Cinainu, a first-in-class, late-stage drug for alopecia areata and other autoimmune diseases

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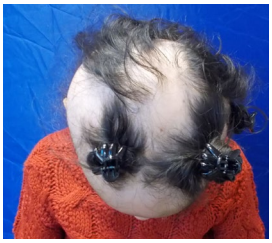
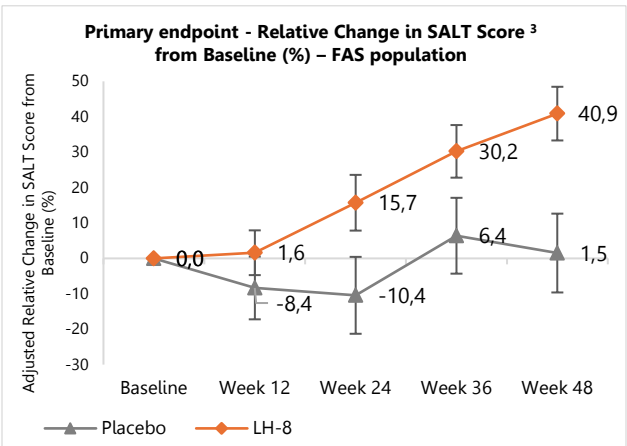
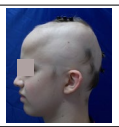
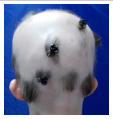
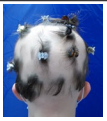
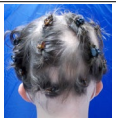


Disease, treatments & market	Alopecia Areata (AA) is a debilitating autoimmune disease characterized by random, disfiguring, hair loss and affecting 3 million people (US, EU). Off-label corticosteroids have not provided relevant efficacy. Lilly, Pfizer, and soon Abbvie have launched oral JAK inhibitors (JAKi) for AA. Oral JAKi are priced at $4'000 per month (US), establishing a price-point for treatment of AA. Analysts project AA market to represent $6b by 2032.
Limitation of current treatments	Black-box safety warning was imposed on oral JAKi because of their potentially severe side-effects. Therefore, US FDA and EMA [1] restricted their use to patients with severe AA, representing only 20% of the patient population. Also, their discontinuation triggers rapid disease relapse.
Unmet medical need	There remains a significant unmet need for a treatment which is safe enough to be used by all patients; especially in early disease, to prevent progression and in childhood, to improve prognosis at adulthood. Because AA is particularly devastating for children, we decided to prioritize them.
Our solution: Cinainu	Cinainu (LH-8) is a cutaneous solution applied to the scalp and composed of four plant-extracts. It was first commercialized as a cosmetic-status lotion for "hair loss" and distributed by Sanofi, Abbott, Galderma, with 2.5 million units sold. Based on patient-cases in AA, relevant MoA and compelling opportunity, Cinainu was pivoted to prescription drug status, becoming a first-in-class botanical drug under development for the treatment of AA and other inflammatory and autoimmune conditions.
RAAINBOW Phase 2/3 trial in AA	RAAINBOW is an international, randomized, double-bind, placebo-controlled Phase 2/3 trial in children and adolescents with moderate to severe AA. Patients were treated for 24 weeks, followed by 24 weeks without treatment. At Week 24, Cinainu was statistically significantly superior to placebo on the primary endpoint (FAS [2] n=62), with a treatment effect of +25.4% (p=0.049). Unlike oral JAK inhibitors, treatment-effect persisted after drug discontinuation, suggesting a disease-modifying effect. At Week 48, treatment-effect was +39.4% (p=0.003). Cinainu improved quality of life, a major outcome in this debilitating disease. Cinainu demonstrated a strong safety profile.



Cinainu treated patient representative of treatment-effect

Timeline	Baseline	Week 24	Week 48
Side			
Back			
SALT score	**87**	**68**	**53**
Relative Change		**21%**	**39%**

Disease duration of the patient = 9 years

1. US Food and Drug Administration; European Medicines Agency. 2. Full Analysis Set population. 3. SALT = Severity of Alopecia Tool. SALT score measures the % of hair loss. SALT 100 = 100% hair loss

Pleiotropic actions	Cinainu was shown to reduce endothelial expression of T-cell chemotaxin il-8, pro-inflammatory adhesion molecules (i.e. E-selectin, ICAM-1) and to restore the expression of peri-follicular anti-apoptotic protein Bcl-2 to near-normal level.
Interest from the scientific community	RAAINBOW data were presented at EADV, AAD, WCHR, ESPD[4]. Thanks to compelling results and safety, request for "compassionate use" access are from physicians around the world.
Superior profile	Creams, gels, ointment are less effective, unpleasant, leading to poor compliance. Cinainu has strong efficacy, excellent tolerance and cosmetically elegant formulation. Independent research has shown that, for treatment of chronic conditions, patients would prefer botanical drugs to synthetic/biological drugs.
Peak-sales potential in AA	Independent third-party research projects Cinainu annual peak-sales to reach $2.9 billion for pediatric and adult AA. US payors have indicated to cover Cinainu at $3'000 per month, close to oral JAK inhibitors for severe AA. Beyond efficacy, Cinainu will be the safest option, and it is hassle-free (no blood-test or safety follow-up). Physicians indicate they would use Cinainu as treatment of choice.
IP	Several patents were granted globally. The latest patent was granted in Sept 2023 in the US, protecting Cinainu until 2043.
Pathway to exit	A top-tier US investment bank has a mandate to transact the company or out-license Cinainu. In 2020-2023, acquisition value of Ph 2 and Ph 3 immunology biotech ranged from $0.8 to $10.9 billion. Acquisition value of immuno-dermatology biotech with Ph 2 positive data represented 1.5-times the estimated annual peak-sales.
Next indications	Clinical trial showed efficacy in persistent Chemotherapy Alopecia. Patient case were reported in atopic dermatitis and psoriasis.
Regulatory strategy	FDA requested we conduct a PK study on AA patients to waive animal toxicity studies. Based on discussions with FDA, the company will try first to file, end-2025, an NDA based on the RAAINBOW study alone. If denied, a Ph 3 trial will be conducted (n=460).
Fund raising rationale	Provided FDA request a Ph 3, total costs until approval (Q2 2029) represents $70m: $32m for Ph 3, $32m for internal costs, $1m for PK, $5m to advance pipeline. The company is seeking to raise $70m: $12m in 1st tranche and $58m in commitments should FDA request a Ph3.
Botanical drugs potential	LH-8 is a prescription botanical drug. Plants' multiple molecules allow pleiotropic action, as seen with LH-8. Botanical drugs are well suited for multi-factorial chronic diseases, requiring long-term treatment.
Company vision	Legacy Healthcare, a Swiss biotech with seasoned founders and team located in Switzerland, US, Japan, is pioneering the new field of botanical drugs. Cinainu is the "proof-of-concept" of our unique know-how to develop safe and efficacious prescription drugs from plant-extracts to better treat, complex, chronic diseases.

4. European Academy of Dermatology and Venerology, American Academy of Dermatology, World Congress of Hair Research, European Society of Pediatric Dermatology

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