



Cassiopea Announces FDA Submission of New Drug Application for Clascoterone Cream 1%, the First New Mechanism of Action for Acne in Nearly 40 Years

Lainate, Italy – August 20, 2019 - Cassiopea SpA (SIX: SKIN), a specialty pharmaceutical company developing and commercializing prescription drugs with novel mechanisms of action (MOA) to address long-standing and essential dermatological conditions, announced today that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking marketing approval for clascoterone cream 1% for the treatment of acne.

Clascoterone cream 1% is under investigation as a first-in-class topical androgen receptor inhibitor for the treatment of acne. Clascoterone is a topically delivered small molecule that penetrates the skin to reach the androgen receptors of the sebaceous gland. It aims to be the first effective and safe topical androgen inhibitor therapy that does not have systemic side effects.

Clascoterone cream 1% targets androgen receptors at the site of application, inhibiting the local (skin) effects of dihydrotestosterone (DHT) a key driver of acne lesion development. Laboratory studies show that clascoterone inhibits lipid production from oil producing cells (sebocytes) and reduces proinflammatory cytokines, mediators influenced by androgens. Thus, pathways that foster acne lesion development are disrupted by clascoterone. Unlike oral hormonal therapies for acne, it may be used in both male and female patients.

“This is noteworthy because it’s been so long since there has been a new, first-in-class molecule for the treatment of acne, particularly given that it is a topical treatment that targets the androgen receptor and works on sebocytes to mediate lipid production and inflammation,” said Dr. Lawrence Eichenfield, Chief of Pediatric and Adolescent Dermatology at Rady Children's Hospital–San Diego. “Giving physicians another treatment option for their patients who struggle with acne is tremendously important.”

Last year, Cassiopea announced topline results from two pivotal phase III clinical trials for clascoterone cream 1% demonstrating highly statistically significant improvements for all primary clinical endpoints. No treatment-related serious adverse events among patients have been recorded during the trials; local skin reactions, if present, were similar to vehicle and predominantly classified as mild. Safety results, announced earlier this year, were confirmed in an open-label safety study for a treatment period of up to one year, with an expanded drug application surface area that included both the face and trunk. The

extended duration and coverage of the topically applied drug did not increase the incidence of significant side effects.

“If approved, clascoterone cream 1% will be the first new mechanism of action in the treatment of acne in nearly 40 years, offering dermatologists and patients a new and effective therapeutic alternative,” said Diana Harbort, CEO of Cassiopea. “We’re focused on the urgency to treat skin conditions that can leave not only physical scars, but also emotional scars. That’s why innovation is so critical. We are committed to finding a way to treat acne that addresses the root causes of the condition.”

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. 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 topically applied androgen receptor inhibitor in late stage development for the treatment of acne (in a 1% cream) and androgenetic alopecia (in a higher strength solution). When applied directly to the skin surface, clascoterone penetrates the skin to reach the androgen receptors within the sebaceous glands and hair follicles. Clascoterone is on track to becoming the first effective and safe topical anti-androgen without systemic side effects.

Next events

CS Small & Mid Cap Conference, Zurich	13-15 November 2019
Jefferies Health Care Conference, London	20-21 November 2019
Full-year results 2019	February 2020

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