

ARA-290 (Cibinetide) — Research Summary

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1. What It Is

ARA-290 (cibinetide) is an 11-amino-acid synthetic peptide derived from the helix-B surface of erythropoietin (EPO), engineered to activate the "innate repair receptor" (IRR) — a heteromer distinct from the classical EPO receptor that drives red-blood-cell production — without stimulating erythropoiesis.

2. Reported Effects in Research Literature

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- Animal data: In a rat spared-nerve-injury model, ARA-290 dose-dependently reduced mechanical and cold allodynia for up to 20 weeks, coupled with suppressed spinal microglia (Iba-1) and astrocyte (GFAP) activation.
- Human data: A randomized, double-blind pilot study in sarcoidosis patients with small-fiber neuropathy found ARA-290 improved neuropathic symptoms.
- Human data: A Phase 2b randomized trial in 64 patients with sarcoidosis-associated small-nerve-fiber loss met its pre-specified primary endpoint, showing increased corneal nerve fiber area (an objective marker of nerve regeneration) versus placebo over 28 days.
- Human data: A published study in type 2 diabetes patients found daily subcutaneous ARA-290 for 28 days improved HbA1c, lipid profiles, and neuropathic symptoms, with increased corneal nerve fiber density.

3. Clinical & Preclinical Study References

Swartjes M, et al. ARA 290 produces long-term relief of neuropathic pain coupled with suppression of the spinal microglia response. *Mol Pain*. 2014;10:13. PMID: 24529189

Dahan A, et al. Safety and Efficacy of ARA 290 in Sarcoidosis Patients with Symptoms of Small Fiber Neuropathy: A Randomized, Double-Blind Pilot Study. *Mol Med*. PMID: 23168581

Culver DA, et al. Cibinetide Improves Corneal Nerve Fiber Abundance in Patients With Sarcoidosis-Associated Small Nerve Fiber Loss and Neuropathic Pain. *Invest Ophthalmol Vis Sci*. 2017.

Brines M, et al. ARA 290 improves metabolic control and neuropathic symptoms in patients with type 2 diabetes. *Mol Med*. PMID: 25387363

Regulatory/Safety Note: Development stalled following the closure of Araim Pharmaceuticals; no Phase 3 trials were initiated and ARA-290 is not legally marketed for human use anywhere.

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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