

Legacy Healthcare's CINAINU® Receives FDA Breakthrough Therapy Designation for Alopecia Areata in Adults, Adolescents and Children Aged 2 Years and Older



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Legacy Healthcare →

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EPALINGES, Switzerland, Oct. 13, 2026 /PRNewswire/ -- Legacy Healthcare, a biopharmaceutical company developing innovative botanical prescription drugs, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation to CINAINU® (LH-8), its investigational cutaneous solution treatment for moderate-to-severe alopecia areata in adults, adolescents and children aged two years and older.

The designation was supported by the RAAINBOW Phase 2/3 trial, a randomized, double-blind, placebo-controlled study involving 107 children and adolescents aged 2–17 years.

Breakthrough Therapy Designation is intended to accelerate the development and review of investigational therapies showing preliminary evidence of substantial improvement over available treatments.

A Broader and Potentially Better Treatment Option for Alopecia Areata patients

Today, oral Janus kinase (JAK) inhibitors are the only approved treatment option for alopecia areata. However, they are limited to adults and adolescents with severe forms of the disease. Patients with moderate forms, who represent the majority of alopecia areata sufferers, have no approved treatment.



Children also have no approved treatment. Importantly, oral JAK inhibitor discontinuation triggers rapid hair loss, and these medicines carry FDA boxed warnings for serious safety risks, including infections, malignancy, cardiovascular events and thrombosis.

CINAINU® is being developed for both moderate and severe alopecia areata, and across all age groups and has demonstrated in its first Phase 2/3 trial meaningful hair regrowth, combined with a favorable tolerability profile and sustained benefit. This profile could make it an attractive first-line option for moderate-to-severe alopecia areata. Subject to further clinical investigation, CINAINU® could also be positioned as a continuation treatment after oral JAK inhibitors.

"The FDA's decision represents a major milestone for CINAINU® and recognizes its potential to address significant unmet needs in alopecia areata," said Saad Harti, CEO of Legacy Healthcare. "Our ambition is to offer patients meaningful hair regrowth, favorable tolerability and sustained benefit after treatment ends, potentially providing a new, transformational, treatment option across a broad age and severity range."

About Legacy Healthcare and CINAINU®

Legacy Healthcare is a biopharmaceutical company developing innovative botanical prescription medicines for diseases with significant unmet medical needs. Its lead product CINAINU® is covered by six granted patents, with patent protection extending to 2043. CINAINU® is the first FDA-regulated multi-plant botanical drug to be granted Breakthrough Therapy Designation. Legacy Healthcare is currently preparing a global pivotal Phase 3 program evaluating CINAINU® in adults, adolescents and children with moderate-to-severe alopecia areata.

www.legacyhealthcare.ch

References

Blume-Peytavi U, Piraccini BM, Reygagne P, et al. British Journal of Dermatology. 2026;194:37–46.
<https://doi.org/10.1093/bjd/ljaf279>

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