Supplemental material

Supplemental Table I. Inclusion and exclusion criteria for the study population

Inclusion criteria 1. Nonimmunocompromised patients 18 years of age or older 2. Have ≥3% total body surface area covered with psoriatic plaques 3. Are candidates for phototherapy or systemic therapy 4. Must be diagnosed at least 6 months prior to entering the study 5. Females must be surgically sterile,[a] postmenopausal for >5 years, or using a highly effective form of birth control (<1% failure rate)[b,c] for at least 30 days prior to treatment, with a negative serum pregnancy test at screening 6. Are considered eligible according to the tuberculosis (TB) screening criteria[d]
Exclusion criteria 1. Pregnant, lactating, or planning to become pregnant during the study 2. Younger than 18 years of age 3. Less than 3% body surface involvement of psoriasis 4. Has erythrodermic or only pustular, guttate, or inverse psoriasis 5. History of known or suspected intolerance to any of the ingredients of the test article (histidine, polysorbate 80, and sucrose) 6. Evidence of skin conditions other than psoriasis that would interfere with study-related evaluations of psoriasis 7. Uncontrolled mental illness or active suicidal ideations based on mental health questionnaire of choice 8. Evidence of active infections, such as fevers, chills, and sweats, or history of untreated Lyme disease and active severe infections within 4 weeks before baseline visit 9. Currently being treated with lithium or who may require treatment with lithium during the study 10. A history of listeriosis; untreated active TB; or persistent or active infections requiring hospitalisation or treatment with intravenous (IV) antibiotics, IV antiretrovirals, or IV antifungals within 4 weeks of baseline or oral antibiotics, antivirals, or antifungals for purpose of treating infection within 2 weeks of baseline 11. A history of latent or active granulomatous infection, including histoplasmosis or coccidioidomycosis, prior to baseline 12. Chest radiograph within 3 months prior to the first administration of test article that shows an abnormality suggestive of cardiac abnormality, malignancy, or current active infection, including TB 13. Nontuberculous mycobacterial infection or opportunistic infection (eg, cytomegalovirus, pneumocystosis, aspergillosis) within 6 months prior to baseline 14. History of immunocompromised status (eg, human immunodeficiency virus [HIV]-positive status or other immune-suppressing drug) or a congenital or acquired immunodeficiency, or testing positive for HIV, hepatitis B, and/or hepatitis C during screening procedures 15. Poorly controlled medical condition including, but not limited to, unstable cardiovascular disease, poorly controlled diabetes, recent stroke, history of recurrent infections, or any other condition for which, in the opinion of the investigator, participation in the study would place the patient at risk 16. History of or ongoing drug or alcohol use disorder 17. Known or suspected to be unable to comply with the study protocol, in the opinion of the investigator 18. Currently enrolled in an investigational drug or device study 19. Intends to receive live viral or bacterial vaccination during the study

20. Abnormal clinical laboratory tests according to the following parameters prior to the first dose of test article
    a. Alanine transaminase, aspartate transaminase, or alkaline phosphatase >1.5× the upper limit of normal
    b. Creatinine >1.5 mg/dL (or >133 μmol/L)
    c. Haemoglobin <10 g/dL
    d. Absolute neutrophil count <1500/mm^3
    e. Platelet count <100,000/mm^3
21. Results of a physical examination outside normal limits or outside clinically acceptable limits to the investigator prior to the first dose of test article
22. Has received any of the following within the indicated time period prior to baseline
    a. Biological agent (including monoclonal antibodies, alefacept) within 1 week
    b. Oral antibiotics, antivirals, or antifungals for purpose of treating infection per exclusion criterion #10, within 2 weeks
    c. Antimalarials within 4 weeks
    d. Live viral or bacterial vaccination within 4 weeks
    e. IV antibiotics, IV antiretrovirals, or IV antifungals within 4 weeks of baseline, per exclusion criterion #10
    f. Any investigational agent (biological or nonbiological) or investigational device treatment within 12 weeks
    g. Bacille Calmette-Guerin vaccination within 12 months

[a] Hysterectomy, bilateral tubal ligation (at least 6 months prior to initiation of baseline treatment), or bilateral oophorectomy.

[b] Highly effective forms of birth control are defined as those, alone or in combination, that result in a low failure rate (ie, <1% per year) when used consistently and correctly. These include (1) intrauterine device (copper or hormonal), (2) implantable hormonal contraception, (3) monogamous relationship with a partner who is sterile (eg, vasectomy performed at least 6 months prior to study entry), (4) total abstinence from heterosexual activity that could result in pregnancy, or (5) using one of each of the following: (a) hormonal contraceptives (eg, oral, transdermal, injectable, or vaginal ring) and (b) double barrier methods (ie, male or female condom, diaphragm with spermicidal foam/gel/film/cream/vaginal suppository, cervical cap with spermicides, or contraceptive sponge). Patients who become sexually active or begin to have heterosexual relations with a partner who is not sterile during the study must agree to use a highly effective form of birth control for the duration of the study.

[c] Women of childbearing potential taking hormonal therapy must be on treatment for at least 12 weeks prior to study entry, continued per label, and must not change their dosing regimen during the study.

[d] To be eligible, patients must have a negative QuantiFERON-TB Gold test result within 1 month prior to baseline, with no signs or symptoms suggestive of active TB upon medical history and/or physical examination, and no recent close contact with a person with active TB; or have a positive QuantiFERON-TB Gold test result within 1 month prior to baseline, with active TB ruled out by chest x-ray, no signs or symptoms suggestive of active TB upon medical history and/or physical examination, and no recent close contact with a person with active TB. Patients with a positive QuantiFERON-TB Gold test result must be documented to have started treatment for latent TB prior to or simultaneously with baseline and have negative posterior-anterior and lateral chest x-ray views that show no evidence of active TB as read by a qualified radiologist within 3 months prior to baseline. Patients with a documented history of latent TB with active TB ruled out by chest x-ray, no signs or symptoms suggestive of active TB upon medical history and/or physical examination, and no recent close contact with a person with active TB could participate in the study with documentation of adequate treatment for latent TB within 3 years prior to baseline, or start of treatment for latent TB prior to or simultaneously with baseline, and negative posterior-anterior and lateral chest x-ray views that show no evidence of active TB as read by a qualified radiologist within 3 months prior to baseline; such patients were not required to undergo the QuantiFERON-TB Gold test, and patients with documentation of having completed adequate treatment as described above are not required to initiate additional treatment for latent TB.

Supplemental Table II. Summary of change from baseline in HRQoL assessments through Week 28─LOCF imputation

Mean (SD)	W4 N = 55	W8 N = 55	W12 N = 55	W16 N = 55	W28 N = 55
PGWBI score	4.2 (10.4)	4.1 (12.2)	4.3 (13.5)	5.1 (13.4)	3.3 (12.3)
Anxiety	0.9 (3.5)	0.8 (4.3)	1.1 (4.0)	1.0 (4.1)	0.6 (3.7)
Depressed mood	0.6 (2.1)	0.3 (2.2)	0.5 (2.2)	0.5 (2.4)	−0.1 (2.3)
Positive well-being	0.7 (2.5)	1.0 (2.8)	1.3 (3.3)	1.3 (2.9)	0.8 (2.9)
Self-control	0.1 (2.0)	0.3 (2.3)	0.1 (2.2)	0.3 (2.5)	0 (2.2)
General health	1.0 (2.0)	1.5 (2.3)	1.0 (2.5)	1.4 (2.4)	1.5 (2.2)
Vitality	0.9 (2.5)	0.3 (2.7)	0.3 (3.3)	0.7 (3.1)	0.5 (2.6)
DLQI score	−3.9 (4.3)	−5.9 (5.2)	−6.4 (5.4)	−6.8 (5.5)	−7.6 (5.1)

Data are shown as the mean (SD) for the intention-to-treat population.

DLQI, Dermatology Life Quality Index; HRQoL, health-related quality of life; LOCF, last observation carried forward; PGWBI, Psychological General Well-Being Index; SD, standard deviation; W, week.

Supplemental Table III. Summary of change from baseline in patient-reported symptoms through Week 28─LOCF imputation

Mean (SD)	W4 N = 55	W8 N = 55	W12 N = 55	W16 N = 55	W28 N = 55
Itch-NRS	−1.7 (2.5)	−2.9 (3.1)	−3.0 (3.2)	−3.7 (2.8)	−3.7 (3.1)
Pain-NRS	−1.2 (2.7)	−1.8 (3.1)	−1.8 (2.9)	−2.2 (2.9)	−2.4 (3.0)
Scaling-NRS	−2.6 (2.4)	−4.0 (3.0)	−4.2 (2.9)	−4.5 (2.5)	−4.6 (2.8)

Data are shown as the mean (SD) for the intention-to-treat population.

LOCF, last observation carried forward; NRS, Numerical Rating Scale; SD, standard deviation; W, week.