Supplemental appendix

Efficacy and safety of risankizumab in patients with psoriasis showing suboptimal response to secukinumab or ixekizumab: Results from a phase 3b, open-label, single-arm (aIMM) study

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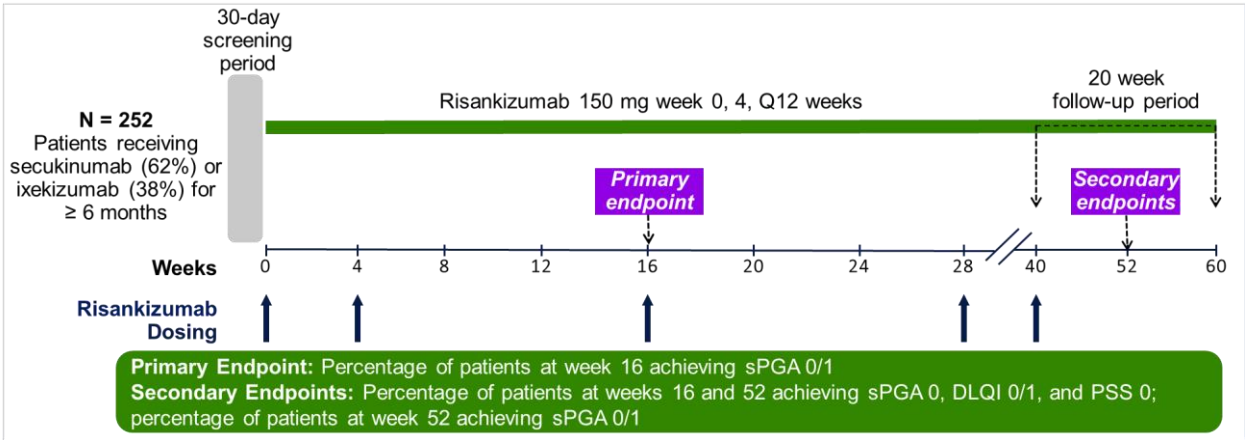
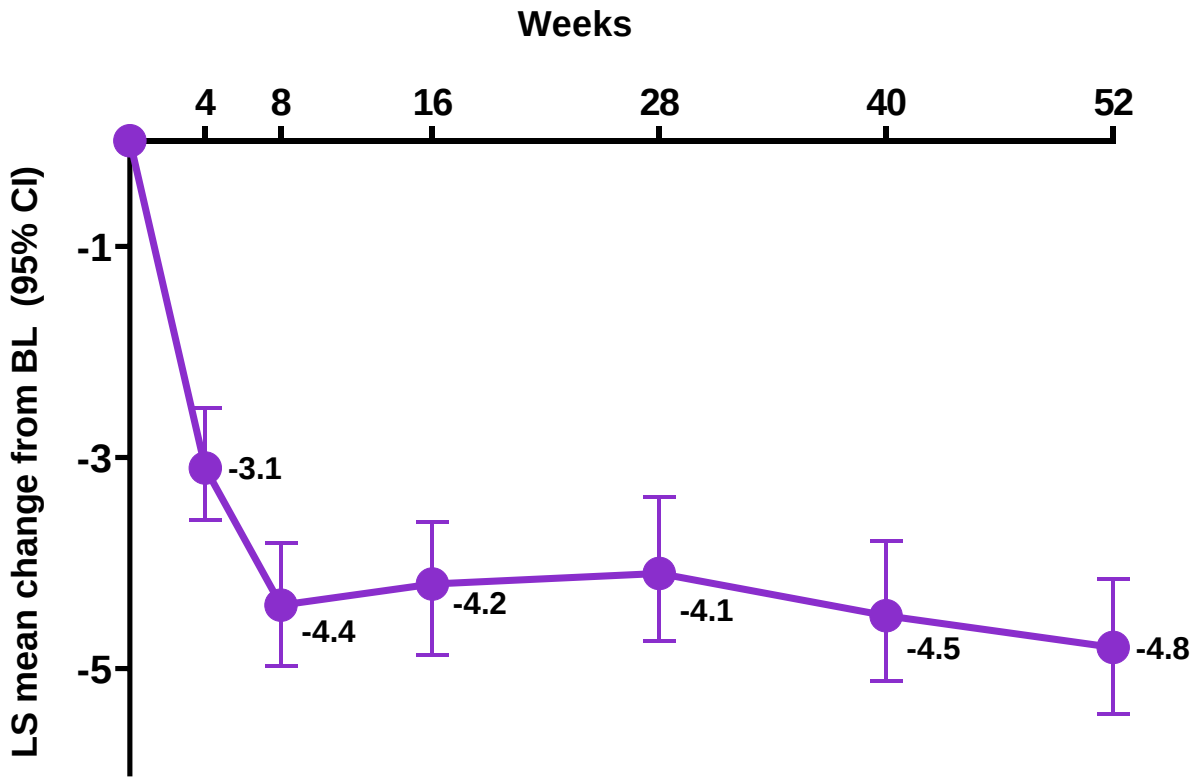
Figure S1. aIMM study design (*NCT04102007)*



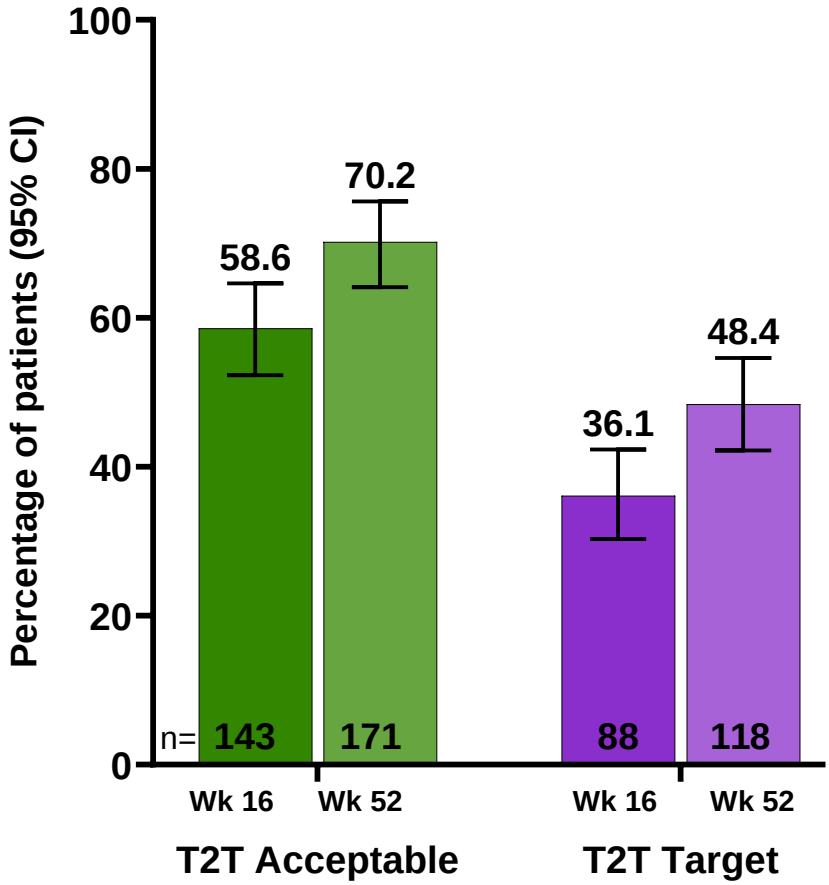
BSA, body surface area; DLQI, Dermatology Life Quality Index; PSS, Psoriasis Symptoms Score; sPGA, static Physician's Global Assessment

Figure S2. Change from baseline in Dermatology Life Quality Index (DLQI) by visit



The baseline was defined as the last non-missing observation on or before the date of the first administration of the study drug. Patients with non-missing baseline and at least one post-baseline value were included in the analyses. A mixed-effect model repeat measurement (MMRM) was conducted using a mixed model, including baseline values and observed measurements at all post-baseline visits. The mixed model included baseline measurements and the categorical fixed effect of visits as covariates.

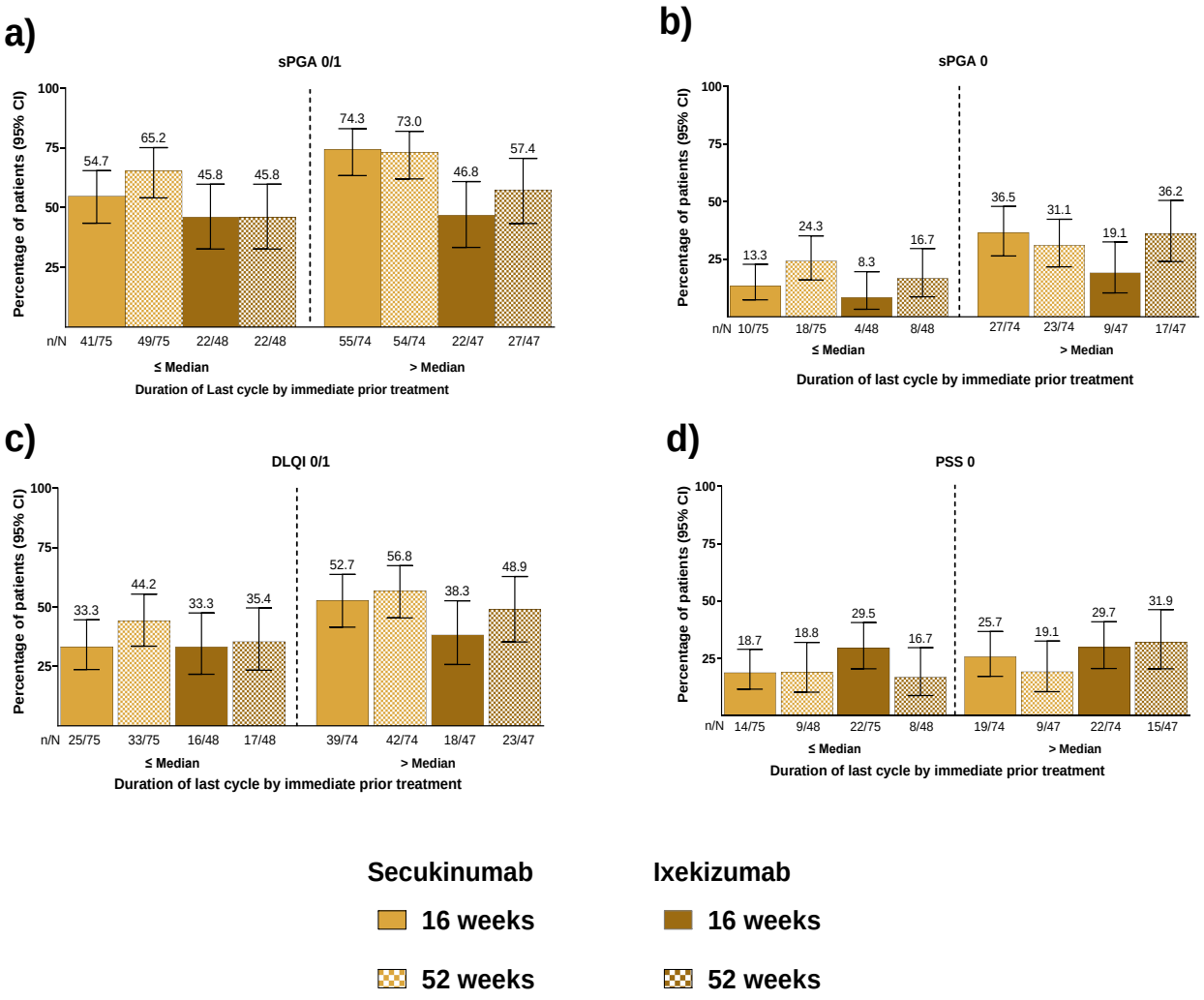
Figure S3. Achievement of National Psoriasis Foundation treat-to-target goals



CI, confidence interval; NPF, National Psoriasis Foundation; T2T, Treat-to-target goal

NPF T2T acceptable goal was defined as body surface area (BSA) response of ≤ 3% or 75% improvement from baseline, and target response as BSA ≤ 1%.

Figure S4. Efficacy stratified by prior treatment duration with secukinumab or ixekizumab. a) sPGA 0/1, b) sPGA 0, c) DLQI 0/1, and d) PSS 0



CI, confidence interval; DLQI, Dermatology Life Quality Index; sPGA, static Physicians Global Assessment; PSS, Psoriasis Symptoms Scale

Table S1. Additional patient eligibility criteria for aIMM

Inclusion criteria
1. Laboratory values meeting the following criteria within the screening period before the first dose of the study drug: Serum aspartate transaminase (AST) < 2 × upper limit of normal (ULN) Serum alanine transaminase (ALT) < 2 × ULN Serum total bilirubin ≤ 2.0 mg/dL, except for patients with isolated elevation of indirect Bilirubin relating to Gilbert syndrome Total white blood cell (WBC) count > 3,000/µL Absolute neutrophil count (ANC) > 1,500/µL Platelet count > 100,000/µL Haemoglobin > 10.0 g/dL (100 g/L) 2. The patient is judged to be in good health, as determined by the investigator, based upon the results of a medical history, physical examination, laboratory profile, and a 12-lead electrocardiogram (ECG) performed during the screening period
Exclusion criteria
1. Patients must not have a history of erythrodermic psoriasis, generalised or localised pustular psoriasis, medication-induced or medication-exacerbated psoriasis, or new onset guttate psoriasis 2. The patient must not have a history of active skin disease other than plaque psoriasis that could interfere with the assessment of plaque psoriasis 3. Patient must not have a history of clinically significant (per investigator's judgement) drug or alcohol abuse within the last six months 4. The patient must not have a history of an allergic reaction or significant sensitivity to constituents of the study drug (and its excipients) and/or other products in the same class 5. Patient must not have had major surgery performed within 12 weeks prior to randomisation or planned during the conduct of the study (e.g., hip replacement, aneurysm removal, stomach ligation) 6. No known active SARS-CoV-2 infection, hepatitis B (HBV), hepatitis C (HCV), human immunodeficiency virus (HIV) infection, or active tuberculosis 7. Active systemic infection/clinically important infection during the last 2 weeks prior to baseline (week 0) visit as assessed by the investigator 8. The patient must not have any of the following medical diseases or disorders: Recent (within the past six months) cerebrovascular accident or myocardial infarction History of an organ transplant that required continued immunosuppression 9. Active or suspected malignancy or history of any malignancy within the last five years except for successfully treated non-melanoma skin cancer (NMSC) or localised carcinoma in situ of the cervix

10. The patient must not have a concurrent clinically significant medical condition other than the indication being studied or any other reason that the investigator determines would interfere with the patient's participation in this study, would make the patient an unsuitable candidate to receive study drug, or would put the patient at risk by participating in the study
11. Patient must not have prior exposure to risankizumab or any IL-23 inhibitors (guselkumab, tildrakizumab, mirikizumab)
12. The patient must not be currently using any approved psoriasis therapy other than secukinumab or ixekizumab for at least six months
13. Patient must not be using topical psoriasis treatments, including but not limited to corticosteroids, anthralin, calcipotriene, topical vitamin D derivatives, retinoids, urea, alpha- or beta-hydroxyl acids, and medicated shampoos (for example those that contain > 3% salicylic acid, corticosteroids, coal tar, or vitamin D3 analogues) for at least two weeks prior to baseline
14. The patient must not have received any live viral or bacterial vaccine within six weeks prior to the first dose of the study drug or expect the need for live vaccine administration during study participation, including at least 140 days (20 weeks or as guided by the local risankizumab label [if approved], whichever is longer) after the last dose of study drug
15. The patient must not have been treated with any investigational drug within 30 days or five half-lives of the drug (whichever is longer) before the first dose of the study drug or currently enrolled in another interventional clinical study.