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AB0738

DUAL NEUTRALISATION OF INTERLEUKIN (IL)-17A AND IL-17F WITH BIMEKIZUMAB IN MODERATE-TO-SEVERE PLAQUE PSORIASIS: 60-WEEK RESULTS FROM A RANDOMISED, DOUBLE-BLINDED, PHASE 2B EXTENSION STUDY

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Background: Psoriasis is a chronic, systemic, immune-mediated inflammatory disease associated with prominent skin manifestations. One in four patients with psoriasis also has psoriatic arthritis,¹ with skin disease preceding joint manifestations in most patients.² Interleukin (IL)-17F shares structural homology and pro-inflammatory function with IL-17A. Preclinical and early clinical data support dual neutralisation of IL-17F, together with IL-17A, as a novel targeting approach for the treatment of immune-mediated inflammatory diseases. Bimekizumab, a monoclonal antibody that potently and selectively neutralises both IL-17A and IL-17F, is in development for the treatment of psoriasis, psoriatic arthritis and ankylosing spondylitis.³⁻⁵ In the 12-week BE ABLE 1 study (NCT02905006), bimekizumab provided rapid and substantial clinical improvements in patients with moderate-to-severe plaque psoriasis, with a safety profile consistent with previous bimekizumab studies.³

Objectives: The objectives of this Phase 2b extension study (BE ABLE 2; NCT03010527) were to assess the long-term safety and efficacy of subcutaneous bimekizumab every four weeks for an additional 48 weeks (60 weeks' total exposure).

Methods: BE ABLE 1 responders ($\geq 90\%$ reduction in Psoriasis Area Severity Index [PASI90] at Week 12) receiving placebo or bimekizumab 64mg, 160mg, 160mg (320mg loading dose [LD]) remained on the same dose; non-responders ($< \text{PASI90}$ at Week 12) were re-assigned from placebo/bimekizumab 64mg to 160mg or from 160mg/160mg (LD) to 320mg. Patients previously receiving bimekizumab 320mg/480mg received 320mg. The primary variable was the exposure-adjusted incidence rate (EAIR) of treatment-emergent adverse events (TEAEs); efficacy assessments were secondary.

Results: 217 patients were enrolled. Across all doses, BE ABLE 1 responders generally maintained complete or almost complete skin clearance for up to an additional 48 weeks: PASI90: 80–100%, non-responder imputation (93–100%, observed); PASI100: 70–83% (80–96%); Investigator's Global Assessment: 78–100% (98–100%). PASI100 was achieved by 33–76% (40–82%) of non-responders (Week 48). EAIR of TEAEs was 206.1/100 patient-years ($n=184/217$ [85%]). EAIR of serious TEAEs was 6.2/100 patient-years ($n=15/217$ [7%]); no serious TEAE was reported by >1 patient. The most frequent TEAEs were oral candidiasis and nasopharyngitis. No cases of suicidal ideation/behaviour, major adverse cardiac events, or inflammatory bowel disease were reported. No new safety findings were observed.

Conclusion: Nearly all BE ABLE 1 responders completing 60 weeks of bimekizumab treatment maintained complete or almost complete skin clearance, with a safety profile consistent with previous studies.³

REFERENCES

- Alinaghi et al. *J Am Acad Dermatol* 2019;80:251-65;
- Gladmann et al. *Ann Rheum Dis* 2005;64:ii14–17;
- Papp et al. *J Am Acad Dermatol* 2018;79:279–286;
- Van der Heijde et al. *Ann Rheum Dis* 2018;77:A70;
- Ritchlin et al. *Arthritis Rheumatol* 2018;70(S10):L17

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THE PREVALENCE OF PSYCHOLOGICAL DISORDERS IN PATIENTS WITH SEVERE PSORIASIS WITH/WITHOUT PSORIATIC ARTHRITIS IN CLINICAL PRACTICE: DATA FROM A SINGLE DERMATOLOGICAL SETTING

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Background: Psoriatic arthritis (PsA) and Psoriasis (PsO) are associated with different psychological disorders. Depression is a risk factor for development of PsA among PsO patients (pts). Diagnosis of PsA in dermatological practice is still problematic. The prevalence of psychological disorders in patients with severe PsO with/without PsA are limited in the Russian Federation.

Objectives: To study the prevalence of anxiety, depression and fatigue in pts with severe PsO with/without PsA in a single dermatological setting.

Methods: 99 unselected pts (male-23/female-76) with severe plaque PsO, mean age 45.82±14.04 years, BSA 56.35±9.11%, PASI 22.50 ± 5.13 were included. PsA was diagnosed by the CASPAR criteria. Anxiety, depression and fatigue were identified by the Hospital Anxiety Scale (HADS-A), HADS-Depression (HADS-D) and Functional Assessment of Chronic Illness Therapy (FACIT) (points) accordingly. The HADS-A/HADS-D was defined as normal - 0-7; presence of disorders - 8-10; psychiatric morbidity >11 points accordingly. FACIT 43.6±9.4 matched with healthy control. The lower the level of FACIT corresponded to higher fatigue. The number of pts with FACIT ≤ 30 were calculated. All pts were treated with different synthetic DMARDs, mostly Methotrexate (subcutaneous 15-20 mg every week), biological DMARDs according local therapy according

to the national guidelines. $M \pm m, \%$, χ^2 , t-test were performed. All $p < 0.05$ were considered to indicate statistical significance.

Results: 20 out of 99 pts (20.2%) had PsA. In all group mean HADS-D/HADS-A/FACIT were $2.59 \pm 3.88/4.61 \pm 6.54/41.47 \pm 6.41$ accordingly. In PsO pts without PsA presence of disorders/psychiatric morbidity by HADS-A were seen in significantly more cases compare to PsO pts with PsA: totally in 30 out of 79 pts (38%)/in 2 out of 20 pts (10%) accordingly (χ^2 , $p=0.025$). In PsO pts without/with PsA presence of disorders/psychiatric morbidity by HADS-D were seen totally in 20 out of 79 pts (25.3%)/in 2 out of 20 pts (10%) accordingly (χ^2 , $p=0.24$). No significant difference were found between groups. In PsO pts without/with PsA FACIT ≤ 30 were seen in 2 out of 79 pts (2.53%)/in 2 out of 20 pts (10%). No significant difference were found between groups (χ^2 , $p=0.17$).

Conclusion: In our real dermatological clinical practice cohort of pts with severe PsO subclinical and clinical anxiety and depression were detected in about 30% of cases. This fact should be taken into account for the early detection of pts at risk for developing PsA.

REFERENCES

- [1] Lewinson RT, Vallerand IA, Lowerison MW. Depression Is Associated with an Increased Risk of Psoriatic Arthritis among Patients with Psoriasis: A Population-Based Study. *J Invest Dermatol*. 2017;137(4):828-835. doi: 10.1016/j.jid.2016.11.032.

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AB0740

USE OF SECUKINUMAB IN PATIENTS WITH PSORIATIC ARTHRITIS. IMPACTS OF COMBINATION WITH METHOTREXATE

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Background: Secukinumab (SECU) is a human IgG1κ monoclonal antibody that binds to the protein interleukin-17A approved for the treatment of psoriasis, ankylosing spondylitis, and psoriatic arthritis (PsA). Recently presented data suggest that combination with methotrexate (MTX) in patients with PsA may not be as necessary as in rheumatoid arthritis as it improves neither efficacy nor sustainability (1,2,3,4).

Objectives: This analysis describes the use of SECU with or without MTX.

Methods: The data of patients with psoriatic arthritis seen since January 1, 2015 (date at which SECU appeared in the Canadian market) at the Institut de Recherche en Rhumatologie de Montréal (IRRM) and the Centre de l'Ostéoporose et de Rhumatologie de Québec (CORQ) was extracted from the Rhumadata[®] clinical database and registry on January 7, 2019. Selected patients initiated SECU either without (MTX-) or with MTX (MTX+). The collected data include baseline characteristics (socio-demographic variables, concomitant and past medication, comorbidities and the Charlson comorbidity index (CCI)), variables measured over time (laboratory test results, patient and physician-reported outcomes, and disease activity measures such as minimal disease activity (MDA), CDAI and DAS28(4)-ESR) and persistence data (treatment duration, reason for cessation). The groups were compared to identify potential confounder, and persistence data were analyzed using Kaplan-Meier and proportional hazard methods.

Results: A total of 96 patients were prescribed SECU since January 1, 2015. Of those, 49% (n=47) treated with MTX. No significant differences in baseline (at treatment initiation) were observed between the MTX+ and MTX- groups. Average age at treatment initiation was 52.4 (standard deviation=11.3) and 53.7 (13.4) in the MTX+ and MTX- groups respectively. Women represent 45% and 55% of these groups, and the average body mass index was 29.9 (6.2) and 28.1 (6.0) kg/m². Patient global,

pain and fatigue assessments, made on a visual analogue scale ranging from 1 to 10, were 4.9 (2.6), 5.3 (2.9) and 4.3 (2.9) in the MTX+ group and 6.3 (2.2), 6.9 (2.1) and 6.5 (2.9) in the MTX- group. Among the 38 (40%) patients ceasing therapy, the principal reason for cessation was "inefficacy" (MTX+: 15/17 (88%) vs MTX-: 15/21 (71%)). Patients remaining on treatment at last follow-up had an average treatment duration of 1.7 (0.8) and 1.5 (0.7) years. The improvement in CDAI, HAQ and the percentage of patients reaching MDA are similar for both groups. No difference in retention was observed between the MTX+ and MTX- groups (log-rank $p=0.4867$). These results remain unchanged when we adjust for age at treatment initiation, gender, disease duration, and comorbidities (Charlson comorbidity index).

Conclusion: Combining MTX to SECU does not improve its sustainability over time. Efficacy was also the same for both cohorts.

REFERENCES

- [1] Mease PJ, et al. *Arthritis Rheumatol*. 2018; 70 (suppl 10). Abstract L11
- [2] Benryane O, et al. *Arthritis Rheumatol*. 2018; 70 (suppl 10). Abstracts 693 and 694
- [3] Benryane O, et al. CRA-2019, Montréal, Canada.

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AB0741

ACHIEVEMENT OF CDAPSA LOW DISEASE ACTIVITY OR REMISSION IS ASSOCIATED WITH CONTROL OF ARTICULAR AND EXTRA-ARTICULAR MANIFESTATIONS OF ACTIVE PSORIATIC ARTHRITIS IN SUBJECTS TREATED WITH APREMILAST

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Background: Therapeutic targets for psoriatic arthritis (PsA) include the achievement of remission (REM) or low disease activity (LDA), measured by the Clinical Disease Activity Index for Psoriatic Arthritis (cDAPSA [0-154]), a composite of swollen and tender joints counts (SJC and TJC), Patient's Assessment of Pain (PAP) and Patient's Global Assessment of Disease Activity (PtGA).

Objectives: We examined the trajectories for improvement in cDAPSA, its core components and PsA manifestations not measured by cDAPSA among subjects achieving cDAPSA REM or LDA by Week 52.

Methods: Pooled analyses of the phase III PALACE 1, 2 and 3 studies were performed for subjects assigned to receive apremilast (APR) 30 mg twice daily at baseline (BL). Subjects with cDAPSA components available