Real-world efficacy and safety of apremilast in Belgian patients with psoriatic arthritis: Results from the prospective observational APOLO study

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Supplementary materials

Table S1. Concomitant medications for psoriatic arthritis at inclusion and during the study (Safety Analysis Set; N = 106).

Concomitant medications for PsA	At enrolment	During the study
Patients with ≥1 concomitant PsA treatment, n (%)	68 (64.2)	29 (27.4)
csDMARDs, n (%)	41 (38.7)	10 (9.4)
Methotrexate	27 (25.5)	7 (6.6)
Leflunomide	10 (9.4)	2 (1.9)
Sulfasalazine	8 (7.5)	1 (0.9)
bDMARDs, n (%)	-	1 (0.9)
Ustekinumab	-	1 (0.9)
NSAIDs, n (%)	28 (26.4)	14 (13.2)
Etoricoxib	7 (6.6)	3 (2.8)
Celecoxib	1 (0.9)	-
Ibuprofen	4 (3.8)	2 (1.9)
Naproxen	3 (2.8)	2 (1.9)
Ketoprofen	1 (0.9)	1 (0.9)
Diclofenac	7 (6.6)	2 (1.9)
Meloxicam	3 (2.8)	1 (0.9)
Piroxicam	1 (0.9)	-
Buprenorphine	1 (0.9)	-
Nabumetone	1 (0.9)	-
Oxaprozin	-	1 (0.9)
Arthrotec	-	1 (0.9)
Pregabalin	-	1 (0.9)
Unspecified herbal and traditional medicine (*Symphytum officinale* root)	1 (0.9)	-
Corticosteroids	21 (19.8)	12 (11.3)
Methylprednisolone	12 (11.3)	8 (7.5)
Prednisolone	6 (5.7)	2 (1.9)
Prednisone	2 (1.9)	1 (0.9)
Corticosteroids, combinations for treatment of acne (Methylprednisolone)	1 (0.9)	-
Diprospan	-	2 (1.9)
Others	6 (5.7)	-

Folic acid	3 (2.8)	-
Paracetamol	4 (3.8)	1 (0.9)
Ultracet	1 (0.9)	-
Tramadol	1 (0.9)	2 (1.9)

bDMARDs, biologic disease-modifying anti rheumatic drugs; csDMARDs, conventional synthetic disease-modifying anti rheumatic drugs; NSAIDs, non-steroidal anti-inflammatory drugs; PsA, psoriatic arthritis.

Table S2a: PsARC Response at Month 6 – SAF

Outcome	**SAF (N=106)**
PsARC response, n (%)	
Yes	32 (30.2)
No	17 (16.0)
Missing data	57 (53.8)
PsARC response rate in patients with non-missing data, n (%); *n*=49	32 (65.3)

n=number of subjects in each category. PsARC: Psoriatic Arthritis Response Criteria; SAF, Safety Analysis Set

Table S2b: PsARC Components – SAF

	Apremilast initiation	**Month 3**	**Month 6**	**Month 9**	**Month 12**
68-joint count					
n	***96***	***66***	***63***	***27***	***26***
Median	10	3	3	5	2
[Min-max]	[0-61]	[0-55]	[0-50]	[0-30]	[0-19]
66-joint count					
n	***96***	***66***	***63***	***27***	***26***
Median	6	2	1	2	0
[Min-max]	[0-31]	[0-25]	[0-13]	[0-12]	[0-17]
PGA, n (%)					
n	***90***	***60***	***59***	***26***	***23***
1	5 (5.6)	16 (26.7)	22 (37.3)	12 (46.2)	12 (52.2)
2	10 (11.1)	25 (41.7)	16 (27.1)	2 (7.7)	4 (17.4)
3	36 (40.0)	12 (20.0)	14 (23.7)	8 (30.8)	4 (17.4)
4	34 (37.8)	6 (10.0)	7 (11.9)	3 (11.5)	3 (13.0)
5	5 (5.6)	1 (1.7)	0 (0.0)	1 (3.8)	0 (0.0)
Missing, n	11	16	9	7	7
PtGA, n (%)					
n	***94***	***64***	***56***	***22***	***25***
1	1 (1.1)	6 (9.4)	11 (19.6)	5 (22.7)	7 (28.0)
2	13 (13.8)	16 (25.0)	15 (26.8)	7 (31.8)	4 (16.0)
3	34 (36.2)	22 (34.4)	18 (32.1)	5 (22.7)	10 (40.0)
4	35 (37.2)	14 (21.9)	10 (17.9)	3 (13.6)	3 (12.0)
5	11 (11.7)	6 (9.4)	2 (3.6)	2 (9.1)	1 (4.0)
Missing, n	7	12	12	11	5

n=number of subjects with non-missing data; percentage calculated from the number of patients with non-missing data.
PGA: Physician Global Assessment; PsARC: Psoriatic Arthritis Response Criteria; PtGA: Patient Global Assessment; SAF: Safety Analysis Set.

Table S3: PsARC Components - REF

	Apremilast initiation	**Month 3**	**Month 6**	**Month 9**	**Month 12**
68-joint count					
n	***65***	***44***	***58***	***24***	***25***
Median	10	3	3	3	2
[Min-max]	[3-61]	[0-41]	[0-50]	[0-30]	[0-18]
66-joint count					
n	***65***	***44***	***58***	***24***	***25***
Median	6	1	1	1	0
[Min-max]	[0-29]	[0-25]	[0-13]	[0-12]	[0-17]
PGA, n (%)					
n	***61***	***39***	***54***	***23***	***21***
1	5 (8.2)	13 (33.3)	22 (40.7)	12 (52.2)	12 (57.1)
2	5 (8.2)	17 (43.6)	15 (27.8)	2 (8.7)	3 (14.3)
3	24 (39.3)	7 (17.9)	11 (20.4)	6 (26.1)	4 (19.0)
4	25 (41.0)	2 (5.1)	6 (11.1)	3 (13.0)	2 (9.5)
5	2 (3.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Missing, n	8	11	8	7	7
PtGA, n (%)					
n	***63***	***40***	***51***	***20***	***24***
1	1 (1.6)	3 (7.5)	11 (21.6)	4 (20.0)	7 (29.2)
2	8 (12.7)	12 (30.0)	13 (25.5)	7 (35.0)	4 (16.7)
3	24 (38.1)	17 (42.5)	16 (31.4)	5 (25.0)	9 (37.5)
4	23 (36.5)	6 (15.0)	9 (17.6)	2 (10.0)	3 (12.5)
5	7 (11.1)	2 (5.0)	2 (3.9)	2 (10.0)	1 (4.2)
Missing, n	6	10	11	10	4

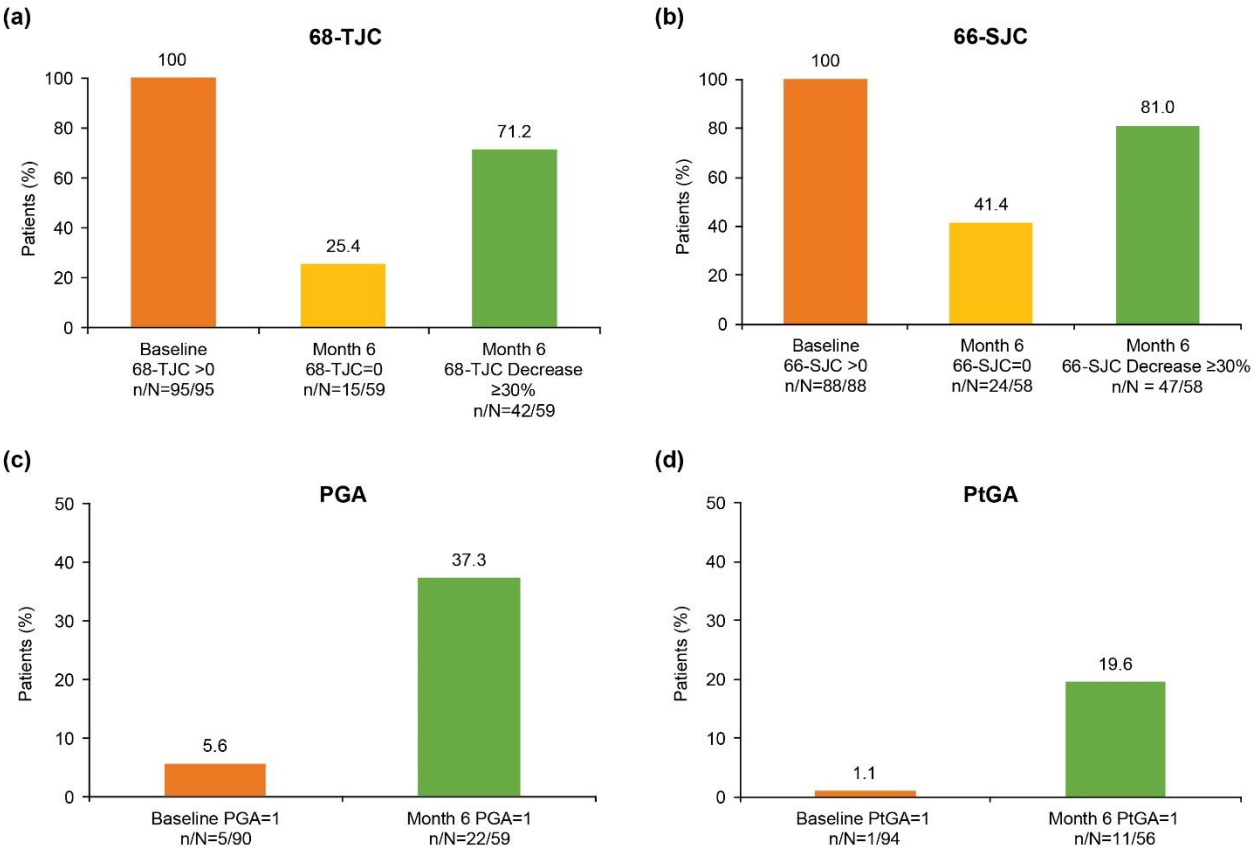
n=number of subjects with non-missing data; percentage calculated from the number of patients with non-missing data.
PGA: Physician Global Assessment; PsARC: Psoriatic Arthritis Response Criteria; PtGA: Patient Global Assessment; REF: Reference set.

Table S4: PsAID12 and HAQ-DI subscores

	Apremilast initiation	Month 3	Month 6
PsAID12 subscores[a] (PsAID12 >4 at baseline)	**n = 60**	**n = 36**	**n = 47**
Pain	7.1 (1.5)	5.1 (2.2)	4.8 (2.4)
Fatigue	7.2 (1.9)	6.1 (2.1)	5.4 (2.3)
Skin problems	5.7 (2.8)	4.0 (3.0)	4.0 (2.8)
Work and/or leisure activities	6.9 (2.1)	6.0 (2.5)	4.6 (2.8)
Functional capacity	6.8 (2.1)	5.7 (2.4)	4.7 (2.7)
Discomfort	6.9 (1.9)	5.5 (2.2)	4.6 (2.7)
Sleep disturbance	6.0 (2.6)	5.0 (3.0)	4.4 (2.9)
Coping	6.3 (1.8)	5.1 (2.6)	4.0 (2.5)
Anxiety/fear and uncertainty	5.4 (2.7)	4.9 (3.1)	3.8 (2.9)
Embarrassment and/or shame	4.9 (3.3)	4.1 (3.1)	3.3 (2.9)
Social participation	5.6 (2.7)	4.3 (3.0)	3.9 (2.7)
Depression	4.1 (2.9)	3.9 (3.1)	2.7 (2.8)
HAQ-DI domain scores[a]	**n = 67**	**n = 43**	**n = 54**
Dressing and grooming	1.5 (0.7)	1.0 (0.6)	0.9 (0.7)
Arising	1.3 (0.8)	1.0 (0.7)	0.9 (0.7)
Eating	1.5 (0.8)	1.1 (0.9)	0.8 (0.9)
Walking	1.1 (0.8)	1.0 (0.9)	0.8 (0.8)
Hygiene	1.4 (0.8)	1.3 (1.0)	0.9 (0.9)
Reach	1.6 (0.8)	1.3 (0.9)	1.2 (0.9)
Grip	1.6 (0.8)	1.2 (0.8)	1.0 (0.9)
Activities	1.7 (0.8)	1.4 (0.8)	1.3 (0.9)

[a]Values represent mean (SD). *n*=number of subjects with non-missing data under specific category. HAQ-DI: Health Assessment Questionnaire Disability Index; PsAID12: Psoriatic Arthritis Impact of Disease 12; SD: Standard deviation.

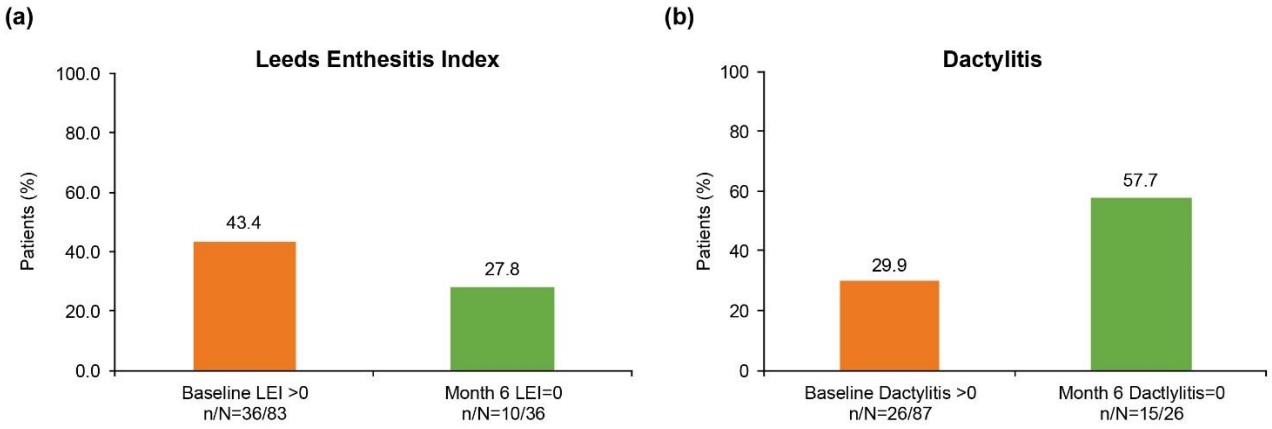
Figure S1. Effect of apremilast on PsARC subscores at month 6 (SAF)



n=number of patients with desired outcome of interest; N=number of patients with non-missing data available at that timepoint.

66-SJC: 66-joint count for swelling; 68-TJC: 68-joint count for pain/tenderness; PGA: Physician Global Assessment; PsARC: Psoriatic Arthritis Response Criteria; PtGA: Patient Global Assessment; SAF: Safety Analysis Set.

Figure S2. Effect of apremilast on enthesitis and dactylitis at 6 months of treatment (SAF)

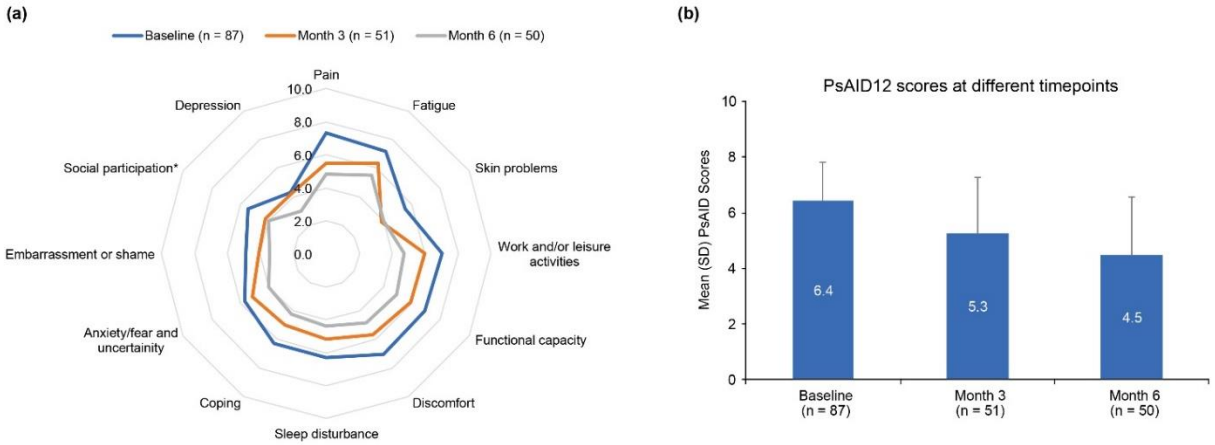


n=number of patients with desired outcome of interest at specific timepoint.

N=number of patients with non-missing data at that timepoint

LEI: Leeds Enthesitis Index; SAF: Safety Analysis Set.

Figure S3. Change in PsAID12 scores among patients with global score >4 at apremilast initiation a) Individual scores and b) Overall score (SAF)



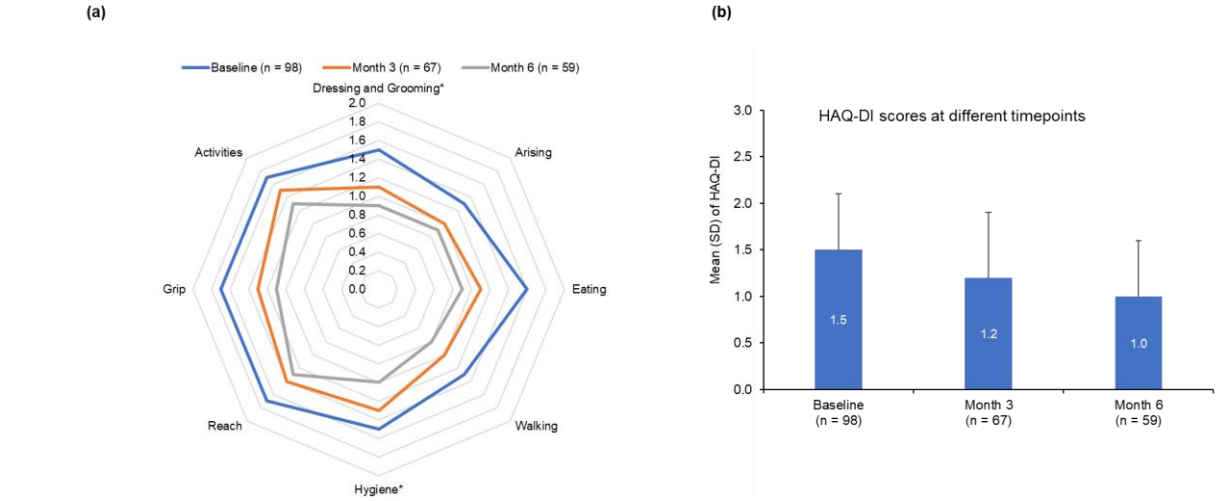
*Data were available for only 49 patients at 6 months for social participation domain.

n=number of subjects with non-missing data at each timepoint.

PsAID12 ranges from 0-10, 10=worst health score

PsAID12: Psoriatic Arthritis Impact of Disease 12; SAF: Safety Analysis Set; SD: Standard deviation.

Figure S4. Change in HAQ-DI a) Individual scores and b) Overall score (SAF)



*Data were available for only 66 and 65 patients at month 3 for dressing and grooming and hygiene domains, respectively.

HAQ-DI: Health Assessment Questionnaire Disability Index; SAF: Safety Analysis Set; SD: Standard deviation.