# Cassiopea Announces Very Positive Top-Line Phase 3 Results for Winlevi® (Clascoterone) cream in Treating Acne

**Lainate, Italy – 10 July 2018** - Cassiopea SpA (SIX: SKIN), a clinical-stage specialty pharmaceutical company focused on developing and commercializing innovative and differentiated medical dermatology products, today announced that top line results from two pivotal phase 3 clinical trials for its topical anti-androgen Winlevi® cream 1% (Clascoterone) demonstrated highly statistically significant improvements for all primary clinical end points.

Winlevi® is the first ever topical antiandrogen for the treatment of acne with a very novel mechanism of action and a very clean safety profile.

"We are enthusiastic about these top-line results," said Cassiopea CEO, Diana Harbort. "The US derm market has not seen a new mechanism for acne since the 1980s. If approved, Winlevi® will be the first topical antiandrogen. Winlevi® works at the top of the cascade of the events generating acne devoid of any significant hormonal side effect. Therefore – if approved – we expect a high interest from doctors and patients."

In two clinical trials (study 25 and 26) a total of 1440 subjects were enrolled in 112 sites in the US and Europe. The trials were identical in design and evaluated the safety and efficacy of Winlevi® (Clascoterone) compared to vehicle (placebo) in acne patients ages > 9 years with an IGA score of 3 or 4. Subjects applied Winlevi® 1% cream or placebo twice daily for 12 weeks. Upon completion of the clinical trials 604 subjects were rolled over into an open label long term safety trial to assess the safety of the treatment for a total duration of 12 months. This safety trial is scheduled to be completed by end of August.

The primary endpoints evaluated in the trials were: 1) the proportion of subjects in each treatment group with at least a two point reduction on IGA (Investigator General Assessment) compared to baseline and an IGA score of 0 (clear) or 1 (almost clear) at week 12, 2) the absolute change from baseline in non-inflammatory lesion counts (NILC) in each treatment group at week 12, and 3) the absolute change from baseline in inflammatory lesion counts (ILC) in each treatment group at week 12.

**Efficacy Results**

In study 25, a two point reduction and an IGA score of 0 (clear) or 1 (almost clear) was achieved in 16.1 % of patients treated with Winlevi® versus 7.0 % in the placebo group in the ITT population (p value = 0.0012), with 16.7% versus 6.5% in the PP (p value = 0.0004) respectively. In study 26, a two point reduction and an IGA score of 0 (clear) or 1 (almost clear) was achieved in 18.7 % of patients treated with Winlevi® versus 4.7 % (p value < 0.0001) in the placebo group in ITT population and in the PP population a two point reduction and an IGA score of 0 (clear) or 1

(almost clear) was achieved in 18.6 % of patients treated with Winlevi® versus 4.0 % in the placebo group (p value = 0.0001).

In study 25, the absolute change from baseline of non-inflammatory lesion counts was -19.8 in patients treated with Winlevi® versus -13.7 in the placebo group (p value = 0.0046) for ITT population and -19.3 for Winlevi® versus -12.1 for placebo in the PP population (p value = 0.0015). In study 26, the absolute change from baseline of non-inflammatory lesion counts was -19.8 in patients treated with Winlevi® versus -11.3 in the placebo group (p value = 0.0001) for ITT and -20.1 vs. -11.5 (p value < 0.0001) for the PP population.

In study 25, the absolute change from baseline of inflammatory lesion counts in the ITT population was -19.8 in patients treated with Winlevi® versus -15.6 in the placebo group (p value = 0.0032), whereas in the PP population patients treated with Winlevi® had -19.8 versus 15.2 (p value = 0.0016). In study 26, the absolute change from baseline of inflammatory lesion counts was -20.2 in patients treated with Winlevi® versus -13.1 in the placebo group (p value <0.0001) and -19.9 for Winlevi® versus -12.9 for placebo (p value < 0.0001).

The secondary endpoints were: 1) absolute and percentage change from baseline in total lesion count at week 12, 2) percentage change from baseline in non-inflammatory lesion count at week 12, and 3) percentage change from baseline in inflammatory lesion count at week 12. Results will be published immediately when available.

No treatment-related serious adverse events among patients treated with Winlevi® have been recorded during the trials.

Local skin reactions, if present, were predominantly classified as mild.

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

**Conference Call**

Cassiopea SpA invites you to participate in a conference call on July 10th, 2018 4 pm CET during which the Company will discuss today's press release.

The dial-in numbers are:

Continental Europe: +41 (0) 58 310 50 00

UK: +44 (0) 207 107 06 13

USA: +1 (1) 613 570 56 13

**About Winlevi®**

Winlevi® (Clascoterone) is a new chemical entity topical anti-androgen 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. It aims to be the first effective and safe topical anti-androgen that does not have systemic effects.

Winlevi® (Clascoterone) helps to prevent that cascade of events that leads to acne. It displaces the androgen hormones from the androgen receptors on the sebaceous gland within the hair follicle.

Winlevi® (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.

A different formulation containing a higher strength of Clascoterone (Breezula®) is also in Phase 2 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.

**Next events**

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