



TRexBio Doses First Participant in Phase 1 Trial of TRB-061, a Novel TNFR2 Agonist for Atopic Dermatitis and Other Inflammatory Diseases

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- *Safety, pharmacokinetic, and pharmacodynamic data from healthy volunteers anticipated in 1H 2026*
- *Designed to activate and expand tissue regulatory T cells (Tregs) without stimulating effector or innate immune cells, TRB-061 offers a potential new approach to immune modulation without broad immunosuppression*

South San Francisco, Calif., June 3, 2025 – TRex Bio, Inc. (“TRexBio”), a clinical-stage biotechnology company decoding human tissue immune biology to create revolutionary therapeutics, today announced that it has initiated dosing of healthy volunteers in its first clinical trial for TRB-061, a novel TNFR2 agonist initially being developed for the treatment of atopic dermatitis (AD).

“We believe TRB-061 has the potential to be a best-in-class therapy with multi-indication application,” said Johnston Erwin, Chief Executive Officer of TRexBio. “Advancing TRB-061 into clinical development marks a significant milestone for the company and an important step in addressing the significant unmet needs of patients with atopic dermatitis and other inflammatory diseases.”

The randomized, double-blind, placebo-controlled Phase 1a study will assess the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of single ascending doses of TRB-061 administered subcutaneously in healthy adult volunteers (Clinicaltrials.gov Identifier: [NCT06934252](https://clinicaltrials.gov/ct2/show/study/NCT06934252)). The study includes assessments of blood-based biomarkers to establish early proof of mechanism. Following completion of the Phase 1a study, TRexBio plans to initiate a Phase 1b proof-of-concept trial in patients with moderate-to-severe AD.

“Despite approved treatments, many patients with atopic dermatitis experience inadequate relief of symptoms and troublesome side effects, highlighting the need for new mechanisms of action,” said Ariella Kelman, M.D., Chief Medical Officer of TRexBio. “TRB-061 is designed to modulate immune balance at the tissue level and may offer improved disease control and tolerability.”

About TRB-061 and TNFR2

TRB-061 is a novel TNFR2-selective agonist designed to activate and expand effector Tregs in the tissue and restore immune balance in inflammatory diseases. TNFR2 is an immune-regulatory receptor highly expressed on Tregs in barrier tissues such as skin and gut. In diseases like atopic dermatitis, impaired Treg function in diseased tissues contributes to chronic inflammation. TRexBio’s Deep Biology platform identified TRB-061 for AD through high-resolution transcriptomic mapping and ex vivo validation of TNFR2-driven Treg activity in AD lesions. TRB-061 selectively activates TNFR2 signaling in Tregs, without stimulating other immune cells including natural killer cells, effector T cells, or macrophages. In preclinical models, the selective activity of TRB-061 translated to potent expansion of effector Tregs in blood and tissue without any unwanted immune activation. These data support TRB-061’s potential as a tissue-targeted, disease-modifying therapy to selectively restore immune balance, where local immune dysregulation drives chronic inflammation.

About Atopic Dermatitis

Atopic dermatitis (AD), also known as eczema, is a chronic inflammatory skin disease characterized by rash, itching, and skin barrier dysfunction. It affects up to 20% of children and 10% of adults, affecting approximately 204 million worldwide. In moderate-to-severe cases, AD is associated with systemic immune activation, extensive body surface area involvement, and substantial quality-of-life impairment.

About TRexBio

TRexBio is a clinical-stage biotechnology company discovering and developing immunoregulatory medicines based on tissue Treg biology by leveraging cutting-edge computational biology tools, a focus on human tissue, and deep immunobiology expertise. The company’s Deep Biology platform maps human tissue Treg behavior to disease processes to identify and characterize novel targets for therapeutic intervention. This platform has yielded multiple development candidates with first-in-class and best-in-class potential across a range of autoimmune and inflammatory diseases. TRexBio is headquartered in South San Francisco, California. For more info, visit www.trex.bio.

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