ONLINE SUPPLEMENTARY DATA

Supplementary Table 1. Shift table for selected laboratory values for maximum grade any time during the 12-week study of Japanese patients with rheumatoid arthritis treated with baricitinib or placebo (Common Terminology for Criteria for Adverse Events Version 4.0)

Treatment	**Post-baseline**				
Baseline grade	**No grade**	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**
Anemia (hemoglobin concentration) No Grade 3 (< 8.0 g/dL) abnormalities were reported at baseline					
Placebo					
No grade	23 (47%)	9 (18%)	0	0	NA
Grade 1 (< LLN and ≥ 10 g/dL)	1 (2%)	9 (18%)	6 (12%)	0	NA
Grade 2 (≥ 8 g/dL < 10 g/dL)	0	0	1 (2%)	0	NA
1 mg baricitinib					
No grade	9 (38%)	8 (33%)	0	0	NA
Grade 1 (< LLN and ≥ 10 g/dL)	0	5 (21%)	1 (4%)	0	NA
Grade 2 (< 10 g/dL and ≥ 8 g/dL)	0	0	1 (4%)	0	NA
2 mg baricitinib					
No grade	8 (33%)	6 (25%)	1 (4%)	0	NA
Grade 1 (< LLN and ≥ 10 g/dL)	0	6 (25%)	1 (4%)	0	NA
Grade 2 (< 10 g/dL and ≥ 8 g/dL)	0	0	2 (8%)	0	NA
4 mg baricitinib					
No grade	15 (63%)	3 (13%)	1 (4%)	0	NA
Grade 1 (< LLN and ≥ 10 g/dL)	0	3 (13%)	2 (8%)	0	NA
Grade 2 (< 10 g/dL and ≥ 8 g/dL)	0	0	0	0	NA
8 mg baricitinib					
No grade	6 (25%)	8 (33%)	0	0	NA
Grade 1 (< LLN and ≥ 10 g/dL)	2 (8%)	5 (21%)	3 (13%)	0	NA
Grade 2 (< 10 g/dL and ≥ 8 g/dL)	0	0	0	0	NA
Neutropenia (neutrophil concentration) No Grade 2 (< 1.5×10^9/L and ≥ 1.0×10^9/L) or higher (< 1.0×10^9/L) abnormalities were reported at baseline					
Placebo					

Treatment	Post-baseline				
Baseline grade	**No grade**	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**
No grade	44 (90%)	4 (8%)	0	0	0
Grade 1 (< LLN and ≥ 1.5 × 10^9/L)	1 (2%)	0	0	0	0
1 mg baricitinib					
No grade	24 (100%)	0	0	0	0
Grade 1 (< LLN and ≥ 1.5 × 10^9/L)	0	0	0	0	0
2 mg baricitinib					
No grade	23 (96%)	1 (4%)	0	0	0
Grade 1 (< LLN and ≥ 1.5 × 10^9/L)	0	0	0	0	0
4 mg baricitinib					
No grade	23 (96%)	0	0	0	0
Grade 1 (< LLN and ≥ 1.5 × 10^9/L)	0	1 (4%)	0	0	0
8 mg baricitinib					
No grade	21 (88%)	1 (4%)	1 (4%)	0	0
Grade 1 (< LLN and ≥ 1.5 × 10^9/L)	0	0	1 (4%)	0	0
Lymphopenia (lymphocyte count) No Grade 3 (< 0.5 × 10^9/L and ≥ 0.2 × 10^9/L) or Grade 4 (< 0.2 × 10^9/L) abnormalities were reported at baseline					
Placebo					
No grade	26 (53%)	10 (20%)	2 (4%)	0	0
Grade 1 (< LLN and ≥ 0.8 × 10^9/L)	1 (2%)	4 (8%)	2 (4%)	0	0
Grade 2 (< 0.8 × 10^9/L and ≥ 0.5 × 10^9/L)	0	2 (4%)	2 (4%)	0	0
1 mg baricitinib					
No grade	15 (63%)	4 (17%)	1 (4%)	0	0
Grade 1 (< LLN and ≥ 0.8 × 10^9/L)	1 (4%)	1 (4%)	1 (4%)	0	0
Grade 2 (< 0.8 × 10^9/L and ≥ 0.5 × 10^9/L)	0	1 (4%)	0	0	0
2 mg baricitinib					
No grade	14 (58%)	2 (8%)	1 (4%)	1 (4%)	0
Grade 1 (< LLN and ≥ 0.8 × 10^9/L)	0	3 (13%)	2 (8%)	0	0
Grade 2 (< 0.8 × 10^9/L and ≥ 0.5 × 10^9/L)	0	0	1 (4%)	0	0
4 mg baricitinib					
No grade	9 (38%)	6 (25%)	3 (13%)	1 (4%)	0

Treatment	**Post-baseline**				
Baseline grade	**No grade**	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**
Grade 1 (< LLN and ≥ 0.8 × 10^9/L)	2 (8%)	0	2 (8%)	0	0
Grade 2 (< 0.8 × 10^9/L and ≥ 0.5 × 10^9/L)	0	0	0	1 (4%)	0
8 mg baricitinib					
No grade	11 (46%)	5 (21%)	1 (4%)	0	0
Grade 1 (< LLN and ≥ 0.8 × 10^9/L)	2 (8%)	0	2 (8%)	1 (4%)	0
Grade 2 (< 0.8 × 10^9/L and ≥ 0.5 × 10^9/L)	0	0	2 (8%)	0	0
Thrombocytopenia (thrombocyte count) No Grade 2 (< 75 × 10^9/L and ≥ 50 × 10^9/L) or higher (< 50 × 10^9/L) abnormalities were reported at baseline					
Placebo					
No grade	48 (98%)	1 (2%)	0	0	0
Grade 1 (< LLN and ≥ 75 × 10^9/L)	0	0	0	0	0
1 mg baricitinb					
No grade	24 (100%)	0	0	0	0
Grade 1 (< LLN and ≥ 75 × 10^9/L)	0	0	0	0	0
2 mg baricitinib					
No grade	23 (96%)	1 (4%)	0	0	0
Grade 1 (< LLN and ≥ 75 × 10^9/L)	0	0	0	0	0
4 mg baricitinib					
No grade	23 (96%)	1 (4%)	0	0	0
Grade 1 (< LLN and ≥ 75 × 10^9/L)	0	0	0	0	0
8 mg baricitinib					
No grade	23 (96%)	0	0	0	0
Grade 1 (< LLN and ≥ 75 × 10^9/L)	0	1 (4%)	0	0	0
Elevated alanine transaminase (ALT) No Grade 3 (> 5 × ULN and ≤ 20 × ULN) or Grade 4 (> 20 × ULN) abnormalities were reported at baseline					
Placebo					
No grade	37 (76%)	10 (20%)	0	0	0
Grade 1 (> ULN and ≤ 3 × ULN)	1 (2%)	1 (2%)	0	0	0
Grade 2 (> 3 × ULN and ≤ 5 × ULN)	0	0	0	0	0
1 mg baricitinb					

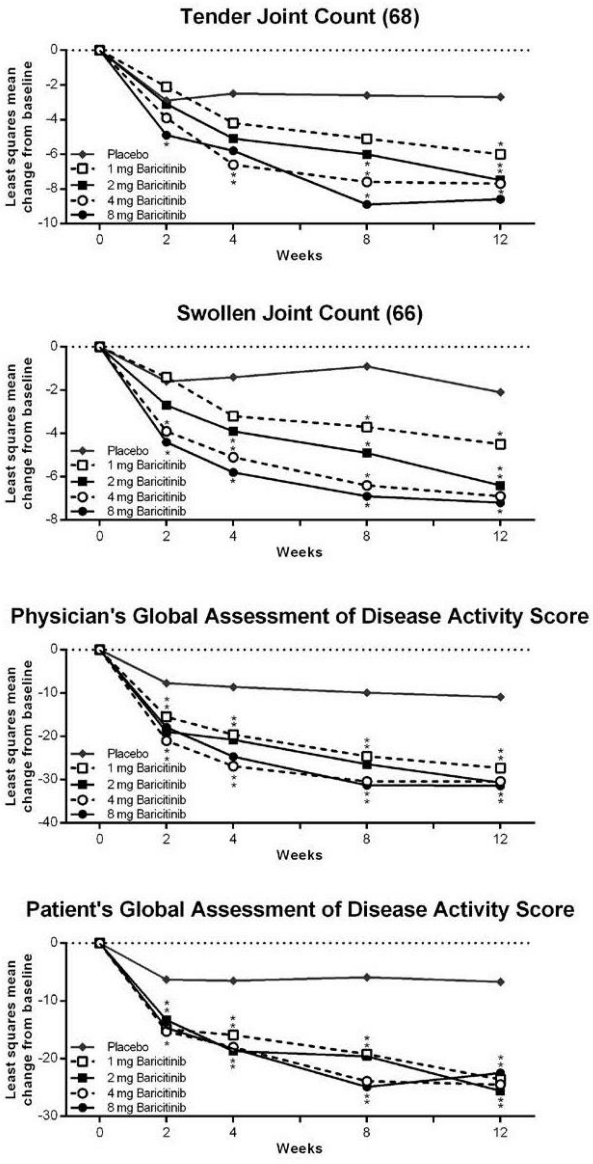
Treatment	Post-baseline				
Baseline grade	**No grade**	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**
No grade	17 (71%)	4 (17%)	0	0	0
Grade 1 (> ULN and ≤ 3 × ULN)	1 (4%)	2 (8%)	0	0	0
Grade 2 (> 3 × ULN and ≤ 5 × ULN)	0	0	0	0	0
2 mg baricitinib					
No grade	18 (75%)	2 (8%)	1 (4%)	0	0
Grade 1 (> ULN and ≤ 3 × ULN)	1 (4%)	1 (4%)	0	0	0
Grade 2 (>3 × ULN and ≤5 × ULN)	0	0	0	1 (4%)	0
4 mg baricitinib					
No grade	16 (67%)	7 (29%)	0	0	0
Grade 1 (> ULN and ≤ 3 × ULN)	0	0	0	1 (4%)	0
Grade 2 (> 3 × ULN and ≤ 5 × ULN)	0	0	0	0	0
8 mg baricitinib					
No grade	14 (58%)	5 (21%)	1 (4%)	1 (4%)	0
Grade 1 (> ULN and ≤ 3 × ULN)	0	3 (13%)	0	0	0
Grade 2 (> 3 × ULN and ≤ 5 × ULN)	0	0	0	0	0
Elevated creatine phosphokinase (CPK) No Grade 2 (> 2.5 × ULN and ≤ 5 × ULN) or higher (> 5 × ULN) abnormalities were reported at baseline					
Placebo					
No grade	42 (86%)	5 (10%)	0	0	0
Grade 1 (> ULN and ≤ 2.5 × ULN)	1 (2%)	1 (2%)	0	0	0
1 mg baricitinb					
No grade	20 (83%)	2 (8%)	0	0	0
Grade 1 (> ULN and ≤ 2.5 × ULN)	1 (4%)	0	1 (4%)	0	0
2 mg baricitinib					
No grade	19 (79%)	3 (13%)	1 (4%)	0	0
Grade 1 (> ULN and ≤ 2.5 × ULN)	1 (4%)	0	0	0	0
4 mg baricitinib					
No grade	12 (50%)	11 (46%)	0	0	0
Grade 1 (> ULN and ≤ 2.5 × ULN)	0	1 (4%)	0	0	0
8 mg baricitinib					

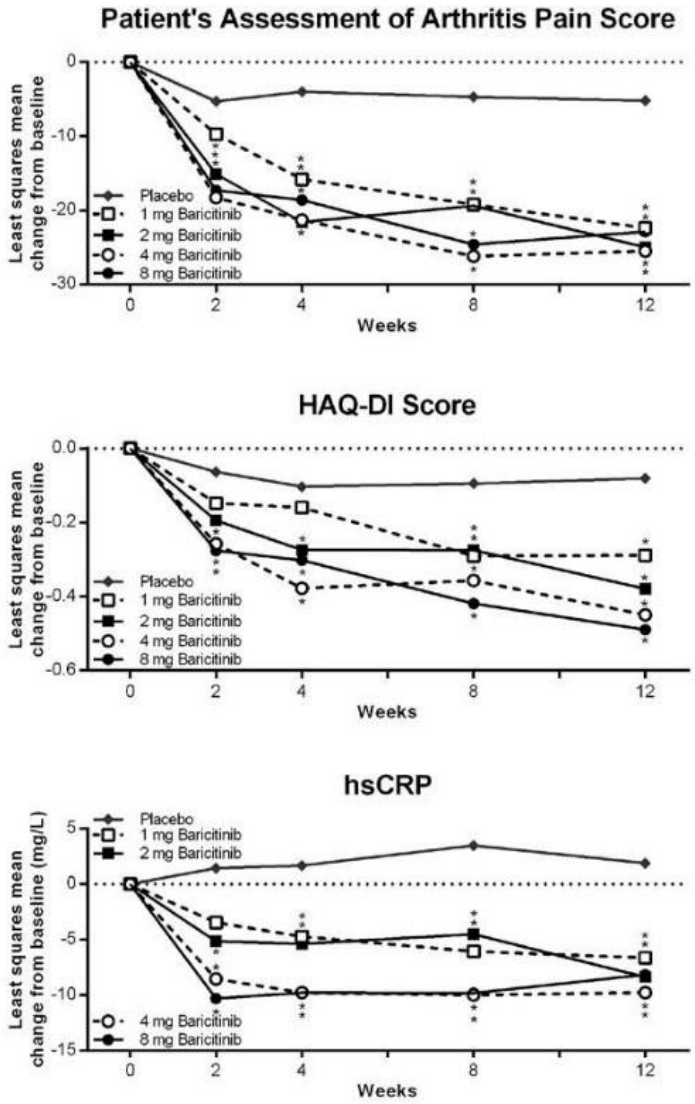
Treatment	Post-baseline				
Baseline grade	**No grade**	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**
No grade	13 (54%)	10 (42%)	0	0	0
Grade 1 (> ULN and ≤ 2.5 × ULN)	0	0	1 (4%)	0	0
Elevated creatinine No Grade 2 (> 1.5 × ULN and ≤ 3.0 × ULN) or higher (> 3.0 × ULN) abnormalities were reported at baseline					
Placebo					
No grade	49 (100%)	0	0	0	0
Grade 1 (> ULN and ≤ 1.5 × ULN)	0	0	0	0	0
1 mg baricitinb					
No grade	23 (96%)	0	0	0	0
Grade 1 (> ULN and ≤ 1.5 × ULN)	0	1 (4%)	0	0	0
2 mg baricitinib					
No grade	24 (100%)	0	0	0	0
Grade 1 (> ULN and ≤ 1.5 × ULN)	0	0	0	0	0
4 mg baricitinib					
No grade	22 (92%)	2 (8%)	0	0	0
Grade 1 (> ULN and ≤ 1.5 × ULN)	0	0	0	0	0
8 mg baricitinib					
No grade	24 (100%)	0	0	0	0
Grade 1 (> ULN and ≤ 1.5 × ULN)	0	0	0	0	0
Elevated low-density lipoprotein (LDL) cholesterol No Grade 4 (≥ 190 mg/dL) abnormalities were reported at baseline					
Placebo					
No grade	14 (29%)	8 (16%)	0	0	0
Grade 1 (≥ 100 mg/dL and < 130 mg/dL)	3 (6%)	11 (22%)	4 (8%)	0	0
Grade 2 (≥ 130 mg/dL and < 160 mg/dL)	0	0	8 (16%)	1 (2%)	0
Grade 3 (≥ 160 mg/dL and < 190 mg/dL)	0	0	0	0	0
1 mg baricitinb					
No grade	9 (38%)	4 (17%)	0	0	0
Grade 1 (≥ 100 mg/dL and < 130 mg/dL)	0	2 (8%)	3 (13%)	0	0
Grade 2 (≥ 130 mg/dL and < 160 mg/dL)	0	0	3 (13%)	2 (8%)	0
Grade 3 (≥ 160 mg/dL and < 190 mg/dL)	0	0	0	1 (4%)	0

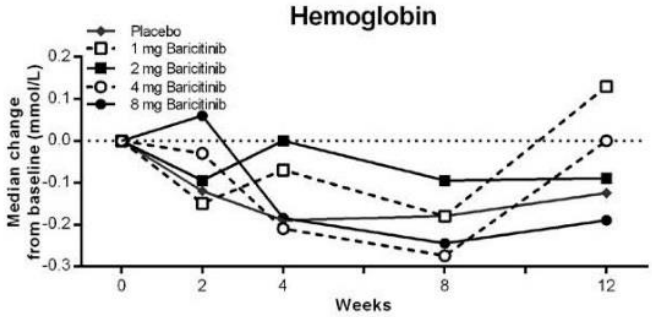
Treatment	**Post-baseline**				
Baseline grade	**No grade**	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**
2 mg baricitinib					
No grade	5 (21%)	5 (21%)	1 (4%)	0	0
Grade 1 (≥ 100 mg/dL and < 130 mg/dL)	0	4 (17%)	5 (21%)	0	0
Grade 2 (≥ 130 mg/dL and < 160 mg/dL)	0	0	2 (8%)	1 (4%)	1 (4%)
Grade 3 (≥ 160 mg/dL and < 190 mg/dL)	0	0	0	0	0
4 mg baricitinib					
No grade	5 (21%)	7 (29%)	0	0	0
Grade 1 (≥ 100 mg/dL and < 130 mg/dL)	0	1 (4%)	6 (25%)	0	0
Grade 2 (≥ 130 mg/dL and < 160 mg/dL)	0	0	1 (4%)	4 (17%)	0
Grade 3 (≥ 160 mg/dL and < 190 mg/dL)	0	0	0	0	0
8 mg baricitinib					
No grade	0	6 (25%)	0	0	0
Grade 1 (≥ 100 mg/dL and < 130 mg/dL)	0	3 (13%)	3 (13%)	0	1 (4%)
Grade 2 (≥ 130 mg/dL and < 160 mg/dL)	0	0	2 (8%)	4 (17%)	2 (8%)
Grade 3 (≥ 160 mg/dL and < 190 mg/dL)	0	0	0	1 (4%)	2 (8%)

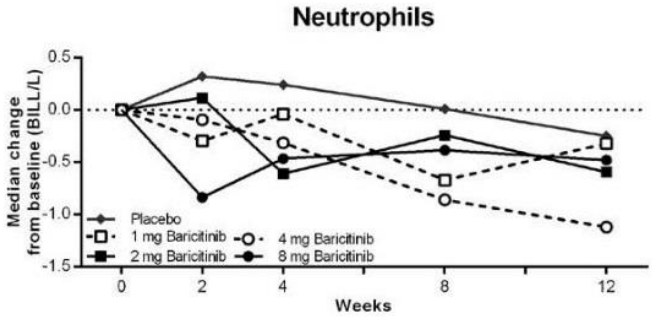
Data are presented as n (%). N = 49 for the placebo group, 24 for each baricitinib group.
Abbreviations: LLN, lower limit of normal; ULN, upper limit of normal.

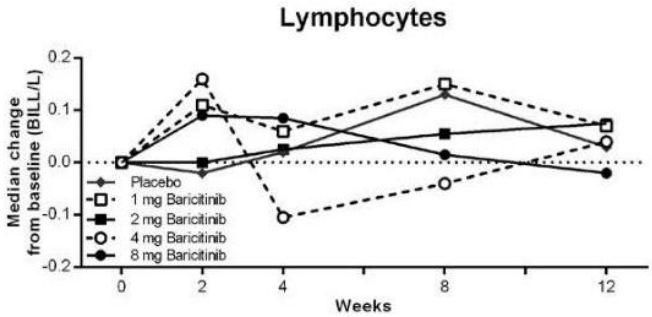
Supplementary Figures. Change in ACR core components during the 12-week study of Japanese patients with rheumatoid arthritis treated with baricitinib or placebo. Least squares mean change from baseline at 2, 4, 8, and 12 weeks of treatment is shown. Statistical comparisons were based on ANCOVA; **P* < 0.05. Abbreviations: HAQ-DI, health assessment questionnaire-disability index; hsCRP, high-sensitivity C-reactive protein; ALT, alanine aminotransferase; CPK, creatine phosphokinase; LDL, low-density lipoprotein.

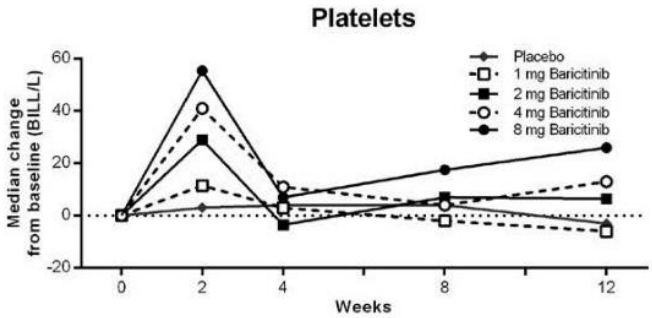


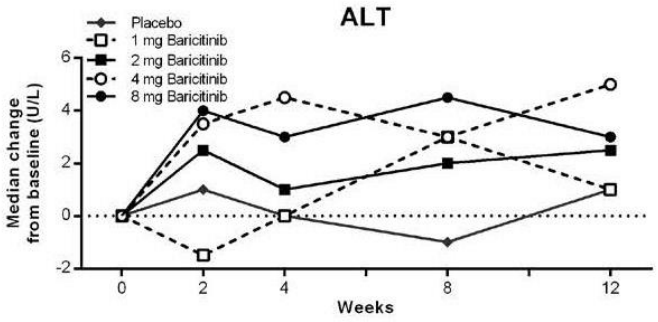

Patient's Assessment of Arthritis Pain Score
Least squares mean change from baseline
0
-10
-20
-30
Placebo
1 mg Baricitinib
2 mg Baricitinib
4 mg Baricitinib
8 mg Baricitinib
0
2
4
8
12
Weeks
HAQ-DI Score
Least squares mean change from baseline
0.0
-0.2
-0.4
-0.6
Placebo
1 mg Baricitinib
2 mg Baricitinib
4 mg Baricitinib
8 mg Baricitinib
0
2
4
8
12
Weeks
hsCRP
Least squares mean change from baseline (mg/L)
5
0
-5
-10
-15
Placebo
1 mg Baricitinib
2 mg Baricitinib
4 mg Baricitinib
8 mg Baricitinib
0
2
4
8
12
Weeks

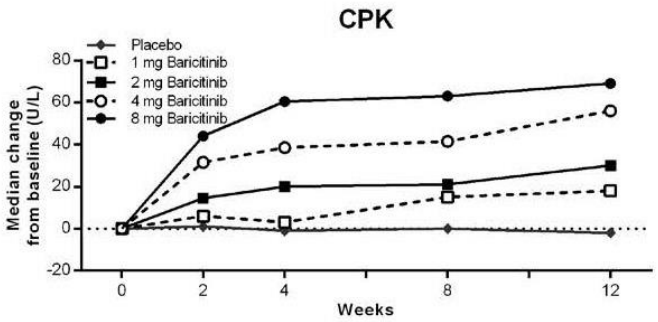

Hemoglobin
Placebo
1 mg Baricitinib
2 mg Baricitinib
4 mg Baricitinib
8 mg Baricitinib
Median change from baseline (mmol/L)
0.2
0.1
0.0
-0.1
-0.2
-0.3
0
2
4
8
12
Weeks

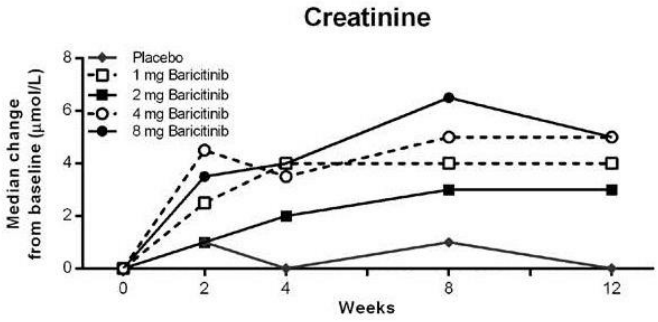

Neutrophils
Median change from baseline (B/LL/L)
0.5
0.0
-0.5
-1.0
-1.5
Placebo
1 mg Baricitinib
2 mg Baricitinib
4 mg Baricitinib
8 mg Baricitinib
0
2
4
8
12
Weeks

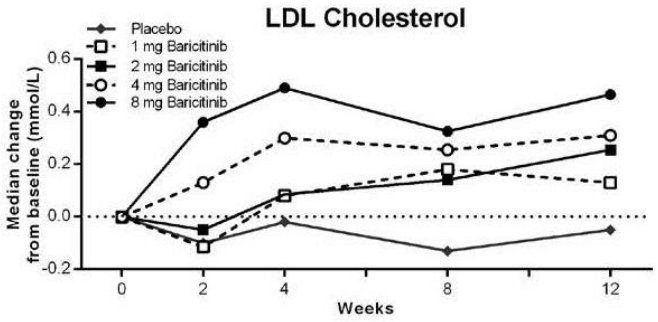

Lymphocytes
Median change from baseline (B/LL/L)
0.2
0.1
0.0
-0.1
-0.2
Placebo
1 mg Baricitinib
2 mg Baricitinib
4 mg Baricitinib
8 mg Baricitinib
0
2
4
8
12
Weeks


Platelets
Median change from baseline (B/LL/L)
60
40
20
0
-20
Placebo
1 mg Baricitinib
2 mg Baricitinib
4 mg Baricitinib
8 mg Baricitinib
0
2
4
8
12
Weeks


ALT
Placebo
1 mg Baricitinib
2 mg Baricitinib
4 mg Baricitinib
8 mg Baricitinib
Median change from baseline (U/L)
6
4
2
0
-2
0
2
4
8
12
Weeks


CPK
Placebo
1 mg Baricitinib
2 mg Baricitinib
4 mg Baricitinib
8 mg Baricitinib
Median change from baseline (U/L)
80
60
40
20
0
-20
0
2
4
8
12
Weeks


Creatinine
Placebo
1 mg Baricitinib
2 mg Baricitinib
4 mg Baricitinib
8 mg Baricitinib
Median change from baseline (µmol/L)
8
6
4
2
0
0
2
4
8
12
Weeks


LDL Cholesterol
Placebo
1 mg Baricitinib
2 mg Baricitinib
4 mg Baricitinib
8 mg Baricitinib
Median change from baseline (mmol/L)
0.6
0.4
0.2
0.0
-0.2
0
2
4
8
12
Weeks