Figure 1. Relative risk of developing cancer between rituximab and csDMARDs. (A) any cancer; (B) all cancer types excluding NMSC; (C) solid tumors; (D) hematological cancer; (E) NMSC; or (F) melanoma. csDMARDs: conventional synthetic disease-modifying antirheumatic drugs. NMSC: non-melanoma skin cancer.

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FRI0113 THE BASELINE SOLUBLE GP130 IS ASSOCIATED WITH THE RESPONSE OF RHEUMATOID ARTHRITIS PATIENTS TO SARILUMAB

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Background: IL-6 contributes significantly to the chronic inflammatory process of rheumatoid arthritis (RA). Sarilumab (SRL), a human anti-human IL-6 receptor alpha monoclonal antibody that blocks the signaling originated by the IL-6/IL-6R complex like tocilizumab, is an effective treatment. However, predictors of the response to sarilumab are still required.

Objectives: We aimed to combine IL-6, soluble IL-6R (sIL-6R) and gp130 (sgp130) levels to identify groups of sarilumab responses.

Methods: This research is a retrospective study. A total of 32 RA patients with SRL therapy in our department from February 1 in 2018 to December 31 in 2019 were included. Serum and clinical data from 32 RA patients were collected before treatment and until the last visit. Follow-up period was up to one year after starting SRL treatment. Serum were tested for IL-6 (Human IL-6 Quantikine ELISA Kit, R&D systems), sIL-6R (Human soluble IL-6R alpha Quantikine ELISA Kit, R&D systems) and sgp130 (Human soluble gp130 Quantikine ELISA Kit, R&D systems), using specific ELISAs according to the manufacturer's instructions. Hierarchical cluster analysis (JMP14.3.0) was used to establish the relationship between IL-6, sIL-6R and sgp130. We evaluated the efficacy of SRL treatment on the last visit using European League Against Rheumatism (EULAR) response criteria in the groups of patients. The other statistical analyses were performed with EZR 1.41, and p Values less than 0.05 were considered significant.

Results: The median age of patients was 70.5 (IQR: 66.5-74.3) years and the median of disease duration was 7.3 (1.7-15.3) years. Nine (28.1%) patients were biologic and Jakinibs naive. The median follow-up periods were 24 (12-26) weeks. The baseline DAS28 was median 4.39 (3.77 - 5.43), and CDAI was 21.1 (11.7-29.5). When comparing responders and non-responders, there were no significant differences in any of the baseline parameters and cytokines. Four statistical significant clusters of RA patients (i.e., Group1, Group2, Group3 and tocilizumab use group before SRL) were defined by serum concentrations of IL-6, sIL-6R and sgp130 at baseline. The levels of IL-6 expressed as median in Group1 patients were 25.6 (14.4-72.2) pg/ml, in Group2 5.9 (3.3-11.3) pg/ml, and in Group3 70.2 (45.4-86.1) pg/ml ($p < 0.002$, significant difference only between Group2 and Group3). The levels of sIL-6R expressed as median in Group1 patients were 38.7 (34.7-45.1) ng/ml, in Group2 35.1 (24.8-41.9) ng/ml, and in Group3 35.7 (34.2-39.8) ng/ml ($p = 0.5477$). The levels of sgp130 expressed as median in Group1 patients were 272.6 (263.0-277.2) ng/ml, in Group2 223.1 (221.0-228.0) ng/ml, and in Group3 204.6 (192.0-207.6) ng/ml ($p < 0.00003$, significant difference between the three groups respectively). There were no significant differences in any of the baseline clinical features and laboratory findings between the three groups. Out of the 8 patients in Group1 had a good or moderate response to SRL. Conversely, the percentage of patients with no response to SRL was higher in Group3 than in Group1 and Group2.

Conclusion: RA patients could be easily stratified prior to the therapeutic intervention with sgp130 related to the IL-6 signal regulation. Group1 patients, who had the best response to SRL, had the highest level of sgp130.

Table 1. Comparison of baseline serum IL-6, sIL-6R and sgp130 of each groups of patients

	TCZ use before SRL	Group 1	Group 2	Group 3	P value
	n=3	N=9	N=8	N=9	
IL-6, pg/mL	69.8, 592.6	Median 25.6 [IQR] [14.4-72.2]	5.9 [3.3-11.3]	70.2 [45.4-86.1]	<0.002 c
sIL-6R, ng/mL	390.5, 481.7	Median 38.7 [IQR] [34.7-45.1]	35.1 [24.8-41.9]	35.7 [34.2-39.8]	0.547
sgp130, ng/mL	205.6, 239.8	Median 273 [IQR] [263-277]	223 [221-228]	205 [192-208]	<0.001 abc

*a, b and c mean that statically significant difference between subgroups as a: group1 vs. 2, b: group 1 vs. 3, c: group 2 vs. 3.

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FRI0114 EFFICACY OF LEVILIMAB, NOVEL MONOCLONAL ANTI-IL-6 RECEPTOR ANTIBODY, IN COMBINATION WITH METHOTREXATE IN PATIENTS WITH RHEUMATOID ARTHRITIS: 1-YEAR RESULTS OF PHASE 2 AURORA STUDY

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Background: Previously, 12-week results of phase 2 clinical study of levilimab (LVL) in patients with active rheumatoid arthritis (RA) have been reported¹. The study has met the primary endpoint at W12 confirming that treatment with LVL 162 mg SC + methotrexate (MTX) either QW or Q2W is superior to MTX alone in patients with RA and inadequate response to methotrexate (MTX-IR). Here we report 1-year efficacy and safety data in QW and Q2W arm of the study.

Objectives: This study was aimed to assess the efficacy and safety of 2 dosing regimens of LVL in active MTX-IR RA subjects.

Methods: This multicenter double-blind placebo-controlled study (NCT03455842) enrolled 105 MTX-IR subjects with active RA (ACR2010). The study design is outlined on Figure 1. Secondary endpoints for the open-label period included ACR20/50/70, LDA, remission rates, and DAS28-CRP(4), among others. The safety was evaluated up to W56.

Figure 1. Study design