Legacy Healthcare's Positive Phase 2/3 Trial of Cinainu, First Drug Candidate Targeting Moderate and Severe Alopecia Areata, Published in British Journal of Dermatology

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- *Results of Phase 2/3 trial show Cinainu cutaneous solution efficacy and safety in moderate to severe alopecia areata, first in children and adolescent,*
- *Cinainu promoted hair regrowth, improved quality of life and showed sustained effect after treatment discontinuation,*
- *Cinainu was well-tolerated, with no immunosuppression-related adverse events,*
- *Data have been published in the British Journal of Dermatology, a top-ranked international dermatology journal.*

LAUSANNE, Switzerland, *British Journal of Dermatology* published the results of the RAAINBOW Phase 2/3 trial showing efficacy and safety of Cinainu in children and adolescents with moderate to severe alopecia areata (AA), a chronic autoimmune disease.

"Beyond its efficacy in regrowing patients' scalp hair, Cinainu has shown to treat this autoimmune disease without immunosuppression-related adverse events, and with persistent efficacy, which, to our knowledge, is a first" said Saad Harti *"Publication in the British Journal of Dermatology marks a key milestone supporting Cinainu efficacy and safety."*

AA is a debilitating autoimmune disease characterized by non-scarring hair loss, significantly impairing patients' quality of life (QoL). Inflammation and immune dysregulation, especially involving chemokines like IL-8 and Janus kinase (JAK)-dependent signaling pathways, underlie AA pathogenesis.

Oral JAK inhibitors have been recently approved for the treatment of severe AA in adults and adolescents, a breakthrough. There is still significant unmet need for a treatment which safety profile allows intervention at early stage to prevent disease progression, which discontinuation does not trigger disease relapse, and for children, the most vulnerable population.

Given its excellent safety profile in previous trials, Cinainu -a topical botanical drug with anti-inflammatory, anti-apoptotic, and antioxidant properties- was authorized for initial evaluation in children and adolescent, and in both severe and earlier-stage moderate AA.

The international, double-blind, placebo-controlled, phase 2/3 RAAINBOW trial enrolled 107 pediatric AA patients randomized (2:1) to Cinainu or placebo for 24 weeks, followed by a 24-week treatment-free follow-up period. The prespecified primary analysis included 62 patients with confirmed moderate-to-severe AA at baseline. The primary endpoint was the relative change in SALT score from baseline to Week 24, where SALT measures the percentage of hair loss.

Cinainu showed significant benefits compared to placebo in the relative change in SALT score from baseline to Week 24: adjusted mean difference (95% CI) +26.3% (0.1, 52.5), p=0.0488, Cohen's d=0.52. Benefits were sustained during the follow-up period: adjusted mean difference (95% CI) +39.4% (13.1, 65.6), p=0.0033, d=0.80 in relative change in SALT score from baseline to Week 48. At Week 48, 47.6% of patients in the Cinainu group achieved a SALT score ≤20 (placebo: 15.0%, p=0.0129, Number Needed to Treat (NNT)=3.1), and 35.7% reached a SALT score ≤10 (placebo: 10%, p=0.0339, NNT=3.9). Cinainu also led to significant QoL improvements at Week 24, with effect sizes of d=0.61-0.79. No serious adverse events were reported in the Cinainu group, and treatment was well-tolerated, with a lower incidence of adverse events compared to the placebo group. Reported events were essentially mild to moderate, local, and transient in nature. No immunosuppression-related adverse events were reported.

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

Legacy Healthcare is a Swiss-based biopharmaceutical company focused on leveraging the pleiotropic activity and safety of plants known safe for human use to develop treatments for chronic diseases.

About the British Journal of Dermatology
The British Journal of Dermatology (BJD) is a top-ranked international dermatology journal, publishing high-quality research to advance the understanding and management of skin disease to improve patient outcomes. The BJD is one of the journals of the British Association of Dermatologists, the professional membership body for dermatologists in the UK.

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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