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FR10126

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

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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. 85% felt insufficiently 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 biosimilars. Patients concerned focused on molecular structure (46%), efficacy (60%) and tolerance (57%) comparatively to original 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 biosimilars. 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.

REFERENCES:

Disclosure of Interest: None declared
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FR10127

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

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Background: Open-label mandatory transitioning to a biosimilar has no impact on disease activity in inflammatory rheumatological 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.

Objectives: To evaluate the effects of non-mandatory transitioning from originator etanercept (ENB) to biosimilar etanetacpent (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 methods.

Results: 635 (99%) patients agreed to transition to SB4 of whom 625 patients were randomized to PBO, who crossed-over at wk16. Data before crossover are presented.

CRP and ESR were similar between baseline and month 6. Persistence rates to a biosimilar. 2 non-mandatory transitioning unfortunately showed suboptimal acceptance and effectiveness in a controlled cohort study of patients with an inflammatory rheumatic disease.


FR10128

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


Background: Intravenous golimumab (IV GLM) is approved for treatment of adults with 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 randomised to GLM at wk4 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.

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.


References:

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Disclosure of Interest: None declared
### Switch Between Reference Etanercept (ETN) and GP2015, an Etanercept Biosimilar, Did Not Impact Efficacy and Safety in Patients with Moderate-to-Severe Rheumatoid Arthritis: 48-Week Results from the Phase 3 EQUIRA Study

M. Matucci-Cerinic, H. Schultze-Koops, M. Buch, A. Kavagna, Y. Allanore, E.J. Kucharz, G. Babic

**Background:**
GP2015 is an etanercept biosimilar. It has shown an equivalent efficacy, and comparable safety and immunogenicity to ETN in patients with moderate-to-severe RA.

**Objectives:**
To compare the efficacy and safety of GP2015 versus ETN in patients with moderate-to-severe rheumatoid arthritis (RA) and evaluate the effects of switching from ETN to GP2015.

**Methods:**
EQUIRA was a 48-week, randomised, double-blind, Phase 3 study. The primary endpoint was equivalent change from baseline (BL) in DAS28-CRP at Week 24. Patients ≥18 years with active RA ACR 1987 or ACR/EULAR 2010 criteria for ≥6 months before BL and active disease defined as DAS28-CRP ≥3.2 and CRP >5 mg/L or ESR >28 mm/h and inadequate response to methotrexate (MTX) were randomised 1:1 to 50 mg GP2015 or ETN subcutaneously once weekly for 24 weeks (Treatment period 1). Patients with at least moderate EULAR response at Week 24 either continued GP2015 treatment or, in the ETN group, response at Week 24 either continued GP2015 treatment or, in the ETN group, were switched to receive 50 mg GP2015 up to 48 weeks (Treatment period 2). All patients continued to receive concomitant MTX (10–25 mg/week) at a stable dose and folic acid. Efficacy outcome measures included change in DAS28- CRP, EULAR and ACR20/50/70 responses.

**Variables**

<table>
<thead>
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<th>Variables</th>
<th>Time</th>
<th>Continued GP2015 n=148</th>
<th>Switched to GP2015 n=131</th>
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<td>EULAR good response, n (%)</td>
<td>W48</td>
<td>40 (54.4)</td>
<td>67 (51.9)</td>
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<tr>
<td>EULAR moderate response, n (%)</td>
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<tr>
<td>ACR70 response, n (%)</td>
<td>W4</td>
<td>93 (63.3)</td>
<td>86 (65.6)</td>
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</table>

**Results:**
Baseline characteristics were comparable between the GP2015 (n=186) and ETN (n=190) groups. The primary endpoint for equivalence was met, the mean change in DAS28-CRP from BL to Week 48 was comparable between the continued and switched to GP2015 groups (TP2 per-protocol set; figure 1). At Week 48, the EULAR and ACR 20/50/70 response rates were comparable between the two groups (table 1). In TP2, treatment-emergent adverse events (AEs) occurred in 42.9% vs 38.0% patients in the continued GP2015 (n=175) vs the switched (n=166) groups; serious AEs occurred in 2.3% vs 2.4% patients (TP2 safety set). Injection site reactions occurred in 6 (3.6%) patients in the switched group but none in the continued GP2015 group. In TP2, 4 (2.4%) patients in the continued GP2015 group had single-event, very low titer, non-neutralising antidrug antibodies detected.

**Conclusions:**
The switch from ETN to GP2015 did not impact on efficacy and safety of etanercept in patients with moderate-to-severe RA.

**References:**

**Disclosure of Interest:**
M. Matucci-Cerinic Grant/research support from: Abbvie, AstraZeneca, Eli Lilly, Pfizer, Roche, Sandoz and UCB, Consultant for: Abbvie, AstraZeneca, Eli Lilly, Pfizer, Roche, Sandoz and UCB, K. Lo: None declared, A. Loe: None declared, K. Lo: None declared, A. Kavagna: None declared.

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**Table 1**

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**Abstract FRI0129 – Figure 1.** Change from Baseline in DAS28-CRP up to Week 48 (TP2 per-protocol set)

**Conclusions:**
The efficacy of GP2015 was comparable to that of ETN. Moreover, the switch from ETN to GP2015 did not impact on efficacy and safety of etanercept in patients with moderate-to-severe RA.

**References:**