Supplementary material

Rapid Onset of Action and Quality-of-Life Improvements in Chinese Patients with Plaque Psoriasis Treated with Calcipotriol Plus Betamethasone Dipropionate Aerosol Foam in a Randomized Phase 3 Trial

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Table S1. List of independent ethics committees

Ethical Review Committee of Peking University People's Hospital
Ethics Committee of Sir Run Run Shaw Hospital, Zhejiang University School of Medicine
Medical Ethics Committee of Zhejiang Provincial People's Hospital
Ethics Committee of The First Affiliated Hospital, College of Medicine, Zhejiang University
Ethics Committee of Shanghai Skin Disease Hospital
The Clinical Trial Ethics Committee of The First Hospital of Jiaxing
Ethics Committee of the First Hospital of Jilin University
Human Research Ethics Committee of The Second Affiliated Hospital Zhejiang University School of Medicine
Clinical Medical Research Ethics Committee of the First Affiliated Hospital of Bengbu Medical College
Ethics Committee for Drug Clinical Trials of the First Affiliated Hospital of Wenzhou Medical University
Ethics Committee of Nanyang First People's Hospital
Medical Ethics Committee of The Second Xiangya Hospital of Central South University
Ethics Committee of Guangdong Provincial People's Hospital
The Clinical Trial Ethics Committee of The First Hospital of Hebei Medical University
Inner Mongolia Baogang Hospital Drug Clinical Trial Ethics Committee
The Clinical Trial Ethics Committee of Shenzhen People's Hospital
The Clinical Trial Ethics Committee of Wuxi Second People's Hospital
Ethics Committee of Chongqing Medical University
Medical Ethics Committee of Dermatology Hospital of Southern Medical University
Medical Ethics Committee of Jinan Central Hospital
Medical Ethics Committee of Dermatology Hospital of Shandong First Medical University
Medical Ethic Committee of Northern Jiangsu People's Hospital
Clinical Trial Ethics Committee of The First Affiliated Hospital of Ningbo University
Medical Ethics Committee of The First Affiliated Hospital of Xi'an Jiaotong University
Medical Ethics Committee of Hangzhou Third People's Hospital
Medical Ethics Committee of Union Hospital Tongji Medical College Huazhong University of Science and Technology
Bioethics Committee of Beijing Friendship Hospital affiliated to Capital Medical University
Medical Ethics Committee of Affiliated Hospital of Chengde Medical University
IEC affiliated hospital of JiangSu University
Human Research Ethics Committee of Ningbo Second Hospital
Clinical Trial Ethics Committee of Baotou Central Hospital
Ethics Committee of Chongqing Traditional Chinese Medicine Hospital
Drug Clinical Trial Ethics Committee, Shengli Oilfield Central Hospital
Ethics Committee of Affiliated Hospital of Inner Mongolia Medical University
Ethics Committee of Suining Central Hospital
The Clinical Trial Ethics Committee of Shiyan Renmin Hospital
The Clinical Trial Ethics Committee Cangzhou People's Hospital
Clinical Medical Research Ethics Committee of The First Affiliated Hospital of Anhui Medical University
Ethics Committee on Clinical Trial, West China Hospital of Sichuan University

Table S2. Subject's Global Assessment of disease severity

Clear	No psoriasis symptoms at all.
Very mild	Very slight psoriasis symptoms, does not interfere with daily life.
Mild	Slight psoriasis symptoms, interferes with daily life only occasionally.
Moderate	Definite psoriasis symptoms, interferes with daily life frequently.
Severe	Intense psoriasis symptoms, interferes with or restricts daily life very frequently.

Table S3. Continuous outcome measures at Week 2 and Week 4

	Week	**Cal/BD foam (N=302) LS mean (n) [95% CI]**	**Cal/BD ointment (N=302) LS mean (n) [95% CI]**	**Difference [95% CI]**	***P*-value**
mPASI % cfb	2	-59.9% (n=295) [-63.3;-56.5]	-54.6% (n=294) [-58.0;-51.2]	-5.3% [-9.3%;-1.3%]	0.0100
	4	-74.7% (n=293) [-78.4%;-71.0%]	-70.2% (n=295) [-73.9%;-66.5%]	-4.5% [-8.8%;-0.1%]	0.0430
BSA % cfb	2	-17.6% (n=295) [-21.3%;-13.8%]	-14.8% (n=294) [-18.6%;-11.1%]	-2.8% [-7.2%;1.7%]	0.2264
	4	-40.1% (n=293) [-45.6%;-34.5%]	-35.3% (n=295) [-40.8%;-29.8%]	-4.8% [-11.3%;1.8%]	0.1550
DLQI cfb	2	-3.9 (n=295) [-4.4;-3.5]	-3.7 (n=295) [-4.2;-3.3]	-0.2 [-0.8;0.4]	0.5012
	4	-5.5 (n=293) [-6.0;-4.9]	-5.3 (n=295) [-5.8;-4.7]	-0.2 [-0.8;0.4]	0.5119
total PSI score cfb	2	-6.7 (n=295) [-7.1;-6.2]	-6.4 (n=295) [-6.8;-5.9]	-0.3 [-0.9;0.2]	0.2317
	4	-8.2 (n=293) [-8.7;-7.7]	-7.9 (n=295) [-8.4;-7.5]	-0.3 [-0.8;0.3]	0.3580

The possible range for DLQI is 0 to 30 and for total PSI score 0 to 32, with higher values indicating worse scores.

Data were analyzed as observed, and missing data were handled by multiple imputation (missing at random within treatment arms). LS means and nominal *P*-values were obtained using an analysis of covariance (ANCOVA) model adjusted for baseline PGA and the baseline score corresponding to each outcome measure.

Abbreviations: BSA = body surface area; Cal/BD = 50 µg/g calcipotriol and 0.5 mg/g betamethasone dipropionate; cfb = change from baseline; CI = confidence interval; DLQI = Dermatology Life Quality Index; LS = least square; mPASI = modified Psoriasis Area and Severity Index; N = number of patients in full analysis set; n = number of patients with an observation; PSI = Psoriasis Symptom Inventory.

Table S4. Binary outcome measures at Week 2 and Week 4

	Week	Cal/BD foam (N=302) Responders, n (%)	Cal/BD ointment (N=302) Responders, n (%)	Odds ratio [95% CI]	*P*-value
PGA 0/1, ≥2-point reduction	2	52 (17.2%)	49 (16.2%)	1.1 [0.70;1.69]	0.7125
	4	151 (50.0%)	128 (42.4%)	1.4 [1.01;1.99]	0.0438
mPASI-75	2	84 (27.8%)	76 (25.2%)	1.1 [0.80;1.65]	0.4647
	4	192 (63.6%)	162 (53.6%)	1.5 [1.10;2.12]	0.0108
mPASI-90	2	19 (6.3%)	17 (5.6%)	1.1 [0.58;2.23]	0.7196
	4	100 (33.1%)	74 (24.5%)	1.5 [1.07;2.19]	0.0199
SGA clear/very mild	2	74 (24.5%)	74 (24.5%)	1.0 [0.68;1.46]	0.9767
	4	160 (53.0%)	143 (47.4%)	1.3 [0.91;1.76]	0.1559

Data are shown as binomial proportion of responders (after imputation). Patients who permanently discontinued treatment prior to Week 2/Week 4 or whose scores were missing at Week 2/Week 4 were imputed as non-responders. Odds ratios and nominal *P*-values were obtained using a logistic regression model adjusted for baseline PGA and, for the mPASI- and SGA-based outcome measures, also adjusted for the corresponding baseline score.

Abbreviations: Cal/BD = 50 µg/g calcipotriol and 0.5 mg/g betamethasone dipropionate; CI = confidence interval; mPASI-75 / mPASI-90 = a decrease in modified Psoriasis Area and Severity Index of at least 75% / 90% from baseline; N = number of patients in full analysis set; n = number of responders (observed = after imputation); PGA 0/1 = score of 0 (clear) or 1 (almost clear) according to Physician's Global Assessment of disease severity; SGA = Subject's Global Assessment of disease severity.