



TRexBio Announces Positive Topline Results from First-in-Human Phase 1a Study of TRB-061, a TNFR2 Agonist in Clinical Development for Atopic Dermatitis

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- *TRB-061 is an investigational TNFR2 agonist with the potential to address a range of immune-mediated diseases*
- *Unblinded single- and multiple-dose results in healthy participants showed consistent pharmacokinetics and reproducible activation and expansion of immunoregulatory Tregs, supporting proof of mechanism for TRB-061*
- *TRB-061 was generally well tolerated across all dose levels, with no treatment-related serious adverse events or dose-limiting toxicities observed*
- *Results support dose selection for the ongoing Phase 1b trial in patients with moderate-to-severe atopic dermatitis, with topline data expected in mid-2027*

SOUTH SAN FRANCISCO, Calif., August 26, 2026 – TRex Bio, Inc.

(“TRexBio”), a clinical-stage biotechnology company focused on tissue Treg biology for the discovery and development of immunoregulatory medicines, today announced unblinded topline results from the first-in-human Phase 1a portion of its ongoing Phase 1a/b clinical trial of TRB-061. Across the single (“SAD”) and multiple (“MAD”) ascending dose cohorts, TRB-061 was generally well tolerated and showed consistent pharmacokinetics. In addition, following single and multiple dose administration of TRB-061, selective, reproducible activation and expansion of exploratory biomarkers including regulatory T cells (“Tregs”) was observed, supporting proof of mechanism and dose selection for the ongoing Phase 1b trial in patients with moderate-to-severe atopic dermatitis.

“This is an important milestone for TRexBio, and we are pleased to report these Phase 1a results demonstrating that TRB-061 was generally well tolerated and showed the potential to selectively activate and expand immunoregulatory Tregs in humans,” said Johnston Erwin, Chief Executive Officer of TRexBio. “These results strengthen our confidence that TRB-061 has the potential to restore immune balance and promote tissue repair in patients with atopic dermatitis and other immune mediated diseases.”

The randomized, double-blind, placebo-controlled Phase 1a portion of the trial

was designed to evaluate the safety, tolerability, pharmacokinetics (“PK”), and pharmacodynamics (“PD”) of subcutaneously delivered TRB-061 in healthy adults. In each of the SAD and MAD portions of the trial, four cohorts of healthy volunteers were randomized 6:2 to receive a single dose or multiple doses of TRB-061 or placebo, administered in the MAD portion every four weeks for three doses. In 65 healthy adult participants, TRB-061 was generally well tolerated across all dose levels, with no treatment-related serious adverse events, dose-limiting toxicities, or treatment-related discontinuations observed. All treatment-emergent adverse events were mild or moderate.

TRB-061 showed an approximately dose-proportional PK profile. Single and multiple doses showed increases in Tregs, including CD39-positive Tregs, a population associated with immunoregulatory activity, and induction of key immunoregulatory biomarkers such as IL-10 and CCR8, with a profile supportive of dosing every four weeks or longer. The combined safety, PK, and PD results support selection of the 24 and 50 mg dose levels being evaluated in the ongoing Phase 1b portion of the trial. The Phase 1b trial is assessing safety, PK, PD biomarkers in blood and skin, and exploratory measures of clinical activity in adults with moderate-to-severe atopic dermatitis. Topline results are expected in mid-2027.

About TRB-061

TRB-061 is a novel, selective, investigational TNFR2 agonist designed to activate and expand Tregs in inflamed tissues and restore immune balance without stimulating unwanted immune cells. TNFR2 is a crucial regulator of immune homeostasis, supporting tissue repair and counteracting inflammation. Defects in TNFR2 signaling are linked to multiple autoimmune and inflammatory diseases. Selective agonism of TNFR2 by TRB-061 may represent a new therapeutic approach for long-term inflammatory disease control. TRB-061 is currently being evaluated in a randomized, double-blind, placebo-controlled Phase 1b study in patients with moderate-to-severe AD. The study includes exploratory PD endpoints assessing Treg expansion in blood and skin, as well as clinical assessments of disease activity.

About TRexBio

TRexBio is a clinical-stage biotechnology company focused on tissue Treg biology for the discovery and development of immunoregulatory medicines designed to restore immune balance and promote tissue repair to address

unmet needs of patients with autoimmune and inflammatory diseases. The Company's Deep Biology platform decodes Treg functionality in human tissue, mapping key drivers of immune dysregulation and uncovering novel targets and insights that inform drug discovery and translational efforts. This platform has generated multiple therapeutic development candidates across TRexBio's wholly owned pipeline and through collaborations with leading pharmaceutical partners. TRexBio is led by an experienced management team and headquartered in South San Francisco, California. For more information, visit www.trex.bio.

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