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FRI0126 PATIENTS' CONCERNS ABOUT AND PERCEPTION OF BIOSIMILARS IN RHEUMATOLOGY : A FRENCH SURVEY

L. Frantzen¹, J.-D. Cohen², S. Tropé³, M. Beck⁴, R. Diebold⁵, M. Sittler⁶, A. Munos⁷, L. Arnaud⁸, J.-E. Gottenberg⁹, J. Sibilia⁸, N. Afif¹, C. Sordet⁸ on behalf of CERBER : Comité d'Etudes et de Réflexion sur les Biosimilaires en Rhumatologie. ¹Service de Rhumatologie, GHR Mulhouse Sud Alsace, Mulhouse; ²Service de rhumatologie, Centre Hospitalier Universitaire de Montpellier; ³ANDAR, Montpellier; ⁴Agence Régionale de Santé; ⁵Service de Rhumatologie, Association France Spondylarthrite; ⁶Hôpitaux Universitaires de Strasbourg, Strasbourg; ⁷Université de Tours, Tours; ⁸Service de Rhumatologie, Hôpitaux Universitaires de Strasbourg, Strasbourg, France

Background: Patient adhesion to biosimilars DMARDs have become a big medico-economic issue. Indeed, savings will depend on penetration rate of biosimilars on the biologics market. Like generics, biosimilars are unknown by the general population and patients reluctance appears to be an obstacle to the diffusion of these therapeutics.

Objectives: To assess patients' knowledge, information and concerns about biosimilars and to identify levers and obstacles to adhesion to biosimilars prescription.

Methods: National cross-sectional study assessing information, knowledge and concerns about biosimilars of french patients treated for a rheumatism (whether they were treated by a bDMARDs or not). The data were collected from march to july 2017 by an online assessment.

Results: 629 patients answered the assessment. 43% knew the definition of biosimilars. 65% felt unsufficiently informed about biosimilars. The principal sources of information were the rheumatologist and the patient associations. 44% of patients treated with a biosimilar were not informed before they received a biosimilar. Patients concerns focused on molecular structure (46%), efficacy (60%) and tolerance (57%) comparatively to originator bDMARDs.

Receiving information about biosimilars and understanding the definition of biosimilarity were two characteristics associated with better adhesion to biosimilars. The rheumatologist was considered the most influent source of information about biosimilar. Patients trust him concerning the decision to switch from the originator biologic to its biosimilar. Patient were reluctant to substitution by the pharmacist (2%).

Conclusions: Biosimilars are largely unknown by french patients at present. Information seems to be instrumental in patient adhesion to biosimilars and in the preservation of the therapeutic relationship.

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FRI0127 OPEN-LABEL NON-MANDATORY TRANSITIONING FROM ORIGINATOR ETANERCEPT TO BIOSIMILAR SB4: 6-MONTH RESULTS FROM A CONTROLLED COHORT STUDY

L. Tweehuysen¹, V.J.B. Huiskes², B.J.F. van den Bemt^{2,3}, J.E. Vriezeolk¹, S. Teerenstra⁴, F.H.J. van den Hoogen^{1,5}, C.H. van den Ende^{1,5}, A.A. den Broeder^{1,5}. ¹Rheumatology; ²Pharmacy, Sint Maartenskliniek; ³Pharmacy; ⁴Radboud Institute for Health Sciences, department for Health Evidence; ⁵Rheumatology, Radboud University Medical Center, Nijmegen, Netherlands

Background: Open-label mandatory transitioning to a biosimilar has no impact on disease activity in inflammatory rheumatic diseases.¹ In light of shared treatment decision-making between patients and physicians, non-mandatory transitioning might be preferable above mandatory transitioning. First attempts with non-mandatory transitioning unfortunately showed suboptimal acceptance and persistence rates to a biosimilar.²

Objectives: To evaluate the effects of non-mandatory transitioning from originator etanercept (ENB) to biosimilar etanercept (SB4) on drug survival and effectiveness in a controlled cohort study of patients with an inflammatory rheumatic disease.

Methods: In 2016, 642 ENB treated patients were asked to transition to SB4 by a structured communication strategy with opt-out option. Consenting patients were eligible for the current study [BIO-SPAN]. ENB treated patients in 2014 were recruited as historical cohort. Drug survival was compared by Cox regression analyses adjusting for age, gender, diagnosis, ENB treatment duration, ENB dose interval, csDMARD and CRP, using a robust variance estimator to account for repeated subjects. Adjusted differences in CRP, DAS28-CRP and BASDAI change over 6 months were assessed.

Results: 635 (99%) patients agreed to transition to SB4 of whom 625 patients (433 RA, 128 PsA, 64 axSpA) were included in the transition cohort. Additionally, 600 patients were included in the historical cohort. Crude 6 months retention rates of SB4 in the transition cohort and ENB in the historical cohort were: 90% (95%CI 88%-93%) vs 92% (95%CI 90%-94%). The transition cohort had a significantly higher relative risk of discontinuation (adjusted HR 1.57, 95% CI 1.05-2.36). Reasons for discontinuing SB4 (n=60) and ENB (n=46) were: lack of effect (43% vs 61%), adverse events (47% vs 28%), malignancy (3% vs 4%), pregnancy (4% vs 4%), other (3% vs 3%). In the transition cohort, 17 patients restarted ENB, 32 patients switched to another biologic and 11 patients maintained biologic-free. DAS28-CRP, BASDAI and CRP were similar between baseline and month 6. Compared with the historical cohort, the transition cohort had a smaller decrease in CRP (adjusted diff 1.8 (95%CI 0.3-3.2)) and DAS28-CRP (adjusted diff 0.15 (95%CI 0.05-0.25)) over 6 months.

Conclusions: Open-label non-mandatory transitioning from ENB to SB4 using a structured communication strategy showed a slightly lower persistence rate and smaller decreases in disease activity compared with a historical cohort, but these differences were considered as not being clinically relevant. The acceptance and persistence rates of SB4 in our transition cohort were similar to those of mandatory transitioning. Since mandatory transitioning is not acceptable in many countries, the use of a communication strategy which might optimise acceptance and persistence rates of non-mandatory transitioning seems attractive.

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FRI0128 INTEGRATED SAFETY DATA ANALYSIS ACROSS PHASE 3 CLINICAL STUDIES FOR INTRAVENOUS GOLIMUMAB IN RHEUMATOID ARTHRITIS, PSORIATIC ARTHRITIS, AND ANKYLOSING SPONDYLITIS

M.E. Husni¹, S. Schwartzman², A. Deodhar³, S. Kafka⁴, S.D. Chakravarty⁵, E. C. Hsia⁶, D.D. Harrison⁷, J.H. Leu⁸, Y. Zhou⁹, K.H. Lo⁹, A. Kavanaugh⁹. ¹Cleveland Clinic, Cleveland; ²Weill Cornell Medical College, New York; ³Oregon Health and Science U, Portland; ⁴Janssen Scientific Affairs, LLC; ⁵Janssen Scientific Affairs, LLC/Drexel U College of Med, Horsham; ⁶Janssen Research and Development, LLC/U Penn, Spring House/Phila; ⁷Janssen Research and Development, LLC, Horsham; ⁸Janssen Research and Development, LLC, Spring House; ⁹UCSD, San Diego, USA

Background: Intravenous golimumab (IV GLM) is approved for treatment of adults w/rheumatoid arthritis (RA), psoriatic arthritis (PsA) and ankylosing spondylitis (AS).

Objectives: To present the integrated safety data from three Phase 3 studies of IV GLM in patients (pts) w/RA, PsA and AS up to 24 weeks (wks). Safety outcomes in pts receiving concomitant methotrexate (MTX) and low-dose oral corticosteroids (CS) were assessed when used in treatment of the indicated disease.

Methods: Integrated safety data from Phase 3 double-blind placebo-controlled trials (RA [GO-FURTHER], PsA [GO-VIBRANT] and AS [GO-ALIVE]) were analysed up to wk24. In general, pts received either IV PBO or IV GLM (2 mg/kg) at 0, 4, 12, and 20 wks. PBO pts crossed over to GLM at wk24 except RA pts randomised to PBO who met early escape criteria crossed over at wk16 and AS pts randomised to PBO, who crossed-over at wk16. Data before crossover are presented. Infusion reactions, infections, serious infections, serious adverse events (SAEs), death, and antidrug antibodies (ADAs) were evaluated.