen.de/117220/
89. https://epub.ub.uni-muenchen.de/117220/1/WNL.0000000000207402.pdf
90. https://stealthbt.com/wp-content/uploads/MDA_2019_MMPOWER-3_Study_Design.pdf
91. https://www.institut-myologie.org/en/2023/08/31/primary-mitochondrial-myopathies-elamipretide-is-well-tolerated-but-does-not-improve-the-6-minute-walk-test-or-fatigue/

92. https://www.neurologylive.com/view/despite-failure-meet-end-points-results-elamipretide-offer-further-insight-on-primary-mitochondrial-myopathy
93. https://pmc.ncbi.nlm.nih.gov/articles/PMC10382259/
94. https://pmc.ncbi.nlm.nih.gov/articles/PMC7432581/
95. https://pmc.ncbi.nlm.nih.gov/articles/PMC9192202/
96. https://journals.plos.org/plosone/article?id=10.1371%2Fjournal.pone.0253849
97. https://go.drugbank.com/drugs/DB11981
98. https://journals.physiology.org/doi/full/10.1152/ajpcell.00407.2025
99. https://pmc.ncbi.nlm.nih.gov/articles/PMC4743543/
100. https://stealthbt.com/wp-content/uploads/CIRCHEARTFAILURE.115.002206.pdf
101. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/215244Orig1s000IntegratedR.pdf
102. https://www.paragonsportsmedicine.com/peptides/ss-31-elamipretide
103. https://www.nature.com/articles/s41598-017-10320-2
104. https://pmc.ncbi.nlm.nih.gov/articles/PMC6075532/
105. https://revolutionhealth.org/blogs/news/peptide-therapy-ss-31
106. https://www.neurology.org/doi/10.1212/WNL.0000000000005255
107. https://www.sciencedirect.com/science/article/pii/S0753332225002501
108. https://www.sciencedirect.com/science/article/abs/pii/S1567724924000047
109. https://www.sciencedirect.com/science/article/pii/S2452302X19300051
110. https://pmc.ncbi.nlm.nih.gov/articles/PMC9388406/
111. https://pubmed.ncbi.nlm.nih.gov/35707274/
112. https://pmc.ncbi.nlm.nih.gov/articles/PMC7334473/
113. https://pmc.ncbi.nlm.nih.gov/articles/PMC7377906/
114. https://www.alzdiscovery.org/uploads/cognitive_vitality_media/SS-31-Cognitive-Vitality-For-Researchers.pdf
115. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/215244s000lbl.pdf
116. https://publications.aap.org/pediatriccare/drug-monograph/18/11063/Elamipretide
117. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2025/215244Orig1s000ltr.pdf
118. https://www.webmd.com/drugs/2/drug-502169/forzinity-elamipretide/details
119. https://reference.medscape.com/drug/forzinity-elamipretide-1000077
120. https://www.medkoo.com/products/6723
121. https://www.innerbody.com/ss-31-peptide
122. https://happypeptides.com/blogs/peptide-research/a-researchers-guide-to-ss-31-elamipretide-a-mitochondria-targeting-peptide-for-in-vitro-studies
123. https://pmc.ncbi.nlm.nih.gov/articles/PMC7368046/
124. https://peptidecrafters.com/8-week-stability-study-of-a-glp-1-post-reconstitution/
125. https://pmc.ncbi.nlm.nih.gov/articles/PMC11816484/
126. https://pmc.ncbi.nlm.nih.gov/articles/PMC7247319/
127. https://www.biorxiv.org/content/10.1101/2024.10.30.620676v1.full.pdf

128. https://revolutionhealth.org/blogs/news/peptide-therapy-ss-31
129. https://pmc.ncbi.nlm.nih.gov/articles/PMC11565897/
130. https://happyhormonesmd.com/wp-content/uploads/2024/12/SS-31-Patient-Information.docx.pdf
131. https://www.prnewswire.com/news-releases/stealth-biotherapeutics-announces-fda-accelerated-approval-of-forzinity-elamipretide-hcl-the-first-therapy-for-progressive-and-life-limiting-ultra-rare-genetic-disease-barth-syndrome-302562058.html
132. https://www.pnas.org/doi/10.1073/pnas.2002250117
133. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/215244Orig1s000IntegratedR.pdf
134. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/215244Orig1s000ChemR.pdf
135. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/215244s000lbl.pdf
136. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/215244Orig1s000Approv.pdf
137. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/215244Orig1s000OtherR.pdf
138. https://www.webmd.com/drugs/2/drug-502169/forzinity-elamipretide/details
139. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/215244Orig1s000ChemR.pdf
140. https://www.benchchem.com/pdf/Preventing_Elamipretide_TFA_degradation_in_solution.pdf
141. https://www.medkoo.com/products/6723
142. https://happypeptides.com/blogs/peptide-research/a-researchers-guide-to-ss-31-elamipretide-a-mitochondria-targeting-peptide-for-in-vitro-studies
143. https://pmc.ncbi.nlm.nih.gov/articles/PMC11816484/
144. https://www.pnas.org/doi/10.1073/pnas.2002250117
145. https://globalgenes.org/raredaily/stealth-resubmits-application-to-fda-for-approval-of-barth-syndrome-drug/
146. https://pmc.ncbi.nlm.nih.gov/articles/PMC12164653/
147. https://www.sciencedirect.com/science/article/pii/S0969996123000360
148. https://www.sciencedirect.com/science/article/pii/S1098360024000716
149. https://stealthbt.com/stealth-biotherapeutics-announces-fda-accelerated-approval-of-forzinity-elamipretide-hcl-the-first-therapy-for-progressive-and-life-limiting-ultra-rare-genetic-disease-barth-syndrome/
150. https://stealthbt.com/wp-content/uploads/Forzinity-Prescribing-Information.pdf
151. https://www.nature.com/articles/s41598-022-24231-4
152. https://www.clinicaltrials.gov/study/NCT05162768
153. https://pmc.ncbi.nlm.nih.gov/articles/PMC11565897/
154. https://www.sciencedirect.com/science/article/abs/pii/S0731708518303698
155. https://reference.medscape.com/drug/forzinity-elamipretide-1000077
156. https://pmc.ncbi.nlm.nih.gov/articles/PMC7368046/
157. https://pubmed.ncbi.nlm.nih.gov/37268435/
158. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/215244Orig1s000IntegratedR.pdf
159. https://clinicaltrials.gov/study/NCT03323749
160. https://stealthbt.com/wp-content/uploads/MDA_2019_MMPOWER-3_Study_Design.pdf
161. https://www.sciencedirect.com/science/article/pii/S1098360024000716

162. https://pmc.ncbi.nlm.nih.gov/articles/PMC10382259/
163. https://www.nature.com/articles/s41436-020-01006-8
164. https://pmc.ncbi.nlm.nih.gov/articles/PMC9388406/
165. https://www.fda.gov/media/182608/download
166. https://www.neurology.org/doi/10.1212/WNL.0000000000207402
167. https://www.clinicaltrials.gov/study/NCT03098797
168. https://www.lifespan.io/road-maps/the-rejuvenation-roadmap/stealth-biotherapeutics-forzinity-elamipretide-for-mitochondrial-myopathies
169. https://www.clinicaltrialsarena.com/projects/forzinity-elamipretide-for-muscle-strength-in-barth-syndrome-usa/
170. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/215244s000lbl.pdf
171. https://academic.oup.com/ehjcr/article/9/2/ytaf030/7966734
172. https://pubmed.ncbi.nlm.nih.gov/41260682/
173. https://stealthbt.com/stealth-biotherapeutics-announces-fda-accelerated-approval-of-forzinity-elamipretide-hcl-the-first-therapy-for-progressive-and-life-limiting-ultra-rare-genetic-disease-barth-syndrome/
174. https://stealthbt.com/wp-content/uploads/ASHG-2019-TAZPOWER-36w-OLE-Results-Final-Slides.pdf
175. https://www.neurologylive.com/view/despite-failure-meet-end-points-results-elamipretide-offer-further-insight-on-primary-mitochondrial-myopathy
176. https://www.prnewswire.com/news-releases/last-patient-completes-treatment-in-stealth-biotherapeutics-phase-2-geographic-atrophy-clinical-trial-301481918.html
177. https://www.sciencedirect.com/science/article/pii/S1098360024000716
178. https://www.fda.gov/media/182608/download
179. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/215244Orig1s000OtherR.pdf
180. https://www.nature.com/articles/s41436-020-01006-8
181. https://stealthbt.com/wp-content/uploads/ACC_2020_TAZPOWER-Poster_Print-at-97_Final-002.pdf
182. https://www.clinicaltrialsarena.com/projects/forzinity-elamipretide-for-muscle-strength-in-barth-syndrome-usa/
183. https://pubmed.ncbi.nlm.nih.gov/38602181/
184. https://pubmed.ncbi.nlm.nih.gov/36056411/
185. https://pubmed.ncbi.nlm.nih.gov/33077895/
186. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/215244Orig1s000IntegratedR.pdf
187. https://www.thecardiologyadvisor.com/news/stealth-seeks-accelerated-approval-for-elamipretide-in-barth-syndrome/
188. https://clinicaltrials.gov/study/NCT03098797
189. https://www.rheumatologyadvisor.com/news/forzinity-gets-accelerated-approval-for-barth-syndrome/
190. https://www.neurology.org/doi/pdfdirect/10.1212/WNL.0000000000207402
191. https://umdf.org/fda-approves-elamipretide/
192. https://www.ircm.qc.ca/en/news-detail/an-exceptional-event-treatment-for-a-rare-genetic-disorder-co-discovered-at-the-ircm-approved-by-the-fda

193. https://stealthbt.com/stealth-biotherapeutics-announces-mito-assist-patient-support-program-and-specialty-pharmacy-partnership-with-anovorx-to-distribute-forzinityelamipretide-injection/
194. https://stealthbt.com/science-pipeline/
195. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/215244Orig1s000RiskR.pdf
196. https://www.neurology.org/doi/10.1212/WNL.0000000000207402
197. https://pmc.ncbi.nlm.nih.gov/articles/PMC10382259/
198. https://www.sciencedirect.com/science/article/pii/S1098360024000716
199. https://www.neurology.org/doi/10.1212/WNL.0000000000005255
200. https://pmc.ncbi.nlm.nih.gov/articles/PMC7432581/
201. https://pmc.ncbi.nlm.nih.gov/articles/PMC9388406/
202. https://www.nature.com/articles/s41436-020-01006-8
203. https://pmc.ncbi.nlm.nih.gov/articles/PMC8282018/
204. https://journals.plos.org/plosone/article?id=10.1371%2Fjournal.pone.0253849
205. https://www.biorxiv.org/content/10.1101/2024.10.30.620676v1.full.pdf
206. https://www.sciencedirect.com/science/article/pii/S2452302X25002979
207. https://stealthbt.com/wp-content/uploads/karaa-neurology-spimm-201.pdf
208. https://pmc.ncbi.nlm.nih.gov/articles/PMC11583740/
209. https://onlinelibrary.wiley.com/doi/10.1002/jcsm.12559
210. https://pubmed.ncbi.nlm.nih.gov/37268435/
211. https://academic.oup.com/ehjcr/article/9/2/ytaf030/7966734
212. https://www.rheumatologyadvisor.com/news/fda-extends-review-of-elamipretide-for-barth-syndrome/
213. https://stealthbt.com/wp-content/uploads/MDA_2019_MMPOWER-3_Study_Design.pdf
214. https://clinicaltrials.gov/study/NCT03323749
215. https://digitalcommons.library.tmc.edu/cgi/viewcontent.cgi?article=3201&context=uthmed_docs
216. https://stealthbt.com/wp-content/uploads/UMDF_2019_TAZPOWER_Study_Design.pdf
217. https://pmc.ncbi.nlm.nih.gov/articles/PMC5890606/
218. https://www.neurology.org/doi/10.1212/WNL.0000000000005255
219. https://pubmed.ncbi.nlm.nih.gov/38602181/
220. https://stealthbt.com/wp-content/uploads/UMDF_2019_TAZPOWER_Cardiolipin_Ratio_Results.pdf
221. https://www.fda.gov/media/182609/download
222. https://pmc.ncbi.nlm.nih.gov/articles/PMC8282018/
223. https://journals.plos.org/plosone/article?id=10.1371%2Fjournal.pone.0253849
224. https://pubmed.ncbi.nlm.nih.gov/37268435/
225. https://pmc.ncbi.nlm.nih.gov/articles/PMC10382259/
226. https://www.sciencedirect.com/science/article/pii/S1098360024000716
227. https://www.nature.com/articles/s41436-020-01006-8
228. https://www.fda.gov/media/182608/download
229. https://pmc.ncbi.nlm.nih.gov/articles/PMC9388406/
230. https://stealthbt.com/wp-content/uploads/karaa-neurology-spimm-201.pdf

231. https://pmc.ncbi.nlm.nih.gov/articles/PMC11816484/
232. https://cdn.clinicaltrials.gov/large-docs/97/NCT03098797/Prot_SAP_000.pdf
233. https://stealthbt.com/mmpower-data-published-neurology/
234. https://onlinelibrary.wiley.com/doi/10.1002/jcsm.12559
235. https://www.sciencedirect.com/science/article/pii/S1878747923010231
236. https://www.fiercebiotech.com/biotech/stealth-stumbles-again-age-related-macular-degeneration-joins-list-clinical-trial-flops
237. https://pure.johnshopkins.edu/en/publications/long-term-efficacy-and-safety-of-elamipretide-in-patients-with-ba
238. https://onlinelibrary.wiley.com/doi/full/10.1002%2Fjimd.12281
239. https://www.institut-myologie.org/en/2023/08/31/primary-mitochondrial-myopathies-elamipretide-is-well-tolerated-but-does-not-improve-the-6-minute-walk-test-or-fatigue/
240. https://www.umdf.org/wp-content/uploads/2016/09/Stealth-BT-Aug-2017-Webinar-Summary-Final.pdf
241. https://www.neurology.org/doi/10.1212/WNL.0000000000005255
242. https://pubmed.ncbi.nlm.nih.gov/38602181/
243. https://pmc.ncbi.nlm.nih.gov/articles/PMC8282018/
244. https://journals.plos.org/plosone/article?id=10.1371%2Fjournal.pone.0253849
245. https://stealthbt.com/wp-content/uploads/UMDF_2019_TAZPOWER_Cardiolipin_Ratio_Results.pdf
246. https://www.fda.gov/media/182609/download
247. https://pmc.ncbi.nlm.nih.gov/articles/PMC5890606/
248. https://pubmed.ncbi.nlm.nih.gov/15800038/
249. https://pmc.ncbi.nlm.nih.gov/articles/PMC556267/
250. https://academic.oup.com/biomedgerontology/article/68/4/447/536072
251. https://www.sciencedirect.com/science/article/pii/S0003269717300398
252. https://pmc.ncbi.nlm.nih.gov/articles/PMC8282018/
253. https://journals.plos.org/plosone/article?id=10.1371%2Fjournal.pone.0253849
254. https://www.sciencedirect.com/science/article/pii/S0002916523239623
255. https://www.nature.com/articles/s41467-021-24956-2
256. https://pmc.ncbi.nlm.nih.gov/articles/PMC8243949/
257. https://journals.plos.org/plosone/article?id=10.1371%2Fjournal.pone.0037237
258. https://pmc.ncbi.nlm.nih.gov/articles/PMC3201762/
259. https://www.mriquestions.com/uploads/3/4/5/7/34572113/mitochondria.pdf
260. https://analyticalsciencejournals.onlinelibrary.wiley.com/doi/full/10.1002/nbm.5031
261. https://www.frontiersin.org/journals/physiology/articles/10.3389/fphys.2020.00644/full
262. https://pubmed.ncbi.nlm.nih.gov/34264994/
263. https://www.pnas.org/doi/10.1073/pnas.93.26.15364
264. https://touroscholar.touro.edu/sjlcas/vol12/iss2/10/
265. https://journals.plos.org/plosone/article/figures?id=10.1371%2Fjournal.pone.0253849
266. https://stealthbt.com/wp-content/uploads/HFSA-2016_Conley-Poster.pdf

267. https://www.clinicaltrials.gov/study/NCT02245620
268. https://journals.plos.org/plosone/article?id=10.1371%2Fjournal.pone.0253849
269. https://pmc.ncbi.nlm.nih.gov/articles/PMC8282018/
270. https://www.clinicaltrials.gov/study/NCT02245620
271. https://journals.plos.org/plosone/article/figures?id=10.1371%2Fjournal.pone.0253849
272. https://stealthbt.com/wp-content/uploads/CIRCHEARTFAILURE.115.002206.pdf
273. https://pubmed.ncbi.nlm.nih.gov/29500292/
274. https://www.alzdiscovery.org/uploads/cognitive_vitality_media/SS-31-Cognitive-Vitality-For-Researchers.pdf
275. https://stealthbt.com/wp-content/uploads/SPIMM-202-MDA-poster.pdf
276. https://go.gale.com/ps/i.do?id=GALE|A668604104&sid=sitemap&v=2.1&it=r&p=HRCA&sw=w
277. https://sites.uw.edu/marcinek/research-2/translational-science/
278. https://www.sec.gov/Archives/edgar/data/1696396/000119312519029051/d587168df1a.htm
279. https://www.biorxiv.org/content/10.1101/2024.10.30.620676v1.full.pdf
280. https://pmc.ncbi.nlm.nih.gov/articles/PMC8692774/
281. https://pubmed.ncbi.nlm.nih.gov/34264994/
282. https://stealthbt.com/wp-content/uploads/HFSA-2016_Conley-Poster.pdf
283. https://pmc.ncbi.nlm.nih.gov/articles/PMC4743543/
284. https://pmc.ncbi.nlm.nih.gov/articles/PMC5890606/
285. https://www.neurology.org/doi/10.1212/WNL.0000000000005255