PsAID9 domains for FIL vs PBO, including pain ($p<0.0001$; **Figure 1b**). A significant improvement in SF-36 PCS, but not in MCS, with FIL vs PBO was observed. The mean change (SD) from baseline in PCS at week 16 was 7.4 (6.6) vs 2.4 (6.6) for FIL vs PBO, respectively (LS mean of group difference 4.67 [2.58, 6.76], $p<0.0001$).

Conclusion: Compared with PBO, FIL significantly improved disease impact in patients with active PsA, as measured by the PsA-specific PsAID9 total score and individual domain scores. Significant improvement in SF-36 PCS score was also seen with FIL.

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SAT0368

GO-DACT: A RANDOMIZED DOUBLE-BLIND PLACEBO-CONTROLLED PROOF-OF-CONCEPT TRIAL OF GOLIMUMAB PLUS METHOTREXATE (MTX) VERSUS MTX MONOTHERAPY, IN IMPROVING DACTYLITIS, IN MTX NAÏVE PSORIATIC ARTHRITIS PATIENTS

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Background: Psoriatic arthritis (PsA) dactylitis is associated with an increased risk of erosions and higher disease activity. Dactylitis treatment

strategies are however controversial due to the absence of evidence from randomized controlled trials studying dactylitis as a primary outcome.

Objectives: To assess the efficacy of golimumab plus MTX versus placebo plus MTX for active dactylitis in PsA patients, in a phase 3b trial.

Methods: GO-DACT was a proof-of-concept multicentric, investigator-initiated randomized, double-blind, placebo-controlled, parallel-design trial, conducted in 13 Portuguese Rheumatology Centers. PsA patients, naïve for MTX and biologic disease modifying anti-rheumatic drugs (bDMARDs), with active dactylitis, were randomly allocated to either golimumab in combination with MTX or MTX monotherapy. The primary endpoint was the change from baseline in the dactylitis severity score (DSS) assessed at week 24. Key secondary endpoints included DSS response and the magnetic resonance imaging (MRI) dactylitis score, as well as composite indexes of PsA activity.

Results: 44 patients were centrally randomized, 21 to golimumab plus MTX and 23 to placebo plus MTX, for 24 weeks, and 1 patient from each arm dropped out. Due to favorable results on a planned interim analysis recruitment was halted. The median MTX dose in the golimumab plus MTX group was 15mg/week and in the MTX monotherapy group 20mg/week. The median baseline DSS was 6 in each arm. Patients treated with golimumab plus MTX experienced significantly greater improvements in the DSS at week 24 (median change of 5) as compared to the MTX group (median change of 2) ($p=0.026$). At week 24, 12 (60.0%) patients treated with golimumab plus MTX and 4 (18.2%) with MTX, achieved the DSS70 response ($p<0.05$). Significant differences were also observed in the median changes from baseline to week 24 in MRI dactylitis score, Disease Activity Score 28 (DAS28), Disease Activity Index for PsA (DAPSA), PsA Disease Activity Score (PASDAS) and Target Nail Psoriasis Severity Index (tNAPSI), favoring the golimumab and MTX association arm. Likewise, higher proportions of patients treated with golimumab plus MTX achieved DSS50 responses and the American College of Rheumatology 20/50 responses, at week 24. There were no new safety issues for golimumab during this trial.

Conclusion: GO-DACT suggests additional benefits from the combination of golimumab and MTX as first-line bDMARD therapy versus MTX monotherapy, in the treatment algorithm of PsA active dactylitis.

REFERENCE

Not applicable

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SAT0369

SECUKINUMAB IMPROVES GRAPPA-OMERACT CORE DOMAINS OF PSORIATIC ARTHRITIS REGARDLESS OF PREVIOUS EXPOSURE TO A TNF INHIBITOR

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Background: Secukinumab, a fully human interleukin 17 (IL-17A) monoclonal antibody, has demonstrated efficacy in psoriatic arthritis (PsA) in phase 3 clinical trials.^{1–4} The PsA core domain set, updated by the