Legacy Healthcare Announces Positive Top-Line Results from Phase 2/3 Trial of Coacillium cutaneous solution, the first drug for children and adolescents with Moderate and Severe Alopecia Areata

NEWS PROVIDED BY
Legacy Healthcare →
Jan 06, 2023, 11:26 ET

RAAINBOW Phase 2/3 trial Meets Primary Endpoint for Scalp Hair Regrowth as well as Key Secondary Endpoints.

96% of responders to Coacillium During the Treatment Period Continue to Improve After Treatment Discontinuation.

Coacillium is the Only Treatment in Development for Children and the Moderate Form of Alopecia Areata.

Trial Data Confirm Coacillium Excellent Safety Profile.

LAUSANNE, Switzerland, Jan. 6, 2023 /PRNewswire/ -- Legacy Healthcare, a clinical-stage biopharmaceutical company today announced positive results from the RAAINBOW phase 2/3 randomized placebo-controlled trial evaluating Coacillium 22.25% cutaneous solution in children and adolescents with moderate and severe alopecia areata, a debilitating

autoimmune condition causing disfiguring scalp hair loss. Coacillium achieved the primary efficacy endpoint of the study, as well as key secondary endpoints. After 6 months treatment, Coacillium was statistically significantly superior compared to placebo in relative change in Severity of Alopecia Tool (SALT) score. The proportion of subjects achieving at least a 40% relative reduction in SALT score was statistically significantly superior in the drug group.

With one oral drug recently approved for severe alopecia areata in adults, and more in progress, interest and understanding of the disease and its impact have increased. Among key learnings is the need for treatments that can be used early enough in the course of the disease, while it is still Moderate, to prevent, delay, or reverse the progression to a Severe stage, as well as treatments that are safer and better tolerated, and treatments which discontinuation does not result in rapid disease relapse.

Coacillium is the first and only drug candidate for alopecia areata in children and adolescents with both moderate and severe forms of the disease. RAAINBOW phase 2/3 trial data showed that patients presenting moderate alopecia areata improved under Coacillium treatment, while the control group of patients receiving placebo worsened to a more severe stage of the disease.

To evaluate potential disease relapse, patients were followed for a period of 6 months after treatment discontinuation. Almost all patients whose alopecia areata improved during the 6-months treatment with Coacillium kept improving after treatment discontinuation, suggestive of a direct long-term action of Coacillium on the physiopathological process causing alopecia areata.

No serious adverse events (AEs) were reported. One adverse event was considered as definitely related to Coacillium (acute scalp and face eczema), and three probably or possibly related. All AEs were cutaneous, mild or moderate, and transient. The excellent safety of the drug observed in the trial was consistent with observations from previous studies. Coacillium is also being evaluated in persistent chemotherapy induced alopecia.

"Thanks to its excellent safety profile, Coacillium is - to our knowledge - the first drug candidate to be developed first in children, for a disease which also affects adults. With these new data, we observe that not only Coacillium treatment works in most patients who use it, but its benefit is maintained after treatment discontinuation - at least during the

period of observation of 6 months. This would represent a significant change in treatment paradigm, for patients, physicians and stakeholders" said Saad Harti, Chief Executive Officer of Legacy Healthcare. "We look forward to bringing this potential new treatment to the ones who suffer from alopecia areata, and people who care for them".

About Alopecia Areata and Pediatric Alopecia Areata

Alopecia areata (AA) is an autoimmune disease characterized by disfiguring, random, patchy hair loss. In alopecia areata, hair loss occurs and persists because of the attack and destruction by immune T-cells of the hair follicle's immune privilege, associated with abnormal hair follicular cells apoptosis. Alopecia areata affects both adults and children. When affecting children below age 18, alopecia areata is referred to as pediatric alopecia areata. It affects all children, without discrimination as to age, gender, or ethnicity.

About Coacillium (LH-8)

Coacillium is an investigational topical botanical drug. Among the actives present in Coacillium, various flavonoids, polyphenols and methylxanthines have been reported to interrupt immuno-inflammatory reactions and their deleterious consequences on hair follicles and adjacent dermal tissues via a pleiotropic mechanism (i.e. multiple targets). More information on botanical drugs can be found at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/botanical-drug-development-guidance-industry

About Phase 2/3 RAAINBOW trial

This randomized, placebo-controlled, double-blind study investigated Coacillium in patients from 2 to 18 years of age with alopecia areata. Patients included had moderate alopecia areata (SALT 25-50) and severe alopecia areata (SALT 50-95), and were experiencing a current episode of alopecia areata that had lasted between six months and three years (n=62). Patients were randomized to receive topical Coacillium or placebo (2:1). A treatment period of 6 months was followed by a treatment-free period of 6 months, to evaluate possible disease recurrence in successfully treated patients. The primary endpoint was the relative change in scalp alopecia areata severity score (SALT) from baseline value to be assessed after 24 weeks of treatment, evaluated through global standardised scalp photographs. A key secondary endpoint was the proportion of the responders, i.e. subjects

achieving at least a 40% relative reduction in SALT score from baseline at the end of 24 weeks' treatment period. SALT is the standard tool for measurement of the amount of scalp hair loss in alopecia areata [1]. More information about the RAAINBOW phase 2/3 trial can be found at

https://clinicaltrials.gov/ct2/show/NCT03240627

About Legacy Healthcare

Legacy Healthcare is a clinical-stage biopharmaceutical company developing a pipeline of novel drug candidates with unparallel safety to address the needs of fragile patients - children, cancer patients, chronic condition sufferers, the elderly) with autoimmune and inflammatory diseases who lack satisfactory treatment options. Legacy Healthcare is supported by the Swiss Government. For additional information, please visit www.legacyhealthcare.ch

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1. Olsen EA, Hordinsky MK, Price VH, et al. Alopecia areata investigational assessment guidelines–part II. National Alopecia Areata Foundation. J Am Acad Dermatol. 2004;51(3):440-447.

SOURCE Legacy Healthcare