Percentage of subjects meeting ACR20/50/70 at 12 weeks.

Figure 2 Average DAS28-CRP is shown for each study visit. Error bars indicate standard error of mean. Percentage of subjects meeting ACR20/50/70 at 12 weeks.

Conclusion: In this pilot study, auricular stimulation was well tolerated and daily use over 12 weeks attenuated RA disease severity. Further evaluation in larger controlled studies are needed to confirm whether a non-invasive wearable device might offer an alternative approach for the treatment of RA.

References:

- [1] Koopman FA, et al. (2016) Vagus nerve stimulation inhibits cytokine production and attenuates disease severity in rheumatoid arthritis. *Proc Natl Acad Sci* 2016; 113: 8284–9.

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SAT0134

COMPARATIVE RISK OF CANCER ASSOCIATED WITH FIRST-LINE DMARDS USE IN RHEUMATOID ARTHRITIS: REAL WORLD EVIDENCE FROM THE OHDSI NETWORK

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Background: Conventional synthetic disease-modifying antirheumatic drugs (csDMARDs) are recommended as first line treatment for rheumatoid arthritis (RA) patients, but limited information exists on the comparative risk of cancer associated with their use.

Objectives: To compare the risk of incident overall (excluding non-melanoma skin) and site-specific cancers (colorectal, lung, lymphoma, leukaemia) associated with first-line use of csDMARDs in patients with RA.

Methods: We conducted a multinational cohort study informed by data from 7 healthcare databases including claims and electronic medical records from 4 countries (SIDIAP-Spain, MDCR-US Optum-US, CCAE-US, IQVIA AMBEMR-US, IQVIA-Germany, THIN-UK) part of the Observational Health Data Sciences and Informatics (OHDSI) network. All patients aged ≥18 years who initiated methotrexate (MTX), hydroxychloroquine (HCQ), sulphasalazine (SSZ), or leflunomide (LEF)

as first-line monotherapy after a diagnosis of RA between 2005 to 2018 were eligible. Individuals with a prior diagnosis of another inflammatory arthropathy or cancer, or <1 year of follow-up were excluded. Patients were followed from 1-year after treatment initiation to the earliest of incident cancer, loss to follow-up, or 5-years. Cox proportional-hazard models for MTX against each other csDMARD were performed after propensity score stratification. A large set of negative control outcomes were analysed to calibrate hazard ratios (cHRs). Estimates were pooled where homogeneity across sources was adequate ($I^2 < 0.4$).

Results: Across the databases, 127,547 RA patients initiating csDMARD therapy were included in the analyses (MTX: 73,996, HCL: 36,381 SSZ: 9,383 LEF: 7,787). The pooled incidence rate of overall cancer for MTX was 22.8 per 1,000 person years. The pooled summary and source-specific estimated cHRs for overall cancer are shown below in Figure 1. While little difference was seen for HCQ and SSZ compared to MTX, LEF was consistently associated with a reduced cancer risk: pooled cHR (95% CI) 0.67 (0.59 to 0.76) and cHRs ranged from 0.53 (0.36 to 0.80) in CCAE-US to 0.84 (0.58 to 1.22) in SIDIAP-Spain. There were insufficient cases to look site-specific cancers within data sources, although pooled results suggest little risk difference in leukemia, lymphoma, colorectal, or lung cancers.

Figure 1. Calibrated hazard ratios (cHRs) of overall cancer risk with their respective confidence intervals (95%CI) by study database. Database estimates not reported where adequate covariate balance not attained. Meta-analysis results not reported where $I^2 > 0.4$.

Conclusion: Compared to MTX users, patients treated with LEF had a lower risk of overall cancer. Risk of four specific cancers did not differ by first line csDMARD exposure.

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SAT0135

COMPARISON OF THE EFFICACY AND SAFETY OF TWO BRIDGING SCHEDULES OF PREDNISOLONE IN EARLY ACTIVE RHEUMATOID ARTHRITIS (CORRA): A DOUBLE-BLIND, RANDOMISED, PLACEBO-CONTROLLED TRIAL

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