Supplementary online materials

Supplementary Table 1. Raw data for key efficacy endpoints by time point.

Patients (%) with ACR20 at each time point (ITT-NRI)

Week	Placebo (N=86)	50 mg q.d. (N=82)	100 mg q.d. (N=85)	200 mg q.d. (N=86)	25 mg b.i.d. (N=86)	50 mg b.i.d. (N=85)	100 mg b.i.d. (N=84)
0	0	0	0	0	0	0	0
1	19	21	34	28	17	22	36
2	28	38	46	49	29	41	52
4	38	43	52	55	45	44	68
8	45	54	65	70	59	54	74
12	44	56	64	69	57	60	79
16	38	56	65	73	55	65	82
20	38	57	69	73	52	66	85
24	42	55	61	73	56	60	80

Patients (%) with ACR50 at each time point (ITT-NRI)

Week	Placebo (N=86)	50 mg q.d. (N=82)	100 mg q.d. (N=85)	200 mg q.d. (N=86)	25 mg b.i.d. (N=86)	50 mg b.i.d. (N=85)	100 mg b.i.d. (N=84)
0	0	0	0	0	0	0	0
1	1	2	5	5	4	7	7
2	6	7	20	11	7	12	21
4	7	13	33	17	15	19	35
8	13	27	35	34	26	34	45
12	15	33	38	43	28	34	55
16	20	38	52	49	30	31	62

20	15	39	46	52	38	41	60
24	16	35	47	50	35	35	55

Patients (%) with ACR70 at each time point (ITT-NRI)

Week	Placebo (N=86)	50 mg q.d. (N=82)	100 mg q.d. (N=85)	200 mg q.d. (N=86)	25 mg b.i.d. (N=86)	50 mg b.i.d. (N=85)	100 mg b.i.d. (N=84)
0	0	0	0	0	0	0	0
1	1	0	0	1	1	2	5
2	1	2	7	6	2	6	4
4	4	7	14	5	6	9	11
8	7	11	24	19	9	14	27
12	8	16	21	24	14	19	31
16	12	18	25	26	10	21	38
20	9	23	29	23	11	24	37
24	9	22	33	29	21	24	39

Mean CDAI score at each time point (ITT-LOCF)

Week	Placebo (N=86)	50 mg q.d. (N=82)	100 mg q.d. (N=85)	200 mg q.d. (N=86)	25 mg b.i.d. (N=86)	50 mg b.i.d. (N=85)	100 mg b.i.d. (N=84)
Baseline	0	0	0	0	0	0	0
1	-8.5	-7.2	-11	-11	-7.3	-9	-12
2	-12	-12	-17	-15	-12	-14	-18
4	-13	-15	-21	-20	-17	-18	-23
8	-16	-19	-23	-24	-21	-22	-27
12	-17	-20	-24	-25	-21	-23	-28
16	-18	-21	-27	-27	-22	-27	-30
20	-17	-21	-28	-30	-23	-27	-31
24	-16	-21	-29	-29	-24	-27	-32

Mean change from baseline in DAS28 (CRP) (ITT-LOCF)

Week	Placebo (N=86)	50 mg q.d. (N=82)	100 mg q.d. (N=85)	200 mg q.d. (N=86)	25 mg b.i.d. (N=86)	50 mg b.i.d. (N=85)	100 mg b.i.d. (N=84)
Baseline	0	0	0	0	0	0	0

1	-0.57	-0.65	-1.0	-1.2	-0.68	-0.84	-1.3
2	-0.8	-0.94	-1.5	-1.5	-1.1	-1.2	-1.8
4	-0.97	-1.3	-1.9	-1.9	-1.5	-1.6	-2.2
8	-1.2	-1.7	-2.1	-2.3	-1.8	-1.9	-2.7
12	-1.2	-1.8	-2.2	-2.5	-1.9	-2.1	-2.8
16	-1.4	-1.9	-2.5	-2.7	-2.0	-2.4	-3.1
20	-1.3	-2.0	-2.7	-2.9	-2.1	-2.4	-3.0
24	-1.2	-2.0	-2.7	-2.8	-2.2	-2.4	-3.2

Mean change from baseline in HAQ-DI (ITT-LOCF)

Week	Placebo (N=86)	50 mg q.d. (N=82)	100 mg q.d. (N=85)	200 mg q.d. (N=86)	25 mg b.i.d. (N=86)	50 mg b.i.d. (N=85)	100 mg b.i.d. (N=84)
0	0.00	0.00	0.00	0.00	0.00	0.00	0.00
1	-0.20	-0.23	-0.32	-0.27	-0.21	-0.22	-0.35
2	-0.23	-0.33	-0.41	-0.45	-0.30	-0.36	-0.48
4	-0.34	-0.39	-0.52	-0.55	-0.45	-0.43	-0.58
8	-0.41	-0.50	-0.64	-0.67	-0.59	-0.52	-0.72
12	-0.38	-0.58	-0.65	-0.75	-0.59	-0.58	-0.84
16	-0.40	-0.66	-0.71	-0.78	-0.58	-0.65	-0.90
20	-0.40	-0.64	-0.78	-0.79	-0.58	-0.65	-0.95
24	-0.37	-0.63	-0.78	-0.82	-0.62	-0.66	-0.90

b.i.d., twice daily; CDAI, Clinical Disease Activity Index; CRP, C-reactive protein; DAS, Disease Activity Score; HAQ-DI, Health Assessment Questionnaire-Disability Index; ITT, intent-to-treat; LOCF, last observation carried forward; N, number of subjects per group; NRI, non-responder imputation; q.d., once daily.

Table 2. Efficacy assessments and disease activity assessments at Weeks 12 and 24 in non-responder* patients who switched treatment groups at Week 12.

		Non-responders* switching to 100 mg/day at Week 12			
		Placebo to 100 mg q.d. (N=15)	**Placebo to 2x50 mg (N=15)**	**50 mg to 100 mg q.d. (N=19)**	**2x25 mg to 2x50 mg (N=17)**
ACR20[a]	W12	7%	7%	0%	0%
	W24	53%	60%	42%	41%
ACR50[a]	W12	0%	0%	0%	0%
	W24	33%	40%	26%	6%
ACR70[a]	W12	0%	0%	0%	0%
	W24	20%	13%	5%	6%
ACR-N[a]	W12, n	1.5	3.5	2.9	4.1
	W24, n	32.0	33.3	25.8	23.9
DAS28 (CRP)[a]	W12, mean change	-0.4	-0.1	-0.1	-0.5
	W24, mean change	-2.1	-2.1	-1.3	-1.7
DAS28 (CRP) remission[a]	W12	0%	0%	0%	0%
	W24	20%	20%	5%	6%
DAS28 (CRP) remission/LDA[a]	W12	0%	0%	0%	0%
	W24	27%	40%	5%	24%
DAS28 (CRP) EULAR response[a]	W12 Moderate Good	 27% 0%	 13% 0%	 5% 0%	 18% 0%
	W24 Moderate Good	 53% 57%	 33% 40%	 74% 5%	 53% 24%
ACR / EULAR remission[b]	W12	0%	0%	0%	0%
	W24	7%	0%	5%	0%
SDAI[a]	W12, mean change	-6.5	-0.9	-1.0	-5.5
	W24, mean change	-24.5	-24.0	-18.5	-21.6
SDAI remission[b]	W12	0%	0%	0%	0%
	W24	13%	0%	0%	0%
CDAI[a]	W12, mean change	-7.1	-1.0	0.7	-4.2
	W24, mean change	-23.3	-22.7	-16.6	-20.3

CDAI remission[b]	W12	0%	0%	0%	0%
	W24	13%	0%	0%	0%
HAQ-DI[a]	W12, mean change	-0.28	0.10	-0.30	-0.28
	W24, mean change	-0.69	-0.25	-0.49	-0.50

*Patients who did not achieve a 20% improvement in swollen joint count based on 66 joints and tender joint count based on 68 joints.

[a]LOCF (ITT population); [b]NRI (ITT population).

ACR, American College of Rheumatology; ACR-N, ACR N% improvement; b.i.d., twice daily; CDAI, Clinical Disease Activity Index; CRP, C-reactive protein; DAS28, Disease Activity Score based on 28 joints and C-reactive protein; EULAR, European League Against Rheumatism; HAQ-DI, Health Assessment Questionnaire – Disability Index; ITT, intent-to-treat; LDA, Low Disease Activity; LOCF, last observation carried forward; N, number of patients per group; n, number of patients with response/change; NRI, non-responder imputation; q.d., once daily; SDAI, Simplified Disease Activity Index.

Table 3. Change from baseline over time in responder* patients who continued on the same treatment throughout the 24-week study for (A) haemoglobin (g/dL); (B) neutrophils (x10^9/L); and (C) platelets (x10^9/L).

	Time point	Placebo N=86	Filgotinib q.d. dose groups			Filgotinib b.i.d. dose groups		
			50 mg N=82	100 mg N=85	200 mg N=86	2x25 mg N=86	2x50 mg N=85	2x100 mg N=84
Haemoglobin	W12, mean change, g/dL	-0.015	0.091	0.243	0.410	0.288	0.153	0.443
	W24, mean change, g/dL	-0.075	0.043	0.326	0.336	0.298	0.144	0.494
Neutrophils	W12, mean change, x10^9/L	-0.08	-0.98	-0.57	-1.06	-0.55	-0.79	-1.60
	W24, mean change, x10^9/L	0.17	-0.79	-0.73	-1.09	-0.86	-1.07	-1.92
Platelets	W12, mean change, x10^9/L	4.17	-21.05	-36.66	-34.51	-26.95	-35.39	-57.77
	W24, mean change, x10^9/L	7.50	-24.55	-48.39	-32.92	-27.64	-34.99	-52.36

*Patients who achieved a 20% improvement in swollen joint count based on 66 joints and tender joint count based on 68 joints