Cassiopea Announces Very Positive Interim Analysis Phase 2 Results for Breezula® (Clascoterone) in Treating Androgenetic Alopecia

Lainate, Italy – 16 July 2018 - Cassiopea SpA (SIX: SKIN), a clinical-stage pharmaceutical company developing and commercializing innovative medical dermatology products, today announced the results of the planned six-month interim analysis from the phase 2 dose ranging clinical trial for its topical antiandrogen Clascoterone (Breezula®). The interim analysis demonstrates statistically significant improvement for Target Area Headcount (TAHC) and directional improvement for Hair Growth Assessment (HGA).

In the dose ranging trial, a total of 404 subjects were enrolled in 6 sites in Germany. This ongoing double-blind trial is evaluating the efficacy and safety of four different doses of Clascoterone compared to vehicle (placebo) in male subjects 18-55 years of age with mild to moderate androgenetic alopecia in temple and vertex region (rating III vertex to V on the Modified Norwood-Hamilton Scale, i.e. IIIv, IV, or V), with a history of ongoing hair loss. All subjects apply Clascoterone or vehicle to the balding areas of the scalp twice daily for a total of 12 months. The eligible subjects were randomly assigned to one of the following five treatment groups: 2.5% Clascoterone solution BID; 5.0% Clascoterone solution BID; 7.5% Clascoterone solution BID; 7.5% Clascoterone solution QD (once a day) and vehicle solution in the evening; vehicle solution BID.

The co-primary efficacy endpoints being evaluated in the trials are: 1) change from baseline in non-vellus TAHC (target area hair count) at month 12 and 2) HGA (hair growth assessment) score at month 12. The target area is defined as an area of one square centimeter.

Six Month Interim Analysis Efficacy Results (PP)

Primary Endpoints at 6 months (interim analysis on 375 subjects)	Clascoterone 2.5% BID	Clascoterone 5% BID	Clascoterone 7.5% BID	Clascoterone 7.5% QD	Vehicle
Mean changes from baseline TAHC	13.0134	12.2109	20.7879	11.5182	-0.1114
P value (vs. baseline)	< 0.0001	< 0.0001	< 0.0001	< 0.0001	0.9660
P value (vs. vehicle)	0.0003	0.0010	< 0.0001	0.0017	--
Favorable HGA (+1, +2, +3)	56%	58%	62%	61%	49%

For the TAHC, statistically significant changes were observed in all active groups with the highest change observed in the 7.5% BID group. For the HGA assessment, the subjects used the Baseline standardized global photograph of their scalp and compared it, side by side, with a “real time” standardized global photo from the Month 6 visit to assess their hair growth using a seven-point scale from -3 to +3. More subjects in all active groups saw an increase in their hair growth compared to the placebo group.

As a reference – these Phase 2 dose ranging interim results for TAHC for the 7.5% BID dose can be compared to the twelve-month TAHC results shown in the oral Propecia NDA – Clascoterone 7.5% BID reaches at six months the efficacy seen by oral Propecia. In the clinical study described in the NDA, Propecia (finasteride) 1 mg oral QD, attained a TAHC of 107 at twelve months treatment for a target area of 1-inch diameter circle (5.1 cm2). This compares to a TAHC in a 1cm2 area (as used in the Clascoterone study) of 20.1 (107 divided by 5.1) for Propecia compared to 20.8 for Clascoterone 7.5% BID. Furthermore, Cassiopea expects that the side effect profile of Clascoterone, a topical antiandrogen, will be much more favorable than that of an oral androgen modulator with its associated systemic side effects.

Upon reviewing the data of this interim analysis, Ken Washenik, MD, PhD, a faculty member in the Department of Dermatology at the New York University School of Medicine, past president of the North American Hair Research Society and the International Society of Hair Restoration Surgery, and Medical Director of the Bosley Medical Group, remarked: “The interim data on Clascoterone represents a dramatic advance in the treatment of AGA that has been on the ”bucket list” of physicians who treat AGA and their patients for decades. The promise of the same, or improved, efficacy, without any systemic androgen-related side effects, from a topical application, compared to a systemic medication, provides important hope for these patients and their physicians.”

Diana Harbort, CEO of Cassiopea said: “We are extremely pleased by these interim results. This data helps us understand our dose curve, provides important input for our upcoming POC trial in women and helps us plan for our Phase 3 studies. We expect that the twelve-month Phase 2 Dose Ranging results will show increasing efficacy consistent with its new antiandrogen mechanism of action. We are committed to bringing this new product to patients and their physicians. The global hair loss market is huge and very underserved with only OTC and generic therapies available.”

If approved, Clascoterone would be the first FDA-approved topical antiandrogen for the treatment of androgenetic alopecia.

Cassiopea plans to present this data at a future medical meeting and also for consideration for publication in a peer-reviewed journal.

Safety Results
There were no treatment-related serious adverse events among patients treated with Clascoterone. Local skin reactions, if present, were predominantly classified as mild.

Initiation of a Proof of Concept Trial in Women
Based on these results, Cassiopea will proceed with a proof of concept clinical trial in women.

About Clascoterone
Clascoterone is a new chemical entity topical antiandrogen in late stage development for the treatment of acne (in a 1% cream) and androgenetic alopecia (in a higher strength solution). It is a topically delivered small molecule that penetrates the skin to reach the androgen receptors of the sebaceous gland and hair follicle. It aims to be the first effective and safe topical antiandrogen that does not have systemic effects.

In androgenetic alopecia (AGA), high concentrations of dihydrotestosterone (DHT) at the hair follicle level shorten the hair cycle and gradually miniaturize scalp follicles inducing them to produce progressively smaller, thinner hairs until they become unable to produce new hair. These DHT dependent effects are considered, in most cases, reversible, so that AGA could be susceptible to medical treatment with drugs such as Clascoterone by blocking DHT interaction with

the specific hair follicle androgen receptors. If successful, Clascoterone would be the only topical antiandrogen approved for use in AGA and could be used in both men and women.

Cassiopea believes that Clascoterone will not have the contraindications and safety warnings of the only other androgen modulator approved for the treatment of AGA, which is administered orally and indicated only for men. Clascoterone does not interfere with the hormonal and, in particular, testosterone profile of patients; libido and sexual behavior are unaffected in clinical trials to date. Clascoterone is metabolized quickly to Cortexolone, a physiological component of the body's endogenous pool of corticosteroids, thus attaining high local activity without having any systemic effects.

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.

Next event: 2018 Half Year Results reporting on 18 July 2018

- The half-year report 2018 as well as the corresponding press release and presentation will be distributed at 07:00 CET on 18 July 2018 and will also be available on http://www.cassiopea.com/investor-relations/financial-reports/yr-2018.aspx, on http://www.cassiopea.com/news-and-media/press-releases/yr-2018.aspx and on http://www.cassiopea.com/investor-relations/presentations/yr-2018.aspx respectively

- There will be a telephone conference on 18 July 2018 at 16:00 CET where Cassiopea's management will discuss the half-year 2018 results and provide an update on the pipeline. This call is scheduled to last 30-45 minutes and will be held in English:

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