Efficacy and safety of clascoterone cream 1% in patients with acne vulgaris across subgroups defined by demographic characteristics

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Background: Clascoterone cream 1% is approved for the treatment of acne vulgaris in patients aged ≥12 years. Pooled efficacy and safety data analyses stratified by age and sex from two Phase 3 studies and a long-term extension study of clascoterone cream 1% in patients ≥12 years of age with moderate-to-severe acne vulgaris are presented.

Methods: Patients with moderate-to-severe acne were randomized 1:1 to twice-daily treatment of the face with clascoterone or vehicle for 12 weeks; all patients continuing into the extension study applied clascoterone for up to 9 additional months. Efficacy was assessed from proportion of randomized patients achieving Investigator's Global Assessment score of 0 or 1 (IGA 0/1) among those completing the extension study per protocol (PP population). Safety was assessed from treatment-emergent adverse events (TEAEs) in all treated patients.

Results: Of 709/712 patients aged ≥12 years originally randomized to clascoterone/vehicle, 63.9%/60.4% were female, with mean ± standard deviation age 19.8 ± 6.1/19.5 ± 6.1 years; 11/13 were male patients aged ≥25 years. Among patients in the PP population randomized to clascoterone/vehicle, 17.3%/3.8% (12–17 years; P <0.0001), 25.3%/8.6% (≥18 years; P <0.0001), and 32.6%/10.1% (female patients ≥25 years; P = 0.0009) achieved IGA 0/1 by Week 12; 45.3%, 55.4%, and 44.4% of extension study patients aged 12–17, ≥18, and female patients ≥25 years, respectively, achieved IGA 0/1 after 12 months applying clascoterone. Frequency of TEAEs through Week 12 in clascoterone/vehicle-treated patients was 10.8%/14.2%, 11.5%/11.6%, and 9.6%/12.9% for ages 12–17, ≥18, and female patients ≥25 years, respectively.

Conclusion: Clascoterone efficacy and safety were maintained in adolescent and adult patients, including female patients aged ≥25 years.

Sponsorship: The studies were funded by Cassiopea S.p.A. and medical writing support for this abstract by Sun Pharma.