Legacy Healthcare Receives Positive Feedback from Japan's Health Authority (PMDA) on Regulatory Pathway and Phase 3 Clinical Program for Cinainu in Japanese Children, Adolescents and Adults with Moderate to Severe Alopecia Areata (AA)

prnewswire.com/news-releases/legacy-healthcare-receives-positive-feedback-from-japans-health-authority-pmda-on-regulatory-pathway-and-phase-3-clinical-program-for-cinainu-in-japanese-children-adolescents-and-adults-with-moderate-to-severe-alopecia-areata--302520941.html

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- *In a European Phase 2/3 trial, Cinainu cutaneous solution was demonstrated to promote hair regrowth, improve quality of life and showed sustained effect after treatment discontinuation; Cinainu was well-tolerated, with no immunosuppression-related adverse events; the trial did not include Japanese subjects,*
- *In an end-of-Phase 2 meeting, the PMDA informed Legacy Healthcare that a single Phase 3 trial would be sufficient to support regulatory approval, if successful,*
- *The trial will include children, adolescents and adults with moderate to severe alopecia areata.*

EPALINGES, Switzerland, /PRNewswire/ -- Today Legacy Healthcare announced it has received feedback from the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan on conducting Phase 3 trial in Japanese patients and regulatory pathway towards potential marketing authorization. In the absence of Japanese patients in the RAAINBOW Phase 2/3 trial, PMDA allowed Cinainu to be evaluated in a Phase 3 trial in Japanese children, adolescents and adults with moderate to severe alopecia areata. Based on feedback from the PMDA, the data from the single Phase 3 registration trial, if positive, will serve as the basis to submit marketing authorization in Japan.

"We are very pleased with the clear feedback from PDMA which represents a key step towards availability of Cinainu to all alopecia areata sufferers in Japan," said Saad Harti *"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."*

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.

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

Results of the RAAINBOW Phase 2/3 trial, which were published in the *British Journal of Dermatology* on July 16, 2025, showed efficacy and safety of Cinainu in children and adolescent with both moderate and severe alopecia areata (AA). 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.

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 prescription botanical drugs to address chronic diseases with unparalleled long-term safely. The company's first product candidate, Cinainu, has demonstrated strong safety, durable effect and safety in the treatment of a chronic autoimmune condition.

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