

# **NB-014: Topical Thyromimetic for Androgenetic Alopecia; Phase 2**

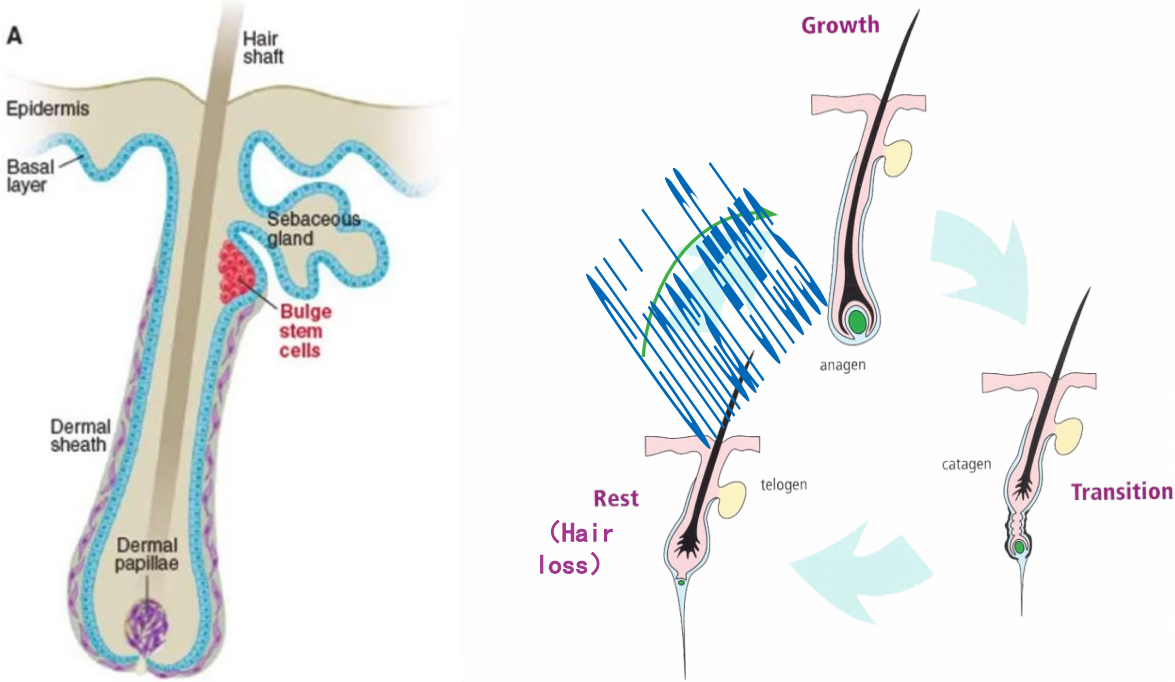


First-in-class Thyromimetic MOA; activates hair follicle stem cells

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## First-in-class Thyromimetic MOA; activates hair follicle stem cells

Targets androgenetic alopecia by inducing resting (telogen) hair follicles to re-enter the active growth (anagen) phase. As a new chemical entity with a well-characterized mechanism of action, it has demonstrated the ability to promote hair growth across multiple preclinical models, including rodent, primate and human scalp organ culture, with excellent efficacy and a favorable safety profile.



### Clinical Development Plan

The program holds broad intellectual property coverage through PCT filings spanning China, the US, Japan and the EU and is targeting NDA/MAA submission by 2030.

The clinical development timeline spans roughly a decade across four phases. Phase 1 first-in-human studies (SAD and MAD) were completed during 2021–2022, followed by Phase 2a proof-of-concept work from 2022–2024, which included 6/9-month toxicology, dose-range finding and the Phase 2a trial itself.

The program is currently in the Phase 2b window (2025–2027), running a one-year trial with End-of-Phase-2 regulatory authority meetings planned. The final stage targets a Phase 3 multi-center trial from 2028–2030, culminating in the regulatory submission.

### Molecular Effect

First receptor signal activation interacts with the "hairless" gene, modulating gene expression, energy metabolism and tissue remodeling.

### Cellular Effect

Activates hair follicle stem cell function in the bulge niche, driving cell growth and differentiation.

### Clinical Effect

Promotes hair regeneration from resting follicles, restoring normal hair density and quality.

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## Patient Population & Market Overview

### Disease Burden

Androgenetic alopecia (AGA) is a slowly progressive, patterned, non-scarring hair loss — commonly known as male or female pattern baldness — typically occurring after puberty. It is characterized by an abundance of resting (telogen) follicles and progressive follicular miniaturization. The prevalence in men **exceeds 50% by middle age** and affects nearly as many women.

Global market for AGA-approved pharmaceuticals currently exceeds **\$1B**, with significant untapped potential due to limited efficacy of existing therapies.

### Market Landscape

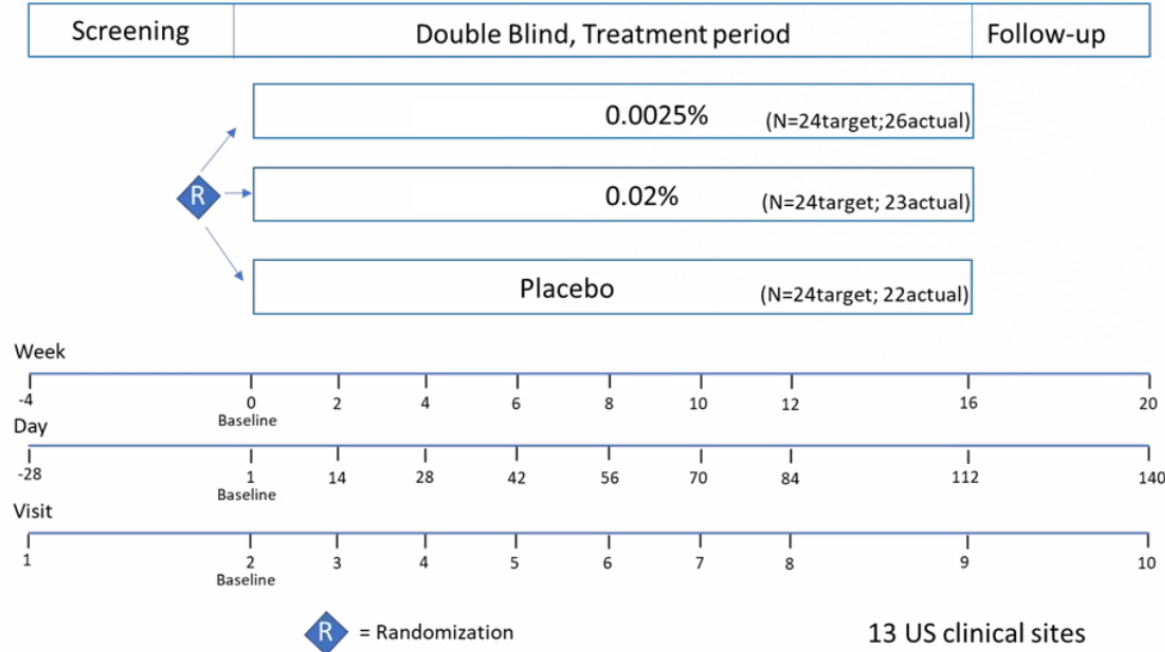
**Minoxidil** and **Finasteride** are the only FDA-approved drugs for AGA treatment. The global minoxidil market was valued at **\$951.8M in 2020**, with a projected **CAGR of 4.8%** through 2027. The Finasteride market is expected to grow from **>\$110M (2020)** to **>\$130M (2026)** at a CAGR of 2.5–3.0%.



Surgical hair restoration and low-level laser devices offer alternative or supplemental options, but overall market penetration remains limited due to inadequate efficacy of available pharmacological solutions.

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## Efficacy and Safety of Topical Solution Administered QD for 16 Weeks



### Study Design

<b>Phase</b>	Phase 2, Randomized, Double-Blind, Placebo-Controlled
<b>Sites</b>	Multicenter (USA)
<b>Population</b>	Males 18–55 yrs, Mild-to-Moderate AGA (IIIv, IV, Modified Norwood-Hamilton Scale)
<b>Treatment</b>	Daily topical application for 16 weeks
<b>Endpoint</b>	Change from Baseline in non-vellus target area hair count at Week 16

### Topline Results

#### Efficacy

Positive treatment response demonstrated. Change from Baseline in non-vellus target area hair count at Week 16:

- 0.02% NB014 = +24.3 (PoC)
- 0.0025% NB014 = +20.3
- Placebo = +14.0.

#### Safety

Well tolerated. 32 TEAEs in 21 subjects (29.6%); no SAEs; no treatment discontinuations; no clinically significant lab, vital sign, or ECG changes.

#### Pharmacokinetics

Extremely low to no systemic exposure — nearly all samples below LLOQ (5 pg/mL), confirming favorable local activity with minimal systemic absorption.

# Accelerating Innovation to Improve Patients' Lives

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



# Let's Connect

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



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