**Spesolimab use for generalized pustular psoriasis flare prevention in patients with concomitant plaque psoriasis: Results from the Effisayil 2 trial**


Department of Dermatology, Department of Medicine, Division of Rheumatology, Washington University School of Medicine, St. Louis, MO, USA; Therapeutics Clinical Research, San Diego, CA, USA; University of California, San Francisco, CA, USA; Department of Dermatology, University of Pittsburgh Medical Center, Pittsburgh, PA, USA; Harvard Medical School, Boston, MA, USA; Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT, USA; Boehringer Ingelheim International GmbH, Ingelheim am Rhein, Germany; Boehringer Ingelheim (China) Investment Corporation Limited, Shanghai, People’s Republic of China; Hofstra School of Medicine at Hofstra Northwell, Manhasset, NY, USA

**Aim**

To report the effect of spesolimab vs placebo on mean changes in TPSS (target plaque severity score) from baseline in patients with GPP and concomitant PsO who participated in the Effisayil 2 Study.

**Introduction**

- GPP is a chronic, inflammatory, and potentially life-threatening skin disease characterized by episodic flares of widespread pustular eruptions and erythema.
- Spesolimab, an anti-interleukin-36 receptor monoclonal antibody, is approved to treat GPP flares in adults in the US, and many other countries.
- Effisayil 2 (NCT04399837) was a pivotal, randomized, placebo-controlled trial that evaluated the efficacy and safety of spesolimab SC in preventing GPP flares.
- An estimated 3–7% of all patients with GPP have concomitant PsO.

This subgroup analysis examines plaque severity in Effisayil 2 study participants with concomitant PsO.

**Conclusions**

- Low baseline TPSS scores observed in this subgroup of 33 GPP patients with concomitant PsO suggest that plaque characteristics in PsO are generally milder to moderate.
- TPSS scores remained low and consistent throughout the trial in both dosing groups, and decreases in TPSS scores by Week 16 (spesolimab-treated) and Week 48 (both groups) compared with baseline were observed.

**Methods**

- In Effisayil 2, eligible patients with a history of GPP were randomized (1:1:1:1) to receive 1 of 3 spesolimab SC regimens or placebo for 48 weeks (Figure 1).

**Results**

- TPSS was measured in 33 of 123 (27%) patients who presented with PsO in the trial (9 placebo, 10 low-dose, 7 medium-dose, 7 high-dose).
- The number of patients with TPSS data declined in both groups over time due to the study protocol because of GPP flare or early discontinuation.

**Figure 1. Study design**

**Figure 2. TPSS Scale on psoriasis severity**

**Figure 3. Mean TPSS of (A) erythema, (B) Induration, and (C) Scaling with total SC spesolimab and placebo**

**Figure 4. Mean of absolute value of TPSS with total SC spesolimab and placebo**

The mean TPSS total scores in placebo and in spesolimab-treated patients were low at baseline, with slight decreases observed for each group by Week 48.