An investigator-initiated, open-label study evaluating the efficacy and safety of ustekinumab in patients with moderate to severe palmar plantar psoriasis. 

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Palmar plantar psoriasis (PPP) is a disabling and disfiguring form of psoriasis that is typically chronic and very difficult to treat. It is characterized by the presence of plaques and/or sterile pustules and fissures on the palms and soles, in addition to typical psoriatic plaques. We designed a small, open-label: 24 week study to evaluate the safety and efficacy of ustekinumab, a fully human IL-12/23 monoclonal antibody, in patients with moderate to severe palmar plantar psoriasis. Eligible subjects ≥ 100 kg received 45 mg of ustekinumab subcutaneously, while subjects > 100 kg received 90 mg at weeks 0, 4, and 16. Clinical assessments of outcomes included: Physician Global Assessment (PGA), pustule and fissure counts, Dermatology Life Quality Index (DLQI), as well as pruritus and pain visual analogue scale (VAS) assessments. Preliminary results of 14 patients who have completed the primary efficacy endpoint of week 16 of the study indicate that ustekinumab is well tolerated and may be effective at improving PPP Mean PGA improved from 5.3 to 1.9 (P = 0.01) and DLQI improved from 12.6 to 6.1 (P = 0.01) from week 0 to week 16. Ustekinumab is well tolerated and may be effective at improving clinical outcomes and quality of life in patients with moderate to severe palmar plantar psoriasis.

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Approved adalimumab dosing regimen associated with greater efficacy and lower cost per responder compared with 40 mg every other week dosing without initial 80 mg dose: Analysis of outcomes from adalimumab psoriasis clinical trial database 

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Objective: Approved adalimumab dosing for moderate to severe psoriasis is 40 mg every other week (20 mg from week 1) vs no initiation dose (NID) (40 mg every other week from week 1). Adalimumab dosing regimen associated with greater efficacy and lower costs per PASI 75 responder than NID group. Evidence (Poster reference number 5559)

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Background: Phosphodiesterase-4 (PDE4) is expressed in cells mediating immune response. Apremilast (APR) is a novel, orally available small molecule that specifically targets PDE4, thereby increasing cellular cAMP which modulates multiple pro- and antiinflammatory mediators. We evaluated the clinical efficacy of APR in the treatment of nail psoriasis.

Methods: In a phase IIb, multicenter, double-blind, placebo (PBO)-controlled, dose-ranging study, subjects with moderate to severe plaque psoriasis (Psoriasis Area and Severity Index [PASI] ≥ 12; body surface area [BSA] ≥ 10%) were equally randomized to oral APR 10 mg (APR10), 20 mg (APR20), 30 mg (APR30) BID, or PBO for 16 wks. After the first 16 wks, PBO subjects were re-randomized to APR20 (P20) or APR30 (P30); the remaining subjects maintained their dosing through week 24. An exploratory prespecified analysis evaluated effects of APR on subjects with nail psoriasis using the Nail Psoriasis Severity Index (NAPSI; 0-8 scale) for a digit nail representing the most severe nail psoriasis involvement; endpoints were percent change from baseline (BL) and proportion of subjects achieving 50% reduction in NAPSI score by week 24.

Results: Of 352 subjects enrolled (65% male; mean age: 44 yrs; mean BMI 31 kg/m²; mean affected BSA 22%; mean PASI 18.5), 221 (62.8%) had nail psoriasis at BL and qualified for the analysis (n = 54/57/treatment group). Mean NAPSI scores at BL were 4.1 at week 16. Mean reductions in NAPSI from BL to week 24 were 16.7% (APR10), 33.5% (APR20), and 42.9% (APR30). NAPSI-50 was achieved by significantly more subjects treated with APR20 (42.1%; P = 0.006) and APR30 (45.5%; P = 0.002) vs PBO (18.2% [APR10], 31.5% [N30]); at week 24, mean reductions in NAPSI from BL were 55.3% (APR10), 83.3% (APR20), and 91.5% (APR30), and 0% (P30 [n = 22]). NAPSI-50 was achieved by 44.4% (APR10), 52.6% (APR20), 52.7% (APR30), 52.9% (P20), and 5.4% (P30) of subjects. Conclusion: APR was previously shown to be effective in the treatment of plaque psoriasis. The current analysis demonstrates APR activity in difficult-to-treat nail psoriasis after 16 weeks of therapy, which appeared to continue through week 24. Phase III studies are under way and will further explore APR efficacy for treatment of nail psoriasis.

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Apremilast is effective in the treatment of scalp and palmoplantar psoriasis. Results from a phase IIb randomized, controlled study 

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Background: Phosphodiesterase-4 (PDE4) is expressed in cells mediating immune response. Apremilast (APR) is a novel, orally available small molecule that specifically targets PDE4, thereby increasing cellular cAMP which modulates multiple pro- and antiinflammatory mediators. We evaluated the clinical efficacy of APR in the treatment of scalp and palmoplantar (PP) psoriasis.

Methods: In a phase IIb, multicenter, double-blind, placebo (PBO)-controlled, dose-ranging study: subjects with moderate to severe plaque psoriasis (PASI ≥ 12; BSA ≥ 10%) were equally randomized to oral APR 10 mg (APR10), 20 mg (APR20), 30 mg (APR30) BID, or PBO. At week 16, PBO subjects were re-randomized to APR20 or APR30; the remaining subjects maintained their dosing through week 24. The efficacy of APR was evaluated using the Physician Global Assessment for lesions on the scalp (ScPGA; 0-5 scale) and palms/soles (PPPGA; 0-4 scale); exploratory efficacy endpoints were the proportion of subjects with baseline scores ≥ 5 achieving PGA scores of “clear” or “almost clear” (0-1) and “clear,” “almost clear,” or “mild” (0-2) at wks 16 and 24.

Results: Of the 352 subjects enrolled, 251 with moderate to severe scalp psoriasis (PBO, n = 53; APR10, n = 62; APR20, n = 57; APR30, n = 59) qualified for the prespecified analysis. At week 16, more APR-treated subjects achieved SCPGA 0-1 (APR10 [22.6%], APR20 [45.6%], APR30 [44.1%]) vs PBO (15.1%). Improvements were still seen at week 24: 21.0% (APR10), 38.6% (APR20), and 40.7% (APR30). Of PBO subjects re-randomized to APR20 or APR30 at week 16, 43.4% achieved PGA 0-1 at week 24. At week 16, SCPGA 0-2 was achieved by 30.2% (PBO), 38.7% (APR10), 55.3% (APR20), and 59.3% (APR30) of subjects. At week 24, 26.7% was achieved by 58.7% (APR10), 52.6% (APR20), and 52.5% (APR30) of subjects. A trend for efficacy was noted in 52 subjects with moderate or severe PP psoriasis (PBO, n = 10; APR10, n = 13; APR20, n = 20; APR30, n = 9). At weeks 16 and 24, 66.7% and 66.7% of APR30-treated subjects achieved PPPGA 0-1 (PBO, 20.0% and 30.0%) and 88.9% and 77.6% achieved PPPGA 0-2 (PBO, 50.0% for both).

Conclusion: APR was previously shown to be effective in the treatment of plaque psoriasis. The current analysis focuses on difficult-to-treat nail psoriasis. APR has demonstrated activity in treating psoriasis lesions on the scalp. Results also suggest activity in treating PP psoriasis lesions. Phase III studies are under way and will further explore APR efficacy for treatment of scalp and PP psoriasis.

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Apremilast is effective in the treatment of nail psoriasis: Results from a phase IIb, randomized, controlled study

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Apremilast is effective in the treatment of scalp and palmoplantar psoriasis. Results from a phase IIb randomized, controlled study

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