Cassiopea Announces First Patient to be Enrolled in Phase II Trial for the Treatment of Androgenetic Alopecia in Females with Clascoterone Solution

Lainate, Italy – November 13, 2019 - Cassiopea SpA (SIX: SKIN), a specialty pharmaceutical company focused on developing and commercializing prescription drugs with novel mechanisms of action (MOA) to address long-standing and essential dermatological conditions, announced today that it has received approval from the German Authority BfArM and the coordinating ethical committee and will now proceed to enrol the first patient in a Phase II trial investigating clascoterone solution for the treatment of androgenetic alopecia (AGA) in females.

The Phase II multicenter, prospective, randomized, double-blind, vehicle controlled, dose ranging study will evaluate the efficacy and safety of clascoterone solution for the treatment of AGA in females. The six-month study will enroll approximately 280 female subjects between 18-55 years of age with mild to moderate AGA in Germany. The four-arm study will enroll 70 subjects per arm in each of four treatment groups: clascoterone solution 5% BID (twice daily), clascoterone solution 7.5% BID (twice daily), minoxidil solution 2% BID (twice daily) and vehicle BID (twice daily). The co-primary endpoints are: (1) change from baseline in non-vellus Target Area Hair Count (TAHC) at month 6 in comparison to vehicle and (2) Hair Growth Assessment (HGA) score at month 6 in comparison to vehicle.

Clascoterone, a new chemical entity, is a proposed first-in-class topical androgen receptor inhibitor currently under review by the U.S. Food and Drug Administration (FDA) for the treatment of acne (in a 1% cream) and in late stage development for the treatment of AGA (in a higher strength solution). Laboratory studies suggest clascoterone competes with androgens, specifically dihydrotestosterone (DHT), for binding to the androgen receptors within the sebaceous gland and hair follicles. Because of clascoterone's likely local effect at the site of application, the risk of off-target, or systemic side effects, is minimized.

AGA is a leading cause of hair loss in men and women. In AGA, high local concentrations of DHT bind to androgen receptors within the scalp hair follicles, resulting in shortening of the hair cycle and gradual miniaturization of scalp follicles in men and women with a genetic predisposition. Over time, these progressively smaller, thinner hair follicles are unable to produce new hair, thus resulting in AGA's characteristic patterned baldness. DHT dependent effects are considered, in most cases, reversible, such that AGA could be responsive to medical treatment with clascoterone solution through its proposed MOA of

direct inhibition of testosterone and DHT binding to local hair follicle androgen receptors. Clascoterone has the potential to be the only topical antiandrogen for use in both men and women with AGA if approved by the FDA.

Based on early clinical review, Cassiopea believes that topical clascoterone will not have the contraindications and safety warnings of an orally administered androgen modulator used for the treatment of AGA in men. It appears Clascoterone does not interfere with the hormonal and, in particular, testosterone profiles of male subjects; libido and sexual behavior changes have not been observed in clinical trials to date. Clascoterone is quickly metabolized to cortexolone, a metabolite with a known safety profile. Due to its rapid metabolism and local activity, there appears to be limited systemic exposure to clascoterone and thus potential systemic side effects are minimized.

On April 16, 2019, Cassiopea announced topline results from the Phase II Dose Ranging trial in males demonstrating statistically significant improvement versus vehicle for TAHC for each dose tested along with directional improvement for HGA at twelve months. No treatment-related serious adverse events among patients were recorded during the trial; local skin reactions, if present, were similar to vehicle and predominantly classified as mild. Cassiopea has an End of Phase II Meeting with FDA scheduled on November 13, 2019, to discuss the AGA Phase III Program in males with clascoterone solution.

“Clascoterone, a unique topical androgen receptor inhibitor, has shown a remarkable increase in hair growth as compared to vehicle with minimal side effects in the Phase II Dose Ranging Study in males. If FDA approved, it will be a very welcomed and important therapy for female and male patterned hair loss, androgenetic alopecia,” said Wilma Bergfeld, Professor of Dermatology and Pathology at Cleveland Clinic and Past President, American Academy of Dermatology and American Society of Dermatopathology.

“If approved, clascoterone solution will be the first new mechanism of action for the treatment of androgenetic alopecia in decades, offering dermatologists and patients a new and potentially effective therapeutic alternative,” said Diana Harbort, CEO of Cassiopea. “We’re focused on the urgency to treat skin and scalp conditions that can leave not only physical scars, but also emotional scars. That’s why innovation is so critical. We are committed to finding a new pathway to treat the most common form of hair loss affecting both men and women.”

About Cassiopea

Cassiopea is a specialty pharmaceutical company focused on developing and commercializing prescription drugs with novel mechanisms of action to address long-standing and essential dermatological conditions, particularly acne, androgenetic alopecia 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. If approved, Cassiopea plans to commercialize the products directly in the U.S. and partner the products for countries outside of the U.S. For further information on Cassiopea, please visit www.cassiopea.com.

About Clascoterone

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Next events

CS Small & Mid Cap Conference, Zurich	November 13, 2019
Jefferies Health Care Conference, London	November 20, 2019
Full-year results 2019	February 2020

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