Cassiopea Announces Positive Results from Phase III Acne Open-Label Safety Study Evaluating Winlevi® (Clascoterone) Topical Cream for Treatment up to 1 Year

Lainate, Italy – 26 March 2019 – Cassiopea SpA (SIX: SKIN), a clinical-stage specialty pharmaceutical company focused on developing and commercializing innovative and differentiated medical dermatology products, today announced positive safety and efficacy data for its Phase III open-label safety study (Study 27) evaluating Winlevi® (clascoterone) in acne for a treatment period of up to 1 year.

The results confirmed that no hormonal imbalance was seen in the patients, even after a long-term treatment and an enlarged drug application surface including both the face and trunk to maximize the patient's exposure area. The topically applied drug did not raise significant side effects.

The open-label safety study enrolled a total of 609 subjects, all of whom had completed twelve weeks of clascoterone or vehicle (placebo) treatment in the preceding double-blind studies (Study 25 and Study 26). Subjects continued on open-label treatment with clascoterone for up to an additional nine months. 416 subjects (safety population) received clascoterone therapy for an overall period of at least 26 weeks and 119 subjects completed participation in the study receiving clascoterone therapy for a total of 52 weeks.

The key safety findings from the study are the following: 18.1% reported treatment-emergent adverse events (TEAEs) during the study. Overall, the most frequently reported TEAEs were nasopharyngitis (common cold 2.6%) and upper respiratory tract infection (1.3%), all the other had an incidence <1%. Of the subjects with related TEAEs (2.3%), 17 TEAEs were dermal adverse events. No serious drug-related adverse events were reported.

At every study visit, the investigator documented application area Local Skin Reactions (LSRs); the overall incidence was mostly less than 10% except for erythema/reddening (24.2% and 16% on the face and trunk respectively) and scaling/dryness (16.6% on the face).

Open-label efficacy was also assessed throughout the additional nine months clascoterone application period, though not the primary study endpoint. The proportion of subjects achieving treatment success, defined as Investigator Global Assessment (IGA) with at least a 2-step improvement resulting in a 0 (clear) or 1 (almost clear), at Week 52 was 57% and 62% and at week 40 was 40% and 49% (of subjects with evaluable assessment) for face and trunk respectively.

Diana Harbort, CEO of Cassiopea SpA, commented: “We are very encouraged that this robust safety evaluation has confirmed prior data from our Phase III program (Study 25 and Study 26). Clascoterone clearly appears to be very well tolerated with an acceptable safety profile and without systemic side effects. We are very pleased to see strong evidence of continued improvement in IGA treatment success over time. We are convinced that Winlevi® (clascoterone) will create a new mechanism of action to treat acne, which hasn’t been seen since the early 1980s. This data completes the final clinical study data set necessary for inclusion in our NDA submission for Winlevi® (clascoterone).”

About Clascoterone

Winlevi® (clascoterone) is a new chemical entity first in class topical androgen receptor inhibitor in late stage development for the treatment of acne (in a 1% cream) and androgenetic alopecia (in a higher strength solution). When applied directly to the skin surface, clascoterone penetrates the skin to reach the androgen receptors within the sebaceous glands. Clascoterone is on course to become the first effective and safe topical androgen receptor inhibitor without systemic side effects.

Clascoterone intervenes at several key points in the acne cascade and works by binding to androgen receptors at the site of application. By competing with circulating androgens at the site of androgen receptors in the sebaceous gland and hair follicle, clascoterone acts as a local, selective androgen inhibitor and limits the acnegenic effects of androgens on sebum production and inflammation. Clascoterone is quickly metabolized to cortexolone, a naturally occurring metabolite found throughout all human tissues, cells, blood and urine; cortexolone’s safety and metabolic fate are well characterized. Due to its rapid metabolism and local activity, clascoterone does not produce worrying systemic side effects.

A different formulation containing a higher strength of clascoterone is also in Phase II clinical development for the treatment of androgenetic alopecia.

About Cassiopea

Cassiopea SpA is a clinical-stage specialty pharmaceutical company focused on developing and commercializing innovative and differentiated medical dermatology products. Our focus is on the topical treatment of acne, androgenic alopecia (or AGA) and genital warts. The portfolio comprises four unencumbered clinical candidates, for which Cassiopea owns the worldwide rights. The company plans to commercialize the products directly in the US and partner the products outside of the US. For further information on Cassiopea, please visit www.cassiopea.com.

Financial Calendar

Jefferies Global Health Care Conference, New York:	June 4-6
Half Year Report 2019:	July
Jefferies Global Health Care Conference, London:	November 13-14
Credit Suisse Small & Mid Cap Conference, Zurich:	November 13-15

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