



Cassiopea attains clinical endpoints in Breezula® alopecia proof of concept trial

Lainate – February 24, 2016 - Cassiopea announced top-line results from the recently completed POC Phase II clinical trial of Breezula® (CB-03-01), a topical antiandrogen for the treatment of androgenetic alopecia. The study evaluated three different groups using vehicle, Breezula® 5% concentration and Minoxidil® 5% solution as active comparator in US subjects with mild to moderate alopecia treated for 6 months.

The preliminary analysis of the data indicates that the study met both its two pre-defined co-primary efficacy endpoints, increase in total area hair count within 1 cm² (TAHC) and subject hair growth assessment (HGA) at Month 6.

Breezula® has shown an evident clinical efficacy in increasing hair count (TAHC mean change 12.70 CB-03-01 vs. 2.92 Vehicle) and a positive patient satisfaction (0.3 vs. negative 0.24 Hair Growth Assessment - HGA) compared to placebo. Breezula® has also shown a clear improvement in the Investigator Global Assessment – IGA (mean increase 0.43 vs. 0.12 placebo).

Breezula® has shown a favorable efficacy profile versus Minoxidil® in both HGA (0.3 vs 0.12) and IGA (0.43 vs 0.4). As for mean increase in TAHC at Month 6 (12.70 Breezula® vs. 18.8 Minoxidil®), it should be considered that the treatment per protocol was 6 months and that it is known that antiandrogens (such as Propecia®) show maximum efficacy at 12 months, while it is also known that Minoxidil® has its efficacy peak at 4 months, so the data were as expected. Our study continued to demonstrate the favorable safety profile of Breezula's® API which is the same active as in Winlevi® (Cassiopea's topical antiandrogen in phase III for acne).

Given the patients sample size (30 per group) the study was not powered to show statistical superiority at this stage.

Diana Harbort, CEO, said: "I am more than happy with these results. Our objective is to develop an efficacious topical antiandrogen product without limiting side effects and with the ability of being used by both men and women. The clinical data are in line with our hopes. Now we are very much looking forward to taking Breezula® into phase II dose ranging studies as quickly as possible".

About Cassiopea

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

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