**Title:** A Pooled Analysis Reporting the Efficacy and Safety of Secukinumab in Male and Female Patients with Ankylosing Spondylitis

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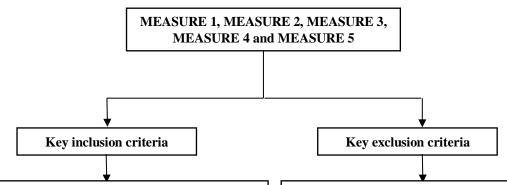
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## Supplementary Figure S1. Key inclusion/exclusion criteria



- 1. Males or non-pregnant, non-lactating female patient at least 18 years of age.
- 2. Diagnosis of moderate to severe AS with prior documented radiologic evidence (X-ray) fulfilling the Modified New York criteria for AS with active and a BASDAI≥4 (0-10) and spinal pain as measured by VAS≥4 cam at baseline.
- 3. Patients should have been on NSAIDs at the highest recommended dose for at least 3 months with an inadequate response or failure to respond, or less 3 months if therapy had to be withdrawn due to intolerance, toxicity or contraindications.
- 4. Patients who are regularly taking NSAIDs (COX-1 or COX-2 inhibitor) as part of their AS therapy are required to be on a stable dose for at least 2 weeks before randomization.
- 5. Patients who have been on an anti-TNF $\alpha$  agent (not more than one) must have experienced an inadequate response to previous or current treatment given at an approved dose for at least 3 months or have been intolerant to at least one administration of anti-TNF $\alpha$  agent.
- 6. Patients who have previously been on a TNFα inhibitor will be allowed to entry into study after appropriate wash-out period prior to randomization: 4 weeks for etanercept, 8 weeks for infliximab, 10 weeks for adalimimab, 10 weeks for golimumab, and 10 weeks for certolizumab.
- 7. Patients taking MTX (7.5 to 25 mg/week) or Sulfasalazine ( $\leq$  3 g/day) must have taken it at least 3 months and have to be on a stable dose for 4 weeks before randomization.
- 8. Patients on MTX must be on a stable folic acid supplementation before randomization.
- 9. Patients who are on DMARD other than MTX or Sulfasalazine must discontinue the DMARD 4 weeks prior to randomization, except for leflunomide, which has to be discontinued for 8 weeks prior to randomization unless a cholestyramine washout has been performed.
- 10. Patients taking systemic corticosteroids have to be on a stable dose of ≤10mg/day prednisolone or equivalent for at least 2 weeks before randomization.

- 1. Chest X-ray with evidence of ongoing infectious or malignant proceed obtained within 3 months of screening and evaluated by a qualified physician.
- 2. Patients with total ankyloses of the spine.
- 3. Patients taking high potency opioid analgesic (e.g. methadone, hydromorphone, or morphine).
- 4. Previous exposure to secukinumab or any other biologic drug directly IL-17 or IL-17 receptor.
- 5. Use of any investigational drug and/or devices within 4 weeks of randomization, or a period of 5 half-lives of the investigational drug, whichever is longer.
- 6. Patients previously treated with any biological immunomodulating agents except for those targeting TNFα.
- 7. Previous treatment with any cell-depleting therapies including but not limited to anti-CD20, investigational agents (e.g., CAMPTH, anti-CD-4, anti-CD-5, anti-CD3, anti-CD19).
- 8. Active ongoing inflammatory disease other than AS that might confound the evaluation of the benefit of secukinumab therapy, including inflammatory bowel disease or uveitis.
- 9. Active systemic infections during last two weeks (exception: common cold) prior randomization.
- 10. History of ongoing, chronic or recurrent infections disease or evidence of tuberculosis infection as defined by either a positive PPD skin test.
- 11. Known infection with HIV, hepatitis B or hepatitis C at screening or randomization.
- 12. History of lymphoproliferative disease or any known malignancy or history of malignancy of any organ system within the past 5 years (except for basal cell carcinoma or actinic keratosis that have been treated with no evidence of recurrence in the past 3 months, carcinoma in situ of the cervix or non-invasive malignant colon polyps that have been removed).
- 13. Any medical or psychiatric condition which, is the Investigator's opinion, would preclude the participant from adhering to the protocol or completing the study per protocol.