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Dose and time dependent efficacy of vilobelimab on wound healing outcomes in patients with ulcerative pyoderma gangrenosum – findings from a Phase 2 trial

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Introduction & Objectives:

Pyoderma gangrenosum (PG) is a clinically challenging, inflammatory disorder characterized by painful, non-healing ulcers, and currently lacks approved treatments in the US or Europe. There is increasing evidence suggesting the role of human complement factor C5a in the dysregulated immune response that hinders normal healing. Vilobelimab is a first-in-class anti-C5a targeted monoclonal antibody, which specifically blocks the biological activity of C5a in human plasma with high selectivity and does not alter the membrane attack complex (C5b-9), aiming to restore immune balance and promote wound repair. This abstract highlights the wound-healing outcomes observed with escalating doses of vilobelimab in PG patients, as assessed in an international, Phase II, proof-of-concept study.

Materials & Methods:

Patients were treated biweekly in three escalating vilobelimab dosing groups of 800 mg (n=6), 1600 mg (n=6) and 2400 mg (n=7) for 26 weeks. Dose escalation to next higher dosing was allowed in patients with insufficient response at week 8 upon safety assessment of the first 4 patients per dosing group.

Wound healing was assessed using the physician global assessment (PGA) score of the target ulcer, standardized photographic documentation, the rate of wound area changes per day, the number of patients achieving >50% and 100% reduction from baseline by Day 189. Other key efficacy and patient reported outcome (PRO) endpoints were PGA score, Quality of Life and Pain measured by DLQI and NRS.

Results:

A total of 9 out of 19 patients (53%) achieved clinical remission defined closure of target ulcer assessed as PGA≤1. Wound ulcer area decreased progressively over time. The highest dosing group (2400 mg) showed the greatest improvement, with reductions up to −90.9% (Day 189) in ulcer area healing; 6 out of 7 patients in this group achieved complete ulcer closure by study end. Across all patients, ≥ 50% wound area reduction was observed in 11.8% of the patients at Day 15, increasing to 77.8% of the patients by Day 189. Complete closure (100%) was seen in 0% at Days 15 and 43, and 35.7% of the patients on Day 99, and 33.3% on Day 189 with highest rates in the 2400 mg group with 85.7%) of the treated patients in this group. The mean time to target ulcer closure through all 3 dosing cohorts was 105 days.

Marked improvements were also observed in quality of life and pain, as measured by DLQI and NRS.

Conclusion:

This study provides the first evidence of dose-dependent efficacy of vilobelimab in the treatment of PG, with the 2400 mg dose showing the most pronounced and consistent improvements of the PG disease shown as complete ulcer closure and reduction of pain.