Cassiopea SpA Announces Topline Results of Phase II Proof of Concept Trial of Clascoterone Solution for the Treatment of Androgenetic Alopecia in Females

Ad hoc announcement pursuant to Art. 53 LR

Lainate, Italy – September 10, 2021: Cassiopea SpA (SIX: SKIN), a specialty pharmaceutical company developing and preparing to commercialize prescription drugs with novel mechanisms of action (MOA) to address long-standing and essential dermatological conditions, today announced the topline results of its phase II Proof of Concept (POC) trial investigating clascoterone solution for the treatment of androgenetic alopecia (AGA) in females.

This Phase II vehicle and 2% minoxidil-controlled dose-ranging study was conducted in Germany and evaluated the 6-month efficacy and safety of 5.0% and 7.5% twice daily application of clascoterone solution, as compared with twice-daily 2% minoxidil or vehicle, in 293 females aged 18-55 experiencing AGA. Approximately 70 eligible subjects were randomly assigned to treatment groups or vehicle; most were Caucasian with an average age of 40.7 years for the per protocol population.

The co-primary efficacy endpoints were 1) change from baseline in non-vellus Target Area Hair count (TAHC) and 2) Hair Growth Assessment (HGA) at Month 6. The target area is defined as one square centimeter. HGA was a study subject self-administered question that provided an indication of the favorability of scalp hair growth compared to baseline using a 7-point scale.

AGA affects an estimated 50% of women over 40 years or an estimated 30 million women in the US.[1] AGA has a complex and less understood etiology compared with male pattern hair loss, yet genetics and aging play a role in both. Although the role of androgens, androgen receptors and androgen synthesis in the skin are is less clear in female AGA, some women with AGA respond to oral androgen receptor treatments, but these therapies are associated with side effects.[2] Also, consistently with previous topical hair loss studies in female subjects treated twice-daily with solutions containing propylene glycol,[3] a significant placebo effect was foreseen and effectively observed, and the study was therefore expected to deliver mixed results. Also, Finasteride 1 mg/day (Propecia®) in a double blind 12 months trial did not increase hair growth or slowed progression of hair thinning in postmenopausal women with AGA.[4]

In the clinical trial, surprisingly, only the subgroup with women less than 30 years of age receiving twice daily application of 5% clascoterone solution showed statistically significant differences from baseline in TAHC at Month 6 (p value=0.0391) although the subgroup was not powered to show statistical significance.

Cassiopea is thus encouraged by the opportunity presented by this data to continue in its effort to treat at least a significant portion of women suffering from AGA and, as a next step, will now analyze in-depth the data to identify the female subgroups that would benefit most from the treatment.

At 6 months, the incidence of AEs across active groups were similar. TEAEs, if they occurred were mostly minimal, mild or trace, with the majority not deemed related to study drug by the investigators. The majority of subjects did not experience any local skin reactions (LSRs) The most frequently observed LSRs across all treatment groups at 6 months were minimal or mild scaling, minimal erythema or minimal pruritus. These data are consistent with previous studies of clascoterone solution.[5,6] No substantive changes in vital signs, weight or laboratory tests at 6 months for any treatment group.

Clascoterone also had encouraging results in terms of favorable cosmetic acceptability and ease of use.

After reviewing the data, Maria Hordinsky, MD, Professor and Head of the Department of Dermatology at the University of Minnesota Medical School, and immediate past President of the American Hair Research Society, commented: "*Androgens and androgen receptors are thought to play a role in female pattern hair loss though the pathophysiology is still not as well understood as it is in males. This could be due to hormonal fluctuations with aging. Clascoterone solution will offer clinicians another tool to recommend for the treatment of female pattern alopecia. The current results also attest to its safety.*"

Diana Harbort, CEO of Cassiopea said: "*Because of complexities of women's hair loss, which depends on age, hormonal changes, genetics and other factors, our study's efficacy results were expected to achieve mixed success. Yet, we are encouraged by the subgroup analysis which showed some women may have a stronger response. Moving forward, we are confident that we will find the right pathway to treat the most common form of hair loss in a significant portion of women. In the meantime, development toward the start of our Phase III program for clascoterone solution in male AGA continues at a steady pace."*

Clascoterone is a topical androgen receptor inhibitor. Clascoterone solution is believed to address male and female AGA by directly inhibiting testosterone and DHT binding to local hair follicle androgen receptors.[7] If approved by the FDA, Clascoterone solution has the potential to be the only topical androgen receptor inhibitor for AGA and the first drug with a new mechanism of action for the treatment of AGA in over two decades.

About Cassiopea:
Cassiopea is a specialty pharmaceutical company developing and preparing to commercialize prescription drugs with novel mechanisms of action (MOA) to address long-standing and essential dermatological conditions, particularly acne, androgenetic alopecia (or AGA) and genital warts. Cassiopea is investing in innovation that is driving scientific advancement in areas that have been largely ignored for decades. The portfolio comprises four unencumbered clinical candidates, for which Cassiopea owns the worldwide rights. The Company's strategy is to leverage this expertise to optimize the commercial potential for its products directly or with a partner. For further information on Cassiopea, please visit www.cassiopea.com.

About Clascoterone:

Clascoterone, a new chemical entity, is a first-in-class topical androgen receptor inhibitor in late stage development for the treatment of androgenetic alopecia in females and males. Although Clascoterone's exact mechanism of action is unknown in the treatment of AGA, laboratory studies suggest Clascoterone competes with androgens, specifically dihydrotestosterone (DHT), for binding to the androgen receptors within the hair follicles.[7]

Next events:

H.C. Wainwright Global Investment Conference	September 13-15, 2021, Virtual, New York
Credit Suisse Equity Conference	November 16-19, 2021, Zurich
Jefferies Global Health Care Conference	November 16-18, 2021, London

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