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Treatment response in ophiasis patients in a phase 2 trial of ATI-501 (an oral Janus kinase 1/3 inhibitor)

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Background: ATI-501, a JAK 1/3 inhibitor, was investigated in a phase 2 study evaluating efficacy and safety in patients with alopecia areata (AA). Patients with ophiasis were included. Results for ophiasis patients from the study are reported.

Methods: This phase 2, randomized, double-blind, multicenter trial evaluated the safety and efficacy of three doses of ATI-501 compared with placebo in 87 AA patients. Eligible patients had 30%-100% scalp hair loss assessed by SALT (Severity of Alopecia Tool) and a current episode of hair loss from 6 months to 12 years. Patients were randomized in a 1:1:1:1 ratio and received either ATI-501 400 mg, 600 mg, 800 mg, or placebo as an oral suspension twice daily for 24 weeks.

Results: The trial's primary end point was the mean percent change from baseline in the SALT score at week 24. Patients in the three ATI-501 dose groups had statistically significant improvements compared with placebo. Thirteen patients had ophiasis: 1 randomized to placebo; 4 randomized to each active dose group. Of the ophiasis patients, 25% receiving ATI-501 reported >50% hair regrowth based on SALT while the ophiasis patient on placebo did not. Of non-ophiasis patients, 26% (400 mg), 31% (600 mg) and 22% (800 mg) reported >50% hair regrowth based on SALT. While not fully powered, this subgroup analysis showed comparable response between ophiasis and non-ophiasis patients. ATI-501 was generally well tolerated. No SAEs occurred. Rates of AEs were similar across groups.

Conclusions: Treatment with ATI-501 resulted in significant hair regrowth in patients with AA (including ophiasis), with acceptable safety.

Commercial disclosure: Aclaris was the study sponsor and covered all costs related to the poster development.

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Validation of patient-reported outcomes information system sleep disturbance and sleep-related impairment in atopic dermatitis patients

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Background: Sleep disturbances are common in adults with atopic dermatitis (AD). Many different patient-reported outcomes exist that could be used to assess sleep disturbances in adults with AD. However, little is known about their measurement properties.

Objective: To determine the measurement properties of Patient-Reported Outcomes Information System (PROMIS) sleep disturbance and sleep-related impairment question banks in adult AD patients.

Methods: Self-administered questionnaires and skin examinations were performed in 719 adult patients (age ≥18 years) with AD in a dermatology practice setting.

Results: PROMIS sleep disturbance and sleep-related impairment questionnaires showed moderate correlations to each other ($r = 0.57$), and weak correlations with frequency of AD symptoms (POEM) ($r = 0.36$, $r = 0.34$), itch intensity (average numerical rating scale [NRS]-itch: $r = 0.33$, $r = 0.31$; worst NRS-itch: $r = 0.34$, $r = 0.31$), and AD severity (EASI: $r = 0.34$, $r = 0.28$; SCORAD: $r = 0.35$, $r = 0.32$) (Spearman correlations, $P < .0001$). PROMIS sleep disturbance and sleep-related impairment showed significant and stepwise increases for each level of severity of self-reported global AD severity (Kruskal Wallis, $P < .0001$ for all). PROMIS sleep disturbance and sleep-related impairment showed good internal consistency (Cronbach's alpha = 0.84, 0.90). Both PROMIS sleep disturbance and sleep-related impairment showed responsiveness in patients with ≥2 point improvement in self-reported AD severity, ≥3.4 and ≥6.6 point improvement in POEM and EASI (minimal clinically important difference).

Conclusions: PROMIS sleep disturbance and sleep-related impairment questionnaires show good construct validity, internal consistency, and responsiveness for use in adult AD patients.

Commercial disclosure: None identified.

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Characteristics associated with progression of hidradenitis suppurativa: 2-year interim results from the HS UNITE registry

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Introduction: The ongoing UNITE registry collects long-term clinical and quality-of-life data for hidradenitis suppurativa (HS) patients. This UNITE interim analysis evaluates the association of patient characteristics at baseline with risk of HS disease progression across the registry's first 2 years.

Methods: Enrolled patients are aged ≥12 years with active HS. Data are collected at baseline and at 6-month follow-up visits. Patient characteristics were determined at registry baseline. HS progression is defined as ≥1 of the following outcomes: lesion spread (abscesses, inflammatory nodules or draining fistulae in a body-region not seen at baseline), scar spread (scarring in a body-region not seen at baseline), and Hurley stage progression (shift to higher stage in any body-region vs baseline). Descriptive and multivariable regression analysis is performed.

Results: 594 patients were enrolled from 29 October 2013 to 29 December 2015. Data for this analysis were collected 29 October 2013 through 7 August 2018; >50% of patients had data available through 24 months. Multivariable logistic regression suggests that HS progression over 2 years is associated with current age (12 to <18 vs 18 to <40) ($P = .002$), longer time to diagnosis ($P = .028$), Hurley Stage (III vs I) ($P = .010$), and tobacco use (ever used vs nonuser) ($P = .013$).

Conclusions: Results suggest that early diagnosis and treatment, and smoking cessation, may be critical in preventing further disease progression, and that early onset of HS may be associated with rapidly progressive disease.

Commercial disclosure: 100% sponsored by AbbVie; medical writing support provided by AbbVie.

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Sunscreens (SPF15) provide sun protection (UVA+UVB) as well as prevent formation of free radicals and skin darkening better than vitamin C

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Background: Exposure of human skin to sun produces a range of acute and chronic adverse effects on skin, such as sunburn, pigmentation, photo dermatoses, photo aging and skin cancer. Current sunscreen standard testing procedures for UVB and UVA protection include the SPF and PA rating systems, respectively. However, the SPF and PA may not capture other biological benefits that the sunscreens could provide in terms of skin health.

Objective: The goal of this research was to explore the benefits of sunscreens beyond SPF compared with a well established multifunctional active such as vitamin C.

Methods: To establish the benefits of sunscreens in skin care formulations, experiments were conducted in vitro on skin keratinocytes, where formulations were applied on PMMA plates, but vitamin C was tested by adding directly to the cells, against UV exposure. The benefits were observed by testing ROS levels, catalase activity, lipid peroxidation and a key anti-aging marker (MMP1). The formulations were also tested on excised human skin for generation of ROS using electron paramagnetic resonance (EPR) spectroscopy.

Results: Results indicated that the body lotion containing SPF15 provided protection from reactive oxygen species (ROS) induced by UV exposure and enhanced catalase activity when compared with neat vitamin C. Interestingly, in ex-plant studies the ROS production was less in the body lotion with SPF15 compared with a marketed skin care formulation containing 10% vitamin C.

Conclusions: The results here clearly indicate that the formulation with SPF15 gives better or similar protection against sun damage as a high vitamin C—containing formulation.

Commercial disclosure: 100% sponsored by Unilever R&D.