Legacy Healthcare to Advance Topical Solution Cinainu into International Phase 3 Trial for Alopecia Areata following US FDA Clearance

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- *RAAINBOW-2 is an international, double-blind, placebo-controlled Phase 3 study for the treatment of moderate to severe alopecia areata (AA) in at least 500 subjects.*
- *Cinainu is the first topical drug-candidate for both patients with severe and moderate AA, allowing early-treatment before disease progression.*

EPALINGES, Switzerland, Jan. 6, 2026 /PRNewswire/ -- Today Legacy Healthcare announced plans to advance topical solution Cinainu into a multi-regional Phase 3 trial (RAAINBOW-2) for moderate to severe AA following US Food and Drug Administration (FDA) clearance.

The FDA cleared the company's IND filing for Cinainu, allowing the botanical drug-candidate to proceed with an international Phase 3 study in patients with moderate to severe AA for New Drug Application (NDA) purpose.

The FDA clearance follows the successful international Phase 2/3 study (RAAINBOW) in children and adolescents with moderate-to-severe AA, and the agreement from Japan's Pharmaceuticals and Medical Devices Agency (PMDA) on the conduct of a global Phase 3 trial including Japanese adult and pediatric patients (from age 2) to support registration in Japan. Discussions with other health authorities to extend the Phase 3 RAAINBOW-2 trial to additional regions will follow.

In the first RAAINBOW study, conducted in pediatric populations with moderate to severe AA and published in the *British Journal of Dermatology*, Cinainu demonstrated clinically meaningful effect sizes, while maintaining an excellent safety profile and showing sustained benefits after treatment discontinuation.

"Beyond its efficacy, Cinainu has shown to treat autoimmune AA without immunosuppression-related adverse events, and with a persistent effect after treatment discontinuation, both of which, to our knowledge, are firsts" said Saad Harti, Founder and CEO of Legacy Healthcare. "FDA-regulated Botanical drug is an overlooked regulatory pathway, but the results of the RAAINBOW trial support that a botanical drug can treat complex chronic diseases without synthetic chemical intervention and no long-term health risks. FDA IND clearance to proceed to Phase 3 marks a key milestone in the development of Cinainu and highlights the growing potential of botanical drug innovation. To our knowledge, Cinainu is the first multi-plant botanical drug candidate granted FDA clearance to advance into Phase 3 trial."

RAAINBOW-2 will be led by Dr Arash Mostaghimi, Vice Chair, Clinical Trials and Innovation, Medical Director, Dermatology Consult Service, Co-Director, Complex Medical Dermatology Fellowship Program at Brigham and Women's Hospital and Associate Professor at Harvard Medical School.

"The approval of three oral JAK inhibitors over the past 3 years has been a major breakthrough for the treatment of patients with severe AA" said Dr Arash Mostaghimi. *"However, there still is a need for a safe, effective, and potentially remittive topical therapy for patients with AA across the spectrum of disease severity."*

The company has initiated a fundraising effort to support the RAAINBOW-2 Phase 3 program and pipeline expansion, including trials in Atopic Dermatitis and Psoriasis where the product has shown efficacy signals, and in Cancer Related Fatigue where an oral form of the product has shown efficacy in an NIH-sponsored study in mice.

About Cinainu

Cinainu is a topical botanical drug-candidate with a well-established safety profile and patent protection until 2043. In clinical and preclinical studies, Cinainu restored peri-follicular anti-apoptotic protein Bcl-2 to near-normal levels, increased epidermal Langerhans cells density, reduced endothelial expression of T-cell chemotaxin IL-8 and pro-inflammatory adhesion molecules (E-selectin, ICAM-1) and increased scalp collagen content. In clinical studies, Cinainu showed good safety profile and positive effects on hair regrowth in patients with androgenetic alopecia, persistent chemotherapy-induced alopecia and alopecia areata. Over 700 patients have been exposed to Cinainu in clinical trials, up to 12 months, with no reported safety concern.

Legacy Healthcare is a biopharmaceutical company focused on leveraging the pleiotropic potential and safety of plant extracts into FDA-regulated botanical drugs.

Blume-Peytavi U et al. (2025), Efficacy and safety of Cinainu in pediatric alopecia areata: an international, double-blind, randomized, placebo-controlled, phase 2/3 trial. British Journal of Dermatology. 2025 Jul 16:ljaf279. doi: 10.1093/bjd/ljaf279.

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For inquiries: contact@legacyhealthcare.ch