NB-015: Topical JAK1/Tyk2 Dual Inhibitor for Atopic Dermatitis

NAVIKA BIO

Targets both the TH2 and TH1 pathways, the primary drivers of AD pathology. This differentiated dual-inhibitor approach is designed to deliver broader and more durable therapeutic response than single-pathway agents.

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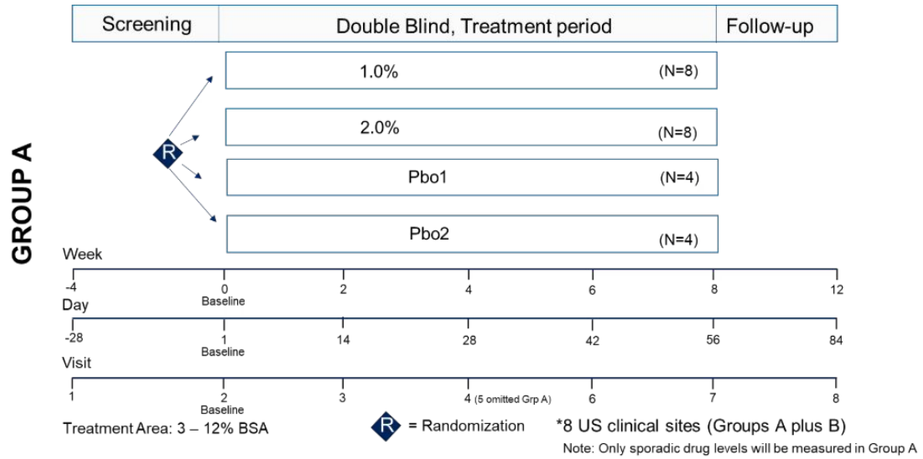

Study Design

Phase	Phase 2, Randomized, Double-Blind, Placebo-Controlled study with open-label PK sub-study
Sites	Multicenter (USA)
Population	Male/female patients ≥18 years with mild-to-moderate AD (m-EASI score 5–16; AD history ≥2 years).
Treatment	Daily topical application for 16 weeks
PK Cohort	Open-label PK cohort: 6 patients treated with NB-015 2.0%

Efficacy

- Positive dose response demonstrated on the registration secondary endpoint (vIGA-AD 0/1 with ≥2-point improvement)
- m-EASI-75/90 clearly achieved in both active treatment groups at Week 8
- BSA improvement clearly achieved in the high-strength 2% group
- Itch (WI-NRS) improvement noted in the 2% NB-015 group
- m-EASI improvement time course most pronounced in the 2% high-strength group across Weeks 2, 4, 6, and 8

Safety

- Well-tolerated overall
- TEAEs: 1 patient on placebo withdrew due to flare at application sites
- No SAEs reported in any group
- No significant Local Site Reaction signal in actives vs. placebo
- No clinically significant changes in lab tests (chemistry, hematology, urinalysis) or vital signs
- No ECG trends suggesting treatment-related changes

Pharmacokinetics

- Limited systemic exposure — favorable for treatment of larger BSA
- Only 2 of 6 patients in the OL 2% cohort (mean BSA 5.2%) had measurable plasma levels, majority under 1 ng/mL

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Patient Population & Market Overview

Disease Burden

Atopic dermatitis/eczema is a chronic, recurrent inflammatory skin disease commonly associated with food allergy, allergic rhinitis, and asthma. Incidence in children reaches 15–20% with a rising trend; adult incidence is 1–3%.

China alone has >20 million affected children, with a comparable burden in the US. Over 90% of patients present with mild-to-moderate severity, the target population for topical therapies.

Global market for atopic dermatitis/eczema drugs exceeds $4B, with robust growth driven by demand for safer, more effective topical therapies.

Treatment Landscape

Mild–Moderate (>90%)

Topical steroids, calcineurin inhibitors, PDE4 inhibitors, JAK inhibitors, antihistamines, moisturizers — but side effects and insufficient efficacy remain key unmet needs.

Severe (<10%)

Biological agents (Dupixent/anti-IL-4R), oral JAK inhibitors (Upadacitinib, Abrocitinib), phototherapy — effective but associated with systemic risks and high cost.

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Clinical Development Plan

Phase 2a PoC Completed; Ph2b in Preparation

Target

JAK1 / Tyk2 dual inhibition, blocking both the TH1 and TH2 pathways — the primary drivers of AD pathology.

Route

Topical ointment administered once daily with a favorable local activity profile and minimal systemic absorption.

Advantage

Differentiated dual-pathway blockade designed to deliver broader and more durable response than single-pathway agents.

IP

Global patent protection across key markets.

2023–2024
Phase 1 SAD & MAD completed; Phase 2a PoC trial completed (US sites)

2025
Reproductive Toxicology GLP study; Phase 2b trial initiation (US sites)

2026–2027
EoP2 Regulatory Authority meetings; Phase 3 multi-center trial

2028
NDA/MAA submission

Accelerating Innovation to Improve Patients' Lives

Navika Bio connects groundbreaking biotech innovation with global pharmaceutical partners to deliver transformative therapies to patients worldwide.

NAVIKA BIO

Let's Connect

For more information about partnership opportunities and to join us on this exciting journey of bringing transformative therapies to patents worldwide, please reach out to:

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