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# 28043 Roflumilast cream significantly improves chronic plaque psoriasis in patients with steroid-sensitive area involvement

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**28022**

## Three concurrent morphologic presentations of eosinophilic granulomatosis with polyangiitis in a patient

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Cutaneous manifestations of eosinophilic granulomatosis with polyangiitis (EGPA) are varied and include palpable purpura, urticaria and tender skin nodules, although only a single morphology tends to be present at each time. We present a patient who presented with multiple concurrent morphologies of rash as a presenting feature of EGPA. A 62-year-old female with adult-onset asthma presented with rashes over the limbs and neck for 2 months, hand and feet numbness and blurring of vision. On examination, she had rashes of multiple morphologies; palpable purpuric papules and hemorrhagic bullae over the right ankle, an indurated subcutaneous nodule over the forearm, and urticarial plaques over the neck. Biochemistry showed eosinophilia and antimyeloperoxidase antibodies. Skin punch biopsy of a hemorrhagic bullae showed leukocytoclastic vasculitis with eosinophils, while biopsy of the right forearm nodule showed a septal granulomatous panniculitis. Neurologic evaluation revealed mononeuritis multiplex and ophthalmology evaluation showed bilateral central retinal artery occlusion. She was diagnosed with EGPA and started on intravenous cyclophosphamide and methylprednisolone. Cutaneous, systemic, and biochemical manifestations improved following treatment. Sequential evolution of skin lesions is commonly seen in ANCA-associated vasculitis as opposed to multiple concurrent morphologies. Eosinophilic vasculitis is a pathognomonic feature in EGPA. Urticaria may be caused by mast cell degranulation secondary to eosinophils. Erythema nodosum-like lesions are associated with autoimmune disease, although the direct pathophysiology remains unclear. Further research in the pathophysiology and mechanistic role of eosinophils in EGPA may help to explain the unique presentation of this case.

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**28032**

## Rapid itch improvement with upadacitinib with or without concomitant topical corticosteroids (TCS) in moderate-to-severe atopic dermatitis (AD): Results from 3 phase 3 studies (Measure Up 1, Measure Up 2, and AD Up)

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Upadacitinib is a novel Janus kinase (JAK) 1-selective inhibitor under investigation for AD. Measure Up 1 (NCT03569293), Measure Up 2 (NCT03607422), and AD Up (NCT03568318) are randomized, phase 3, double-blinded, placebo-controlled, multicenter studies evaluating upadacitinib in adolescents and adults with moderate-to-severe AD. Patients were randomized 1:1:1 to receive oral upadacitinib 15mg, 30mg, or placebo once daily alone (Measure Up 1 and 2) or with concomitant TCS (AD Up). In Measure Up 1, Measure Up 2, and AD Up, respectively, significantly greater proportions of patients with Worst Pruritus Numerical Rating Scale (NRS) ≥4 at baseline who were treated with upadacitinib vs placebo ($P < .001$) achieved Worst Pruritus NRS improvement ≥4 at weeks 1 and 16—week 1 (15mg: 15.0%, 7.4%, 12.2%; 30mg: 19.6%, 15.7%, 19.2%; placebo: 0.4%, 0.7%, 3.1%), and week 16 (15mg: 52.2%, 41.9%, 51.7%; 30mg: 60.0%, 59.6%, 63.9%; placebo: 11.8%, 9.1%, 15.0%). In Measure Up 1, and Measure Up 2, respectively, significant differences ($P < .001$) were observed as early as days 2 and 3—day 2 (30mg: 11.8%, 7.9%; placebo: 3.7%, 0.7%), and day 3 (15mg: 16.4%, 11.5%; placebo: 3.3%, 3.0%). In all 3 studies, these findings were supported by the mean percent change in Worst Pruritus NRS at weeks 1 and 16. In summary, upadacitinib with or without concomitant TCS rapidly and significantly improves itch in patients with moderate-to-severe AD and Worst Pruritus NRS ≥4 at baseline.

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**28036**

## Phase 2 randomized, placebo-controlled, dose-ranging study to evaluate the safety and efficacy of onabotulinumtoxina for the treatment of platysma prominence

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Purpose: To evaluate the safety and efficacy of onabotulinumtoxinA compared with placebo to reduce the appearance of platysma prominence in adult participants.

Methods: This randomized, placebo-controlled, double-blind study evaluated onabotulinumtoxinA in participants with at least moderate platysma prominence (eg, vertical neck bands). Participants meeting all eligibility criteria were randomized in a 1:1:1 ratio to receive a single treatment of onabotulinumtoxinA high dose (HD), onabotulinumtoxinA low dose (LD), or placebo on day 1 and followed for 4 months. Efficacy was assessed by the investigator and participant independently using a valid severity scale, and analyzed by a serial gatekeeping multiple comparisons procedure.

Results: A total of 171 participants enrolled; 169 were included in the safety population. Participants were predominantly female and white (each >92%); mean age was 50 years and mean body mass index was 22.9 kg/m2. Treatment with onabotulinumtoxinA HD and LD was associated with a significant ≥1-grade improvement vs placebo at day 14 by investigators (88.2%, 77.8% vs 12.0%, respectively; $P < .0001$) and participants (88.2%, 75.9% vs 18.0%, respectively; $P < .0001$). Most treatment-related adverse events (AEs) were procedure related, mild in severity, and consistent with previously published studies; all resolved by study end (HD, 18.5%; LD, 13.6%; placebo, 12.5%). There were no treatment-related serious adverse events. The most common onabotulinumtoxinA-related AE was neck muscle weakness, reported in 5 participants in the HD group.

Conclusion: Treatment of platysma prominence with onabotulinumtoxinA HD or LD is more effective than placebo. OnabotulinumtoxinA yielded a safety profile consistent with the literature.

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**28043**

## Roflumilast cream significantly improves chronic plaque psoriasis in patients with steroid-sensitive area involvement

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Roflumilast cream is a nonsteroidal, selective phosphodiesterase-4 inhibitor in development for plaque psoriasis (PsO). A double-blind, phase 2b trial randomized adults with PsO to once daily roflumilast 0.3%, 0.15%, or vehicle for 12 weeks (NCT03638258).(1) Efficacy was assessed using Investigator Global Assessment (IGA), Worst Itch Numeric Rating Scale (WI—NRS), and Psoriasis Symptom Diary (PSD). This posthoc analysis reports efficacy and safety in patients with steroid-sensitive area involvement (plaques on the face, neck, or in intertriginous areas). Of 331 patients, 160 had steroid-sensitive area involvement. The primary endpoint in the study, IGA status clear/almost clear at Week 6 was met by 27.2% patients with steroid sensitive areas ($P = .007$ vs vehicle), 22.3% ($P = .026$), and 6.3% on roflumilast 0.3%, roflumilast 0.15%, and vehicle, respectively; relative to 30.1% ($P = .026$), 24.1% ($P = .098$), and 12.0% patients without steroid-sensitive areas. Among patients with baseline WI—NRS score ≥4, 73.5%, 55.6%, and 32.6% of those with steroid-sensitive areas and 45.9%, 72.7%, and 23.7% of those without steroid-sensitive areas achieved a 4-point reduction with roflumilast 0.3%, 0.15%, or vehicle at Week 12. PSD improvement from baseline at Week 12 for patients with steroid-sensitive areas was -48.3 ($P < .001$), -43.1 ($P = .012$), and -24.9, and for patients without steroid-sensitive areas -35.7 ($P = .003$), -44.6 ($P < .001$), and -17.1. Most treatment emergent adverse events were mild to moderate and there was no evidence of local irritation. Once-daily roflumilast cream was well tolerated with significant improvements in investigator and patient assessed PsO outcomes in patients with steroid-sensitive area involvement on the face, neck, or intertriginous areas.

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