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Dupilumab with concomitant topical corticosteroids promotes rapid and sustained improvement in clinical signs in patients with moderate to severe atopic dermatitis: LIBERTY AD CHRONOS trial

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Background: Dupilumab is approved in the USA for adults and adolescents with inadequately controlled moderate to severe atopic dermatitis (AD).

Objective: To report the effect of dupilumab on AD signs measured by Global Individual Signs Score (GISS) using data from the phase 3 LIBERTY AD CHRONOS trial (NCT02260986).

Methods: Adults with moderate to severe AD were randomized 1:3 to dupilumab 300 mg plus topical corticosteroids (TCS) every 2 weeks (q2w+TCS) or placebo+TCS (control) for 52 weeks (wks). Least squares (LS) mean scores (standard error [SE]) for total GISS (score range 0-12) and its components (erythema, infiltration/papulation, excoriations, lichenification; score range per item 0-3) are reported. *P* values are for q2w+TCS vs control for change from baseline.

Results: 421 patients were randomized (q2w+TCS n = 106; control n = 315). Dupilumab treatment significantly improved total GISS as early as wk 2 with improvements sustained through wk 52 (LS mean [SE] score (q2w+TCS/control): baseline: 8.9 (0.14)/8.8 (0.08); wk 2: 6.1 (0.19)/7.0 (0.12) [$P < .0001$]; wk 52: 3.2 (0.24)/5.1 (0.22) [$P < .0001$]). Similarly, dupilumab+TCS also improved scores for erythema (baseline: 2.4 (0.04)/2.4 (0.03); wk 2: 1.7 (0.06)/1.9 (0.03) [$P = .0063$]; wk 52: 1.2 (0.08)/1.5 (0.07) [$P = .0001$]); infiltration/papulation (baseline: 2.2 (0.05)/2.2 (0.03); wk 2: 1.5 (0.06)/1.8 (0.04) [$P = .0003$]; wk 52: 0.8 (0.07)/1.3 (0.07) [$P < .0001$]); excoriations (baseline: 2.0 (0.07)/2.1 (0.04); wk 2: 1.2 (0.07)/1.6 (0.04) [$P < .0001$]; wk 52: 0.6 (0.07)/1.1 (0.07) [$P < .0001$]); and lichenification (baseline: 2.3 (0.06)/2.1 (0.03) [$P = .0050$]; wk 2: 1.6 (0.06)/1.8 (0.04) [$P = .0359$]; wk 52: 0.6 (0.08)/1.1 (0.07) [$P < .0001$]). Dupilumab was generally well tolerated.

Conclusions: Dupilumab 300 mg q2w+TCS resulted in rapid and sustained improvements in AD signs (erythema, infiltration/papulation, excoriations, lichenification) compared with control as measured by GISS in adults with moderate to severe AD.

Commercial disclosure: Medical writing/editorial assistance provided by Excerpta Medica, funded by Sanofi Genzyme and Regeneron Pharmaceuticals.

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Improving patient arrival times in an outpatient dermatology clinic

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Background: Clinic efficiency is paramount. Patients' lack of punctuality diminishes efficiency by increasing wait times for other patients and creates a pressured environment that can compromise patient/provider safety as staff may take shortcuts in order to accommodate a late arrival. Few studies have examined patient unpunctuality and thus practical solutions are restricted. This project sought to improve patient arrival times by changing patient appointment times from 10-min increments to 15-min increments in hopes that patients would be more likely to recall their scheduled appointment time resulting in greater punctuality. The primary end point was the percentage of late attendant and no-show patients in SLUCare Dermatology Senior Resident Clinic post-intervention for 1 month compared with 3 months pre-intervention and establish statistical significance.

Results: demonstrated that the percentage of late patients in the intervention cohort was a higher non-statistically significant proportion (29%) than the control group (21%). Percentage of no-show patients between the two cohorts (22% in intervention group vs 22.9% in control) was virtually equal and thus no statistically significant difference. Hence, this intervention failed to improve patient arrival times. Limitations of this study include short post-intervention period, lack of evaluation of seasonal variability on patient unpunctuality or assessment of the primary end point stratified by whether the patient is a new or established patient. This study reveals that further work is needed to better characterize late arrivals and no-show patients in outpatient dermatology clinics and strategies to mitigate this behavior.

Commercial disclosure: None identified.

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ARQ-151, roflumilast cream, improved psoriasis in phase 2a study

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Background: Objective: To assess the safety and efficacy of ARQ-151 (roflumilast cream), a highly potent and selective phosphodiesterase-4 (PDE-4) inhibitor, in subjects with chronic plaque psoriasis.

Methods: In this parallel group, double-blinded study, 89 psoriasis subjects (0.5% to ≤5% body surface area) were randomized 1:1:1 to ARQ-151 cream 0.5%, 0.15%, or vehicle applied once-daily for 28 days. Target plaques were analyzed for Target Plaque Severity Score (TPSS) and Target Plaque Area (TPA). Adverse events (AEs), clinical laboratory values, electrocardiograms, and pharmacokinetic (PK) parameters were measured.

Results: Statistically significantly greater mean percentage changes from baseline at week 4 in TPSS × TPA were observed for ARQ-151 cream 0.5% ($P = .0007$) and 0.15% ($P = .0011$) compared with vehicle. Both ARQ-151 doses showed similar efficacy through week 4, reaching statistical significance versus vehicle by week 2. Mean percentage change from baseline TPSS and TPA were significantly greater than vehicle for both ARQ-151 doses at week 4 ($P \leq 0.001$ and $P < .05$, respectively). Treatment emergent AEs (TEAEs) were mild or moderate, occurring with similar frequencies across groups. The most common TEAEs included application site erythema, application site pain, nasopharyngitis, and muscle strain. No serious AEs (SAEs) were reported. No TEAEs caused study discontinuation. day 28 PK plasma concentration vs time profiles suggested that exposure of roflumilast and roflumilast N-oxide achieved steady-state levels and increased dose-dependently.

Conclusions: ARQ-151, an investigational once-daily roflumilast cream, was well tolerated and led to substantial and early improvements in plaque psoriasis in this phase 2a study.

Commercial disclosure: 100% of the costs associated with poster creation weree paid by Arcutis, the study sponsor.

15310

Treatment of acne with spironolactone: A retrospective review of 395 adult patients at Mayo Clinic, 2007-2017

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Background: Importance: Few large studies have assessed spironolactone treatment of adult female acne.

Objective: To explore the role of spironolactone in the treatment of adult female acne.

Design: Retrospective chart review.

Setting: Tertiary care academic medical center.

Participants: Women evaluated at Mayo Clinic in Rochester, Minnesota, from 2007 through 2017.

Interventions: Spironolactone.

Main Outcomes and Measures: Assessing the efficacy of spironolactone treatment of a cohort of women evaluated at Mayo Clinic in Rochester, Minnesota, from 2007 through 2017.

Results: In total, 395 patients (median age, 32 years) received a median spironolactone dose of 100 mg daily. Approximately two-thirds of patients (66.1%) had a complete response; 85.1% had a complete response or a partial response greater than 50%. Median times to initial response and maximum response were 3 months and 5 months. Efficacy was observed across all severity subtypes of acne, including those with papulopustular and nodulocystic acne. Patients received long-term treatment with spironolactone (median duration, 13 months) and had few adverse effects.

Conclusions: and Relevance: Spironolactone is a safe and effective treatment of acne for women.

Commercial disclosure: None identified.