Abstract N°: 6316

Flare burden in generalized pustular psoriasis (GPP): analysis of pre-trial historical experience of patients enrolled in EFFISAYIL 2

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Introduction & Objectives: GPP is a chronic, systemic, neutrophilic inflammatory disease. In the EFFISAYIL 2 trial,1 the IL-36 receptor inhibitor spesolimab (600 mg subcutaneous [SC] loading dose; 300 mg SC every 4 weeks) significantly reduced GPP flare risk over 48 weeks.

Materials & Methods: Analysis of patient flare history prior to randomization in EFFISAYIL 2 based on electronic case report forms completed at screening.

Results: Data were available for 73% of 123 patients for 'most recent flare', 79% for 'most severe flare', 87% for 'typical flare', and 64% for 'longest flare'. Despite 75% of patients having received ≥1 systemic medication, 86% did not have clear skin at baseline (GPPGA total score: 1). Prior to randomization, one in four patients (25%) had a flare lasting >9 weeks, 19% had skin involvement/pustules for >12 weeks after flare onset, and 15% reported <1 week with clear/almost clear skin in the past year. Most patients also experienced pain during flares, with systemic signs (fever and fatigue). In 57% of patients, the most severe flare lasted 3-<9 weeks. Over 50% of flares led to hospitalization, and 63% of patients were hospitalized for 1-<5 weeks for their most severe flare (pustules, scaling and erythema worsened in ~50% of the most severe flares). Post-flare, 37% of patients did not have clear/almost clear skin; time to complete clearance was 3-<9 weeks in 54-61% of patients.

Conclusion: Patients with GPP have a high burden of disease. New treatments are needed to provide long-term disease control.

1. Morita A, et al. Lancet. 2023;402:1541-1551.

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