**Table 2. Changes in RA parameters in patients treated with tofacitinib, n=374 (M±SE).**

<table>
<thead>
<tr>
<th>Disease characteristics</th>
<th>Baseline</th>
<th>Year 1*</th>
<th>Year 2*</th>
<th>Year 3*</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRP, mg/L</td>
<td>30.1±35.0</td>
<td>8.3±12.8</td>
<td>7.6±10.7</td>
<td>9.4±13.5</td>
</tr>
<tr>
<td>ESR, mm/h</td>
<td>35.2±21.2</td>
<td>22.7±17.2</td>
<td>21.9±17.7</td>
<td>23.2±17.3</td>
</tr>
<tr>
<td>NTJ from 28</td>
<td>11.2±6.5</td>
<td>4.6±4.9</td>
<td>4.8±5.0</td>
<td>3.9±3.8</td>
</tr>
<tr>
<td>NTJ from 28</td>
<td>7.6±5.1</td>
<td>2.4±3.2</td>
<td>1.7±3.1</td>
<td>1.4±2.8</td>
</tr>
</tbody>
</table>

*difference with baseline is significant with p<0.000. *±28 days

**Conclusion:** According to the real world data treatment with tofacitinib may provide good response rates in RA patients, refractory to the previous csDMARDs treatment in long-term perspective.

**Acknowledgments:** Pfizer

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**SAT0142 MATCHING ADJUSTED INDIRECT COMPARISON OF FILGOTINIB VS. TOFACITINIB IN MODERATE-TO-SEVERE ACTIVE RHEUMATOID ARTHRITIS PATIENTS WITH INADEQUATE RESPONSE TO METHOTREXATE**

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**Background:** Filgotinib (FILG) is a JAK1 inhibitor that has been investigated in combination with methotrexate (MTX) for the treatment of moderate-to-severe rheumatoid arthritis (RA). To date, no head-to-head trial has compared the efficacy of FILG versus tofacitinib (TOFA).

**Objectives:** To compare the efficacy of FILG 200 mg + MTX with TOFA 5 mg + MTX using matching adjusted indirect comparison (MAIC).

**Methods:** MAIC technique uses individual patient data (IPD) from one trial and aggregate data from the other to enable comparison of outcomes after matching on baseline characteristics [1]. An anchored MAIC was conducted using IPD from the FINCH-1 trial of FILG 200 mg + MTX vs adalimumab (ADA) 40 mg + MTX and published data from ORAL STRATEGY [2] trial of TOFA 5 mg + MTX vs ADA 40 mg + MTX. Patients in the FINCH-1 trial were reweighted based on age, sex, race, tender joint count 28, swollen joint count 28, C-reactive protein and patient's global assessment to match baseline characteristics of the comparator. After matching, Wald tests were used to test for significant differences in ACR 20/50/70 and clinical remission outcomes (SDAI≤3.3, CDAI≤2.8, ESS= effective sample size; SD = standard deviation).

**Results:** After matching, baseline characteristics were balanced across the trial populations [Table 1]. FILG 200 mg + MTX patients experienced significantly greater improvement in 12 week ACR50 and ACR70 outcomes compared to TOFA 5 mg + MTX with a mean difference in difference (DD) of 13.5% (p < .05) and 8.3% (p < .05) respectively, as well as numerical improvements on other ACR outcomes at 12, 24 and 52 weeks [Figure 1]. At 24 weeks, FILG 200 mg + MTX patients experienced significantly greater improvement in DAS28(CRP) clinical remission compared to TOFA 5 mg + MTX with DD of 13.2% (p < .05) [Figure 2] as well as numerical improvements on other efficacy outcomes. In this MAIC, compared to TOFA 5 mg + MTX, FILG 200 mg + MTX appears to produce improved efficacy outcomes (ACR20/50/70, DAS28(CRP), SDAI, CDAI and Boolean Remission) at weeks 12, 24 and 52.

**References:**


**Acknowledgments:** The study was funded by Gilead Sciences Inc
A PHASE 1 STUDY IN HEALTHY VOLUNTEERS EXPLORING THE SAFETY, PHARMACOKINETICS AND PHARMACODYNAMICS OF ATI-450: A NOVEL ORAL MIK2 INHIBITOR

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Methods: Safety, PK and PD were assessed in a randomized, observer-blind, placebo-controlled, phase 1 study in male and female healthy subjects aged 18-55 (n=77).

- Part A: Single Ascending Dose (SAD) (n=32, 8 subjects per dose cohort - 2 placebo, 6 active). A single dose of 10mg, 30mg, 50mg and 100mg was tested.
- Part B: Multiple Ascending Dose (MAD) (n=30, 10 subjects per dose cohort - 2 placebo, 6 active). 10mg BID, 30mg BID and 50mg BID doses were tested over 7 days of administration.

Results: Safety and tolerability of ATI-450 was evaluated based on adverse events, clinical laboratory, vital signs, 12-lead ECG, Holter monitoring, and physical examination. Blood was drawn for PK analysis at 0.5, 1, 2, 4, 6, 8, 12 hours, 24, 36, and 48 hours post dose in the SAD cohort and on day 7 of the MAD cohort. PD of ATI-450 were explored by investigating the inhibition of a target biomarker, phospho-HSP27 (pHSP27) and proinflammatory cytokines, TNFα, IL-1β, IL-6 and IL8 in ex-vivo LPS-stimulated blood samples collected 4 and 12 hours post dose on day 7 from subjects in the MAD cohorts.

Conclusions: ATI-450 was generally well tolerated. No serious adverse events or study discontinuations were reported, and no adverse events led to discontinuation of the study medication. The most common adverse events (reported by 2-7 from subjects in the MAD cohorts.

- Male sex, n (%) 18 (13.8) 3 (17.6) 0.6
- Mean age at diagnosis (SD) 58.5 (15.6) 70.6 (12.2) 0.9
- Rheumatoid arthritis factor, n (%) 87 (66.9) 12 (70.6) 0.7
- Positive anti CCP, n (%) 109 (85.8) 13 (76.4) 0.2
- Erosions at baseline, n (%) 25 (19.2) 7 (41.1) 0.03
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