Cassiopea Announces Top Line Positive Proof of Concept Phase II Results for CB-06-02 Immune Modulator in Treating Genital Warts

Lainate, Italy – 19 July 2018 - Cassiopea SpA (SIX: SKIN), a clinical-stage pharmaceutical company developing and commercializing innovative medical dermatology products, today announced that the proof of concept phase II clinical trial for its CB-06-02 topical 15% immune modulator tellurium-based gel for the treatment of external genital warts in women demonstrated statistically significant successful complete clearance rates in the PP population and successful complete clearance rates in the ITT population.

The Phase II, multicenter, randomized, double-blinded, vehicle (placebo) controlled study evaluated the efficacy, safety and tolerability of topical CB-06-02 15% gel as compared to vehicle in female subjects with external genital warts. The study was conducted in six sites in Israel. 68 women 18 years of age and older were treated in two groups. Either CB-06-02 15% or vehicle gel were administered topically once a day with the gel being left on the skin overnight. The primary efficacy endpoint evaluated in the trial was the proportion of subjects achieving complete clearance of external genital warts using CB-06-02 15% or vehicle by the end (14^{th} week) of treatment. Several other secondary endpoints are also being evaluated.

Top Line Efficacy Results in Primary Endpoint

In the PP population (56 subjects), 75% of the CB-06-02 group achieved complete clearance of external genital warts while 40.6% of subjects achieved complete clearance using vehicle. These results are statistically significant with a p value of 0.0111. In the ITT population (67 subjects), 56.3% of the CB-06-02 group achieved complete clearance of external genitals warts while 37.1% of subjects achieved complete clearance using vehicle.

Diana Harbort, CEO Cassiopea, said: “We are very encouraged by these results, which pave the way for further successful development. These data will allow us to continue working to bring this new mechanism for the treatment of genital warts to patients and their physicians. We will now focus on doing the development work to prepare for a dose ranging trial.”

Safety Results

There were no treatment-related serious adverse events among patients treated with CB-06-02.

About Genital Warts

Genital warts, also known as Condyloma Acuminata, have their clinical manifestation in ~1% of the sexually active population. The Human Papilloma Virus (HPV) types 6 and 11 are particularly associated with genital warts and are responsible for ~90% of the cases. The warts manifest themselves as external visible lesions of the anogenital area.

About CB-06-02

CB-06-02, a NCE, immune modulator is being developed for the treatment of genital warts. Cassiopea believes it is the first potential treatment for this condition based on tellurium, a rare element. It acts as a low-toxicity immunomodulator in supporting the natural immune response against Human Papilloma Virus, or HPV. Based on the drug profiling Cassiopea has performed to date, the Company believes CB-06-02 has the potential to have a faster onset of action and a lower recurrence rate than currently available treatments.

CB-06-02 gel was previously tested in subjects with external genital warts in an open label study to assess the safety and efficacy of the improved formulation of the CB-06-02 gel. In the study (ended July 2013), the BAS024 formulation was tested in 11 female subjects with external genital warts who applied the formulation twice daily for up to 16 weeks. Efficacy and safety data were collected; data regarding the satisfaction of the subjects from the treatment, comfort of application, etc. was collected as well. The treatment was found safe and tolerable, showing relatively minimal skin irritation and no SAEs. Complete clearance of warts was achieved by 8 (73%) of the treated subjects while all 3 other subjects achieved partial clearance. No recurrence was observed during 3 months post treatment follow up. The CB-06-02 gel was highly graded for comfort and easy to apply by most of the participants.

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

Jefferies Health Care Conference (London)	14-15 November 2018
CS Small & Mid Cas Conference (Zurich)	16 November 2018
Full-year results 2018 reporting	February 2019

Contact:

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