VASCULAR DISEASE, VASCULITIS

IMPROVEMENTS AND CORRELATIONS IN ORAL ULCERS, DISEASE ACTIVITY, AND QOL IN BEHçET'S SYNDROME PATIENTS TREATED WITH APREMILAST: A PHASE III RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY (RELIEF)

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Introduction: Apremilast demonstrated efficacy in the treatment of the oral ulcers (OU) of Behçet's syndrome in a phase III, multicenter, randomized, double-blind, placebo-controlled study (RELIEF).

Objective: To assess apremilast efficacy in patients with Behçet's syndrome for OU, OU pain, disease activity, and QoL, as well as their relationship.

Materials and Methods: 207 patients were randomized (1:1) to apremilast 30 mg BID or placebo for 12 weeks, followed by a 52-week active treatment extension. Patients had active Behçet's syndrome, with ≥3 OU at randomization or ≥2 OU at screening and randomization, without active major organ involvement. The primary endpoint was area under the curve for number of OU through 12 weeks (AUCWk0-12). Clinical improvement of OU was evaluated by OU pain assessments (100-mm VAS) and measures of disease activity using the Behçet's Syndrome Activity Score (BSAS), Behçet's Disease Current Activity Form (BDCAF), and Behçet's Disease QoL (BDQoL). Pearson's correlation coefficients and associated P values assessed the relationship in change from baseline scores at 12 weeks among BSAS, BDCAI, and BDQoL with OU number and change in OU pain.

Results: AUCWk0-12 was significantly lower in apremilast vs. placebo (P<0.0001). This treatment effect is supported by significant improvements in OU number and pain (both P<0.0001), disease activity using BSAS (P<0.0001), BDCAI (P=0.0335), and BDQoL (P=0.0003) at Week 12. With apremilast, significant correlations were observed between numbers of OU vs. change in BSAS (P<0.0001) and BDCAI (P=0.0081); change in OU pain vs. BSAS (P<0.0001), BDQoL (P=0.0036), and BDCAI (P=0.0146); and change in BSAS vs. BDQoL (P=0.0237) and BDCAI (P=0.0007).

Conclusions: Apremilast demonstrated significant improvements in number and pain of OU, measures of disease activity and QoL. Significant correlations between improvements in OU number and pain, disease activity, and QoL in apremilast-treated patients suggest that beneficial effects of apremilast are internally consistent.