

# Cassiopea Announces Completion of Enrollment in a Phase II Trial of Clascoterone Solution for the Treatment of Androgenetic Alopecia in Females

Lainate, Italy – October 8, 2020 - Cassiopea SpA (SIX: SKIN), today announced that it has completed the enrollment of its 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 enrolled 293 female subjects between 18-55 years of age with mild to moderate AGA in Germany. The four-arm study enrolled approximately 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 are expected to be available in Q2 2021.

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 solution has the potential to be the only topical androgen receptor inhibitor for use in both men and women with AGA if approved by the FDA.

"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 potentially unique 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 developing and commercializing 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. Once approved, the Company plans to determine the optimal way of commercializing the products directly in the U.S. and partner the products for countries outside of the US. For further information on Cassiopea, please visit <u>www.cassiopea.com</u>.

#### 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, laboratory studies suggest Clascoterone competes with androgens, specifically dihydrotestosterone (DHT), for binding to the androgen receptors within the sebaceous gland and hair follicles.

### Next events:

Jefferies Global Health Care Conference Credit Suisse Small & Mid Cap Conference 17-19 November 2020, Virtual 18-20 November 2020, Virtual

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