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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 can reduce healthcare costs. Several studies have shown that switching does not affect the efficacy for rheumatoid arthritis (RA) patients^(1,2), however prospectively collected data on pharmacokinetics, immunogenicity and quality of life (QoL) is scarce.

Objectives: We report data collected from RA patients in clinical remission enrolled 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 for up to 16 weeks. The IBD cohort of this study has been published elsewhere (3).

Methods: In this prospective, open-label, interventional, 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 CT-P13. Patients were followed for 16 weeks (2 infusions) after switching. Primary endpoint was the IFX serum concentration at through measured with a bridging enzyme-linked immunosorbent assay (ELISA) 16 weeks after switch. Secondary endpoints included antidrug antibodies (ADA), clinical disease activity measured with the DAS score, CRP and quality of life measured with the EQ5D, 8 and/or 16 weeks after switching.

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 EQ5D thermometer -3.19 (-9.78;3.41) and EQ5D Health status -0.05 (-0.08,-0.01). These changes were not clinically relevant.

In total 76 AEs 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). No ADA's were detected by inclusion or during the follow-up period.

Conclusion: In this prospective, interventional study in RA patients in clinical remission there were no clinically relevant changes in clinical and biochemical efficacy, quality of life and tolerability 16 weeks after switching to the biosimilar IFX CT-P13 compared to the originator. This study is sponsored by Mundipharma Pharmaceuticals BV.

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AB0396

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

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Background: Indocyanine (ICG)-enhanced fluorescence optical imaging (FOI) by the Xiralite[®] system enables visualization of inflammation in the hands in rheumatic joint diseases.

Objectives: To investigate the ability of monitoring treatment response under Certolizumab 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-naïve patients with RA were eligible for this study, which consisted of an open-label 52-weeks 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 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 0-3) 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 tenosynovitis by the US7 score also 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 provide an additional method to evaluate inflammation of wrist and finger joints of RA patients in follow-up studies.