Conclusions: Abatacept continues to be a safe and effective treatment option for patients with RA who are biologic naïve or after discontinuation of prior biologic due to failure or intolerance. A significant number of patients continue on abatacept even after 4 years.

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SAT0199 SWITCH FROM INNOVATOR ETANERCEPT TO BIOSIMILAR ETANERCEPT IN INFLAMMATORY RHEUMATIC DISEASES: THE EXPERIENCE OF COCHIN UNIVERSITY HOSPITAL PARIS-FRANCE.

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Background: Etanercept biosimilar (bETN) is available for treatment of spondyloarthritis (SpA) and rheumatoid arthritis (RA) since 2016 in France. Data showing effectiveness and safety of bETN are still limited.
Objectives: 1/To evaluate the RA and SpA patients' and treating rheumatologists' characteristics associated with the switch 2/To evaluate the safety and efficiency of bETN.
Methods: Patients: All the patients receiving innovator etanercept for at least 3 months on October 2016 and monitored in the department of rheumatology B of Cochin hospital. Physicians: All the 9 physicians in charge of at least one patient. Study design: After information (one hour session) on the biosimilars, all the physicians were invited to propose a switch from innovator etanercept to bETN. Data collected: physicians' characteristics, patients' characteristics (demographics, diagnosis of the rheumatic disease, disease activity parameters).
Results: Of the 435 outpatients who had received etanercept; 304 were receiving etanercept in 2016 and 183 were eligible for a potential switch (the remaining 121 patients did not attend any out-patient-clinic between October 1st 2016 and April 1st 2017).
The percentage of patients who switched to bETN was 51.6% (94 patients).
This switch was more frequently performed in patients monitored by older physicians (mean age: 50.4±14.3 *vs* 44.8±11.3, p=0.005) and by physicians with a full-time academical position (56.4 % *vs* 13.5 %, p<0.001)
The patients' characteristics were similar: % RA (51.1% *vs* 44.9%), age (52.1±15 *vs* 50.5±15), female gender (57.4% *vs* 51.6%), disease duration (16.8±11.9 *vs* 14.8±11.3) except for the NSAID intake (28.3 % *vs* 12.3 %, p=0.014) and the global evaluation (25.2±19.4 *vs* 19.1±21.8, p=0.02) in the switchers vs non-switchers, respectively. However, no independent factors were associated with the switch in the multivariate analysis.
The bETN retention rate was 83 % [0.76–0.92] after a 6 month follow-up period. The bETN was discontinued in 26 patients with the following reasons: inefficiency 13 patients, adverse event 13 patients (painful injection site n = 4, fatigue = 2, pruritus n = 2, "allergic reaction" n =1, headache n = 1, pollakiuria n = 1, dizziness n = 1, supply problem n = 1).
The univariate analysis aimed at evaluating the baseline predisposing factors of bETN discontinuation overtime picked up the baseline objective sign of inflammation (defined by CRP≥6 mg/L or ESA ≥28 mm) (OR=4.18 [1.19 – 14.66] p=0.0256), p=0.002) and global disease activity score (OR = 1.57 [1.04 – 2.36], p=0.03). Nevertheless, no independent factors were associated with the switch in the multivariate analysis.
There was no difference in the changes in the disease activity parameters in both the completer and ITT population.
Conclusions: This study suggests that:
1/The probability to switch from etanercept innovator to bETN was mainly related to physicians' behavior
2/Using an open design, the percentage of patients complaining of a lower efficiency and/or a worse safety profile of the biosimilar was high
3/There was no objective parameter permitting to conclude at a lower efficiency and/or a worse safety profile of the bETN in comparison to the innovator etanercept.
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SAT0200 LONG TERM SAFETY OF FILGOTINIB IN THE TREATMENT OF RHEUMATOID ARTHRITIS: WEEK 108 DATA FROM A PHASE 2B OPEN-LABEL EXTENSION STUDY

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Background: Filgotinib (FIL) is an orally administered, selective inhibitor of Janus Kinase 1 (JAK1) in Phase 3 development for the treatment of rheumatoid arthritis (RA).
Objectives: Assess the long-term safety and efficacy of FIL in the DARWIN 3 open-label extension study.
Methods: Two 24-week Phase 2b studies were completed in patients (pts) with moderately to severely active RA (DARWIN 1, DARWIN 2; Ref 1, 2). Following study completion, pts were offered FIL in the ongoing DARWIN 3 extension study: 100 mg QD (US males), 200 mg QD, or 100 mg BID. This report summarizes safety data from the first dose of FIL in the DARWIN program to 11 Oct 2017 and efficacy data from the DARWIN 3 baseline visit to Week 108, which all ongoing pts have completed.
Results: Of 877 pts, 790 (90%) completed DARWIN 1/2, and 739 (84%) enrolled in DARWIN 3; 603 (82%) were female, mean age 53 years. At analysis, 491/739 (66%) were on study. Cumulative patient years of exposure (PYE) was 1931, median time on study drug was 1072 days. Key data are summarized in table 1. 87%, 68%, and 48% of pts achieved ACR20/50/70, respectively, and 72% achieved DAS28-CRP≤3.2 (by observed case analysis).

Table 1 Key Safety Events and Lab Abnormalities per 100 PYE*

	Filgotinib + MTX		Filgotinib Monotherapy	Total* (N=739)
Events Per 100 PYE	100 mg BID (N=249)	200 mg QD (N=250)	200 mg QD (N=222)	
Treatment-emergent AEs (TEAEs)	146.7	141.7	150.3	146.2
Serious TEAEs	5.9	3.9	7.4	5.7
TEAEs for Infections	44.5	39.3	37.2	40.0
Serious TEAEs for Infections	1.2	0.6	2.2	1.3
Malignancy (excl. NMSC†)	0.8	0.4	0.7	0.6
Herpes Zoster	1.2	1.5	1.1	1.2
Deep Vein Thrombosis‡	0.2	0	0	0.1
Pulmonary Embolism‡	0.2	0	0	0.1
Active Tuberculosis	0	0	0	0
≥ Grade 3 Laboratory Abnormalities				
Hemoglobin ↓	0.5	0.1	0	0.2
Lymphocytes ↓	1.2	0.9	0.4	0.8
Neutrophils ↓	0.3	0.1	0.2	0.2
Platelets ↓	0	0.3	0	0.1
ALT ↑	0.2	0.1	0.2	0.2
Creatinine ↑	0.3	0	0	0.1
LDL ≥ 190 mg/dL	17.0	5.5	18.4	13.1
HDL <40 mg/dL	5.4	7.3	6.9	7.1

* Treatment groups with fewer than 10 subjects were omitted for clarity; †Non-melanoma skin cancer; ‡Single patient DVT leading to PE

* Treatment groups with fewer than 10 subjects were omitted for clarity; †Non-melanoma skin cancer; ‡Single patient DVT leading to PE

Conclusions: Filgotinib long-term RA data demonstrates an acceptable safety and durable efficacy profile.

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