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Safety and tolerability of Apremilast up to 182 weeks: Pooled analyses from phase-III clinical trials

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Apremilast (APR) is an oral phosphodiesterase 4 inhibitor efficacious in moderate to severe plaque psoriasis (ESTEEM 1 and 2) and psoriatic arthritis (PALACE 1-3). Safety and tolerability of APR was assessed over 3 years (yrs) in these studies. Analysis was conducted on data available through February 14, 2015. In the pooled ESTEEM 1 and 2 analysis, 1,184 patients (pts) were exposed to APR 30 mg BID (APR30; 1902.2 pt-yrs). Between week (wk) 0 and 52, AEs occurring in ≥5% of pts included diarrhea, nausea, upper respiratory tract infection, nasopharyngitis, headache and tension. AEs, serious AEs and discontinuation of study drug due to AEs did not increase with long-term exposure. Exposure-adjusted incidence rates (EAIR)/100 pt-yrs for serious AEs was 5.9 (0 to ≤52 wks: 6.4) and for discontinuation due to AEs was 7.0 (0 to ≤52 wks: 10.2). Between wk 0 and 182, EAIR for MACE (0.5), malignancies (1.2), depression (1.8) or suicide attempt (0.1) were noted. Three deaths (1 per year) occurred (EAIR 0.2). Mean (median) percent change from baseline in weight was −1.53% (−1.20%); weight loss >5% was experienced by 21.9% of pts. These results were similar to the pooled ESTEEM and PALACE 1-3 trials including 1,905 pts treated with APR30 (3527.5 pt-yrs) over 182 wks. APR30 was safe and generally well tolerated for up to 182 wks with no new signals or increases in severity or frequency of AEs with long-term treatment.

Biography

Kim Alexander Papp is the Founder and President of Probity Medical Research Inc., an organization that guides the conduct of clinical researchers. He has received his Doctor of Medicine degree from the University of Calgary, Medical School and was a Resident in Internal Medicine and Dermatology at the University of Toronto. Over the past 15 years, he has conducted more than 220 clinical trials and followed over 3,000 subjects. He has authored or co-authored more than 250 publications and abstracts and has investigated over 50 unique compounds in development for the treatment of psoriasis.

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