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AB0395
NO CLINICAL RELEVANT CHANGES IN EFFICACY, QUALITY OF LIFE AND TOLERABILITY FOR RA PATIENTS IN CLINICAL REMISSION 16 WEEKS AFTER SWITCHING TO THE BIOSIMILAR IFX CT-P13 COMPARED TO THE ORIGINATOR; A DESCRIPTIVE REPORT

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Background: Switching patients from originator infliximab (IFX) to biosimilar IFX CT-P13 compared to the originator.

Methods: In this prospective, open-label, intervention, non-inferiority, multicenter, phase IV trial, adult RA patients in clinical remission >30 weeks (DAS<3.2) at stable IFX dose were switched from originator IFX to IFX CT-P13 for up to 16 weeks. The IBD cohort of this study has been published elsewhere (3).

Results: Between July 2015 and December 2016, 34 RA patients were recruited. Two patients were excluded from the safety population (1 no IMP exposure; 1 no efficacy assessment) and two patients discontinued before week 16 (1 AE: renal colic; 1 personal reasons), leaving 30 patients in the intent to treat population. For 11 patients, blood samples were obtained at baseline and week 16. The IFX ratio at week 16 (biosimilar) compared to baseline (originator) was 107.40% (90 CI 90.35:127.66), indicating non inferiority. The number of included patients was too low for firm conclusions. The mean difference (95% CI) at week 16 compared to baseline was for the CRP -0.22 (-1.80:1.37), for DAS 0.12 (-0.06:0.30), for EQOD thermometer -0.319 (-0.97:0.34) and EQOD Health status -0.05 (-0.08:0.01). These changes were not clinical relevant.

Conclusion: In total 76 AE were reported by 29 (90.6%) patients; 27 of these AEs were related to the study treatment. The most frequently reported AEs (>5% subjects) were fatigue (9.4%), headache (6.3%), arthralgia (15.6%), back pain (9.4%), cough (6.3%), viral upper respiratory tract infection (15.6%) bursitis (6.3%) and pain in extremity (6.3%). Two non-related serious AEs were reported (ovarian cyst and benign parathyroid tumour).

References:

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Background: Indocyanine (ICG)-enhanced fluorescence optical imaging (FOI) treated with anti-TNFi therapy

AB0396
MONITORING OF PATIENTS WITH RHEUMATOID ARTHRITIS BY INDOCYANINE GREEN (ICG) ENHANCED FLUORESCENCE OPTICAL IMAGING TREATED WITH ANTI-TNF THERAPY

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Background: In rheumatoid arthritis (RA), diagnosis of remission by clinical assessment is limited. FOI in phase 1 appears to be a valuable tool for fast and easy monitoring of treatment response to CZP in a clinical setting. FOI

References:

Disclosure of Interests: Michael Nurmohamed Grant/research support from: Abbvie, Bristol-Myers Squibb, Celgene, Eli Lilly, Janssen, Menarini, MSD, Mundipharma, Pfizer, Roche, Sanofi and UCB, Consultant for: Abbvie, Bristol-Myers Squibb, Celgene, Eli Lilly, Janssen, Menarini, MSD, Mundipharma, Pfizer, Roche, Sanofi and UCB, Patients included in the SECURE study (IFX4501; registered at www.clinicaltrialsregister.eu 2014-004904-31). In SECURE we collected IFX serum concentrations, efficacy, quality of life (QoL) and safety data of patients switched from originator IFX to biosimilar IFX CT-P13 over a period of 52 weeks. The IFX ratio at week 16 (biosimilar) compared to baseline (originator) was 107.40% (90 CI 90.35:127.66), indicating non inferiority. The number of included patients was too low for firm conclusions.

Background: Indocyanine (ICG)-enhanced fluorescence optical imaging (FOI) by the Xiralite® system enables visualization of inflammation in the hands in rheumatoid arthritis (RA) during treatment with CZP.

Objectives: To investigate the ability of monitoring treatment response under Cetolizumab pegol (CZP) in patients with rheumatoid arthritis (RA) by the ICG-enhanced FOI method Xiralite® as compared to clinical disease activity, laboratory parameters, and musculoskeletal ultrasound (US).

Methods: CZP-naive patients with RA were eligible for this study, which consisted of an open-label 52-week treatment period with CZP. Disease activity was monitored by the clinical score DAS28, laboratory parameters for systemic inflammation (CRP and ESR), ultrasonography (US7 score [1]) and by FOI at baseline (before CZP) and after 6, 12, 24, and 52 weeks under CZP therapy.

Results: In this study, 28 patients (female 92.9%, mean age 49.4±13.3) with RA were included and treated with CZP over a period of 52 weeks. All patients received CZP for at least 12 weeks (w), n=27 until w24, and n=18 received CZP throughout the entire 52 weeks. DAS28 decreased from moderate disease activity (median 4.6) at baseline to low disease activity (median 2.7) at w52 (p<0.001). CRP/ESR values also reduced from baseline to w52 (n.s.). FOI in phase 1 showed a continuous decrease of treatment enhancement during the course of the treatment period: from baseline (median 1.5, IQR 0.9-5) to w6 (median 1.0, IQR 0-3), to w12 (median 0.5, IQR 0-3), to w24 (median 0.0, IQR 0-2) and visit w52 (median 0.0, IQR 0-2). An image example is given by the Figure for baseline and w52. The results for other FOI phases 2, 3 and PVM did not show a decrease over the treatment period. US-detected synovitis and US7-synovitis in PD were presented to be responsive under therapy. Especially US7-synovitis in Power Doppler (PD) was reduced from baseline (median 2.0, IQR 1-4) to w52 (median 0.5, IQR 0-2).

Conclusion: FOI in phase 1 appears to be a valuable tool for fast and easy monitoring of treatment response to CZP in a clinical setting. FOI may moreover be an additional method to evaluate inflammation of wrist and finger joints of RA patients in follow-up studies.