Session/Poster# Presenter

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Apremilast 30 mg twice daily combined with dupilumab for the treatment of recalcitrant moderate-to-severe atopic dermatitis

Rationale: Atopic dermatitis (AD), primarily due to overactive type 2 inflammation, can also have Th1/Th17 activation. Many AD patients are not fully controlled on dupilumab, an interleukin (IL)-4 receptor alpha antagonist that blocks IL-4 and IL-13. Apremilast, an oral phosphodiesterase-4 inhibitor, can block TNF-alpha, interferon-gamma, IL-2, IL-12, IL-13, and IL-17. We investigated whether apremilast used in combination with dupilumab would give added benefit to patients.

Methods: Our open-label, prospective phase 2 study evaluated apremilast 30 mg twice daily for up to 24 weeks when added to dupilumab 300 mg for 10 patients with inadequately controlled moderate-to-severe AD. The primary endpoint was the proportion of patients who achieved an Investigator's Global Assessment (IGA) score of 0 (clear) or 1 (almost clear) at week 16. Body Surface Area (BSA), Dermatology Life Quality Index (DLQI), itch on Numerical Rating Scale (NRS), and Eczema Area and Severity Index (EASI) were also recorded.

Results: An intention to treat analysis was performed using last-observation-carried-forward, including all patients who received apremilast. 2 patients reached the primary endpoint by week 16, and by week 24, this increased to 3. At week 16, 4/10 patients achieved BSA 3% or less. BSA, DLQI, NRS pruritus, and EASI decreased by a mean of 4.5 +/- 5.2% (+/- SD), 3.9 +/- 3.1 points, 2.1 +/- 1.1 points, and 3.02 +/- 2.8, respectively. Mean % change from baseline BSA, DLQI, NRS pruritus, and EASI was -37.6 +/- 26.6%, -36.9 +/- 54.8%, -45.9 +/- 17.8%, and -32.6 +/- 42.6%, respectively, at week 16. 4 patients completed 16 study weeks, with no discontinuations due to lack of efficacy. 8 patients had mild adverse events, commonly nausea, diarrhea, or headache.

Discussion: Concomitant apremilast and dupilumab may be a promising combination for AD patients with an inadequate response to dupilumab. Larger, randomized studies must be conducted to confirm efficacy and safety.