Supplementary Material

**Fig. S1** Efficacy over time with tofacitinib in the LTE study, as measured by ACR20, ACR50, and ACR70 response rates,
b mean change from baseline in DAS28-4(ESR) score, and c mean change from baseline in HAQ-DI score (FAS, no imputation).

ACR American College of Rheumatology, BID twice daily, DAS28-4(ESR) Disease Activity Score in 28 joints, erythrocyte sedimentation rate, FAS full analysis set, HAQ-DI Health Assessment Questionnaire-Disability Index, LTE long-term extension, SE standard error, TDD total daily dose.

a Data were pooled for patients receiving a TDD of tofacitinib 5 mg BID (n = 2) and tofacitinib 10 mg BID (n = 97). One patient receiving tofacitinib 5 mg BID discontinued treatment after month 3.
**Fig. S2** Summary of pooled PRO data from phase III studies, showing changes from baseline in **a** PtGA (VAS), **b** pain (VAS), **c** fatigue (FACIT-F), and **d** sleep disturbance (MOS sleep scale) (FAS, no imputation).

Table S1  Analysis of pooled PRO data from phase III studies, showing the proportion of patients reporting improvements greater than or equal to the MCID at months 1 and 3 (FAS, no imputation)

<table>
<thead>
<tr>
<th>PRO</th>
<th>Month 1</th>
<th>Month 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tofacitinib 5 mg BID (N = 33)</td>
<td>Tofacitinib 10 mg BID (N = 47)</td>
</tr>
<tr>
<td>PtGA (VAS)</td>
<td>25 (75.8)</td>
<td>26 (55.3)</td>
</tr>
<tr>
<td>Pain (VAS)</td>
<td>22 (66.7)</td>
<td>32 (68.1)</td>
</tr>
<tr>
<td>SF-36 PCS score</td>
<td>19 (57.6)</td>
<td>34 (72.3)</td>
</tr>
<tr>
<td>SF-36 MCS score</td>
<td>Patients reporting improvements</td>
<td>≥ MCID [2.5], n (%)</td>
</tr>
<tr>
<td>-----------------</td>
<td>--------------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>17 (51.5) 21 (44.7) 6 (46.2) 18 (54.6) 23 (50.0) 5 (41.7)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Fatigue (FACIT-F)&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Patients reporting improvements</th>
<th>≥ MCID [4], n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>17 (51.5) 20 (44.4) 5 (38.5) 20 (60.6) 24 (54.6) 3 (25.0)</td>
</tr>
</tbody>
</table>


<sup>a</sup> For FACIT-F, *N* = 45 for tofacitinib 10 mg BID at month 1 and *N* = 44 for tofacitinib 10 mg BID at month 3.
Table S2 Number (%) of subjects with laboratory values meeting protocol criteria for monitoring and discontinuation

<table>
<thead>
<tr>
<th></th>
<th>Tofacitinib&lt;sup&gt;a&lt;/sup&gt; (N = 99)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hemoglobin, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Any single value &lt; 8 g/dl or ≥ 2 g/dl decrease from baseline</td>
<td>13 (13.1)</td>
</tr>
<tr>
<td>Two sequential values ≤ 8 g/l or ≥ 30% decrease from baseline&lt;sup&gt;b&lt;/sup&gt;</td>
<td>1 (1.0)</td>
</tr>
<tr>
<td><strong>Neutropenia, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Any count &lt; 1000 cells/mm&lt;sup&gt;3&lt;/sup&gt;</td>
<td>1 (1.0)</td>
</tr>
<tr>
<td>Two sequential counts &lt; 500 cells/mm&lt;sup&gt;3&lt;/sup&gt;</td>
<td>0</td>
</tr>
<tr>
<td><strong>Lymphopenia, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Any single lymphocyte count &lt; 500 cells/mm&lt;sup&gt;3&lt;/sup&gt;</td>
<td>13 (13.1)</td>
</tr>
<tr>
<td>Two sequential counts &lt; 500 cells/mm&lt;sup&gt;3&lt;/sup&gt;</td>
<td>2 (2.0)</td>
</tr>
<tr>
<td><strong>Aminotransferases, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Any single AST and/or ALT elevation &gt; 3 × ULN regardless of the total bilirubin value</td>
<td>4 (4.0)</td>
</tr>
<tr>
<td>Two sequential AST or ALT elevations &gt; 3 × ULN with at least one total bilirubin value &gt; 2 × ULN&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0</td>
</tr>
<tr>
<td>Two sequential AST or ALT elevations &gt; 3 × ULN</td>
<td>0</td>
</tr>
</tbody>
</table>
accompanied by elevated INR\(^b\)

Two sequential AST or ALT elevations > 5 × ULN regardless of total bilirubin value or accompanying symptoms\(^b\)

### Serum creatinine, \(n\) (%)

- Two sequential increases > 50% from average of screening and baseline values\(^b\): 5 (5.1)
- Elevations ≥ 33% from average of screening and baseline values at study completion: 5 (5.1)

\(ALT\) alanine aminotransferase, \(AST\) aspartate aminotransferase, \(BID\) twice daily, \(INR\) International Normalized Ratio, \(TDD\) total daily dose, \(ULN\) upper limit of normal.

\(^a\) Includes patients receiving a TDD of tofacitinib 5 mg BID \((n = 2)\) and 10 mg BID \((n = 97)\).

The patient receiving tofacitinib 5 mg BID discontinued treatment after month 3.

\(^b\) Confirmed