PSORIASIS

INFLUENCE OF BASELINE DEMOGRAPHICS ON EFFICACY OF A SELECTIVE ORAL TYK2 INHIBITOR, BMS-986165, IN PATIENTS WITH MODERATE-TO-SEVERE PLAQUE PSORIASIS IN A PHASE 2, RANDOMIZED, PLACEBO-CONTROLLED TRIAL

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Introduction: Tyrosine kinase 2 (TYK2) activates STAT-dependent cytokine signaling pathways involved in psoriasis pathophysiology. In a Phase 2 trial of BMS-986165, a highly selective oral TYK2 inhibitor, 67–75% of patients with plaque psoriasis receiving doses ≥3mg twice daily (BID) achieved PASI 75 at Week 12 (primary endpoint). Adverse events were generally mild-to-moderate.

Objective: To report the influence of baseline characteristics (weight, body mass index [BMI], age) on Week 12 efficacy for the three effective doses of ≥3mg BID.

Materials and Methods: Adults with moderate-to-severe plaque psoriasis (body surface area ≥10%, PASI ≥12, static Physicians Global Assessment [sPGA] ≥3) were randomized equally across five doses of BMS-986165 (3mg every other day, 3mg every day [QD], 3mg BID, 6mg BID, 12mg QD) or placebo.

Results: 267 patients were treated. At Week 12, among patients reporting PASI scores, those treated with BMS-986165 ≥3mg BID (n=134) achieved PASI 75, PASI 90, and sPGA
0/1 consistently across subgroups. By weight (<100kg, n=102 vs ≥100kg, n=32) PASI 75 responses, 69–76% vs 55–73%; PASI 90, 42–53% vs 18–46%; sPGA 0/1, 65–77% vs 64–73%. By BMI (<25, n=41; 25–<30, n=46; ≥30, n=47), PASI 75, 74–89%, 56–74%, 60–69%; PASI 90, 58–77%, 19–55%, 20–44%; sPGA 0/1, 63–89%, 64–79%, 63–81%. By age (18–45 years, n=66 vs ≥45 years, n=68), PASI 75, 67–80% vs 61–71%; PASI 90, 45–58% vs 29–42%; sPGA 0/1, 71–85% vs 57–74%.

Conclusions: BMS-986165 at doses ≥3mg BID demonstrated consistent PASI 75, PASI 90, and sPGA 0/1 responses in patients with moderate-to-severe plaque psoriasis, regardless of baseline weight, BMI, or age. Small patient numbers may underlie some fluctuations; findings will be evaluated further in ongoing Phase 3 studies.