SAT0161 PRELIMINARY REAL WORLD DATA ON SWITCHING PATTERNS BETWEEN ETANERCEPT, ITS RECENTLY MARKETED BIOSIMILAR COUNTERPART AND ITS COMPETITOR ADALIMUMAB, USING SWEDISH PRESCRIPTION REGISTRY

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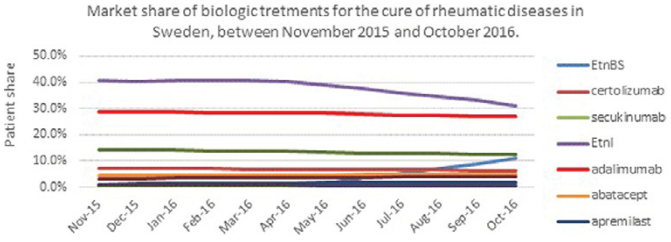
Background: The increasing availability of biologic treatments over the past 10 years has revolutionized the management of chronic inflammatory autoimmune diseases such as rheumatic diseases. In April 2016, the first etanercept biosimilar (EtnBS) was launched in Sweden, which may represent a cheaper option to its innovator counterpart and other anti-TNF agents.
Objectives: The objective of this study was to describe the position of etanercept innovator (EtnI) within the Swedish biologic market for rheumatic diseases, before and after the launch of its biosimilar. The study also provides early real-world data on the market penetration of EtnBS by evaluating switching dynamics to and from this drug since the date of launch.
Methods: The overall biologic market share across all type of rheumatic diseases was monthly tracked over the last year of available data in the Swedish Prescription Registry (100% coverage). The proportion of patients receiving a rheumatologists' prescription for any biologic in each month, from November 2015 to October 2016, was recorded. In addition, switching dynamics of patients initiating EtnBS treatment between April 2016 and October 2016 were studied. The proportion of patients receiving no biologic treatment (naïve) and of those on treatment with EtnI, adalimumab and other biologic agents in the 12 months prior to initiate EtnBS was reported. Further, the proportion of patients who switched from EtnBS back to EtnI or adalimumab and the mean time to this second switch were also evaluated.
Results: EtnI and adalimumab dominate the biologic market for rheumatic diseases in Sweden, holding the 40% and 28% of market share, respectively, up to April 2016. However, in the 6 months after EtnBS was launched, the share of EtnI decreased constantly, dropping to 31% in October 2016 (Figure 1). Since April 2016, we identified in total 2,439 patients receiving first prescription of EtnBS by a rheumatologist. Of these, 977 (40.1%) were naïve to biologic, 1,179 (48.3%) had prior treatment with EtnI, 107 (4.4%) with adalimumab, 176 (7.2%) with other biologics. Among the patients who changed to EtnBS from prior EtnI, the 7% switched back to EtnI after an average time of 43 days. Similarly, of those who were on previous adalimumab treatment, 6% switched back to adalimumab after, on average, 57 days.



Conclusions: Many patients changed from EtnI to its biosimilar treatment since its launch in Sweden. However, this study showed that 7% of these patients switch back to their original treatment after short time. Despite the change from a brand biologic to the biosimilar is very likely made for economic reasons, the reasons for switching back to the innovator are not clear and may imply patients' preference or clinical reasons. Interestingly, the same pattern is observed for patients changing from adalimumab to EtnBS. Longer-term studies are required to confirm these early observations and investigate the reasons for switching back.
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SAT0162 SWITCHING FROM ETANERCEPT TO CHS-0214: A ONE YEAR, RANDOMIZED, DOUBLE-BLIND STUDY IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: CHS-0214 is in development as a proposed biosimilar of etanercept for the treatment of rheumatoid arthritis (RA) and other auto-immune diseases.
Objectives: Equivalence of CHS-0214 to etanercept was demonstrated at 24 weeks in a global confirmatory, safety and efficacy study in patients with RA. This update provides efficacy results at 48 weeks and safety results over 52 weeks (or over 48 weeks for subjects who continued to the open-label safety extension study).
Methods: Patients had moderate/severe RA and an inadequate response to methotrexate (MTX). Patients were randomized to CHS-0214 or etanercept (commercial European-sourced) at 50 mg SC QW for 24 weeks (Part 1). Patients achieving ACR20 at Week 24 with no safety concerns then received CHS-0214 50 mg SC QW open-label for 24 weeks (Part 2). Patients continued their stable dose of MTX throughout the study.
Results: At Week 24, the response rates were 91.0% vs. 90.6% for ACR20, 67.6% vs. 63.7% for ACR50, and 38.3% vs. 37.9% for ACR70, in the CHS-0214 group (n=256) vs. etanercept group (n=256), respectively. At Week 48, the response rates were 93.8% vs. 92.7% for ACR20, 75.0% vs. 73.6% for ACR50, and 49.6% vs. 51.4% for ACR70, in patients who received CHS-0214 for 48 weeks (n=224) vs. patients who received etanercept for 24 weeks and then switched to CHS-0214 for 24 weeks (n=220), respectively. Thus, response rates were maintained both in patients who were switched at Week 24 from etanercept to CHS-0214 and in patients who received CHS-0214 for 48 weeks.
Over the 52-week study, adverse events (AE) were reported in 74.4% of patients who received CHS-0214 for 48 weeks and 76.6% who received etanercept for 24 weeks and were switched to CHS-0214 for 24 weeks. The majority of adverse events were mild or moderate in severity. No deaths were reported. Serious AEs were reported in 4.6% and 7.5% of patients, and serious AEs related to study drug per the investigator were reported in 0.9% and 1.9% of patients in the CHS-0214 and etanercept/CHS-0214 groups. Binding anti-drug antibodies (ADA) occurred in 1.3% and 4.7% of patients receiving CHS-0214 and etanercept during Part 1. In Part 2, treatment-emergent binding ADA occurred in 1.4% of patients receiving CHS-0214 and 0.7% of patients who switched from etanercept to CHS-0214.
Conclusions: This randomized, double-blind, active-control, global study demonstrated equivalence of CHS-0214 to etanercept based on the primary endpoint (ACR20 at Week 24) and maintenance of the efficacy response through Week 48. CHS-0214 was well tolerated and effective in patients with rheumatoid arthritis with no clinically meaningful differences to etanercept with regard to safety and immunogenicity. Over the 52-week study, no clinically meaningful differences in safety, immunogenicity, or efficacy were observed in patients who were switched from etanercept to CHS-0214 in comparison with those who only received CHS-0214.
Disclosure of Interest: J. O'Dell Consultant for: Coherus BioSciences, A. Kivitz: None declared, T. Takeuchi Consultant for: AbbVie, Asahi Kasei Pharma, Astellas, Astra Zeneca, BMS, Celtrion, Chugai, Daiichi-Sankyo, Eisai, Eli-Lilly Japan, Janssen, Mitsubishi Tanabe, Nippon Kayaku, Novartis, Pfizer, Sanofi-Aventis, Santen, Taisho Toyama, Takeda, Teijin Pharma, Y. Tanaka Consultant for: Abbvie, Astellas, BMS, Chugai, Daiichi-Sankyo, Eisai, GSK, Janssen, Mitsubishi-Tanabe, MSD, Novartis, Pfizer, Santen, Takeda, UCB, I. Louw: None declared, T. Tiabut Grant/research support from: Coherus BioSciences, S. Nakashima Employee of: Daiichi-Sankyo, J. Hodge Shareholder of: Coherus BioSciences, Employee of: Coherus BioSciences, H. Tang Shareholder of: Coherus BioSciences, Employee of: Coherus BioSciences, B. Finck Shareholder of: Coherus BioSciences, Employee of: Coherus BioSciences
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SAT0163 SYSTEMATIC SWITCH FROM INNOVATOR INFLIXIMAB TO BIOSIMILAR INFLIXIMAB IN INFLAMMATORY RHEUMATIC DISEASES IN DAILY CLINICAL PRACTICE: THE EXPERIENCE OF COCHIN HOSPITAL, PARIS, FRANCE

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Background: Biosimilars of originator biologic therapeutics are going to change medical practices. In October 2015, the medical community of Cochin Hospital decided to systematically propose the switch from innovator infliximab to biosimilar infliximab to all treated patients.
Objectives: To investigate efficacy and safety of switching treatment from innovator infliximab to biosimilar infliximab.
Methods: This is a usual care study conducted in patients aged >18 years who agreed to switch to biosimilar infliximab, and who received at least 3 infusions of innovator infliximab prior to the switch.
The primary outcome of the study was the retention rate of biosimilar infliximab at the time of the third infusion. Secondary outcomes included the factors associated with biosimilar discontinuation, the change between baseline and the last visit (July 2016) in DAS28-CRP (rheumatoid arthritis, RA), BASDAI/ASDAS (axial