

Melanotan I (Afamelanotide) — Research Summary

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1. What It Is

Melanotan I (afamelanotide) is a linear 13-amino-acid analog of alpha-melanocyte-stimulating hormone (α -MSH), selective for the MC1R receptor on skin melanocytes, with limited central nervous system activity at approved doses.

Unlike Melanotan II, afamelanotide IS an FDA-approved prescription drug (brand name Scenesse), approved in October 2019 specifically for adults with erythropoietic protoporphyria (EPP) to increase pain-free light exposure, delivered via a controlled-release subcutaneous implant — not injected as a research peptide.

2. Reported Effects in Research Literature

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- Human data: The pivotal randomized controlled trial (published in NEJM) found EPP patients receiving afamelanotide accumulated a median 69.4 pain-free hours in direct sunlight versus 40.8 hours on placebo.
- Human data: A 2021 review (Wensink et al., Expert Review of Clinical Pharmacology) summarizes the Phase III RCT evidence base (studies CUV029, CUV030, CUV039) supporting the FDA approval.

3. Clinical & Preclinical Study References

Langendonk JG, et al. Afamelanotide for erythropoietic protoporphyria. N Engl J Med. 2015.

Wensink D, Wagenmakers M, et al. Afamelanotide focused review of Phase III evidence. Expert Rev Clin Pharmacol. 2021.

Kim ES, Garnock-Jones KP. Afamelanotide drug review. Am J Clin Dermatol. 2016.

Regulatory/Safety Note: Afamelanotide (Scenesse) is FDA-approved ONLY as a prescription implant for EPP phototoxicity — not for cosmetic tanning. Research-labeled "Melanotan I" material sold outside that approved implant is not the approved product and is not covered by that approval.

This compound has not been evaluated by the FDA and is not intended to diagnose, treat, cure, or prevent any disease in humans or animals.

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