INTRODUCTION: BMS-986165, a highly selective oral tyrosine kinase 2 (TYK2) inhibitor, showed a favorable safety profile, and PASI 75 responses were highest at doses ≥3mg twice daily (BID; 67–75%) vs placebo (7%; p<0.001; primary endpoint) in a 12-week, Phase 2 trial in patients with moderate-to-severe plaque psoriasis.

OBJECTIVE: We report efficacy in patient subgroups based on baseline disease characteristics for the three effective doses of ≥3mg BID.

MATERIALS AND METHODS: Adults with moderate-to-severe plaque psoriasis (body surface area [BSA] ≥10%, PASI ≥12, static Physicians Global Assessment [sPGA] ≥3) were randomized equally to 1 of 5 BMS-986165 doses (3mg every other day, 3mg every day [QD], 3mg BID, 6mg BID, 12mg QD) or placebo.

RESULTS: Overall, 267 patients were treated. At doses ≥3mg BID (n=134), BMS-986165 showed no meaningful differences in efficacy, with some variability across subgroups based on baseline disease characteristics. By age of onset (in years; <18, n=38; 18–<45, n=76;
≥45, n=20) PASI 75: 50–78%, 71–77%, 55–67%; PASI 90: 19–54%, 43–62%, 17–36%; sPGA 0/1: 56–85%, 69–76%, 67–73%. In patients with disease duration <15 yrs (n=60) vs ≥15 yrs (n=74), PASI 75: 62–72% vs 65–81%; PASI 90: 23–55% vs 35–52%; sPGA 0/1: 54–68% vs 65–85%. Similar response consistency was reported regardless of baseline PASI score (<20, n=96; ≥20, n=38), sPGA score (<4, n=89; ≥4, n=44), BSA (<20, n=73; ≥20, n=61), Dermatology Life Quality Index score (<10, n=52; 10–<20, n=62; ≥20, n=20), and presence of musculoskeletal symptoms (yes, n=37; no, n=97).

Conclusions: In patients with moderate-to-severe plaque psoriasis, BMS-986165 at doses ≥3mg BID demonstrated consistent efficacy regardless of age at onset, severity, or duration of disease. Small patient numbers may underlie fluctuations; two Phase 3 trials in psoriasis are underway.