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Efficacy of Apremilast sustained through week 52 in patients with moderate to severe psoriasis who continued on Apremilast or switched from Etanercept treatment: Results from the LIBERATE study

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LIBERATE, a phase 3b trial, evaluated the efficacy and safety of Apremilast (APR) or Etanercept (ETN) vs. placebo (PBO) in biologic-naïve patients (pts) with moderate to severe plaque psoriasis. Efficacy through Wk52 is reported. Pts (n=250) were randomized 1:1:1 to PBO, APR 30 mg BID or ETN 50 mg QW through Wk16; thereafter, all pts were switched to or continued on APR through Wk104. PASI-75 (primary endpoint, Wk16), mean percent change from baseline (MPCBL) in PASI score and safety were assessed at Wk16 and Wk52. At Wk16, PASI-75 response was achieved by significantly more pts receiving APR (39.8%) and ETN (48.2%) vs. PBO (11.9%; $P<0.0001$, both; APR vs. ETN, $P=0.2565$); the MPCBL in PASI score was -38.0% (PBO), -61.0% (APR) and -69.1% (ETN). At Wk52, PASI-75 was achieved by 46.4% (PBO/APR), 50.6% (APR/APR) and 55.4% (ETN/APR) of pts; the MPCBL in PASI score was -71.1% (PBO/APR), -73.0% (APR/APR) and -75.4% (ETN/APR). Diarrhea, nausea and headache, AEs occurring in $\geq 5\%$ of pts were mild to moderate in severity throughout the study. The exposure-adjusted incidence rates/100 pt-years for serious AEs and discontinuation rates due to AEs did not increase compared to the first 16 Wks. Weight loss $>5\%$ was experienced by 18.6%, 10.0% and 8.0% of pts in the PBO/APR, APR/APR and ETN/APR groups, respectively. In the first 16 Wks, APR was well tolerated and efficacious compared to PBO. The safety and efficacy of APR was sustained through Wk52 and maintained in pts treated with ETN who switched to APR.

Biography

Kristian Reich is a Professor of Dermatology at the Georg-August-Universität Göttingen and leads the inflammation center at the Dermatologikum Hamburg, an international center of excellence for dermatology, plastic and vascular surgery, dermatopathology, microbiology and molecular biology. He is founding Partner and Medical Director at SCIderm, a CRO and research institute dedicated to the development of new therapies in dermatology. He is a Member of the Psoriasis Guideline Group of the German Society of Dermatology, chairs the Scientific Advisory Committee of the German Psoriasis Registry and is Board Member of the Alfred-Marchionini Foundation, the Foundation Dermatologikum and the ProDerma Foundation.

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