

TB-500 — Research Summary

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1. What It Is

TB-500 is a synthetic peptide fragment corresponding to the actin-binding region of thymosin beta-4 (Tβ4), a 43-amino-acid protein naturally present in nearly all human cells at high concentration in platelets and healing tissue. Commercial sources describe the fragment inconsistently — most commonly as the 7-residue sequence Ac-LKKTETQ, though some describe a longer 17-residue N-acetylated fragment (Ac-LKKTETQ-OH); this naming inconsistency itself is worth noting in documentation.

Mechanism: Acts as a G-actin-sequestering peptide, promoting cell migration, angiogenesis, and reduced myofibroblast formation (associated with reduced scarring) in wound-healing models. Also reported to activate integrin-linked kinase (ILK) via the Akt pathway in cardiac repair models.

2. Reported Effects in Research Literature

Most TB-500 evidence comes from animal and cell studies; the strongest human trial data uses the full-length Tβ4 protein in a topical eye-drop formulation (RGN-259), not the injected TB-500 fragment specifically.

- Foundational animal data: Malinda et al. (1999) found topical or intraperitoneal Tβ4 increased skin re-epithelialization by 42% at day 4 and up to 61% at day 7 versus controls.
- Philp, Badamchian, Scheremeta, et al. (2003) found Tβ4 and a synthetic peptide containing its actin-binding domain accelerated wound closure in impaired-healing models, including diabetic (db/db) and aged mice.
- Cardiac repair (animal): Bock-Marquette et al. (2004, Nature) found Tβ4 promotes cardiac repair by mobilizing epicardial progenitor cells contributing to neovascularization and myocardial regeneration after infarction.
- Human data (full-length Tβ4, not TB-500 fragment): A Phase 2 randomized trial of topical Tβ4 (RGN-259) in 72 subjects found a 59% reduction in corneal staining and 35% reduction in ocular discomfort in dry eye disease.
- A separate Phase 2 randomized trial (Sosne, Dunn, Kim, 2015) found Tβ4 significantly improved signs and symptoms of severe dry eye.
- Human data (recent, 2025): A Stem Cell Reports study used human brain organoids to examine Tβ4 as a potential Alzheimer's disease intervention target — mechanistic, not a treatment trial.
- A 2024 biochemical study proposed that TB-500's wound-healing activity may actually derive from one of its metabolites (Ac-LKKTE) rather than the parent fragment itself — a mechanistic nuance affecting how the compound should be understood, not yet resolved in human data.
- No completed, published randomized controlled human trial exists for the TB-500 fragment specifically (as opposed to full-length Tβ4) for any musculoskeletal or tissue-repair indication.
- PCAC/FDA update: The FDA published a Federal Register notice (April 16, 2026) listing TB-500 (free base and acetate forms) for review at the July 23, 2026 Pharmacy Compounding Advisory Committee meeting; PCAC voted 8–6 (one abstention) to recommend inclusion on the 503A Bulk Drug Substances List, overriding FDA staff's recommendation against inclusion. This is non-binding advisory only. TB-500/thymosin-beta-4-class peptides are on the WADA Prohibited List.

3. Clinical & Preclinical Study References

Malinda KM, Sidhu GS, Mani H, et al. "Thymosin beta4 accelerates wound healing." J Invest Dermatol. 1999;113(3):364-8. PMID: 10469335

Philp D, Badamchian M, Scheremeta B, et al. "Thymosin beta 4 and a synthetic peptide containing its actin-binding domain promote dermal wound repair in db/db diabetic mice and in aged mice." Wound Repair Regen. 2003;11(1):19-24. PMID: 12581422

Bock-Marquette I, et al. Tβ4 mobilizes epicardial progenitor cells for cardiac repair. Nature. 2004.

Sosne G, Dunn SP, Kim C. "Thymosin β4 Significantly Improves Signs and Symptoms of Severe Dry Eye in a Phase 2 Randomized Trial." Cornea. 2015;34:491-496.

Scoping review: "Thymosin Beta-4 and TB-500 in Tissue Healing, Regeneration, and Musculoskeletal Repair." 2026.

Xing Y, et al. "Thymosin beta 4 as an Alzheimer disease intervention target identified using human brain organoids." Stem Cell Reports. 2025. PMID: 40816274

Regulatory/Safety Note: TB-500 is not approved by the FDA for any indication and is under active FDA compounding-list review (July 2026 PCAC). Full-length thymosin beta-4 clinical trial data (RGN-259 dry-eye trials) should not be conflated with TB-500 fragment-specific evidence.

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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