PSORIASIS

EVALUATING THE INFLUENCE OF BASELINE DISEASE CHARACTERISTICS ON EFFICACY OF A SELECTIVE ORAL TYK2 INHIBITOR, BMS-986165, IN PATIENTS WITH MODERATE-TO-SEVERE PLAQUE PSORIASIS IN A PHASE 2 TRIAL

K Gordon [1] - K Papp [2] - M Gooderham [3] - D Thaçi [4] - P Foley [5] - A Morita [6] - S Kundu [7] - R Kisa [8] - A Napoli [8] - S Banerjee [9]

Medical College Of Wisconsin, Dermatology, Milwaukee, United States [1] - K Papp Clinical Research And Probity Medical Research, Dermatology, Waterloo, Canada [2] - Skin Centre For Dermatology, Queen's University And Probity Medical Research, Dermatology, Peterborough, Canada [3] - University Of Luebeck, Comprehensive Center For Inflammation Medicine, Luebeck, Germany [4] - The University Of Melbourne, St Vincent's Hospital Melbourne & Probity Medical Research, Skin & Cancer Foundation Inc, Dermatology, Melbourne, Australia [5] - Nagoya City University Graduate School Of Medical Sciences, Department Of Geriatric And Environmental Dermatology, Nagoya, Japan [6] - Bristol-myers Squibb, Biostatistics, Princeton, United States [7] - Bristol-myers Squibb, Specialty Nrdg & De Strategy, Princeton, United States [8] - Bristol-myers Squibb, Innovative, Clinical And Medicines Development, Princeton, United States [9]

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.