



Cassiopea announces completion of phase II proof of concept of its novel antibiotic for acne and decision to pursue further development

Lainate – October 18, 2016 - Cassiopea SpA (SIX: SKIN) announced today the results of its proof of concept trial of its novel topical antibiotic CB-06-01 in subjects with moderately to severe acne and the decision to proceed with further development.

The aim of this POC trial was the evaluation of efficacy and safety of a CB-0601, new antibiotic composition, topically applied to moderate to severe facial acne patients.

90 subjects were enrolled and 86 of them completed the treatment.

This POC study in a small number of patients was the first trial in humans and was not powered to obtain a statistically significant result but was designed to be a first indication of the potential product efficacy and safety profile.

The results suggest that CB-0601 could potentially be an efficacious drug for the selected indication, even though further investigations will be needed to assess the full drug potential.

Notwithstanding the limitations implicit in the study, there is clear evidence that the drug reduced inflammatory lesions within the Full Analysis Set population after 12 weeks of treatment by 66.2% (median value), a median reduction of 9% greater than vehicle. This efficacy trend has been confirmed by the changes in the total lesion count, where a reduction in median of 17.2% was observed versus vehicle in the FAS population. In the same population, a two point reduction in IGA score, a particularly important endpoint in Phase 3 pivotal studies, was recorded in 17.8% of patients in the CB-06-01 group versus 6.7% in the vehicle group.

No Serious Adverse Events were reported in the trial, nor evident local skin reactions.

The Company believes that there is clear potential for further exploitation and has therefore decided to move ahead to optimize the formulation and then conduct a formal Phase II b Dose Ranging Program to be started soon.

Separately Cassiopea announces that Louise Dube, Director of R&D is retiring at year end. Her responsibilities will be assumed by CSO Luigi Moro and Alessandro Mazzetti, CMO of Cosmo Pharmaceuticals.

Diana Harbort, CEO of Cassiopea SpA, commented: "The antibiotic segment is one of the largest markets for the treatment of acne. However antibiotic resistance in *P acnes* is increasing, with many countries reporting that more than 50% of *P acnes* strains are resistant to topical macrolides. The data we obtained has encouraged us to pursue further development of CB-06-01. I am

convinced that the continued advancement of our innovative portfolio has us on track to establish ourselves as a key player in the dermatology field.”

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.

Next events

Jefferies Global Health Care Conference
Credit Suisse Small & Mid Cap Conference

London, November 16, 2016
Zurich, November 17, 2016 (one on ones only)

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