was 64% lower among pts treated with ABA vs placebo. After adjusting for heterogeneity across studies, the frequency (95% CI) of OI remained lower for the ABA group (0.15% [0.06, 0.42] vs the placebo group (0.48% [0.22, 1.04]).

**Conclusions:** Abatacept-treated pts had a lower incidence rate of OI compared with placebo. The OI and herpes infection incidence rates in the cumulative data are similar or lower to those reported in the literature.[1–3]

**References:**
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## OP0102 PATIENT REPORTED BENEFITS OF SARILUMAB MONOTHERAPY VERSUS ADALIMUMAB MONOTHERAPY IN ADULT PATIENTS WITH ACTIVE RHEUMATOID ARTHRITIS

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**Background:** The phase 3 MONARCH superiority study (NCT02332590) compared efficacy and safety of sarilumab (a human anti-IL-6Rα monoclonal antibody [mAb]) 200 mg administered subcutaneously every 2 weeks (q2w), with adalimumab (an anti-TNF-α mAb) 40 mg administered q2w, in patients with active rheumatoid arthritis (RA) who were either intolerant of, or inadequate responders to methotrexate treatment. Sarilumab monotherapy demonstrated superiority to adalimumab monotherapy in reduction of disease activity and improvements in physical function and signs and symptoms of RA, with safety and tolerability consistent with IL-6R or TNF blockade.

**Objectives:** To compare patient-reported outcomes (PROs) with sarilumab vs adalimumab from MONARCH.

**Methods:** PROs assessed at baseline, weeks 12 and 24 included ACR components (Patient Global Assessment of Disease Activity [PtGA], Pain visual analog scale [VAS], Health Assessment Questionnaire Disability Index [HAQ-DI]), Medical Outcomes Study Short Form-36 (SF-36), Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F), Morning Stiffness VAS, RA Impact of Disease (RAID) and RA-specific Work Productivity Survey (WPS-RA). Least-squares mean (LSM) between-group differences were determined by mixed-model for repeated measures with treatment, visit, treatment-by-visit interaction and region as fixed effects, and the corresponding baseline PRO scores as continuous covariates. A *P*-value $<0.05$ was considered statistically significant for PROs in a predefined hierarchy (ACR components, SF-36 physical component summary [PCS], FACIT-F and SF-36 mental component summary [MCS] scores). For PROs not in the hierarchy, significance is not claimed. Changes from baseline were compared with published values for minimum clinically important differences (MCIDs).

**Results:** Baseline demographics, disease characteristics and PROs were generally balanced between treatment groups (n=184 sarilumab; n=185 adalimumab). Improvements from baseline to week 24 were greater with sarilumab vs adalimumab across PtGA, Pain VAS, HAQ-DI, SF-36 PCS, Morning Stiffness VAS, RAID and WPS-RA global scores (all $P<0.05$, statistical significance is claimed only for PROs in the hierarchy; see table). Between-group differences in FACIT-F and SF-36 MCS scores were not significant. Improvements ≥MCID were reported by a greater percentage of patients with sarilumab than adalimumab for HAQ-DI (≥0.22 units), RAID (≥3 units), SF-36 PCS (≥2.5), and Morning Stiffness VAS (≥10) (all nominal $P<0.05$).

**Table. Mean change from baseline to week 24 with sarilumab 200 mg q2w or adalimumab 40 mg q2w**

| PRO | Mean (SD) Baseline score | | LSM Changes (SE) from Baseline to Week 24 | | Least-Squares Mean Between-Group Difference (95% CI) | *P*-value* |
|---|---|---|---|---|---|---|
| | Sarilumab 200 mg q2w (n=184) | Adalimumab 40 mg q2w (n=185) | Sarilumab 200 mg q2w (n=184) | Adalimumab 40 mg q2w (n=185) | | |
| **ACR components** | | | | | | |
| HAQ-DI | 1.64 (0.54) | 1.62 (0.64) | -0.61 (0.05) | -0.43 (0.05) | -0.18 (-0.31, -0.06) | <0.005 |
| Pain VAS | 70.93 (18.77) | 70.32 (19.31) | -36.19 (1.78) | -27.41 (1.80) | -8.78 (-13.66, -3.90) | <0.001 |
| PtGA | 68.22 (17.38) | 67.51 (18.27) | -33.30 (1.73) | -24.82 (1.75) | -8.48 (-13.24, -3.72) | <0.001 |
| **SF-36** | | | | | | |
| PCS | 30.77 (6.09) | 31.53 (6.48) | 8.74 (0.56) | 6.09 (0.56) | 2.65 (1.15, 4.15) | <0.001 |
| MCS | 36.43 (10.43) | 36.93 (11.59) | 7.86 (0.77) | 6.83 (0.77) | 1.04 (-1.06, 3.13) | 0.332 |
| Physical functioning | 33.26 (19.68) | 35.53 (22.01) | 22.38 (1.64) | 15.01 (1.65) | 7.37 (2.91, 11.83) | <0.005 |
| Role-physical | 34.31 (18.03) | 34.89 (20.51) | 20.80 (1.61) | 16.23 (1.63) | 4.57 (0.18, 8.96) | <0.05 |
| Bodily pain | 36.77 (15.84) | 39.15 (16.87) | 25.69 (1.46) | 19.40 (1.47) | 6.28 (2.32, 10.25) | <0.005 |
| General health | 34.00 (16.03) | 36.45 (15.85) | 13.96 (1.18) | 11.05 (1.19) | 2.91 (-0.30, 6.12) | 0.076 |
| Vitality | 33.29 (16.35) | 35.51 (17.39) | 17.95 (1.42) | 14.39 (1.43) | 3.56 (-0.31, 7.43) | 0.071 |
| Social functioning | 46.27 (23.18) | 47.55 (26.18) | 21.41 (1.81) | 15.04 (1.83) | 6.37 (1.43, 11.30) | <0.05 |
| Role emotional | 47.15 (24.38) | 47.57 (27.15) | 18.04 (1.79) | 14.10 (1.81) | 3.94 (-0.94, 8.82) | 0.113 |
| Mental health | 48.16 (18.01) | 49.81 (19.44) | 14.29 (1.31) | 13.26 (1.32) | 1.02 (-2.54, 4.58) | 0.572 |
| FACIT-F | 23.59 (8.92) | 24.43 (10.26) | 10.18 (0.70) | 8.41 (0.71) | 1.77 (-0.14, 3.67) | 0.069 |
| Morning stiffness VAS | 70.76 (18.93) | 68.95 (21.42) | -36.08 (1.95) | -29.29 (1.97) | -6.80 (-11.10, -0.50) | <0.05 |
| RAID | 6.89 (1.69) | 6.28 (2.06) | -3.08 (0.17) | -2.30 (0.17) | -0.78 (-1.23, -0.32) | <0.001 |
| WPS-RA (global)† | N/A | N/A | N/A | N/A | N/A | <0.005 |

*Least-squares mean between-group differences (sarilumab vs adalimumab).
Items above the dotted line were part of the hierarchy and thus statistical significance may be claimed. Between-group differences were not significant for FACIT-F and SF-36 MCS. Items below the dotted line are outside of the hierarchy and thus statistical significance is not claimed and nominal *P*-values are provided.
†Global test for the chance from baseline in the eight WPS-RA scores.

**Conclusions:** Sarilumab monotherapy compared with adalimumab monotherapy resulted in greater and clinically meaningful improvements in many PROs, including patient-reported disease activity, pain, physical function, morning stiffness, productivity, health related quality of life and health status.

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## OP0103 THE EFFECT OF SIRUKUMAB PLUS METHOTREXATE ON CIRCULATING BIOMARKERS OF JOINT DESTRUCTION IN MODERATE TO SEVERE RHEUMATOID ARTHRITIS PATIENTS FROM THE SIRROUND-D PHASE 3 STUDY

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**Background:** Rheumatoid arthritis (RA) is an autoimmune disease characterized by chronic inflammation that can lead to progressive bone and joint damage. The cytokine interleukin-6 (IL-6) is implicated in inflammatory pathways associated with bone and cartilage degradation in RA. Inhibition of IL-6 signaling by sirukumab (SIR), an anti-IL6 cytokine monoclonal antibody, was shown to significantly reduce structural damage progression, relative to placebo (pbo), in disease-modifying antirheumatic drug inadequate responder (DMARD-IR) RA patients (pts) in the Phase 3 SIRROUND-D study.

**Objectives:** To investigate the mechanism of SIR on joint tissue remodeling, a panel of serum biomarkers associated with matrix metalloproteinase (MMP)-driven interstitial matrix and basement membrane degradation (C1M, C3M, C4M), bone turnover (β-isomerized C-terminal telopeptides of type I collagen, CTX-I), osteoblast formation (osteocalcin/NMID), synovial destruction (MMP-3), and tissue inflammation (MMP-mediated destruction of CRP/CRPM) were assessed in pts with moderate to severe RA from SIRROUND-D.

**Methods:** Serum samples from a sub-cohort of SIRROUND-D (for whom radiographic data were available) were analyzed ad hoc for the following biomarkers: C1M, C3M, C4M, CRPM, MMP-3, CTX, and osteocalcin. Samples from 100 pts treated with pbo and methotrexate (MTX) and 100 pts treated with SIR 50mg q4w + MTX were tested. Biomarkers were measured in all pts at baseline (BL) and Wk 4; samples from SIR and pbo-treated pts (50/group) were tested at Wk 52. Differences between groups were evaluated by comparing within-subject $\log_2$ ratio of Wk 4 or Wk 52 over BL values between treatment groups. Structural damage progressors versus non-progressors were defined based on changes from BL in Sharp/van der Heijde score (SHS) at Wk 52 (≥5 vs <5). Differences between groups were tested using General Linear Models.

**Results:** SIR significantly reduced serum levels of C1M (-48%), C3M (-30%), C4M2 (-42%), and CRPM (-22%) by Wk 4 vs pbo ($P<0.001$), with similar reductions observed at Wk 52; MMP-3 levels were more substantially decreased by SIR at Wk 52 (-39%) vs Wk 4 (-20%). In contrast, treatment with SIR resulted in increased levels of CTX-I (+20%) and osteocalcin (+12%) by Wk 4 ($P<0.001$; Figure 1). As 95% of the total study population included in this biomarker analysis did not progress (defined as ≥5 Wk 52 change in SHS), we were unable to demonstrate an association between changes in pharmacodynamic markers and radiographic progression. Nor were significant associations with pharmacodynamic changes with SIR treatment observed for comparisons among patients grouped by Wk 52 changes in SHS of ≥5 (n=5), <5 to ≥0.5 (n=41),

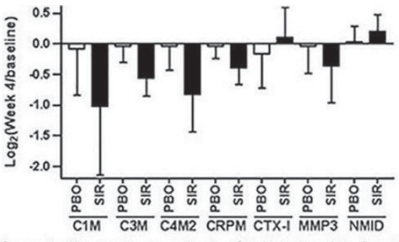


**Figure 1.** Changes in serum levels of indicated analyte (x-axis), displayed as mean ± SD of log2-transform of within-subject week 4/baseline ratios, stratified by treatment group (PBO, placebo; SIR, sirukumab 50mg q4w). P<0.05 for SIR vs. PBO for each analyte.

and <0.5 (n=51). BL or Wk 4 changes in levels of individual analytes were not associated with Wk 24 ACR50 or DAS28-CRP responses.
**Conclusions:** SIR 50mg q4w + MTX, vs pbo + MTX, inhibited radiographic progression in RA pts in SIRROUND-D and strongly inhibited biomarkers of joint and tissue destruction while enhancing markers of bone formation. These data suggest SIR may actively suppress inflammatory pathways implicated in joint destruction in RA pts.
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## OP0104 TOCILIZUMAB: DOSE REDUCTION OR INTERVAL SPACING – WHICH PROVES A BETTER TAPERING STRATEGY FOR RHEUMATOID ARTHRITIS IN CLINICAL REMISSION?

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**Background:** A number of studies have revealed that reduction of biological disease-modifying anti-rheumatic drugs (bDMARDs) is possible for some rheumatoid arthritis (RA) patients in whom bDMARD treatment has induced clinical remission or low disease activity.
For tocilizumab (TCZ), while there have been studies concerning tapering, there have been no studies regarding which tapering option is better in RA after clinical remission has been achieved: a dose reduction strategy (DRS) or an interval spacing strategy (ISS).
We previously demonstrated that a twin target strategy [targeting both a simplified disease activity index (SDAI) score of less than 3.3 and normalization of matrix metalloproteinase (MMP) 3 levels] can achieve effects non-inferior to standard care with regard to maintaining clinical remission in the rT-4study.
**Objectives:** To evaluate any significant differences that may be present between the two strategies (DRS and ISS) while tapering TCZ in RA patients who satisfied the SDAI remission and MMP-3 normalization targets under the twin target scheme.
**Methods:** DRS was used in patients treated with intravenous (IV) TCZ, whereas ISS was used for those treated by subcutaneous injection (SC). 57 RA patients who demonstrated SDAI remission and MMP-3 normalization using TCZ (IV, n=42; SC, n=15) participated. Dose reduction methodology (every 3 months): DRS- dose reduced by 80mg; ISS- period between injections increased by one week; up to a minimum dose of: DRS- 80 mg every 4 weeks; ISS-162 mg every 6 weeks. The dose was reverted to the previous level in the event that the target scores were exceeded, and the lower dose was eventually reattempted after the target was re-achieved. The primary outcome was the difference in the number of the times when a patient's SDAI exceeded 3.3 across the four time points.
**Results:** Fifty-five patients completed the observation period of 12 months and were analyzed (ITT). There were differences in the number of the times which SDAI scores exceed the target over the 12 months in the DRS group vs the ISS group: 2.4±1.7 and 0.9±1.2, respectively (p=0.0027). DRS had a duration (months) of maintained SDAI remission significantly shorter than that of ISS (3.9±5.0 vs 7.4±5.1, p=0.0213). At month 12, the proportions for DRS and ISS, respectively, for $\Delta$mTTS$\leq$0.5 were 71.4 and 66.7% (p=0.7293); for maintained HAQDI=0 were 83.3 and 66.7 (p=0.4227) and for AE were 81.0 and 46.7 (p=0.0112). The total dose for TCZ in DRS tended to be lower than that for ISS (1367±840vs 1626±583mg, p=0.0824). The rate of total TCZ reduction showed a significant difference between DRS and ISS (29.3±15.2% vs41.8±15.0%, p=0.0037). Comparing three groups consisting of 400mg<, 401<<500mg and 500mg< across the DRS with ISS groups, there were significantly greater number of times when SDAI exceeded 3.3 in the DRS vs the ISS group; 2.3±1.6, 2.7±1.8 and 2.4±1.9, p=0.0395.
**Conclusions:** ISS using the twin targets as defined by the rT-4 study is an excellent strategy that is both safe and cost-effective for RA patients who are both being treated with TCZ and have reached said targets.
**Disclosure of Interest:** None declared
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## OP0105 LONG-TERM SAFETY OF TOCILIZUMAB FROM LARGE CLINICAL TRIAL AND POSTMARKETING POPULATIONS

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**Background:** Tocilizumab (TCZ) is a recombinant humanized monoclonal antibody targeted against the interleukin-6 receptor that was approved to treat rheumatoid arthritis (RA) in the EU in 2009 and in the US in 2010. TCZ has now completed long-term extension (LTE) follow-ups in a number of intravenous and subcutaneous RA trials.
**Objectives:** To provide an updated report on the incidence of safety events during TCZ treatment in patients with RA using data from multiple completed clinical trials and their LTEs, as well as to provide an update from the global TCZ postmarketing safety database.
**Methods:** Incidence and reporting rates of adverse events (AEs) of special interest, including infections, malignancies, anaphylaxis, bleeding events, myocardial infarctions, gastrointestinal perforations, strokes, hepatic events and demyelination, were estimated from 2 distinct patient data sets. Incidence rates were calculated from 12 completed TCZ RA clinical trials and their LTE periods and are reported as events per 100 patient-years (PY). Reporting rates were also estimated from the global TCZ postmarketing safety database (Oct 2008 to Oct 2015), which includes information from all spontaneously reported cases and non-interventional programs as well as literature cases, and are reported as cases per 100 patients.
**Results:** The clinical trial all-exposure population consisted of 7647 TCZ-treated patients with RA (81.6% female; mean [SD] age, 52 [12.6] years), constituting 22,394 PY (mean follow-up, 2.93 years) of exposure. The overall rate (95% CI) of serious AEs in the clinical trial population was 14.16 (13.67–14.66) per 100 PY. Overall incidence rates for individual events for the clinical trial population are reported in the Table and were consistent in each 6-month period over the 5-year duration. The global postmarketing population included 606,937 patients. The overall spontaneous reporting rate (range) of AEs of special interest in the postmarketing population was 9.37 (7.35–10.56) cases per 100 patients. Reporting rates of individual safety events of interest in the global postmarketing population are shown in the Table and were consistent in each 6-month period over the 7-year duration.

**Table.** Adverse Events Across 12 RA Clinical Trials and the Global Postmarketing Safety Database in Patients Who Received TCZ

| | RA Clinical Trial All-Exposure Population (N = 7647; 22,394 PY) | | Global Postmarketing Safety Database Population* (N = 606,937) | |
|---|---|---|---|---|
| Adverse Event of Special Interest | Patients With ≥ 1 AE, n (%) | Incidence Rate (95% CI), Events/100 PY | Cases, n | Reporting Rate (range), Cases/100 Pts |
| Serious infections | 730 (9.5) | 4.29 (4.02-4.57) | 17,350 | 2.86 (2.11-3.62) |
| Malignancies† | 242 (3.2) | 1.18 (1.05-1.33) | 1560 | 0.26 (0.18-0.51) |
| Injection site reactions | 444 (5.8) | 6.51 (6.18-6.85) | NA | NA |
| Strokes/cerebrovascular disorders | 130 (1.7) | 0.67 (0.56-0.78) | 2069 | 0.34 (0.22-0.94) |
| Serious bleeding events | 89 (1.2) | 0.43 (0.35-0.52) | 2440‡ | 0.40‡ (0.28-0.76) |
| Myocardial infarction | 72 (0.9) | 0.33 (0.26-0.42) | 1946 | 0.32 (0.21-0.88) |
| Gastrointestinal perforations† | 39 (0.5) | 0.20 (0.15-0.27) | 632 | 0.10 (0.06-0.30) |
| Serious hypersensitivity reactions§ | 56 (0.7) | 0.26 (0.20-0.33) | NA | NA |
| Anaphylaxis | 21 (0.3) | 0.09 (0.06-0.14) | 1222 | 0.20 (0.09-0.38) |
| Serious hepatic events | 9 (0.1) | 0.04 (0.02-0.08) | 3567‡ | 0. 59‡ (0.34-1.21) |
| Demyelination | 8 (0.1) | 0.04 (0.02-0.07) | 66 | 0.01 (0.00-0.02) |

AE, adverse event; NA, not available; pt, patient; PY, patient year; RA, rheumatoid arthritis; TCZ, tocilizumab.
* Data are for multiple indications and from several sources (spontaneous reports, non-interventional programs, literature cases) reported following market authorization.
† Events of malignancies and gastrointestinal perforations were medically confirmed.
‡ Includes both serious and non-serious cases.
§ Serious hypersensitivity was defined as a serious adverse event occurring during or within 24 hours of the injection or infusion, excluding injection site reactions, and not judged unrelated to study treatment by the investigator.

**Conclusions:** The safety profile of TCZ in the current analysis, which includes information about safety events from 12 clinical trials and their LTEs and across 7 years of real-world postmarketing reports encompassing ≈ 600,000 patients, was consistent with previous safety reports. These findings are consistent with the previously reported profile of TCZ and indicate that there is no evidence of increased safety risk with increasing exposure to TCZ.
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