Cassiopea announces completion of recruitment of Phase II proof of concept trial of CB-06-02 trial in genital warts

Lainate – December 7, 2017 - Cassiopea SpA (SIX: SKIN) today announced that the enrolment of the phase II proof of concept trial for the treatment of genital warts with CB-06-02 has been completed.

The double blind, two parallel arm trial, conducted in Israel screened 75 subjects and randomized 68 subjects, for 14 weeks of treatment and 3 months of follow up with 15% gel (QD) versus placebo (QD). The objective was the assessment of efficacy, safety and tolerability evaluation of CB 06-02 15% gel versus vehicle, in the treatment of genital warts in women. In the follow-up post treatment period, subjects with complete clearance were assessed after 12 weeks; subjects with partial clearance or that withdrawn for other reasons were assessed after 4 weeks.

Primary endpoints:

- Proportion of subjects achieving success in each treatment group by the end (week 14th) of CB-06-02 15% or vehicle gel treatment, with success defined as complete clearance of external genital warts.

Secondary endpoints:

- Proportion of subject achieving success in each treatment group at week 2, 4, 6, 8, 10, 12, with success defined as complete clearance of external genital warts.
- Time to complete clearance in subjects treated with CB-06-02 15% or vehicle gel topical treatment.
- Proportion of subjects in each treatment group with partial clearance, defined as reduction of >50% in the number of external genital warts, or in total wart surface area, by the end (14th week) of CB-06-02 15% or vehicle gel treatment.
- Proportion of subjects in each treatment group, with partial clearance, defined as reduction of >50% in the number of external genital warts, or in total wart surface area, at week 2, 4, 6, 8, 10, and 12.
- Time to partial clearance in subjects treated with CB 06-02 15% or vehicle gel topical treatment.
- Proportion of subjects in each treatment group, who achieved complete clearance and with recurrence, defined as appearance of a wart in the same previously treated spot.
- Time to recurrence in subjects treated with CB-06-02 15% or vehicle gel topical treatment.
- Absolute and percent change in total number of warts that completely or partially cleared at week 2, 4, 6, 8, 10, and 12 and by the end of CB 06-02 15% or vehicle gel topical treatment.

Diana Harbort, CEO of Cassiopea SpA, comments: ”The genital warts market is characterized by products with low efficacy and high recurrence rates. CB 06-02 acts as a low toxicity immunomodulator in supporting the natural immune response against HPV and genital warts for potentially quicker clearance and reduced recurrence. We look forward to the proof of concept results which we expect in H1, 2018”.

About Cassiopea

Cassiopea is a clinical-stage specialty pharmaceutical company focused on developing and commercializing innovative and differentiated medical dermatology products. Initial 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

Dermatology Summit San Francisco	January 7, 2018
2018 AAD Annual Meeting	February 16-20
Full-year results 2017 reporting	February 2018

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