**Supplementary text.**

**PPS and FAS criteria**

1. The FAS consisted of subjects randomised to a study treatment. In addition, the FAS criteria could include the following:
2. Administered at least one injection of study treatment
3. Completed all assessments relevant to the DAS28-ESR scoring at baseline and at least one post-baseline assessment time.
4. Two PPSs were defined: one for the week 24 (PPS-24w) data analysis and the other for the week 52 (PPS-52w) data analysis. To be included in the PPS-52w data analysis, the subjects were to meet the criteria at both weeks 24 and 52.

The per-protocol set (PPS) consisted of subjects meeting the FAS criteria. Additional PPS criteria could include the following:

1. Met all inclusion and exclusion criteria
2. DAS28-ESR assessment at baseline and week 24/week 52 (per analysis visit window)
3. At least 80% compliance to the study treatment during the first 24 weeks/52 weeks of treatment
4. No discontinuation of the study treatment for more than 2 consecutive weeks during the 4 weeks prior to the DAS28-ESR assessment at week 24/week 52 (per analysis visit window)
5. A week-long temporary hold of MTX administration for no more than 5 times in total during the first 24 weeks of the study period (for week 24 data analysis). To qualify for the week 52 data analysis, an additional no more than 6 times during the second 28-week period (weeks 24–52), i.e., no more than 11 times in total during the 52 weeks period
6. No major protocol violations that could affect DAS28-ESR assessment during the first 24 weeks/52 weeks of treatment.

**Supplementary figure legends**

**Supplementary figure S1.** Study design. ETN-RP, etanercept reference product.

This study consisted of three periods; screening period, treatment period, and post-treatment follow-up period. Screening period was a period for confirming patient eligibility for study participation, defined as a period from obtaining Informed Consent to the day before treatment randomisation. Treatment period was a period for assessing efficacy and safety of the study drugs in this study, defined as a period from treatment randomization to the completion of week 52 assessments or the completion of assessments for premature withdrawal from the study prior to the scheduled week 52 visit.

Post-treatment follow-up period was a period for assessing post-treatment safety of the study drugs, defined as a 2-week period from the last visit of treatment period (the completion of assessments at week 52 or the time of the premature withdrawal from the treatment period).

**Supplementary figure S2.** Percentages of patients achieving remission (A) and low disease activity (PPS) (B). ETN-RP, etanercept reference product.

**Supplementary figure S3.** Serum trough concentrations (pharmacokinetics analysis set). Blood for pharmacokinetics analysis was drawn on 7 ± 2 days after drug administration. On days 8 or 9 after administration, blood was collected in more patients for analysis at week 52 (LBEC group: 15.5%, Enbrel group: 11.0%) than at weeks 12 or 24 (LBEC group: 7.6% at week 12, 5.7% at week 24, Enbrel group: 5.4% at week 12, 5.0% at week 24). ETN-RP, etanercept reference product.