Supplementary materials for: Repeated switching between CT-P17 and EU reference adalimumab in patients with moderate-to-severe chronic plaque psoriasis: A randomized, double-blind, active-controlled, phase 3, interchangeability study

Mark G. Lebwohl[1], John Y. Koo[2], Janusz Jaworski[3], Jakub Trefler[4], Stefan Daniluk[5], Anna Dudek[6], Wojciech Baran[7], Witold Owczarek[8], Joanna Kolinek[9], Paweł Brzewski[10], Mariusz Sikora[11], Marek Krogulec[12], SungHyun Kim[13], YunJu Bae[13], DaBee Jeon[13], EunJin Choi[13], JungBin Cha[13], HyunJin Lee[13], SuJin Choi[13], David M. Pariser[14]

[1]Icahn School of Medicine at Mount Sinai, New York, NY, USA;

[2]UCSF Psoriasis and Skin Treatment Center, San Francisco, CA, USA;

[3]Centrum Medyczne Reuma Park, Warsaw, Poland;

[4]Reuma Centrum, Warsaw, Poland;

[5]ClinicMed Daniluk, Nowak Sp.k., Białystok, Poland;

[6]Centrum Medyczne AMED, Warsaw, Poland;

[7]Department of Dermatology, Venereology and Allergology, Wroclaw Medical University, Wroclaw, Poland;

[8]Royalderm/Department of Dermatology, Military Institute of Medicine - National Research Institute, Warsaw, Poland;

[9]Medycyna Kliniczna, Warsaw, Poland;

[10]Specjalistyczny Gabinet Dermatologiczny Aplikacyjno-Badawczy, Krakow, Poland;

[11]National Institute of Geriatrics, Rheumatology and Rehabilitation, Warsaw, Poland;

[12]Rheumatology Clinic NZOZ Lecznica MAK-MED, Nadarzyn, Poland;

[13]Celltrion, Inc., Incheon, Republic of Korea;

[14]Eastern Virginia Medical School and Virginia Clinical Research, Inc., Norfolk, VA, USA.

Correspondence: Dr David M. Pariser, 6160 Kempsville Circle, Suite 200A, Norfolk, VA, 23502, USA

E-mail address: dpariser@pariserderm.com

Telephone number: 757-622-6315

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Table S1. Study centers and institutional review boards/ethics committees.

Country	Study centers	IRB/ IEC
Poland	Centrum Medyczne AMED Warszawa Targowek REUMA CENTRUM, REUMATOLOG WARSZAWA Specjalistyczna Praktyka lekarska Centrum Badan Klinicznych PI-House sp. z o.o. Zdrowie Osteo-Medic S.C. Lidia i Artur Racewicz, Agnieszka i Jerzy Supronik Uniwersytecki Szpital Kliniczny im. Fryderyka Chopina w Rzeszowie WRO MEDICA[a] Specjalistyczny Gabinet Dermatologiczny Aplikacyjno-Badawczy Marek Brzewski, Paweł Brzewski s.c DermoDent Centrum Medyczne Aldona Czajkowska Rafal Rheumatology Clinic NZOZ Lecznica MAK-M	Komisja Bioetyczna przy Dolnoslaskiej Izbie Lekarskiej, ul. Kazimierza Wielkiego 45, Wroclaw, Dolnoslaskie 50-077, Poland Chair: Włodzimierz Bednorz, dr n. med.

	ClinicMed Daniluk, Nowak Spólka Komandytowa Klinika Ambroziak Centrym Medyczne AMED oddzial w Lodzi - Gruszowa 2 MICS Centrum Medyczne T AES - AS - Clinical Best Solutions – Warszawa Dermoklinika-Centrum Medyczne s.c Medycyna Kliniczna Marzena Waszczak-Jeka dermMEDICA Sp. z o.o Royalderm	
Estonia	Clinical Research Centre Ltd Confido Meditsiinikeskus MediTrials OÜ Innomedica Center for Clinical and Basic Research	Ethics committee for medicinal products, Nooruse 1, Tartu, Tartu maakond 50411, Estonia Chair: Katrin Kaarna, MD

[a]Master ethics committee.

IEC, institutional ethics committee; IRB, institutional review board.

Table S2: Percent improvement from baseline in PASI score (safety population).

	Switching (*n* = 172)	**Continuous EU-adalimumab (*n* = 173)**
Week 3		
n	172	172
Mean (SD)	31.81 (23.16)	34.67 (23.52)
Week 7		
n	172	172
Mean (SD)	65.05 (24.00)	65.96 (24.27)
Week 11		
n	172	173
Mean (SD)	83.38 (20.06)	83.12 (17.30)
Week 13		
n	172	173
Mean (SD)	88.17 (17.56)	87.70 (15.60)
Week 17		
n	171	169
Mean (SD)	90.75 (13.79)	89.46 (13.31)
Week 21		
n	168	166
Mean (SD)	91.35 (16.46)	89.49 (16.29)
Week 25		
n	162	164
Mean (SD)	92.42 (17.28)	90.35 (15.55)
Week 27		
n	162	166

	Switching (*n* = 172)	**Continuous EU-adalimumab (*n* = 173)**
Mean (SD)	92.34 (19.24)	91.27 (15.33)

EU-adalimumab: European Union reference adalimumab; PASI: Psoriasis Area and Severity Index; SD: Standard deviation.

Table S3: Proportions of patients achieving PASI 50/75/90/100 (safety population).

	Switching (*n* = 172)	Continuous EU-adalimumab (*n* = 173)
PASI 50		
Week 3	36 (20.9)	43 (24.9)
Week 7	133 (77.3)	132 (76.3)
Week 11	159 (92.4)	166 (96.0)
Week 13	165 (95.9)	166 (96.0)
Week 17	164 (95.3)	166 (96.0)
Week 21	161 (93.6)	160 (92.5)
Week 25	157 (91.3)	157 (90.8)
Week 27	158 (91.9)	159 (91.9)
PASI 75		
Week 3	6 (3.5)	12 (6.9)
Week 7	67 (39.0)	74 (42.8)
Week 11	137 (79.7)	129 (74.6)
Week 13	149 (86.6)	148 (85.5)
Week 17	155 (90.1)	148 (85.5)
Week 21	152 (88.4)	147 (85.0)
Week 25	151 (87.8)	149 (86.1)
Week 27	150 (87.2)	153 (88.4)
PASI 90		
Week 3	3 (1.7)	1 (0.6)
Week 7	29 (16.9)	24 (13.9)
Week 11	89 (51.7)	75 (43.4)
Week 13	105 (61.0)	102 (59.0)
Week 17	120 (69.8)	106 (61.3)
Week 21	128 (74.4)	108 (62.4)
Week 25	128 (74.4)	112 (64.7)
Week 27	128 (74.4)	120 (69.4)

	Switching (*n* = 172)	Continuous EU-adalimumab (*n* = 173)
PASI 100		
Week 3	1 (0.6)	0
Week 7	11 (6.4)	14 (8.1)
Week 11	40 (23.3)	39 (22.5)
Week 13	55 (32.0)	51 (29.5)
Week 17	62 (36.0)	58 (33.5)
Week 21	70 (40.7)	60 (34.7)
Week 25	77 (44.8)	58 (33.5)
Week 27	82 (47.7)	72 (41.6)

Data are presented as *n* (%) of patients. EU-adalimumab: European Union reference adalimumab; PASI: Psoriasis Area and Severity Index; PASI 50/75/90/100, 50/75/90/100% improvement from baseline in Psoriasis Area and Severity Index.

Table S4: Proportions of patients with an sPGA score of 0 or 1 (safety population).

	Switching (*n* = 172)	**Continuous EU-adalimumab (*n* = 173)**
Baseline	0	0
Week 3	23 (13.4)	30 (17.3)
Week 7	89 (51.7)	98 (56.6)
Week 11	137 (79.7)	140 (80.9)
Week 13	148 (86.0)	148 (85.5)
Week 17	154 (89.5)	147 (85.0)
Week 21	150 (87.2)	141 (81.5)
Week 25	147 (85.5)	143 (82.7)
Week 27	146 (84.9)	144 (83.2)

Data are presented as *n* (%) of patients. EU-adalimumab: European Union reference adalimumab; sPGA: Static Physician's Global Assessment.

Table S5: Summary of TEAEs during the lead-in period (safety population).[a]

	Switching (*n* = 172)	**Continuous EU-adalimumab (*n* = 173)**
Patients with ≥1 TEAE	65 (37.8)	65 (37.6)
Related to the study drug	10 (5.8)	20 (11.6)
Grade ≥3 in intensity[b]	5 (2.9)	8 (4.6)
Patients with ≥1 TESAE	1 (0.6)	2 (1.2)
Related to the study drug	0	1 (0.6)
Patients with ≥1 TEAE classified as an ISR	3 (1.7)	5 (2.9)
Related to the study drug	3 (1.7)	5 (2.9)
Patients with ≥1 TEAE classified as infection	34 (19.8)	37 (21.4)
Related to the study drug	5 (2.9)	13 (7.5)

Data are presented as *n* (%) of patients. Note: At each level of summarization, patients were counted once if they reported ≥1 events. Only the most severe event was counted. The event was considered to be related if the relationship was defined as 'possible', 'probable', or 'definite'. [a]No TEAEs led to discontinuation of study drug or death; no TEAEs classified as hypersensitivity (including anaphylaxis), malignancy, myelinating disease, heart failure, or lupus-like syndrome were reported. [b]No Grade 4 or 5 TEAEs were reported. EU-adalimumab: European Union reference adalimumab; ISR: Injection-site reaction; TEAE: Treatment-emergent adverse event; TESAE: Treatment-emergent serious adverse event.

Table S6: TEAEs reported for ≥3% of patients in either treatment group during the switching period (weeks 13–27), by System Organ Class and Preferred Term (safety population).

System Organ Class Preferred Term	Switching (*n* = 172)	Continuous EU-adalimumab (*n* = 173)
Infections and infestations	13 (7.6)	7 (4.0)
Upper respiratory tract infection	7 (4.1)	5 (2.9)
Nasopharyngitis	6 (3.5)	2 (1.2)
Metabolism and nutrition disorders	7 (4.1)	3 (1.7)
Hypertriglyceridemia	7 (4.1)	3 (1.7)
Investigations	4 (2.3)	8 (4.6)
Alanine aminotransferase increased	4 (2.3)	8 (4.6)
General disorders and administration-site conditions	3 (1.7)	6 (3.5)
Injection-site reaction	3 (1.7)	6 (3.5)

Data are presented as *n* (%) of patients. Note: At each level of summarization, patients were counted once if they reported ≥1 events. System Organ Classes and Preferred Terms were coded using the Medical Dictionary for Regulatory Activities, version 26.0. EU-adalimumab: European Union reference adalimumab; TEAE: Treatment-emergent adverse event.

Table S7: Summary of immunogenicity results until week 27 (safety population).

	Switching (*n* = 172)	Continuous EU-adalimumab (*n* = 173)
Overall (day 1–week 27)		
ADA positive	148 (86.0)	159 (91.9)
NAb positive	139 (80.8)	151 (87.3)
Week 0		
ADA positive	6 (3.5)	6 (3.5)
NAb positive	4 (2.3)	4 (2.3)
Week 3		
ADA positive	75 (43.6)	75 (43.4)
NAb positive	50 (29.1)	49 (28.3)
Week 7		
ADA positive	72 (41.9)	72 (41.6)
NAb positive	65 (37.8)	71 (41.0)
Week 11		
ADA positive	105 (61.0)	105 (60.7)
NAb positive	101 (58.7)	103 (59.5)
Week 13		
ADA positive	120 (69.8)	124 (71.7)
NAb positive	115 (66.9)	123 (71.1)
Week 17		
ADA positive	130 (75.6)	137 (79.2)
NAb positive	128 (74.4)	131 (75.7)
Week 21		
ADA positive	129 (75.0)	136 (78.6)
NAb positive	118 (68.6)	126 (72.8)

	Switching (*n* = 172)	Continuous EU-adalimumab (*n* = 173)
Week 25		
ADA positive	123 (71.5)	136 (78.6)
NAb positive	112 (65.1)	126 (72.8)
Week 27		
ADA positive	121 (70.3)	138 (79.8)
NAb positive	109 (63.4)	127 (73.4)

Data are presented as *n* (%) of patients. Note: NAb screening was only conducted on ADA-positive samples. ADA: Anti-drug antibody; EU-adalimumab: European Union reference adalimumab; NAb: Neutralizing antibody.