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# FRI0493 DISEASE ACTIVITY TOGETHER WITH DEPRESSION CONTRIBUTES TO WORK DISABILITY IN PSORIATIC

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Background: Work disability (WD) is an important functional outcome measure in inflammatory arthritis, which has been studied comprehensively in rheumatoid arthritis and ankylosing spondylitis, however limited data are available in psoriatic arthritis (PsA)<sup>1</sup>. Depression and anxiety are well known comorbidities in psoriasis and PsA with higher prevalence in PsA2.

Objectives: The aim of this study was to compare 1) patient-reported outcomes (PROs), including depression/anxiety scores; 2) physician-assessed measures and 3) disease activity using minimal disease activity (MDA) and Composite Psoriatic Disease Activity Index (CPDAI) in PsA patients with and without WD.

Methods: Consecutive patients with PsA fulfilling the CASPAR criteria were enrolled. Patients on disability pension, those with early retirement due to arthritis, those unemployed, away from work due to sick leave were considered as having WD. Patients have completed questionnaires on physical function and health-related quality of life and they were assessed for depression/anxiety using the Hospital Anxiety and Depression Scale (HADS-A and HADS-D) and Penn State Worry Questionnaire (PSWQ). Patients underwent musculoskeletal and skin assessments. Disease activity was compared between work-disabled and employed patients using MDA and CPDAI. Mann-Whitney, Chi-square tests and linear regression model were used to perform statistical analysis.

Results: 100 PsA patients were recruited, 18 were natural retirees, leaving 82 patients available for analysis. Thirty-one (17 male, age 50.9±9.97 years) participants of working age had work disability versus fifty-one (29 male, age 49.1±8.65 years) employed patients. Work-disabled patients had significantly higher HADS-D score (5.07±3.01 vs. 2.57±2.64; p<0.001) and significantly worse PROMs, including HAQ, PsAQoL, EQ-5D, BASDAI, BASFI, ASQoL, BRAF-NRS, pain and general health VAS. HADS-A and PSWQ scores were similar in both groups. Leeds enthesitis index and ESR were significantly higher (p=0.008; p=0.04, respectively) in patients with WD compared to those employed; furthermore the % of patients with CPDAI>4, suggesting moderate to severe disease activity were significantly higher (51.6% vs. 28%; p=0.032) in the WD group. There was no significant difference in MDA status between the two groups. Multiple regression analysis revealed significant relationship between HADS-D scores and CPDAI (B=0.566; p=0.03).

Conclusions: Consistent with previous studies we have observed that the WD rate is high (37.8%) among patients with PsA. This is the first study assessing the relationship between depression and disease activity using CPDAI in PsA patients with work disability. We have found significantly higher HADS-D score and higher % of patients with CPDAI>4 in the WD group compared to those employed. Significant relationship was revealed between depression and CPDAI, which suggests that disease activity together with depression contributes to work disability in PsA.

# References:

[1] Tillett W. Rheumatology (Oxford) 2012.

[2] McDonough E. JRheumatol 2014.

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### FRI0494 SECUKINUMAB PROVIDES RAPID AND SUSTAINED PAIN RELIEF IN PSORIATIC ARTHRITIS: 2-YEAR RESULTS FROM THE FUTURE 2 STUDY

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Background: Pain remains a major clinical challenge in the treatment of psoriatic arthritis (PsA). Secukinumab (SEC) has demonstrated significant efficacy in PsA patients (pts), across a range of quality of life related outcome measures.<sup>1,2</sup> Objectives: This post-hoc analysis evaluated change in pain scores from baseline (BL) to Week (Wk) 104 in PsA pts receiving SEC in the FUTURE 2 study. Methods: FUTURE 2 study design has been reported.2 Mean change from BL in pain VAS and SF-36 bodily pain domain scores were evaluated using mixedeffect model for repeated measures (MMRM) through Wk 16 and as observed through Wk 104. Proportion of pts reporting improvements ≥clinically meaningful differences in pain VAS (mean change from BL ≥20%) was assessed. Results are reported for SEC 300 and 150mg in overall population and stratified by prior use of TNF inhibitor (TNFi; TNFi-naïve vs. inadequate responder/intolerant [TNFi-IR]).

EQ-5D-3L pain item scores (no-, moderate- or extreme-pain/discomfort) were assessed as proportions.

Results: Mean changes from BL in pain VAS were greater with SEC vs. placebo (PBO) by Wk 3 (least squares mean [LSM]: -16.9, -12.6 with SEC 300 and 150mg, respectively vs. -5.75 with PBO: P<0.05), and Wk 16 (LSM: -24.0 and -23.0 for SEC 300 and 150mg, respectively vs. -8.41 with PBO; P<0.05). Mean changes were sustained through Wk 104 (-26.1 and -25.9 with SEC 300 and 150mg, respectively). In both SEC groups, >50% pts reported improvements of  $\geq$ 20% by Wk 3 and this increased through Wk 104. Similarly, SF-36 bodily pain domain scores improved from BL by Wk 4 and 16 with SEC vs. PBO, exceeding minimum clinically important differences of 5.0 (Wk 4: LSM: 16.2 and 16.3 for SEC 300 and 150mg, respectively vs. 5.9 with PBO; P<0.05 and Wk 16: LSM: 21.1 and 22.0 for SEC 300 and 150mg, respectively vs. 6.9 with PBO; P<0.05). Improvements in pain were consistent in TNFi-naïve and TNFi-IR pts; and of greater magnitude in the naïve subgroup (table). Based on the EQ-5D-3L pain/discomfort item, 99% pts reported moderate to extreme pain or discomfort at BL. At Wk 4, the proportion of pts with no pain or discomfort was greater for the SEC 300mg (15%) and 150mg (10%) vs. PBO (5%) and increased through Wk 104 to 28% and 16% with SEC 300 and 150mg, respectively.

Table 1. Summary of results by TNFi status at baseline

|              | TNFi-naïve |                    |       | TNFi-IR            |                   |      |
|--------------|------------|--------------------|-------|--------------------|-------------------|------|
|              | SEC 300mg  | SEC 150mg          | PBO   | SEC 300mg          | SEC 150mg         | PBO  |
| N            | 67         | 63                 | 63    | 33                 | 37                | 35   |
| Pain VAS     |            |                    |       |                    |                   |      |
| Wk 16        | -27.8*     | -25.1 <sup>†</sup> | -11.3 | -18.2 <sup>‡</sup> | -21.1§            | -4.4 |
| Wk 104       | -29.6      | -28.3              | _     | -19.3              | -20.4             | _    |
| SF-36 bodily | pain       |                    |       |                    |                   |      |
| Wk 16        | 23.8*      | 25.4*              | 8.6   | 18.3§              | 17.9§             | 5.2  |
| Wk 104       | 24.2       | 22.2               | _     | 24.5               | 14.0 <sup>¶</sup> | _    |

\*P<0.0001; †P<0.001; \$P<0.01; ‡P<0.05 vs. PBO. P-values and LS mean change at Wk 16 from MMRM analysis. Mean change at Wk 104 from observed data in n=57 (300mg) and 53 (150mg) for TNFi-naïve and n=29 (300mg) and 24 (150mg) for TNFi-IR; ¶n=26

Conclusions: SEC provides rapid and sustained pain relief through 104 wks in pts with PsA as assessed by multiple clinically relevant patient-reported measures of pain. Improvements were reported by pts regardless of their prior TNFi therapy status

#### References:

[1] Strand V, et al. Ann Rheum Dis 2017;76:203-7.

[2] McInnes IB, et al. Lancet 2015;386:1137-46.

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## FRI0495 USE OF MELATONIN IN PATIENTS WITH PSORIATIC ARTHRITIS VIOLATIONS OF EMOTIONAL STATUS

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Background: The ability of melatonin to reduce the activity of the sympathetic nervous system tone and of pituitary-adrenal system ensures its anti-stress properties. It can be used to reduce psycho-emotional manifestations of chronic pain in patients with psoriatic arthritis (PsA).

Objectives: To evaluate the effect of combined therapy with the use of melatonin on the expression of psycho-emotional disorders, and pain in patients with PsA. Methods: High levels of anxiety and depressive disorders were established in the survey on Spielberger Anxiety Scale and on Hamilton Rating Scale for Depression (HRDS) in 43 patients with PsA (≥5 SJC and ≥5 TJC; CRP ≥0.3 mg/dL). The quality of life was studied by questionnaire Medical Outcomes Study Short Form (SF-36); the severity of morning stiffness, pain, patient's health status (EWS) - using the 100-mm visual analog scale (VAS). All patients were receiving a stable dose of MTX for at least 6 months. They were divided into two groups; 1 group (n=22) additionally received 3 mg of melatonin at bedtime for 2 months of observation Results: At the end of the observation period the frequency and the level of