Demographical (age, sex) and RA activity data (DAS28, SDAI, number of tender and swollen joints (NTJ, NSJ), erythrocytes sedimentation rate (ESR), C-reactive protein (CRP), and HAQ, EQSD were collected, table 1. Statistical analysis performed in SPSS2017. p-value <0.05 considered as significant.

**Results:** At baseline 12 (10%) were treated with NSAIDs, 15 (26.5%) with 5-10 mg/day of prednisolone, 82 (88.9%) with sulfasalazine (2.0-3.0 g/day).

**Abstract THU0171 – Table 1.** Baseline characteristics of the patients with RA (n=119)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male, n (%)</td>
<td>24 (20.6)</td>
</tr>
<tr>
<td>Age of disease onset, years (mean ±SD)</td>
<td>41 ±11.5</td>
</tr>
<tr>
<td>Symptoms duration, month (mean ±SD)</td>
<td>113 ±76.9</td>
</tr>
<tr>
<td>Positive rheumatoid factor, n (%)</td>
<td>68 (34.17)</td>
</tr>
<tr>
<td>Positive antibodies to cyclic citrullinated peptide (anti-CCP), n (%)</td>
<td>82 (88.9)</td>
</tr>
<tr>
<td>Erosions of hand joints (X-rays), n (%)</td>
<td>28 (23.5)</td>
</tr>
<tr>
<td>BMI, kg/m²(mean ±SD)</td>
<td>21.82±5.37</td>
</tr>
<tr>
<td>Smokers (current and in the past), n (%)</td>
<td>42 (35.8)</td>
</tr>
</tbody>
</table>

Changes in the disease activity in patients with RA, treated with tofacitinib after csDMARD are presented in Table 2

**Abstract THU0101 – Table 1.** Efficacy outcomes in patients with RA treated with tofacitinib

<table>
<thead>
<tr>
<th>NTJ</th>
<th>NSJ</th>
<th>Patients</th>
<th>CRP, mg/l</th>
<th>DAS28</th>
<th>HAQ</th>
<th>EQ-SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>8.48</td>
<td>3.68</td>
<td>52.48</td>
<td>39.23</td>
<td>19.10±1.78</td>
<td>5.65</td>
</tr>
<tr>
<td>Month³</td>
<td>6.29</td>
<td>1.0</td>
<td>39.29</td>
<td>22.29</td>
<td>8.43</td>
<td>3.84</td>
</tr>
<tr>
<td>Month⁴</td>
<td>±5.64</td>
<td>±3.52</td>
<td>±20.41</td>
<td>±19.51</td>
<td>±27.5</td>
<td>±1.33</td>
</tr>
<tr>
<td>Month⁵</td>
<td>6.49</td>
<td>2.34</td>
<td>37.51</td>
<td>27.12</td>
<td>10.86</td>
<td>3.85</td>
</tr>
<tr>
<td>Month⁶</td>
<td>±4.6</td>
<td>±3.2</td>
<td>±20.22</td>
<td>±20.54</td>
<td>±17.47</td>
<td>±3.13</td>
</tr>
<tr>
<td>Month⁷</td>
<td>4.61</td>
<td>2.28</td>
<td>36.23</td>
<td>26.85</td>
<td>10.91</td>
<td>3.80</td>
</tr>
<tr>
<td>Month¹²</td>
<td>±5.51</td>
<td>±3.56</td>
<td>±20.6</td>
<td>±19.96</td>
<td>±29.67</td>
<td>±3.13</td>
</tr>
</tbody>
</table>

**Results:** At visit 3 DAS28 <3.2 achieved 80 (67.22%) of the patients: 71 patients on 20 mg of TF (59.66%) and 9 patients on 10 mg of TF (83%). Patients at visit 3 had DAS28 <3.2 achieved 80 (67.22%) of the patients: 71 patients on 20 mg of TF (59.66%) and 9 patients on 10 mg of TF (83%).

**Conclusion:** Treatment with TF may provide good response rates in RA patients, refractory previous csDMARDs.

**Acknowledgement:** Study sponsored by Pfizer

**Disclosure of Interests:** Inna Gaydukova Grant/research support from: JSC BIOCAD, Speakers bureau: payment from Pfizer, Novartis, Abbvie, Biocad, Selgene, MSD, Sanofi. None declared, Evgeny Nasonov: None declared, Natalya Yudina: None declared

**References:**

1. Genovese, et al. 2018; Lancet.18;31116-4

**UPADACITINIB IN PATIENTS WITH RHEUMATOID ARTHRITIS AND INADEQUATE RESPONSE OR INTOLERANCE TO BIOLOGICAL DMARDs: RESULTS AT 60 WEEKS FROM THE SELECT-BEYOND STUDY**

**Objectives:** We assessed UPA safety and efficacy through Wk60 in an ongoing extension of the phase 3 SELECT-BEYOND study.

**Methods:** SELECT-BEYOND enrolled a population of patients with active RA who had failed at least one prior biologic therapy. 1. Pts received UPA 15mg or 30mg once daily (QD) or placebo (PBO) on top of background csDMARD treatment for 12 wks. From Wk12, pts randomized to UPA at baseline (BL) continued their assigned doses while pts initially randomized to PBO received UPA 15mg or 30mg QD per pre-specified assignment at BL. Patients who completed Wk 24 entered the blinded long-term extension. Dose adjustments to UPA were not allowed. Adverse events (AE) per 100 pt years (PY) are summarized based on a cut-off date of 16 April 2018. Efficacy data up to the Wk60 visit are reported “As Observed”.

**Results:** 418/498 (84%) pts were randomized, completed 24 wks and entered the extension on study drug. By the safety data cut-off date, 19 pts discontinued study drug: 5 due to AE, 4 due to lack of efficacy, 3 withdrew consent, 2 were lost to follow-up, and 5 discontinued due to other reasons. Cumulative exposures to UPA15 and UPA30 were 301.7 and 290.7 PYs, respectively. Rates (Events/100PYs) of treatment-emergent AEs are reported (Table 1), and were numerically higher in the UPA30 vs UPA15 arm for serious AEs, AEs leading to discontinuation, serious infections, herpes zoster and hepatic disorders. Based on As Observed analysis, for pts completing Wk60 on UPA15 [172/216 (80%)] and UPA30 [168/202 (83%)], clinical and functional outcomes continued to improve compared to Baseline, or were maintained from Wk24 onwards in pts initially randomized to UPA15 or 30; Remission by CDAI<28 at Wk60 was achieved by 20% and 32%, respectively, and DAS28-CP<2.6 was achieved by 53% and 52%. Pts who were switched to UPA from PBO at Wk12 had comparable efficacy to pts initially randomized to UPA (Table 2).

**Conclusion:** The benefit/risk of upadacitinib treatment in this refractory population remains favorable. No new safety signals were identified. Some AEs were numerically higher for UPA30 vs 15; however the clinical significance of this, the assessment of rare safety events in this study, and the overall benefit/risk of upadacitinib 15mg and 30mg in the treatment of RA are best evaluated in an integrated analysis across the phase 3 program. UPA15mg and 30mg continued to be effective in treating RA signs and symptoms, and in improving physical function.

**Acknowledgement:** AbbVie, Inc was the study sponsor, contributed to study design, data collection, analysis & interpretation, and to writing, reviewing, and approval of final version. Medical writing support was provided by Nina Barretto, of AbbVie, Inc.

**Disclosure of Interests:** Mark C. Genovese Grant/research support from: Sanofi/Genzyme, Genentech/Roche, RPharm, Consultant for: Sanofi/Genzyme, Genentech/Roche, RPharm, Bernard Combe Consultant for: Abbvie, Bristol-Myers Squibb, Gilead, Janssen, Eli Lilly, MSD, Novartis, Pfizer, Roche-Chugai, Sanofi, UCB, Stephen Hall Grant/research support from: Bristol-Myers Squibb, Gilead, Janssen, Eli Lilly, MSD, Novartis, Pfizer, Roche-Chugai, Sanofi, UCB, Stephen Hall Grant/research support from: Bristol-Myers Squibb, Gilead, Janssen, Eli Lilly, MSD, Novartis, Pfizer, Roche-Chugai, Sanofi, UCB, Stephen Hall Grant/research support from:
Filgotinib in Patients with Rheumatoid Arthritis (RA) in the Phase 3 FINCH2 Study in bDMARD-IR Patients with RA Regardless of Geography or Race

Methods: FINCH2 enrolled 449 bDMARD-IR patients with active RA, who were randomized in a 1:1:1 manner to receive Fil, 200 mg, Fil 100 mg, or placebo (PBO) on a background of csDMARDs for 24 weeks. In this prespecified subgroup analysis, patient and disease characteristics and treatment effects were analyzed by race and geographic region (Region 1: AU, BE, FR, DE, IS, IT, NL, KR, ES, CH, UK, US; Region 2: HU, CZ, PL; Region 3: AR, PR, MX; Region 4: JP).

Results: 448 patients received ≥1 dose of study drug; they were 80.4% female, with a mean [SD] age of 56 [12.2] years, and 23.4% had received ≥3 prior bDMARDs. Baseline characteristics were similar across regions and race. The primary endpoint and all key secondary endpoints were met in the primary analysis.1 Efficacy and safety parameters were assessed by geography and race and shown below. There were 2 MACE (white Region 1, 1 Fil 100/1 PBO), 4 cases of uncomplicated herpes zoster (2 white/Region 1/Fil 200), but no cases of DVT/PE, opportunistic infection, active tuberculosis, malignancy, gastrointestinal perforation, or death.

Table 1. Week 24 key efficacy and safety measures by geographic region.

<table>
<thead>
<tr>
<th>Regimen</th>
<th>N</th>
<th>ACR20</th>
<th>DAS28(CRP) &lt;2.6</th>
<th>CFB HAQ-DI</th>
<th>TEAE</th>
<th>SAE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>Region</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fil 200</td>
<td>111</td>
<td>67†</td>
<td>31†</td>
<td>-0.7 (0.6)</td>
<td>73</td>
<td>5</td>
</tr>
<tr>
<td>1</td>
<td>100</td>
<td>75</td>
<td>25</td>
<td>-0.7 (0.7)</td>
<td>58</td>
<td>0</td>
</tr>
<tr>
<td>1</td>
<td>100</td>
<td>75</td>
<td>33</td>
<td>-0.6 (0.5)</td>
<td>75</td>
<td>17</td>
</tr>
<tr>
<td>1</td>
<td>111</td>
<td>67</td>
<td>31</td>
<td>-0.5 (0.5)</td>
<td>73</td>
<td>0</td>
</tr>
<tr>
<td>1</td>
<td>12</td>
<td>67</td>
<td>17</td>
<td>-1.2 (0.6)</td>
<td>42</td>
<td>8</td>
</tr>
<tr>
<td>1</td>
<td>16</td>
<td>81</td>
<td>38</td>
<td>-1.1 (0.7)</td>
<td>44</td>
<td>0</td>
</tr>
<tr>
<td>1</td>
<td>15</td>
<td>60</td>
<td>27</td>
<td>-0.5 (0.7)</td>
<td>60</td>
<td>0</td>
</tr>
<tr>
<td>1</td>
<td>15</td>
<td>60</td>
<td>0</td>
<td>-0.1 (0.6)</td>
<td>77</td>
<td>0</td>
</tr>
</tbody>
</table>

1‰ for HAQ-DI at week 24 were different. 2Nonresponder imputation. *p<0.05, †p<0.01, ‡p<0.001 vs PBO. CFB, change from baseline as mean (SD); SAE, serious adverse events; TEAE, treatment-emergent adverse events.

Conclusion: Fil demonstrated consistent safety and efficacy in bDMARD-IR patients with RA regardless of geography or race.

References: