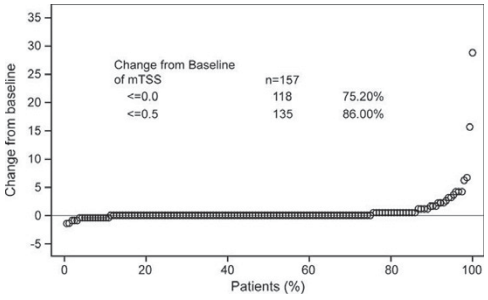

Tanabe, Takeda, Daiichi-Sankyo, Chugai, Bristol-Myers, MSD, Astellas, Abbvie, Eisai, Consultant for: Abbvie, Chugai, Daiichi-Sankyo, Bristol-Myers, Mitsubishi Tanabe, Astellas, Takeda, Pfizer, Teijin, Asahi-kasei, YL Biologics, Sanofi, Janssen, Eli Lilly, GlaxoSmithKline, T. Mimori Grant/research support from: Acterion, Ayumi, Astellas, Bristol-Myers Squibb, Chugai, Daiichi-Sankyo, Eisai, Mitsubishi Tanabe, Speakers bureau: Chugai, Mitsubishi Tanabe, H. Yamanaka Grant/research support from: MSD, Ayumi, AbbVie, Eisai, Ono, Astellas, Daiichi-Sankyo, Taisyo-Toyama, Takeda, Tanabe-Mitsubishi, Chugai, Teijin Pharma, Torii, Nippon Shinyaku, Pfizer, UCB. Nippon Kayaku, YL biologics, Bayer, Bristol-Meyers, Consultant for: MSD, Ayumi, AbbVie, Eisai, Ono, Astellas, Daiichi-Sankyo, Taisyo-Toyama, Takeda, Tanabe-Mitsubishi, Chugai, Teijin Pharma, Torii, Nippon Shinyaku, Pfizer, UCB, Nippon Kayaku, YL biologics, Bayer, Bristol-Meyers, R. Nakajima Employee of: AbbVie GK, K. Morita Employee of: AbbVie GK, J. Kimura Employee of: AbbVie GK, T. Takeuchi Grant/research support from: AbbVie, Astellas, Bristol-Myers, Chugai, Daiichi Sankyo, Eisai, Janssen, Mitsubishi Tanabe, Nippon Shinyaku, Pfizer, Sanofi, Santen, Takeda, Teijin, Consultant for: AstraZeneca, Eli Lilly, Novartis, Mitsubishi Tanabe, Asahi Kasei Medical, Speakers bureau: AbbVie, Bristol-Myers Squibb, Chugai, Eisai, Janssen, Mitsubishi Tanabe, Pfizer, Takeda

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FRI0211 **A DESCRIPTIVE ANALYSIS OF REAL-WORLD TREATMENT PATTERNS OF INNOVATOR INFLIXIMAB (REMICADE) AND BIOSIMILAR INFLIXIMAB IN A TREATMENT NAÏVE TURKISH RHEUMATOLOGIC DISEASE POPULATION**

Y. Yazici[1], L. Xie[2], A. Ogbomo[2], D. Parenti[3], K. Goyal[3], A. Teeple[3], L. Ellis[3], I. Simsek[4]. *[1]NYU Hospital for Joint Diseases, New York; [2]STATinMED Research Inc, Ann Arbor; [3]Janssen Scientific Affairs, LLC, Horsham, United States; [4]Guven Hospital, Ankara, Turkey*

Objectives: This retrospective healthcare claims analysis examined treatment patterns of innovator infliximab (IFX) and biosimilar infliximab (CT-P13) in a Turkish rheumatologic disease population after CT-P13 availability in July, 2014.
Methods: Adult patients (pts) with ≥1 diagnosis code (ICD-10-CM) for rheumatoid arthritis (RA) were identified in a national Turkish healthcare database during the study period (01DEC2010–01DEC2015). Eligible pts had continuous medical/pharmacy enrollment ≥12 months before and ≥6 months after IFX or CT-P13 initiation (index date). Patients were naïve to IFX or CT-P13 (i.e. had no IFX or CT-P13 within 12 months before the index date). Demographics, concomitant diseases and medications, and treatment patterns, eg., dose, interval, discontinuation, and switch were summarized. Confirmed discontinuation was defined as a switch to another biologic medication or the absence of an index biologic claim for ≥120 days without censoring.
Results: Key results are shown in the Table. A total of 1044 patients initiated either medication. The majority (80%; n=831) initiated IFX. The IFX cohort had a mean age of 42 years; 56% were women and mean follow up was 12 months. The CT-P13 cohort consisted of 213 pts with mean age of 43 years; 58% women; and mean follow up of 9 months. Approximately one-third of pts in each cohort had a concomitant diagnosis of ankylosing spondylitis (AS; TABLE). Other concomitant diseases and medications appeared balanced between cohorts. Pts in the IFX cohort had an average of 5.2 infusions and mean dose of 4.7 vials per infusion approximately every 8 weeks. Pts in the CT-P13 cohort had an average of 3.6 doses and mean dose of 5.8 vials per dispensing approximately 9 weeks apart.
A confirmed discontinuation occurred in 55% of the IFX cohort; driven in part by switching. 24% of IFX pts had ≥1 biologic switch with 8% initially switching to CT-P13. Time to any discontinuation or censoring of IFX is shown in the Table.
In the CT-P13 cohort, a confirmed discontinuation was observed in 63%; 31% switched to another biologic therapy; and 20% initially switched to IFX. Time to any discontinuation or censoring of CT-P13 is shown in the Table.
Conclusions: These findings in a single country indicate that real world utilization patterns may differ between innovator IFX and CT-P13, with predominantly more patients initiating IFX; greater overall CT-P13 discontinuation and a higher proportion of patients switching from CT-P13 to IFX. Further studies are needed to understand the reasons for these observed differences.
Disclosure of Interest: Y. Yazici Grant/research support from: Janssen Scientific Affairs, LLC, L. Xie Consultant for: Janssen Scientific Affairs, LLC, A. Ogbomo Consultant for: Janssen Scientific Affairs, LLC, D. Parenti Employee of: Janssen Scientific Affairs, LLC, K. Goyal Employee of: Janssen Scientific Affairs, LLC, A. Teeple Employee of: Janssen Scientific Affairs, LLC, L. Ellis Employee of: Janssen Scientific Affairs, LLC, I. Simsek Grant/research support from: Janssen Scientific Affairs, LLC

	Innovator IFX Cohort (N= 831)		CT-P13Cohort (N=213)	
	N/Mean	%/SD	N/Mean	%/SD
Age (Mean)	42	13	43	12
Gender				
Female	465	56%	124	58 %
Average Length of Follow up Period (in Months)	12	3	9	2
Concomitant Disease During Baseline Period				
Ankylosing Spondylitis	230	28%	70	33%
Psoriatic Arthritis	130	16%	24	11%
Crohn's Disease	65	8%	11	5%
Ulcerative Colitis	64	8%	10	5%
Concomitant RA-Medications During Follow up Period				
Methotrexate	253	30%	69	32%
Sulfasalazine	147	18%	46	22%
Dosing Characteristics				
Average # of doses within follow up period	5.2	2.6	3.6	1.8
Mean # of weeks between doses	8.2	4.2	9.0	4.7
Mean # of days between 1st and 2nd dose	38	37	50	41
Mean # of days between 2nd and 3rd dose	53	33	60	38
Mean # of days between 3rd and 4th dose	65	34	67	31
Switching				
# and % of patients with ≥1 switch	203	24%	66	31%
# of patient switches between Infliximab Types				
Switch to CT-P13	64	8%		
Switch to Innovator Infliximab			42	20%
Discontinuations				
# of Patients Confirmed to Have Discontinued	453	55%	134	63%
Time to confirmed discontinuation (days)	155	93	107	66
Time to any discontinuation or censoring (days):	239	130	169	102

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FRIDAY, 16 JUNE 2017

Rheumatoid arthritis - other biologic treatment

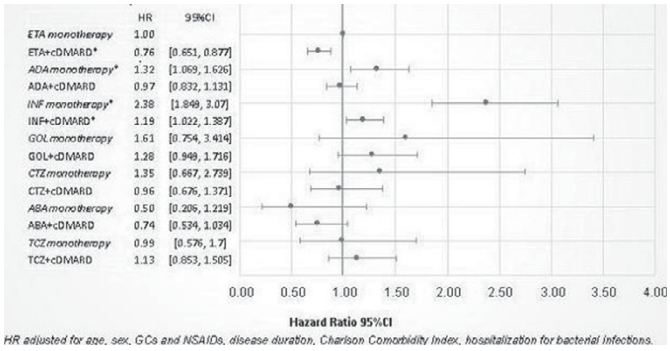
FRI0212 **COMPARATIVE EFFECTIVENESS OF FIRST-LINE BIOLOGIC MONOTHERAPY IN RHEUMATOID ARTHRITIS**

E. Silvagni[1], A. Bortoluzzi[1], G. Carrara[2], M. Govoni[1], C. Scirè[1,3]. *[1]1Department of Medical Science, Rheumatology Unit, University of Ferrara and Azienda Ospedaliero-Universitaria Sant'anna, Cona (Ferrara), ITALY, Ferrara (FE); [2]Epidemiology Unit, Italian Society for Rheumatology; [3]Epidemiology Unit, Italian Society for Rheumatology, Milan, Italy*

Background: Non-Biological disease modifying antirheumatic drugs (csDMARDs) are recommended in association to biologics (bDMARDS) in the treatment of Rheumatoid Arthritis (RA) and combination therapy is superior than bDMARD monotherapy with a better drug survival. Limited data are available in literature about the best biological treatment choice when a monotherapy is necessary in biologic-naïve patients.
Objectives: To assess comparative effectiveness (drug survival) of different first-line bDMARDs when administered in monotherapy in a large population-based sample of RA deriving from the administrative health database of the Lombardy region in Italy.
Methods: Data were obtained from health database of the Lombardy Region between 1/1/2004 and 31/12/2013. Patients with RA, diagnosed by a rheumatologist, with a certified diagnosis (exemption code 006.714.0) and treated with first-line approved bDMARDs (Abatacept [ABA], Adalimumab [ADA], Certolizumab [CTZ], Etanercept [ETA], Golimumab [GOL], Infliximab [INF] and Tocilizumab [TCZ]) were included; the presence of a combination therapy of any duration with a concomitant csDMARD (Methotrexate, Leflunomide, Sulfasalazine, Cyclosporine and Hydroxychloroquine) was compared to monotherapy. Clinical characteristics recorded were age, sex, disease duration, Charlson Comorbidity Index, hospitalization for bacterial infections, use of concomitant glucocorticoid (GCs) or Nonsteroidal Anti-Inflammatory Drugs (NSAIDs). Propensity to treatment with monotherapy was assessed by logistic models and results were presented as odds ratios and 95%confidence intervals (CI) Effectiveness was evaluated as drug survival using Cox proportional hazard models.
Results are presented as hazard ratios (HR) and CI, crude and adjusted for pre-specified confounders.
Results: 4478 RA patients who started a first-line bDMARD were included; 840 (18.8%) in monotherapy and 3638 (81.2%) in association to at least one csDMARD. Among biologic-naïve monotherapy patients, N.398 (47.4%) received ETA, N.215 (25.6%) ADA, N.92 (10.9%) INF, N.48 (5.7%) TCZ, N.35 (4,2%) ABA, N.30 (3,6%) CTZ, N.22 (2,6%) GOL. Median survival on treatment was 19.9 months (7.9–45.1).
Monotherapy was associated with a lower age, longer disease duration, a consistently higher Charlson Comorbidity Index (in particular hepatic or renal disease), lower GCs and NSAIDs intake.

Compared to monotherapy, combination therapy was associated with a lower drug failure (crude HR 0.75 [95% CI 0.68–0.82]; adjusted HR 0.78 [95% CI 0.70–0.86]; $p<0.0001$).

In patients in monotherapy, considering ETA as reference and adjusting for the above mentioned clinical characteristics, the HR for bDMARD failure was 1.32 for ADA (95% CI 1.07–1.63) and 2.38 for INF (95% CI 1.85–3.07).



HR adjusted for age, sex, GCs and NSAIDs, disease duration, Charlson Comorbidity Index, hospitalization for bacterial infections.

Conclusions: Monotherapy with bDMARDs is consistenly associated with lower retention rate in first-line therapy for anti-TNF drugs. Comparing bDMARDs administered in monotherapy, INF and ADA show a higher risk of withdrawal than ETA. Real life data support the currently recommended use of bDMARDs in association to csDMARDs.

References:
[1] Souto et al. Rheum (Oxford)2016;55(3):523–34.
[2] Choy et al. Rheum (Oxford)2016; 21.

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Disclosure of Interest: None declared
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FRI0213 COMPARATIVE EFFECTIVENESS OF ABATACEPT, RITUXIMAB, TOCILIZUMAB AND ANTI-TNF BIOLOGICAL DMARDS IN RA: RESULTS FROM THE NATIONWIDE SWEDISH REGISTER

T. Frisell[1], M. Dehlin[2], D. Di Giuseppe[1], N. Feltelius[3], A. Kastbom[4], C. Turesson[5], J. Askling[1] on behalf of the ARTIS Study Group. *[1]Karolinska Institutet, Stockholm; [2]Sahlgrenska Academy, University of Gothenburg, Göteborg; [3]Medical Products Agency, Uppsala; [4]Rheumatology/AIR, Linköping; [5]Rheumatology, Department of Clinical Sciences, Malmö, Lund University, Malmö, Sweden*

Background: Many current guidelines rank abatacept (ABA), rituximab (RTX), tocilizumab (TOC), and the TNFi bDMARDs as equal in effectiveness for the treatment of RA, at least as second line therapies. This is mainly based on evidence from separate RCTs, with few direct comparisons and limited comparative effectiveness data from clinical practice.
Objectives: To describe outcomes in clinical practice among RA patients starting different bDMARDs as first bDMARD, and after switch from initial TNFi.
Methods: The Swedish Rheumatology Register was linked to nationwide registers with data on demographics and medical history. We included all patients with RA starting a first ever bDMARD, or switching to a new bDMARD after a TNFi as first bDMARD, in 2010 - 2014, with follow-up through 2015. Effectiveness was assessed at 1 year (±90 days) after starting therapy, and measured as 1) the proportion remaining on therapy, or the proportion remaining on therapy and with 2) Good EULAR response, 3) HAQ improvement >0.2, 4) no swollen or tender joints. Relative response was estimated with log-binomial regression adjusting for potential confounders.
Results: Patients starting non-TNFi were older than those starting a TNFi, had lower socioeconomic status, and more often a history of diseases including malignancy, serious infections, and diabetes. After switch from TNFi, those starting non-TNFi also had higher disease activity.
Non-TNFi were associated with better drug survival and higher proportion reaching response outcomes compared to TNFi as first bDMARD. After switch from TNFi, RTX and TOC, but not ABA, were associated with significantly better drug survival and response. Differences remained after adjusting for identified potential confounders.
Conclusions: Despite channeling of older and sicker individuals to non-TNFi-bDMARDs, treatment outcomes were in general better in these groups, particularly for TOC and RTX. In interpreting this, the risk of residual confounding should be remembered, and that we did not include safety or long term outcomes.
Acknowledgements: The ARTIS registry has been, or is, supported by agreements with Abbvie, BMS, MSD, Pfizer, Roche, Samsung, and UCB.
Disclosure of Interest: T. Frisell: None declared, M. Dehlin: None declared, D. Di Giuseppe: None declared, N. Feltelius: None declared, A. Kastbom Consultant for: Bristol-Myers Squibb, Pfizer, Roche, UCB, Paid instructor for: Bristol-Myers Squibb, Pfizer, Roche, UCB, C. Turesson Grant/research support from: Abbvie, Pfizer, Roche, Consultant for: MSD, Pfizer, Roche, Paid instructor for: Abbvie, Bristol-Myers Squibb, Janssen, MSD, Pfizer, Roche and UCB, J. Askling Grant/research support from: Abbvie, UCB, Pfizer, Merck, Samsung, Roche, Lilly
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FRI0214 LONG-TERM EFFICACY AND SAFETY OF SIRUKUMAB IN PATIENTS WITH ACTIVE RHEUMATOID ARTHRITIS DESPITE ANTI-TUMOR NECROSIS FACTOR THERAPY: RESULTS OF THE RANDOMIZED, PHASE 3 SIRROUND-T STUDY

Y. Tanaka[1], D. Aletaha[2], P. Agarwal[3], R. Kurrasch[4], P.P. Tak[5], S. Popik[3]. *[1]Department of Internal Medicine, University of Occupational and Environmental Health, Kitakyushu, Japan; [2]Division of Rheumatology, Medical University of Vienna, Vienna, Austria; [3]Janssen Research & Development, LLC, Spring House, PA; [4]GlaxoSmithKline, Collegeville, PA, United States; [5]GlaxoSmithKline, Stevenage, United Kingdom*

Background: Sirukumab, a selective, high-affinity human monoclonal antibody to the interleukin-6 (IL-6) cytokine, is under development for rheumatoid arthritis (RA) and other diseases.
Objectives: To evaluate long-term efficacy and safety of sirukumab in patients (pts) with RA refractory or intolerant to anti-tumor necrosis factor (TNF) agents.
Methods: This phase 3 study included pts ≥18 years with moderate to severe active RA, and a lack of benefit to ≥1 anti-TNF or intolerance to ≥2 anti-TNFs. Eligible pts were initially randomized 1:1:1 to sirukumab subcutaneous (SC) 50mg q4w, sirukumab SC 100mg q2w, or placebo SC q2w for 24 wks. Placebo-treated pts with <20% improvement in tender and swollen joints at Wk 18 (early escape [EE]) and those remaining on placebo at Wk 24 (crossover) were re-randomized to sirukumab through Wk 52. Efficacy endpoints included ACR response, HAQ-DI scores, DAS28 (CRP) remission rates, and SF-36 scores. Results are presented for these key endpoints at Week 52.
Results: 878 pts were initially randomized to placebo (n=294), sirukumab 50 mg q4w (n=292), or sirukumab 100 mg q2w (n=292). Of placebo-treated pts, 94 met EE criteria at Wk 18 and 158 crossed over at Wk 24 and were re-randomized to sirukumab. 60% of pts had received ≥2 prior biologics, including non-TNF–targeted biologics. RA signs and symptoms and patient-reported outcomes (PROs [SF-36 scores]) improved significantly with sirukumab versus placebo through Wk 24. Improvements were maintained through Wk 52 with no dose response (Table 1). Through Wk 52 in the combined sirukumab 50mg q4w and 100mg q2w groups, respectively, an adverse event (AE) was reported for 79.6% and 81.3% of pts and a serious AE was reported for 14.2% and 13.2% of pts; injection-site reactions and alanine aminotransferase increases were the most commonly reported AEs.
Conclusions: In this population intolerant or refractory to anti-TNFs/other biologics, sirukumab SC 50mg q4w and 100mg q2w were well tolerated and reduced signs and symptoms of RA and improved PROs through 52 wks of treatment, also among pts who switched from placebo to sirukumab.
Disclosure of Interest: Y. Tanaka Grant/research support from: Mitsubishi-Tanabe, Takeda, Daiichi-Sankyo, Chugai, Bristol-Myers, MSD, Astellas, Abbvie, and Eisai, Speakers bureau: Abbvie, Chugai, Daiichi-Sankyo, Bristol-Myers, Mitsubishi-Tanabe, Astellas, Takeda, Pfizer, Teijin, Asahi-kasei, YL Biologics, Sanofi, Janssen, Eli Lilly, and GlaxoSmithKline, D. Aletaha Grant/research support from: AbbVie, Pfizer, Grünenthal, Merck Medac, UCB, Mitsubishi/Tanabe, Janssen, and Roche, Consultant for: AbbVie, Pfizer, Grünenthal, Merck Medac, UCB, Mitsubishi/Tanabe, Janssen, and Roche, P. Agarwal Shareholder of:

Abstract FRI0213 – Table 1. Status at 12 months among all patients with RA initiating a biologic DMARD 2010–2014 in Sweden

	TNFi	RTX		TOC		ABA	
	%	%	RR†	%	RR†	%	RR†
First bDMARD	N=5568	N=654		N=202		N=240	
On drug	68.4	87.8	1.34 (1.27–1.41)	75.5	1.20 (1.09–1.31)	77.7	1.15 (1.05–1.27)
On drug + EULAR Good resp.	26.1	31.1	1.42 (1.19–1.69)	53.1	2.03 (1.70–2.42)	34.3	1.37 (1.10–1.72)
On drug + HAQ Improvement	26.7	39.2	1.64 (1.40–1.93)	45.0	1.54 (1.27–1.87)	36.8	1.37 (1.09–1.71)
On drug + 28 Joint count = 0	20.3	22.4	1.13 (0.89–1.43)	30.9	1.60 (1.21–2.11)	22.8	1.26 (0.91–1.74)
Switch from TNFi	N=1840	N=408		N=320		N=256	
On drug	57.7	80.2	1.48 (1.37–1.60)	73.0	1.36 (1.23–1.49)	65.1	1.11 (0.98–1.26)
On drug + EULAR Good resp.	11.4	24.0	1.87 (1.41–2.49)	36.8	3.06 (2.37–3.94)	14.6	1.16 (0.76–1.76)
On drug + HAQ Improvement	16.6	34.3	1.85 (1.49–2.30)	32.4	1.71 (1.33–2.19)	20.4	1.10 (0.78–1.53)
On drug + 28 Joint count = 0	12.3	20.8	1.96 (1.43–2.70)	19.9	2.12 (1.48–3.02)	11.2	0.86 (0.48–1.52)

†Adj. for region, sex, age, birth country, RF, dis. dur., HAQ, DAS28, co-medication, recent history of malignancy, infection, SSRI, and hospital days last 5 yrs.