Cassiopea announces that the FDA has agreed to the Special Protocol for the Winlevi phase III trial

Lainate, August 4, 2015; Cassiopea SpA ("Cassiopea"), a clinical stage specialty pharmaceutical company focused on developing and commercializing innovative and differentiated medical dermatology products addressed to the topical treatment of acne, androgenic alopecia (AGA) and genital warts announced today that the FDA has agreed to its clinical protocol in a special protocol assessment.

The protocol is titled, "A Phase 3, Multicenter, Randomized, Double-Blind, Vehicle Controlled Study to Evaluate the Safety and Efficacy of Cortexolone 17α-Propionate (CB-03-01) 1% Cream Applied Twice Daily for 12 Weeks in Subjects with Facial Acne Vulgaris".

The agreed primary endpoints to be assessed for each treatment group at Week 12 are:

1) Investigator's Global Assessment (IGA) success defined as scoring 0 or 1 (clear or almost clear) AND at least 2-grade improvement from baseline.
2) Absolute change from baseline in non-inflammatory lesion counts (NILC).
3) Absolute change from baseline in inflammatory lesion counts (ILC).

Diana Harbort, CEO commented: "I am very pleased that the FDA agreed with our clinical protocol. Now we will execute our plan for the phase 3 trials. We expect to enroll the first patient in the last week of October."

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. For further information on Cassiopea, please visit www.cassiopea.com.

Cassiopea SpA
Dr. Chris Tanner, CFO & Head of Investor Relations
Tel: +39 02 868 91 124