SUPPLEMENTARY MATERIAL

Certolizumab Pegol for the Treatment of Plaque Psoriasis in Routine Clinical Practice: One-Year Results from the CIMREAL Study

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Assessment of PSO severity

Patient inclusion in this study was based on the physician's assessment during routine examinations confirming the patients' diagnosis status of moderate to severe psoriasis (PSO) as per European guidelines[1] and eligibility for biologic therapy as per locally applicable criteria.

Assessment of PASI

Physicians assessed PASI on patient's body using the following approach:

1. The body was divided into four areas: head, arms, trunk to groin, and legs to the top of buttocks.
2. An average score was assigned for erythema, thickness, and scaling (scored individually) for each of the four body areas, ranging from 0 (clear) to 4 (very marked). These scores for redness, thickness, and scaliness were recorded in the eCRF.
3. The percentage of skin covered with PSO for each body area was determined and converted to a 0 to 6 scale (0 = 0%; 1 = <10%; 2 = 10% to <30%; 3 = 30% to <50%; 4 = 50% to <70%; 5 = 70% to <90%; 6 = 90%–100%).

The PASI at baseline was collected up to 6 weeks before the first dose of CZP.

Assessment of DLQI

The DLQI is a skin disease-specific questionnaire used for adult patients with PSO that describes the overall impact of skin disease on a patient's life as follows: 0–1 = "no effect," 2–5 = "small effect," 6–10 = "moderate effect," 11–20 = "very large effect," and 21–30 = "extremely large effect". The DLQI was collected up to 6 weeks before the first dose of CZP.[1]

Assessment of Self-injection Assessment Questionnaire (SIAQ)

SIAQ, a validated questionnaire assesses patient-perceived advantages and potential limitations of self-injection of subcutaneous medication.

Post-SIAQ (version 2.1) comprises 21 questions with no specific recall period. The post-SIAQ items were grouped into six domains: feelings about injection (3 items), self-image (1 item), self-confidence (3 items), pain and skin reactions during or after the injection (2 questions/8 items), ease of use of the self-injection device (5 items), and satisfaction with self-injection (7 items). Patients responded on a 5-point or 6-point semantic scale, with scores ranging from 0 to 10, indicating a better experience with self-injection.
Responses to the post-SIAQ version 2.1 were obtained during routine clinical practice for self-injecting patients, and the study staff recorded whether the assessment was completed as outlined in the Schedule of Study Assessments.

Safety Assessment

The relevant safety information collected by the treating physician and reported through the routine practice pharmacovigilance system included reports of (serious) adverse events ([S]AEs) and/or (serious) adverse drug reactions ([S]ADRs), including (serious) adverse events of interest. Pregnancy/breastfeeding information was also collected. (Serious) adverse device effects ([S]ADEs) (for patients using ava electronic device only). Device deficiencies (for patients using ava electronic device only).

Supplementary Table 1. Country-wise psoriasis treatment history (SAS)

Country	Variable n (%)	Total
Belgium, n=33	Female	22 (66.7)
	BMI, mean ± SD	25.5 ± 3.9
	Treatment Type, n (%)	
	Any Prior Psoriasis Medications	33 (100)
	Prior Non-Biologic Systemic Agent[a]	31 (93.9)
	Methotrexate	29 (87.9)
	Cyclosporine	24 (72.7)
	Apremilast	2 (6.1)
	Acitretin	1 (3.0)
	Tacrolimus	1 (3.0)
	Prior Biologic Agent	8 (24.2)
Canada, n=36	Females	23 (63.9)
	BMI, mean ± SD	34.0 ± 9.9
	Treatment Type, n (%)	
	Any Prior Psoriasis Medications	36 (100)
	Prior Non-Biologic Systemic Agent[a]	22 (61.1)
	Methotrexate	14 (38.9)
	Apremilast	5 (13.9)
	Acitretin	4 (11.1)
	Prednisone	4 (11.1)
	Cyclosporine	3 (8.3)
	Prior Biologic Agent	17 (47.2)
Czech Republic, n= 25	Females	15 (60.0)
	BMI, mean ± SD	28.6 ± 6.5
	Treatment Type, n (%)	
	Any Prior Psoriasis Medications	24 (96.0)
	Prior Non-Biologic Systemic Agent[a]	23 (92.0)
	Methotrexate	21 (84.0)
	Acitretin	12 (48.0)
	Cyclosporine	9 (36.0)
	Apremilast	5 (20)
	Prior Biologic Agent	5 (20.0)

France, n=20	Females	13 (65.0)
	BMI, mean ± SD	27.7 ± 4.5
	Treatment Type, n (%)	
	Any Prior Psoriasis Medications	20 (100)
	Prior Non-Biologic Systemic Agent[a]	17 (85.0)
	Methotrexate	10 (50.0)
	Apremilast	6 (30.0)
	Cyclosporine	3 (15.0)
	Acitretin	2 (10.0)
	Prior Biologic Agent	10 (50.0)
Germany, n=86	Females	54 (62.8)
	BMI, mean ± SD	27.4 ± 6.2
	Treatment Type, n (%)	
	Any Prior Psoriasis Medications	69 (80.2)
	Prior Non-Biologic Systemic Agent[a]	51 (59.3)
	Methotrexate	27 (31.4)
	Fumaric acid esters	16 (18.6)
	Dimethyl Fumarate	14 (16.3)
	Apremilast	9 (10.5)
	Cyclosporine	5 (5.8)
	Acitretin	1 (1.2)
	Prior Biologic Agent	22 (25.6)
Greece, n=106	Females	67 (63.2)
	BMI, mean ± SD	29.4 ± 6.8
	Treatment Type, n (%)	
	Any Prior Psoriasis Medications	101 (95.3)
	Prior Non-Biologic Systemic Agent[a]	66 (62.3)
	Apremilast	37 (34.9)
	Cyclosporine	23 (21.7)
	Methotrexate	13 (12.3)
	Acitretin	12 (11.3)
	Prior Biologic Agent	46 (43.4)
Italy, n=57	Females	49 (86.0)
	BMI, mean ± SD	26.0 ± 5.3
	Treatment Type, n (%)	
	Any Prior Psoriasis Medications	53 (93.0)
	Prior Non-Biologic Systemic Agent[a]	38 (66.7)
	Cyclosporine	22 (38.6)
	Methotrexate	14 (24.6)
	Dimethyl Fumarate	3 (5.3)
	Acitretin	3 (5.3)

	Apremilast	2 (3.5)
	Prior Biologic Agent	14 (24.6)
Spain, n=17	Females	11 (64.7)
	BMI, mean ± SD	29.1 ± 3.8
	Treatment Type, n (%)	
	Any Prior Psoriasis Medications	14 (82.4)
	Prior Non-Biologic Systemic Agent[a]	7 (41.2)
	Methotrexate	6 (35.3)
	Cyclosporine	6 (35.3)
	Acitretin	1 (5.9)
	Apremilast	1 (5.9)
	Prior Biologic Agent	10 (58.8)
United Kingdom, n=19	Females	18 (94.7)
	BMI, mean ± SD	29.8 ± 9.3
	Treatment Type, n (%)	
	Any Prior Psoriasis Medications	19 (100)
	Prior Non-Biologic Systemic Agent[a]	17 (89.5)
	Methotrexate	14 (73.7)
	Cyclosporine	13 (68.4)
	Fumaric acid esters	3 (15.8)
	Apremilast	2 (10.5)
	Prior Biologic Agent	11 (57.9)

[a]Only the most representative drugs are included in the table. BMI, body mass index; SD, standard deviation.

Supplementary Table 2. Evolution of PASI and DLQI in all countries (FAS; OC)

	Belgium		Czech Republic		Canada		France		Germany		Greece		Italy		Spain		United Kingdom	
	n	**mean**	**n**	**mean**	**n**	**mean**	**n**	**mean**	**n**	**mean**	**n**	**mean**	**n**	**mean**	**n**	**mean**	**n**	**mean**
PASI																		
Baseline	27	**16.7**	23	**18.0**	36	**11.9**	15	**8.9**	82	**12.4**	101	**13.8**	57	**12.7**	15	**11.2**	15	**8.7**
Month 3	29	**5.7**	22	**4.1**	32	**3.0**	14	**3.8**	79	**4.9**	99	**4.9**	41	**5.0**	14	**4.1**	13	**2.6**
Month 12	15	**1.3**	17	**1.5**	26	**1.8**	8	**1.9**	65	**2.8**	95	**1.2**	44	**0.9**	6	**2.0**	7	**5.0**
DLQI																		
Baseline	27	**9.6**	23	**16.9**	36	**15.1**	13	**10.5**	81	**12.8**	101	**12.1**	45	**10.1**	15	**13.1**	14	**11.4**
Month 3	19	**4.6**	22	**6.0**	31	**6.3**	12	**4.6**	80	**5.9**	98	**5.8**	33	**5.4**	13	**7.5**	14	**7.6**
Month 12	14	**1.3**	17	**1.7**	26	**3.8**	7	**1.7**	64	**3.0**	95	**1.4**	36	**1.8**	6	**3.2**	6	**9.0**

DLQI, Dermatology Life Quality Index; FAS, full analysis set, OC, observed case; PASI, Psoriasis Area and Severity Index.

Supplementary Table 3. PASI and DLQI outcomes in subgroup populations (OC)

Subgroup, n/N (%)	**PASI 75**		**PASI 90**		**DLQI (0/1)**	
	3 months	12 months	3 months	12 months	3 months	12 months
Sex						
Male	49/110 **(44.5)**	70/92 **(76.1)**	23/110 **(20.9)**	47/92 **(51.2)**	37/109 **(33.9)**	63/92 **(68.5)**
Female	101/223 **(45.3)**	148/191 **(77.5)**	55/223 **(24.7)**	113/191 **(59.2)**	55/214 **(25.7)**	99/182 **(54.4)**
Biological treatment status						
Bionaïve	102/214 **(47.7)**	143/180 **(79.4)**	53/214 **(24.8)**	104/180 **(57.8)**	62/208 **(29.8)**	100/177 **(56.5)**
Biologic experienced	48/119 **(40.3)**	75/103 **(72.8)**	25/119 **(21.0)**	56/103 **(54.4)**	30/115 **(26.1)**	62/97 **(63.9)**
Disease severity at Baseline						
PASI and DLQI ≤ 10	22/62 **(35.5)**	30/51 **(58.8)**	17/62 **(27.4)**	22/51 **(43.1)**	24/63 **(38.1)**	34/51 **(66.7)**
PASI and DLQI > 10	124/266 **(46.6)**	185/226 **(81.9)**	57/266 **(21.4)**	135/226 **(59.7)**	68/260 **(26.2)**	128/222 **(57.7)**
Comorbidities						
With comorbidities	71/145 **(49.0)**	95/120 **(79.2)**	38/145 **(26.2)**	65/120 **(54.2)**	37/109 **(33.9)**	63/92 **(68.5)**
Without comorbidities	79/188 **(42.0)**	123/163 **(75.5)**	40/188 **(21.3)**	95/163 **(58.3)**	55/214 **(25.7)**	99/182 **(54.4)**
Maintenance dose at baseline						

200 mg Q2W	112/242 **(46.3)**	156/203 **(76.8)**	63/242 **(26.0)**	117/203 **(57.6)**	67/231 **(29.8)**	112/195 **(56.5)**
400 mg Q2W	38/91 **(41.8)**	61/80 **(77.5)**	15/91 **(16.5)**	43/80 **(53.8)**	25/92 **(27.2)**	50/79 **(63.3)**

DLQI: Dermatology Life Quality Index; OC: observed case; PASI: Psoriasis Area Severity Index; Q2W: every two weeks.

Reference(s):

Reference

1. Hongbo Y, Thomas CL, Harrison MA, et al. Translating the science of quality of life into practice: What do dermatology life quality index scores mean? *J Invest Dermatol* 2005; **125**:659-64.