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Ocular involvement of erosive lichen planus treated with apremilast and acitretin

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Lichen planus (LP) with ocular involvement is exceptionally rare. We report a case of an 83-year-old female with a 14-month history of biopsy proven erosive lichen planus presented with lacy reticulate white plaques in the bilateral inferior conjunctiva. She also had involvement of the buccal mucosa, gingiva, bilateral cheeks and upper extremities. She displayed no evidence of symptomatic cicatricial conjunctivitis. Her condition was recalcitrant to cyclosporine and mycophenolate mofetil. Past medical history was significant for follicular lymphoma diagnosed 7 years ago, as well as diabetes and dementia. There are a limited number of ocular LP cases reported in literature and little available treatment guidance. This patient presents a unique challenge where preventing progression to cicatricial conjunctivitis and vision loss must be balanced with the risk associated with immunosuppressive therapy in a patient with history of lymphoma. We report the use of apremilast and acitretin for the treatment of erosive lichen planus with ocular involvement.

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OnabotulinumtoxinA (BOTOX) displays superior activity to incobotulinumtoxinA drug product (Xeomin) in multiple in vitro and in vivo assays

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Objectives: Introduction of incobotulinumtoxinA (IncoA) to the market has led to an ongoing clinical controversy on whether incobotulinumtoxinA is interchangeable with onabotulinumtoxinA (OnaA). This study was to assess in vivo and in vitro activity of 50U, 100U and 200U vials of IncoA in relation to 100U OnaA product.

Methods: 50U, 100U and 200U vials of IncoA and 100U OnaA were diluted and tested at equal BoNT/A product label activity units in 4 distinct assays: rat compound muscle activity (cMAP), mouse digit abduction score (DAS), cell based potency assay (CBPA), light chain activity (LCA) assay.

Results: Multiple orthogonal assays demonstrated that the biological activity of Merz Units is less than Allergan Units. Higher doses of IncoA were required to cause 50% inhibition (ID50) in the cMAP assay, demonstrating that OnaA displays greater biological activity compared to IncoA. Superior biological activity was displayed by OnoA in the DAS assay demonstrating statistical differences between OnoA and IncoA. cMAP and DAS data were corroborated by CBPA data. Additionally, greater light chain activity was displayed by 100U OnaA when evaluated against 50U, 100U and 200U IncoA. Light chain activities of 50U, 100U and 200U products were approximately 50% predicted values. No atypical cleavage products were observed when testing any of the IncoA products, which differs from previous 50U and 100U results suggesting that changes have been made to the product.

Conclusions: Data from 4 different assays establish that, on a unit for unit basis, OnoA displays greater biological activity than IncoA confirming that units of OnoA and IncoA are not interchangeable. Data presented here emphasize that non-interchangeability and product-specific potency must be considered when dosing patients.

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Olumacostat glasaretil (DRM01) for the treatment of acne vulgaris: Primary results from the DRM01-ACN02 phase 2b randomized controlled trial

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Background: Sebum production, a critical factor in acne pathophysiology, is not addressed by available topical therapies. Olumacostat glasaretil (OG) inhibits acetyl coenzyme A carboxylase, a key regulator of the synthesis of sebum lipid components. This phase 2b trial assessed the safety and efficacy of OG gel in patients (pts) with facial acne vulgaris.

Methods: DRM01-ACN02 (NCT02431052) was a randomized, double-blind, vehicle (VEH)-controlled, dose-ranging, 12-week (wk) trial. Eligible pts were adults with facial acne vulgaris (≥20 inflammatory acne lesions [IALs], ≥20 non-inflammatory acne lesions [NIALs], and an Investigator Global Assessment [IGA] score of 3 or 4). Pts were randomized 2:2:2:1:1 to receive OG 4% once daily (QD), OG 7.5%-QD, OG 7.5% twice daily (BID), VEH-QD, or VEH-BID. Primary efficacy endpoints were IAL and NIAL counts, and IGA response rate (≥2-point improvement from baseline [BL]) at Wk12. MCMC multiple imputation was used to impute missing values in the ITT population. Significance was calculated vs combined VEH group using ANCOVA model (IAL, NIAL count) and Cochran-Mantel-Haenszel test (IGA response).

Results: 420 pts were randomized to receive OG 4%-QD, OG 7.5%-QD, OG 7.5%-BID, VEH-QD or VEH-BID; BL characteristics were similar. Significantly greater IAL and NIAL count reductions from BL were reported in OG groups vs combined VEH group at Wk12, with improvements seen from Wk4; highest efficacy was observed in the 7.5%-BID group (OG 7.5%-BID vs combined VEH: Wk4: IAL: -9.2 [-33.7%] vs -7.2 [-26.7%], $P = .107$; NIAL: -8.6 [-22.7%] vs -6.8 [-16.5%], $P = .283$; Wk12: IAL: -15.0 [-55.6%] vs -10.7 [-40.0%], $P = .001$; NIAL: -17.5 [-47.8%] vs -9.3 [-28.7%], $P < .001$). Clinically meaningful changes were observed in acne severity, with IGA response rate greater in all OG-treated groups than in combined VEH groups (OG 7.5%-BID vs combined VEH: Wk4: 4.1% vs 2.3%, $P = .495$; Wk12: 25.9% vs 9.8%, $P = .004$). Adverse events (AEs) occurred in 20.8%, 25.7% and 27.7% vs 19.2% and 26.0% of pts treated with OG 4%-QD, OG 7.5%-QD, and OG 7.5%-BID vs VEH-QD and VEH-BID, respectively. The most common AEs were nasopharyngitis, upper respiratory tract infection and application site pruritus.

Conclusions: OG-treated pts had reduced IAL and NIAL counts, and improved IGA scores, compared to VEH-treated pts from Wk4, with 7.5%-BID dosing producing the greatest response in all primary endpoints. OG gel was well tolerated at all tested doses during the 12-wk treatment period.

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Onset of morphea in a psoriatic patient under ustekinumab: Coexistence or adverse effect?

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Background: Psoriasis is a chronic inflammatory immune-mediated disease. It has been associated with several connective tissue diseases like dermatomyositis, rheumatoid arthritis, systemic sclerosis or systemic erythematous lupus and morphea.

Case Report: We present a 63-year-old woman with a 4-year history of plaque and palmoplantar pustular psoriasis. She was initially treated with topical corticosteroids and calcipotriol with good response. Relapse of psoriasis required further systemic therapy that was initially treated with phototherapy without response. Ustekinumab was then prescribed. At 6th month follow-up visit the patient has clinically improved from psoriasis but physical examination revealed two whitish well circumscribed plaques on her legs suggestive of morphea. A biopsy was performed from one of the lesions and the diagnosis of morphea was confirmed. Ustekinumab has been discontinued and phototherapy has been prescribed again.

Discussion: To our knowledge only 19 cases of psoriasis and morphea in a single patient have been described in the literature up to date. Different hypothesis have been raised between the authors: (a) a merely coincidence, (b) a miss regulation of the immunologic mechanism implicated in both diseases and (c) one can trigger the other due the Koebner phenomenon. In our patient a fourth hypothesis rise: (d) the onset of morphea might be an adverse event due to ustekinumab. We have found data supporting previous hypothesis, specially an immunologic explanation based on a misregulation of cytokines and lymphocytic pathways. To our knowledge, morphea hasn't been reported as an adverse effect due to ustekinumab since its approval in June 2008 by FDA. Ustekinumab is a monoclonal IgG1 antibody against IL-12/23, however, etanercept, an anti-TNF immunoglobulin, has been associated with morphea.

Conclusion: Either immunological mechanism in a psoriatic patient with an underlying morphea or an adverse event due to ustekinumab therapy cannot be ruled out. Available data in the literature supports an immunological defect but prior exposition to ustekinumab, no previous morpheaform lesions on the patient and non-progression of morphea after ustekinumab discontinuation makes adverse event a plausible explanation.

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