418 Treatment of patients experiencing dupilumab facial redness with itraconazole and fluconazole: A single institutional retrospective medical record review

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In this retrospective study, we investigated the management of DFR with itraconazole or fluconazole as a potential treatment for DFR. Methods: Inclusion criteria were: patients on dupilumab for at least 6 months, had a diagnosis of DFR, and completed at least two weeks of itraconazole or fluconazole. Results: Of 43 patients prescribed itraconazole, 22 (51.2%) patients were diagnosed with DFR and prescribed an azole. Of 16 patients completing a course of itraconazole, 11 (68%) had a post-treatment IGA of clear or almost clear (0 or 1), and the average self-reported improvement was 52%. Of the four patients treated with fluconazole, two (50%) had an IGA of clear or almost clear (0 or 1), and the average self-reported improvement was 50%. Conclusion: Du suppression with double-antifungal use provided further, preliminary evidence that itraconazole may improve DFR.

420 Topical hypericin ointment photodynamic therapy is effective and safe in CTCL (FLASH study)

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Additional cutaneous T-cell lymphoma (CTCL) therapies with better short/long term side effects are needed. Topical synthetic hypericin ointment 0.2%-5% (SGX101) activated with external cool-white visible light is a novel, non-destructive photodynamic therapy. We conducted a randomized, placebo-controlled, observed-blind multicenter Phase 3 trial evaluating its efficacy/safety in early-stage IA/IB CTCL across 37 U.S. sites. SGX101 was applied to 3 index lesions twice weekly, 18-24 hours prior to light therapy for a 6-week cycle for 3 treatment cycles. Cycle 1 (169 patients randomized) 2:1 SGX101 placebo control. Cycle 2 (all received SGX101) were required. Cycle 3 (index and additional lesions treated with SGX101) was optional. Index lesion response rate (IRR) and adverse events (AEs) were assessed 2 weeks after each cycle then monthly for 6 months. The trial primary endpoint was IRR based on the Composite Assessment Index for Lesion Severity (CAILS) score in patients treated with SGX101 vs placebo treated. 150% of patients (p=0.04). IRR for subjects who received 2 cycles of SGX101 was 40% (p=0.001) and 49%/p=0.0011 after Cycle 1. SGX101 effective for both p抱怨42%, p=0.001 after 2 cycles) and positive (58%, p=0.0039) treatments. The most common AEs were Grade 1-2 local application site skin reactions (15% of subjects) and only 1% of subjects discontinued the study due to AEs. No drug-related serious AEs occurred and SGX101 was not found systemically. SGX101 is effective in early stage CTCL with a highly favorable safety profile.

422 The Ichthyosis Scoring System (ISS): Development and validation of a novel ichthyosis severity assessment instrument

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Background: Ichthyosis clinical trials require reliable, validated severity assessments to identify appropriate subjects and quantify treatment outcomes. There is no validated scale to measure ichthyosis severity across the entire body. Objective: To create and validate a comprehensive and user-friendly instrument to measure total body ichthyosis severity in adults and children. Methods: We divided the body into 10 regions to score special regions of interest. Likert scales (0-4) were established to quantify scale and erythema, with descriptors of improvement have been established in CLE using the Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI), which is used in clinical trials, but has not been defined for cutaneous lupus erythematosus (CLE). The definition of improvement have been established in CLE using the Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI) for the change in CLASI activity (CLASI-A) score that corresponds to a meaningful flare in disease activity. In this retrospective study of our longitudinal database, we correlated change in CLASI-A with change in physician assessments of skin improvement in PGA-A. ILRR for subjects who received 2 cycles of SGX101 was 40% (p=0.001) and 49%/p=0.0011 after Cycle 1. SGX101 effective for both p抱怨42%, p=0.001 after 2 cycles) and positive (58%, p=0.0039) treatments. The most common AEs were Grade 1-2 local application site skin reactions (15% of subjects) and only 1% of subjects discontinued the study due to AEs. No drug-related serious AEs occurred and SGX101 was not found systemically. SGX101 is effective in early stage CTCL with a highly favorable safety profile.

423 Factors impacting likelihood of discontinuing immunosuppressive therapy for dermatomyositis: A single-center study

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Dermatomyositis (DM) is a chronic idiopathic inflammatory myopathy typically requiring chronic immunosuppressive therapy, but little is known regarding the likelihood of discontinuing these medications. We conducted a retrospective cohort study of our Stanford cohort of 257 patients with a median follow-up time from disease onset of 4.9 years and a median time for medication discontinuation of 5.1 years. Log rank analysis indicated that patients with a clinically amyopathic course (p=0.014) or DM-specific autoantibodies (p=0.039) had a greater likelihood of discontinuing these medications. In addition, non-Hispanic patients trended towards discontinuing medications earlier than Hispanic patients (p=0.077). Cox proportional hazards regression modeling demonstrated hazard ratios of 0.15 (0.017-2.72), 4.11 (0.37-43.8) and 3.62 (1.45-9.06) for relative risk of discontinuing medication for the clinically amyopathic, anti-NXP2, and anti-SAE1 groups, respectively. Our data demonstrate DM patients placed on immunosuppressive therapy take many years to discontinue medications (median 5.1 years) and suggest that clinical, laboratory, and demographic factors are associated with medication cessation.