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Supplementary Materials for

Effects of AIN457, a Fully Human Antibody to Interleukin-17A, on Psoriasis, Rheumatoid Arthritis, and Uveitis

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Investigators in the study listed by indication and site.

Materials and Methods

1. Appendix 1: sample size calculations for the three proof-of-concept studies

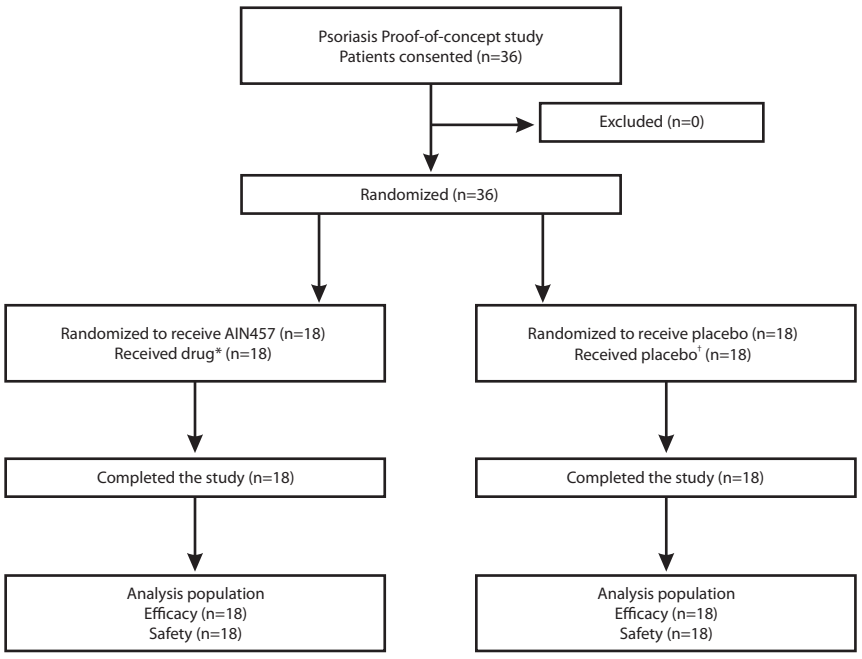
In the psoriasis study, the sample size was based on the number of patients required to show a statistically significant difference between the treatment groups in the mean change from baseline in PASI as the endpoint. Assuming complete data from at least 14 patients per treatment group, this study had 90% power assuming a true difference between the treatment group of 20%, a between-patient variability of 20%, and a one-sided significance level of 10%.

The rheumatoid arthritis trial, with a sample size of 26 per treatment group, had approximately 80% power to detect a statistically significant difference between the treatment groups in the primary endpoint if the true response rates were 45% and 20%, respectively. The sample size calculations were based on the rationale to expose as few patients as possible to an experimental compound with unknown safety and uncertain efficacy, yet maintaining adequate confidence in the observed outcome to justify further development. We assumed a one-sided type I error of 20% for this first-in-human study; thus $P<0.2$ was considered a priori to be statistically significant.

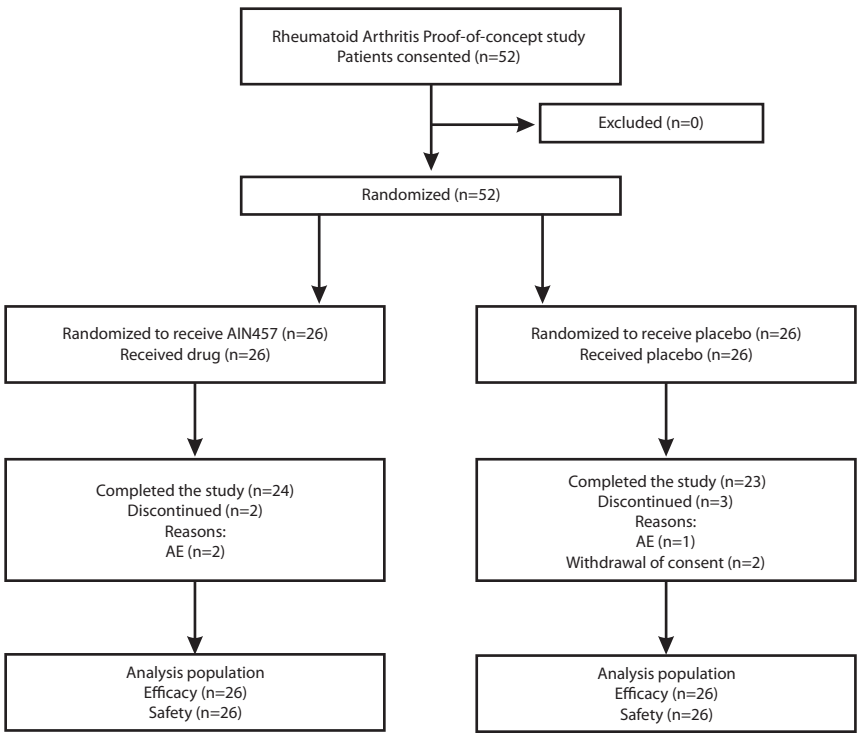
In the uveitis trial, with a sample size of 10 completers in the AIN457 treatment group using a Fisher's exact test, a statistically significant difference in favor of the infliximab historical control group in the efficacy endpoint could be detected if less than 50% of patients in the AIN457 group were responders at week 8. The sample size calculations assumed a one-sided type I error of 5%; thus $p<0{\cdot}05$ was considered a priori to be statistically significant.

Figure S1. Patient disposition for the psoriasis study (panel A), the rheumatoid arthritis study (panel B), and the noninfectious uveitis study (panel C)

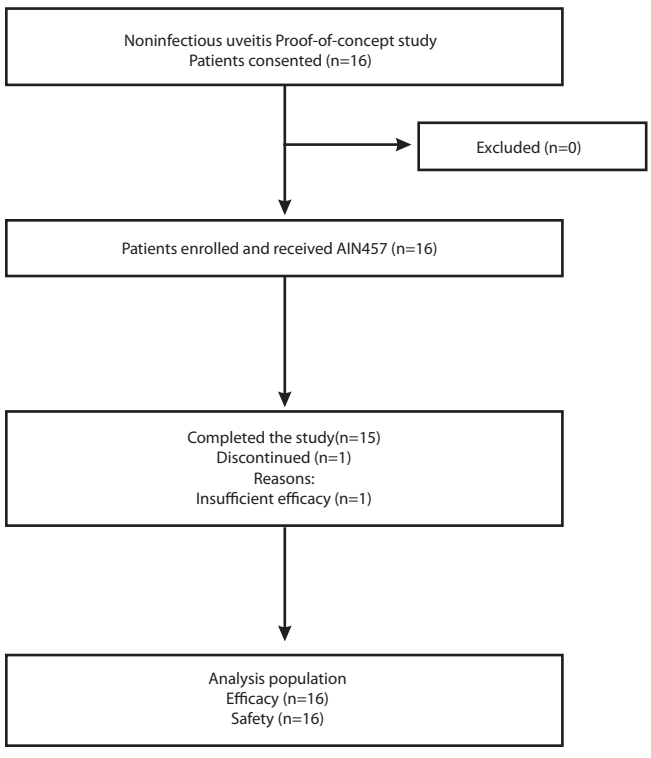
Panel A



Panel B



Panel C



*1 patient assigned to AIN457 received placebo by error. This patient was analyzed in the placebo group; †1 patient assigned to placebo received AIN457

Investigators in studies listed by indication and site.

Psoriasis: US— Z Draelos, MH Gold, L Kircik, AJ Kivitz, R Matheson, ES Rafal, D Stoll, JH Tu; **Rheumatoid arthritis**: Belgium — P Durez; Germany — B Manger, U Müller-Ladner, H Schulze-Koops; Republic of Singapore — D Koh, K Yoon; The Netherlands — P-P Tak, PLC Van Riel; Spain — F Blanco, JJ Gomez-Reino, J Tornero; United States — V Chindalore, S Clevinger, C Codding, M Cohen, R DiGiovanni, J Kenik, AJ Kivitz, A Sebba, B Wittmer; **Uveitis**: US — D Callanan, DS Chu, N S Falk, CS Foster, RY Kim, QD Nguyen, CM Samson.