

Supplementary Table 1

Additional Inclusion Criteria

- Patients using nonsteroidal anti-inflammatory drugs or other analgesics for RA should be on a stable dose for ≥ 4 weeks before randomization.
- Patients who were not pregnant or nursing at screening and not planning to become pregnant from the time of screening until 5 months after last drug dose were included.
- Patients of childbearing age agreed to use at least 2 forms of contraception from screening until 5 months after last drug dose.
- Patients had to understand the implications of the trial and follow study requirements.

Additional Exclusion Criteria

- Patients taking or planning to take live or live-attenuated vaccines within 8 weeks before randomization or during the study
- Patients with abnormal renal or hepatic function, abnormal hematologic parameters, positive serologic test for hepatitis B or hepatitis C virus, or a history of HIV infection
- Patients with chronic recurrent infections or history of infection of joint prosthesis
- Patients with history of congestive heart failure, uncontrolled diabetes mellitus, demyelinating disorders, malignancy (during the previous 5 years), lymphoproliferative disease (including lymphoma), organ transplantation
- Patients with physical incapacitation (ACR functional class IV or wheelchair-/bed-bound)

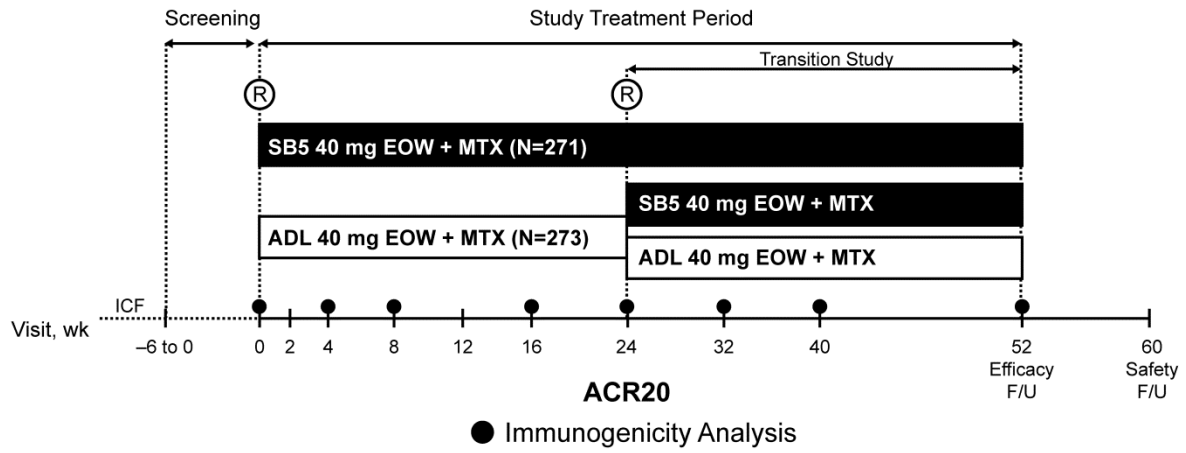
- Patients who had a substance abuse problem within 3 years before screening

Supplementary Table 2. DAS28-ESR, SDAI, CDAI at Week 24

	SB5 (N=269)	ADL (N=273)
Mean ± SD change in DAS28-ESR	-2.74±1.297	-2.68±1.277
Remission: DAS28-ESR <2.6, n/N (%)	55/255 (21.6)	51/257 (19.8)
LDA: DAS28-ESR ≤3.2, n/N (%)	87/255 (34.1)	90/257 (35.0)
Mean ± SD change in SDAI	-25.98±13.312	-25.00±12.02
Remission: SDAI ≤3.3, n/N (%)	28/254 (11.0)	37/257 (14.4)
LDA: 3.3 < SDAI ≤11.0, n/N (%)	79/254 (31.1)	80/257 (31.1)
Change in CDAI, mean ± SD	-25.39±12.886	-24.33±12.023
Remission: CDAI ≤2.8, n/N (%)	29/256 (11.3)	35/258 (13.6)
LDA: CDAI 2.8 to ≤10.0, n/N (%)	76/256 (29.7)	76/258 (29.5)

ADL=reference adalimumab; CDAI=clinical disease activity; DAS28=disease activity score in 28 joints; ESR=erythrocyte sedimentation rate; LDA=low disease activity; SDAI=simplified disease activity.

Supplementary Figure 1. Study design. ACR20=American College of Rheumatology 20% response criteria; ADL=reference adalimumab; EOW=every other week; F/U=follow up; ICF=informed consent form; MTX=methotrexate; R=randomization.



Supplementary Figure 2. ACR responses by ADA status up to week 24: ACR20 responses (A), ACR50 responses (B), ACR70 responses (C), and ACR-N (D). ACR20/50/70=American College of Rheumatology 20%/50%/70% response criteria; ACR-N=numeric index of the ACR response; ADA=antidrug antibodies; ADL=reference adalimumab.

