Supplementary Tables

SupplementalTable S1. Concomitant MTX and concomitant leflunomide-only subgroups[a]: baseline disease characteristics in Part 1

Patient Disease Characteristics	Concomitant MTX N=2656	Concomitant Leflunomide Only N=303
	n=2617	n=301
DAS28-CRP, Mean	5.43	5.25
	n=2656	n=303
DAS28-ESR, Mean	5.99	5.79
	n=2609	n=300
SDAI, Mean	36.88	34.56
	n=2654	n=303
HAQ-DI, Mean	1.44	1.36

[a]The concomitant MTX subgroup includes any patients who received concomitant MTX, including those receiving concomitant MTX+leflunomide (n=282), in Part 1. The concomitant leflunomide-only subgroup includes patients who received only concomitant leflunomide during Part 1.

CRP = C-reactive protein; DAS28 = 28-joint disease activity score; ESR = erythrocyte sedimentation rate; HAQ-DI = Health Assessment Questionnaire Disability Index; MTX = methotrexate; SDAI = simplified disease activity index.

Table S2. Concomitant MTX and concomitant leflunomide-only subgroups:[a] summary of patients with TEAEs in Part 1

Patients with TEAEs	Concomitant MTX N=2656 n (%)	Concomitant Leflunomide Only N=309 n (%)
≥1 TEAE	1459 (54.93)	176 (56.96)
TEAEs possibly or probably related to study medication	720 (27.11)	106 (34.30)
TEAEs leading to early withdrawal	100 (3.77)	21 (6.80)
Injection site reactions	16 (0.60)	0
Deaths	5 (0.19)[b]	0
Serious TEAEs	136 (5.12)	21 (6.80)
Infections and infestations	48 (1.81)	2 (0.65)
Musculoskeletal and connective tissue disorders	17 (0.64)	2 (0.65)
Injury, poisoning, and procedural complications	14 (0.53)	5 (1.62)
Respiratory, thoracic and mediastinal disorders	12 (0.45)	3 (0.97)
Cardiac disorders	11 (0.41)	1 (0.32)
Neoplasms benign, malignant, and unspecified	11 (0.41)	2 (0.65)
General disorders and administration site conditions	10 (0.38)	0
Gastrointestinal disorders	9 (0.34)	2 (0.65)
Nervous system disorders	6 (0.23)	3 (0.97)
Renal and urinary disorders	5 (0.19)	1 (0.32)
Vascular disorders	5 (0.19)	2 (0.65)
Blood and lymphatic system disorders	3 (0.11)	0
Hepatobiliary disorders	3 (0.11)	0

Investigations	3 (0.11)	0
Reproductive system and breast disorders	3 (0.11)	0
Surgical and medical procedures	3 (0.11)	0
Immune system disorders	2 (0.08)	0
Psychiatric disorders	2 (0.08)	1 (0.32)
Skin and subcutaneous tissue disorders	2 (0.08)	1 (0.32)
Ear and labyrinth disorders	1 (0.04)	0
Eye disorders	1 (0.04)	0

[a]The concomitant MTX subgroup includes any patients in the efficacy-evaluable population who received concomitant MTX, including those receiving concomitant MTX+leflunomide (n=282), in Part 1. The concomitant leflunomide-only subgroup includes any patients in the safety population who received only concomitant leflunomide during Part 1.

[b]1 additional death occurred in a patient in the safety but not efficacy-evaluable population. 4 additional events that led to death occurred in patients more than 30 days after their last dose of study medication.

MTX = methotrexate; TEAE = treatment-emergent adverse event.