



Cassiopea Announces JAAD Publication of Positive Results from A Long-Term Safety Study of Clascoterone Cream 1% for the Treatment of Acne

Lainate, Italy – 23 June 2020 - Cassiopea SpA (SIX: SKIN), a specialty pharmaceutical company developing and preparing to commercialize prescription drugs with novel mechanisms of action (MOA) to address long-standing and essential dermatological conditions, today announced the publication of positive safety data from a long-term extension study evaluating Clascoterone cream 1% for acne in the online issue of [Journal of the American Academy of Dermatology \(JAAD\)](#).

The study demonstrated that Clascoterone cream 1%, has favorable long-term safety for the treatment of acne with low rates of treatment related adverse events (AEs).

“These results underscore the promise of Clascoterone cream 1% as a first in class topical acne treatment with a favorable safety profile that targets the androgen receptor in both males and females 9 years of age and older,” said Dr. Linda Stein Gold, Director of Dermatology Clinical Research at Henry Ford Health System in Detroit, Michigan. “Clascoterone is a topical androgen receptor inhibitor that fights acne through a novel mechanism of action, by limiting dihydrotestosterone binding to the androgen receptors in the sebaceous gland. Androgen receptor inhibitors target acne by affecting sebaceous gland activity, which may reduce lipid (sebum) production and inflammatory cytokine synthesis by sebocytes. Safety data published in JAAD showed that Clascoterone has a consistent and favorable safety profile.”

The multi-center, open-label, long-term extension study, CB-03-01/27, enrolled a total of 609 subjects from the pivotal studies /25 and /26, with 347 completing the study (n = 179 Clascoterone cream, n = 168 vehicle cream, original group assignment). Eligible patients for CB-03-01/27 must have completed one of the 12-week Phase III pivotal studies. The two Phase III vehicle-controlled studies (CB-03-01/25 and CB-03-01/26) published in [JAMA Dermatology](#) showed Clascoterone cream significantly improved Investigator’s Global Assessment (IGA) scores and lesion counts in subjects greater than 9 years of age with moderate to severe acne. Clascoterone and vehicle treated subjects from these pivotal Phase III trials participated in this study, CB-03-01/27; the extent of drug exposure and adverse events were assessed, evaluating long-term safety of Clascoterone cream.

All subjects applied Clascoterone cream 1% twice daily to the face for up to twelve months and/or trunk for up to nine months. Patient visits occurred at months 1, 3, 6, and 9 where disease severity (IGA score), medication use, vital signs, AEs, treatment emergent adverse events (TEAEs), and serious adverse events (SAEs) were assessed in all patients.

Subjects were assessed on the IGA 5-point scale from clear to severe; if subject was more than mild at an evaluation visit, the treatment regimen continued.

Key safety findings showed that Clascoterone cream 1% had a low frequency of TEAE's over long-term observed treatment. Local skin reactions were mostly mild. Long-term efficacy was not a primary endpoint of this study.

Diana Harbort, CEO of Cassiopea, commented: "June is acne awareness month and we are proud that JAAD has accepted our study results for publication, ensuring that a broad range of dermatology health care professionals globally will have access to these important data. Acne affects millions of people worldwide, and, if approved, Clascoterone cream 1% brings the first new MOA in acne treatment in nearly 40 years. Our New Drug Application is under review by the US FDA and we look forward to the PDUFA date of August 27, 2020."

About Cassiopea

Cassiopea is a specialty pharmaceutical company developing and commercializing prescription drugs with novel mechanisms of action (MOA) to address long-standing and essential dermatological conditions, particularly acne, androgenetic alopecia (or AGA) and genital warts. Cassiopea is investing in innovation that is driving scientific advancement in areas that have been largely ignored for decades. The portfolio comprises four unencumbered clinical candidates, for which Cassiopea owns the worldwide rights. Once approved, the Company plans to commercialize the products directly in the U.S. and partner the products for countries outside of the US. For further information on Cassiopea, please visit www.cassiopea.com.

About Clascoterone

Clascoterone, a new chemical entity, is a proposed first-in-class topical androgen receptor inhibitor under U.S. Food and Drug Administration (FDA) review for the treatment of acne (in a 1% cream) and in late stage development for the treatment of androgenetic alopecia (in a higher strength solution) in males. Although Clascoterone's exact mechanism of action is unknown, laboratory studies suggest clascoterone competes with androgens, specifically dihydrotestosterone (DHT), for binding to the androgen receptors within the sebaceous gland and hair follicles. Because of Clascoterone's likely local effect at the site of application, the risk of off-target, or systemic side effects, is minimized.

Next events:

Half Year Report 2020	29 July 2020
Investora	23-24 September 2020, Zurich
Jefferies Global Health Care Conference	17-19 November 2020, London
Credit Suisse Small & Mid Cap Conference	18-20 November 2020, Zurich

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