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LETTER

Androgen Receptor Inhibitors in the Treatment of Acne Vulgaris: Efficacy and Safety Profiles of Clascoterone 1% Cream [Letter]

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Dear editor

We read the review by Sanchez et al[1] that summarizes the clinical data evaluating clascoterone cream 1% for acne vulgaris treatment. We identified several data errors and numerous inaccuracies in how the literature was cited within their article that require correction. We would like to highlight the most significant errors. In the Phase 2a study, the percentage of patients with abnormal hypothalamic pituitary adrenal axis suppression was 7% (3 of 42 patients) and not 42.7% as stated in the review.[2] Further, the study had an open-label design and was not a randomized controlled trial.[2] The authors also incorrectly reported the percentages of males and females enrolled in the study and mean maximum clascoterone concentrations in plasma; 36% (15 of 42) of patients were male and 64% (27 of 42) were female, and the mean maximum clascoterone concentrations in plasma were 4.4 ng/mL (Cohort 1) and 4.6 ng/mL (Cohort 2).[2]

When describing the Phase 2b dose-escalating study,[3] authors accurately report the number of individuals experiencing at least 1 adverse event (AE) for those who received vehicle and clascoterone 0.1% twice daily, but then reported the number of patients with more than 1 AE for the clascoterone 1.0% twice daily group. Further, the percentage of patients with mild erythema was 36.8% and not 32.6%.[3] In Table 1 of the review, the median change in inflammatory lesion count (ILC) is reported as 13.5, but it should be −13.5.[3] The minus sign appears to have remained on the previous line rather than with the value.

Errors also exist in the summary of Phase 3 data.[4,5] In Table 1 of the review, the authors only report data from one of the two Phase 3 pivotal trials. The data from both should be reported. The text in this column should start with "in the two studies" rather than "in two of the sites." Further, the correct *P*-value for ILC reductions with clascoterone cream 1% vs vehicle was 0.003,[5] not $P < 0.001$. Additionally, the authors report that "18% of 347 subjects" developed treatment-emergent AEs in the open-label extension study, but the denominator should be 607 patients (safety population) and not 347.[4] The authors also state that nasopharyngitis occurred in 20 of 179 patients, whereas 20 events were reported in 16 of 607 patients in the cited source.[4]

Given the number and seriousness of these errors, we strongly request that the authors address them and provide a corrected version of the article.

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Disclosure

AM is employed as the chief medical officer for Cassiopea S.p.A., and holds stock options in the company, and has served as the chief medical officer of Cosmo Pharmaceuticals. KK is an employee of Sun Pharmaceutical Industries, Inc. LM served as CSO of Cassiopea S.p.A. The authors report no other conflicts in this communication.

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