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Real-World Effectiveness and Tolerability of Apremilast in Psoriatic Arthritis in Germany: Results from LAPIS-PsA

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Supplementary Results

Summary of Individual Treatment-Related SAEs

The SAE “drug ineffective” occurred in 7 patients and treatment with apremilast was permanently discontinued as a result. All were suspected by the investigator to be related to apremilast treatment but only one was judged as possible by Celgene/Amgen.

Worsening of PsA occurred in 5 patients, leading to hospitalization in 3 patients, all of whom recovered. No action was taken with apremilast in 2 of the patients and treatment was discontinued in the other 3 as a result of the event. All were suspected by the investigator to be related to apremilast treatment and 3 were judged as possibly related by Celgene/Amgen.

Diarrhea occurred in 3 patients, 2 of whom were hospitalized due to the event. All patients recovered and all patients discontinued treatment due to the SAE. All were suspected by the investigator to be related to apremilast treatment and judged as possibly related by Celgene/Amgen.

Increased psoriasis skin activity was reported in 2 patients, one of whom was hospitalized. Treatment was discontinued in both patients. The outcome is not known for either. Both were suspected by the investigator to be related to apremilast treatment but only one was suspected to be related by Celgene/Amgen.

One 73-year-old female patient was hospitalized for grade 2 intolerance to apremilast 10 days after starting treatment. SAEs of diarrhea and vomiting were also reported in this patient. Treatment was discontinued and the patient recovered after 6 days. The event was suspected by the investigator and Celgene/Amgen to be related to apremilast treatment.

One 49-year-old patient underwent an arthroscopic synovectomy of the lower knee approximately 6 months after starting therapy. Treatment with apremilast was discontinued. The event outcome is recorded as unrecovered. The association with apremilast was judged to be related by the investigator and Celgene/Amgen. Severe abdominal pain occurred in a 52-year-old patient 3 months after starting therapy. The patient also experienced an SAE of diarrhea. Treatment was discontinued and both events resolved after 20 days. The event was suspected by the investigator to be related to apremilast treatment and judged as possibly related by Celgene/Amgen.

Abducens nerve palsy (NCI-CTC grade 2) occurred in a 78-year-old patient with comorbid hypertension approximately 6 months after starting treatment. The

patient was admitted to the hospital and recovered after 3 days. No action was taken with apremilast. The connection with apremilast was initially assessed as not suspected by the investigator and as unrelated by Celgene/Amgen. The causality was later reassessed by the investigator as suspected and by Celgene/Amgen as possible.

Bladder cancer recurrence occurred in a 57-year-old patient. Relevant comorbidities stated were status after bladder cancer (2010), relapse (2011) and organ-preserving surgery, depression, smoking until 2010, and working with metals. The patient was currently in his second relapse. On January 31, 2017 (3 months after starting apremilast) the patient was suspected of having a recurrence of bladder cancer (NCI-CTC grade 2). After biopsy, the patient underwent transurethral resection of the bladder and right double pigtail stent on February 27, 2017. The event outcome was reported as unrecoverable. The patient was discharged on March 2, 2017. In April 2017, cystoscopy showed papillary resection of the right ostium. No action was taken with apremilast. The connection with apremilast was assessed as suspected by the investigator and Celgene/Amgen. One 57-year-old patient with latent hypothyroidism was hospitalized with grade 2 pneumonia 5 months after starting apremilast. No action was taken with apremilast and the patient recovered from the event after 5 days. The connection with apremilast was considered suspected by the investigator and possible by Celgene/Amgen. Depression occurred in a 56-year-old patient 2 months after starting treatment with apremilast which resulted in treatment discontinuation and was reported as unrecovered. The connection with apremilast was considered suspected by the investigator and possible by Celgene/Amgen.

Osteoarthritis occurred in a 55-year-old patient 3 months after starting apremilast. No action was taken with apremilast the event is reported as recovered. The association with apremilast was assessed as related by the investigator and unrelated by Celgene/Amgen.

Type II diabetes was reported in a 27-year-old patient grade 2 obesity (BMI 40.77). No action was taken with apremilast. The connection with apremilast was considered suspected by the investigator and possible by Celgene/Amgen.

Table S1. Outcomes in LAPIS-PsA study of the effectiveness and tolerability of apremilast for the treatment of PsA in German clinical practice.

Outcome	Scale	Time Frame
Primary		
PhGA, reduction in score (ie, improvement) by at least 1 point relative to baseline	0 (no symptoms) to 4 (very strong symptoms)	Month ~7
Secondary		
PtGA, reduction in score (ie, improvement) by at least 1 point relative to baseline	0 (excellent) to 4 (very bad)	Month ~1, ~4, ~7, ~10, ~13
PhGA, reduction in score (ie, improvement) by at least 1 point relative to baseline	0 (no symptoms) to 4 (very strong symptoms)	Month ~1, ~4, ~10, ~13
TJC-68, mean values and percent change from baseline	0–68 (higher values indicate more tenderness)	Month ~1, ~4, ~7, ~10, ~13
SJC-66, mean values and percent change from baseline	0–66 (higher values indicate more swelling)	Month ~1, ~4, ~7, ~10, ~13
Percentage of patients with resolution of dactylitis (ie, dactylitis count=0)	0–20	Month ~1, ~4, ~7, ~10, ~13
LEI, mean score	0 (no tender entheses) to 6 (6 tender entheses)	Month ~1, ~4, ~7, ~10, ~13
Percentage BSA involvement	0% to 100%	Month ~1, ~4, ~7, ~10, ~13
Pain VAS, mean values and change from baseline	0–100 (higher values indicate worse pain)	Month ~1, ~4, ~7, ~10, ~13
Pruritus VAS, mean values and change from baseline	0–100 (higher values indicate worse pruritus)	Month ~1, ~4, ~7, ~10, ~13
PsAID-9	0–10 (higher values indicate greater impact of disease)	Months ~1, ~4, ~7, and ~13
PPQ	N/A	Months ~7 and ~13
FFbH	0 to 100% (higher percentages indicate greater functioning capacity	Months ~1, ~4, ~7, and ~13
Exploratory		
MDA	0–7 items (≥5 of 7=MDA)	Months ~1, ~4, ~7, and ~13
Post hoc		
PhGA, proportion of patients in each category	0 (no symptoms) to 4 (very strong symptoms)	Months ~1, ~4, ~7, ~10, and ~13
PtGA, proportion of patients in each category	0 (excellent) to 4 (very bad)	Months ~1, ~4, ~7, ~10, and ~13

HAQ-DI, mean score	0 (without any difficulty) to 3 (unable to do)	Months ~1, ~4, ~7, ~10, and ~13
Safety		
Adverse events	N/A	Month ~25

BSA, body surface area; FFbH, Hannover Functional Ability Questionnaire; HAQ-DI, Health Assessment Questionnaire-Disability Index; LEI, Leeds Enthesitis Index; MDA, minimal disease activity; N/A, not applicable; PhGA, Physician's Global Assessment; PPQ, Patient Preference Questionnaire; PsAID-9, Psoriatic Arthritis Impact of Disease 9-item; PtGA, questionnaire; PtGA, Patient Global Assessment; SJC-66, swollen joint count; TJC-68, tender joint count; VAS, visual analog scale.

Table S2. Previous therapies in patients with PsA receiving apremilast in German clinical practice.

	FAS N=418
Previous PsA therapies, n (%)	
Conventional systemic	397 (95.0)
Methotrexate	362 (86.6)
Leflunomide	136 (32.5)
Glucocorticosteroids	125 (29.9)
Sulfasalazine	77 (18.4)
Cyclosporine	22 (5.3)
Azathioprine	3 (0.7)
Other	25 (6.0)
Biologic	108 (25.8)
Adalimumab	59 (14.1)
Etanercept	47 (11.2)
Golimumab	29 (6.9)
Secukinumab	15 (3.6)
Certolizumab pegol	14 (3.3)
Infliximab	12 (2.9)
Ustekinumab	10 (2.4)
Other	5 (1.2)
Previous psoriasis therapies, n (%)	
Conventional systemic	155 (37.1)
Methotrexate	139 (33.3)
Glucocorticosteroids	27 (6.5)
Leflunomide*	24 (5.7)
Sulfasalazine*	9 (2.2)
Cyclosporine	6 (1.4)
Other	3 (0.7)
Fumaric acid esters[†]	27 (6.5)
Biologic	34 (8.1)
Adalimumab	15 (3.6)
Etanercept	14 (3.3)
Golimumab	9 (2.2)
Certolizumab pegol	4 (1.0)
Infliximab	4 (1.0)
Ustekinumab	4 (1.0)
Secukinumab	3 (0.7)
Other	3 (0.7)
Topical therapies	90 (21.5)
Phototherapy	38 (9.1)

FAS, full analysis set; PsA, psoriatic arthritis.
*Leflunomide and sulfasalazine are conventional systemic therapies for rheumatoid arthritis/arthritic diseases.
[†]Not counted in the conventional systemic category.

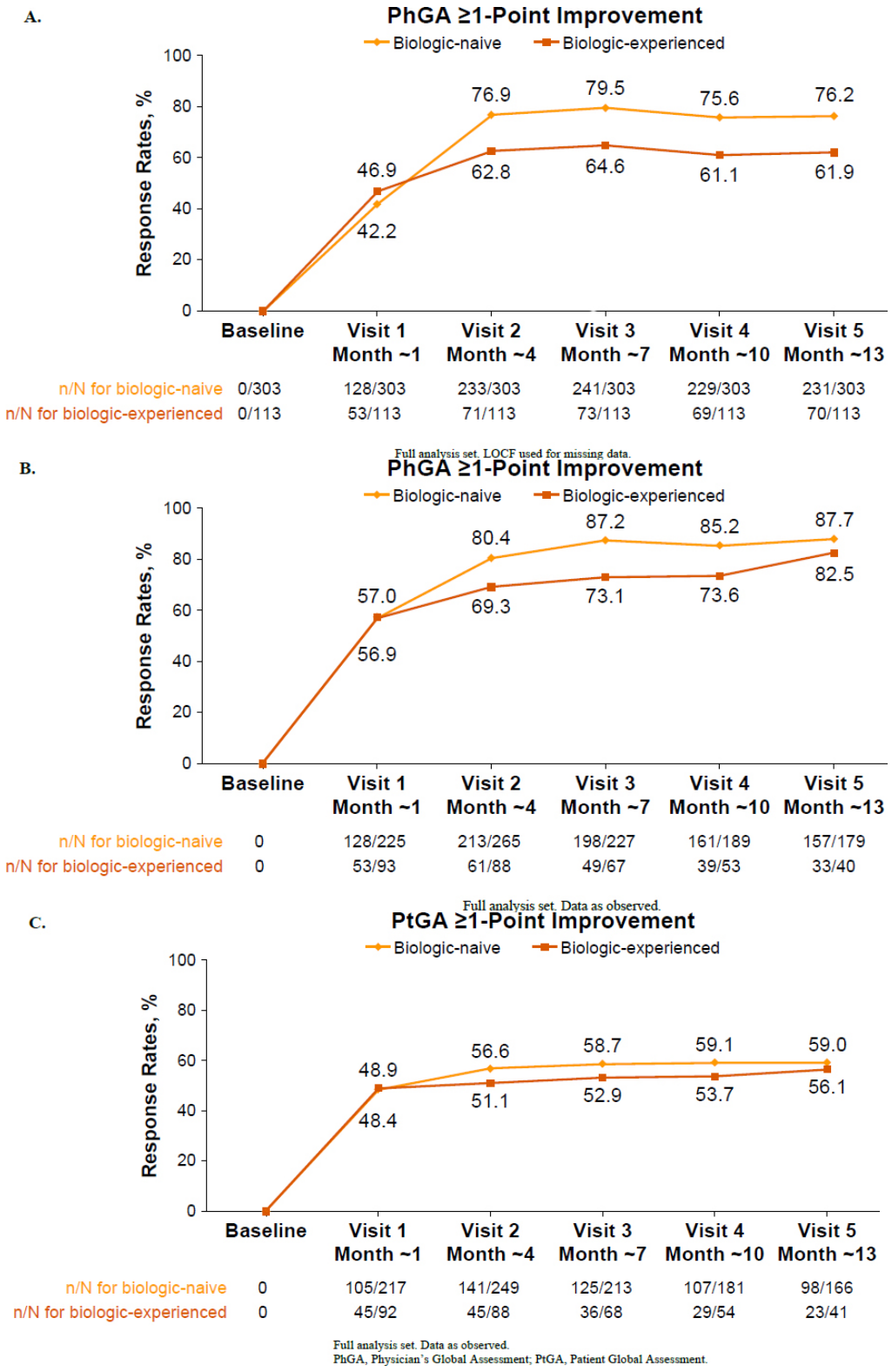
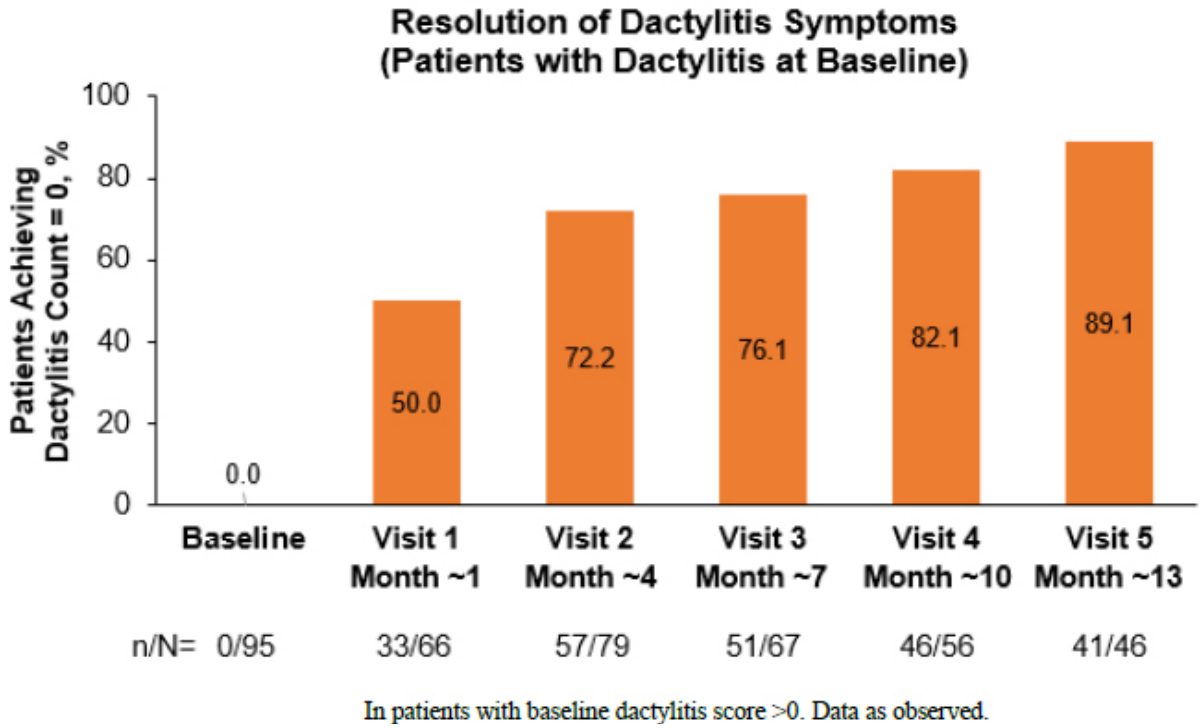


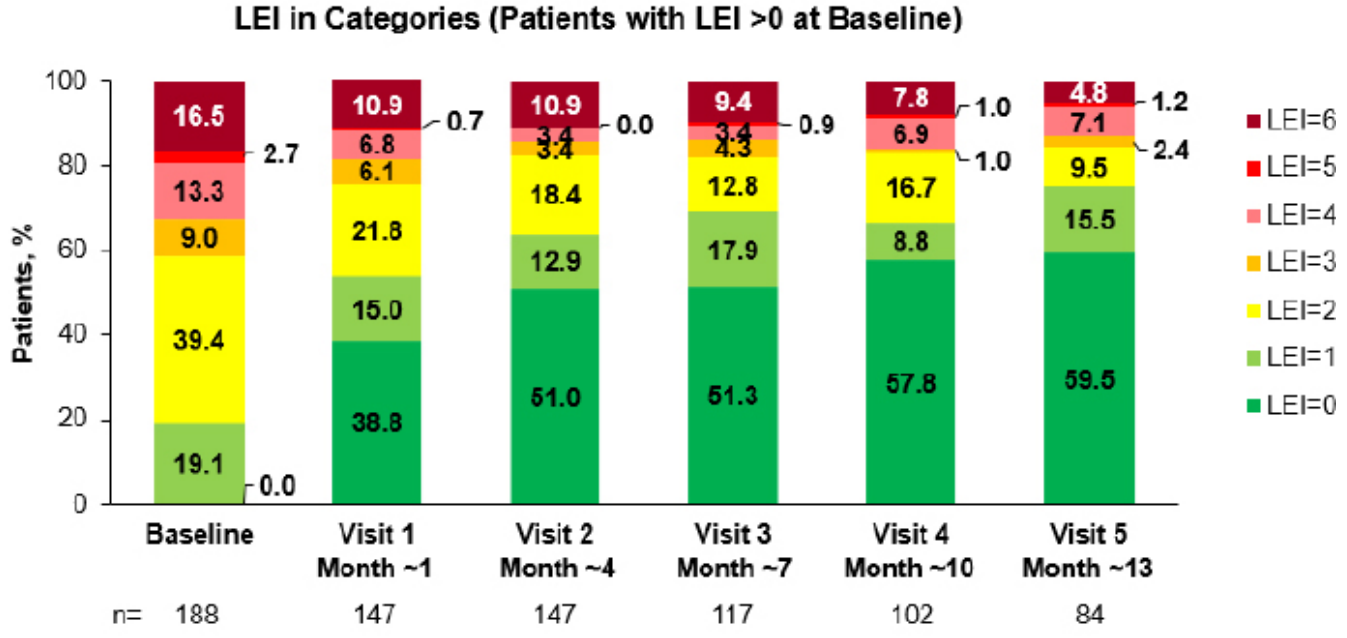
Fig. (S1). Proportions of patients achieving ≥1-point improvement in **A**) PhGA (LOCF), **B**) PhGA (data as observed), and **C**) PtGA (data as observed) over time summarized by prior use of biologic therapy.

A.



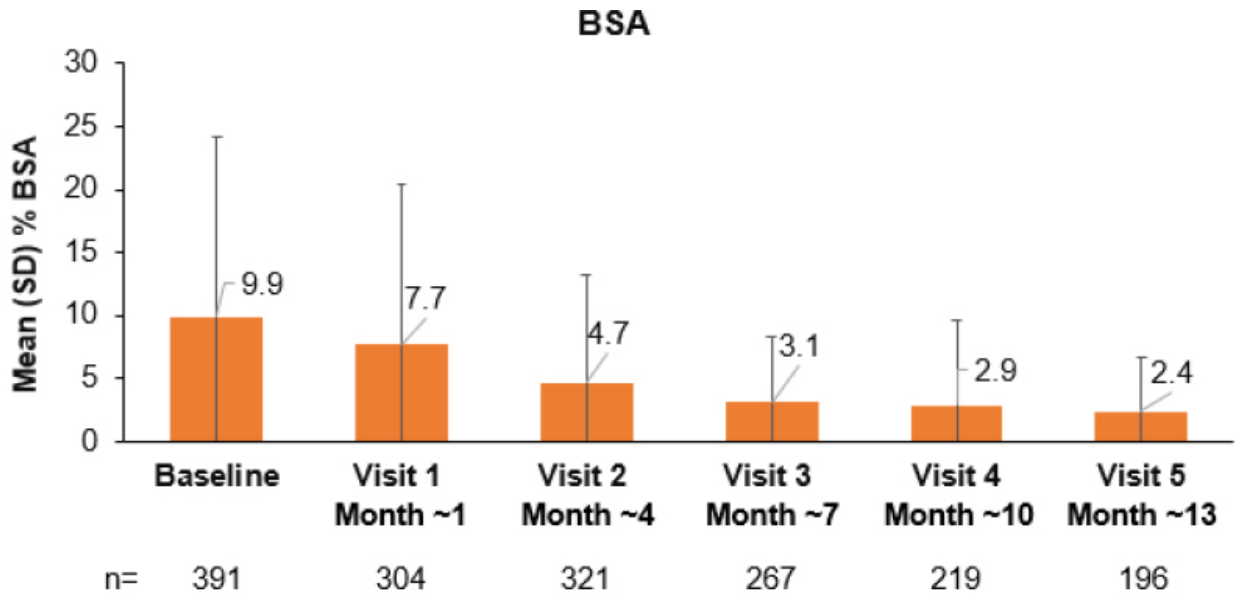
In patients with baseline dactylitis score >0. Data as observed.

B.



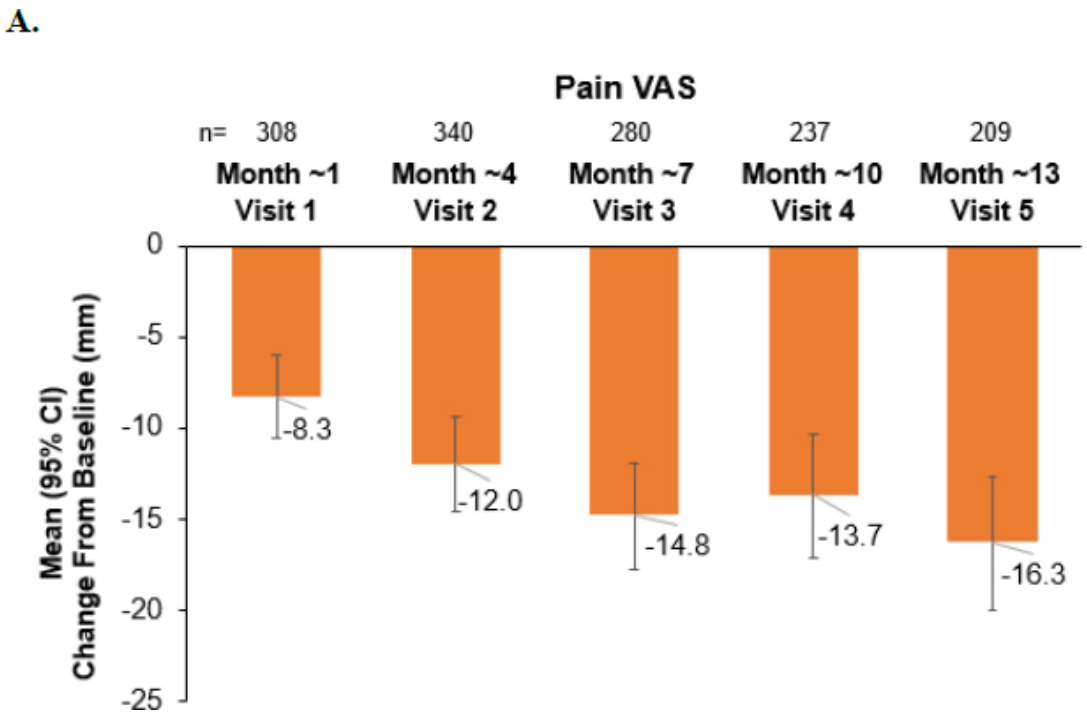
In patients with baseline LEI >0. Data as observed.
LEI, Leeds Enthesitis Index; PsA, psoriatic arthritis.

Fig. (S2). Dactylitis and enthesitis over time in patients with PsA receiving apremilast in German clinical practice.



Full analysis set. Data as observed.
BSA, body surface area; PsA, psoriatic arthritis; PsO, psoriasis; SD, standard deviation.

Fig. (S3). Skin involvement was measured by BSA affected by PsO over time in patients with PsA receiving apremilast in German clinical practice.



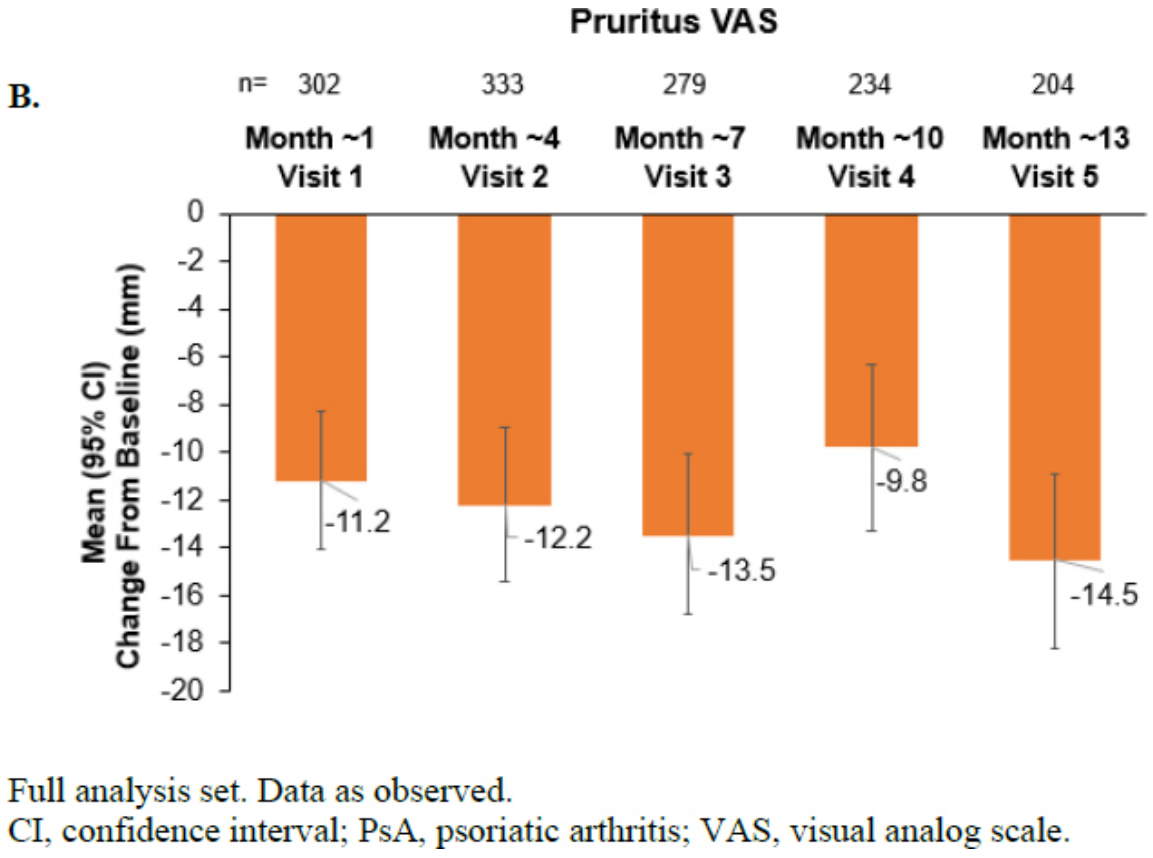
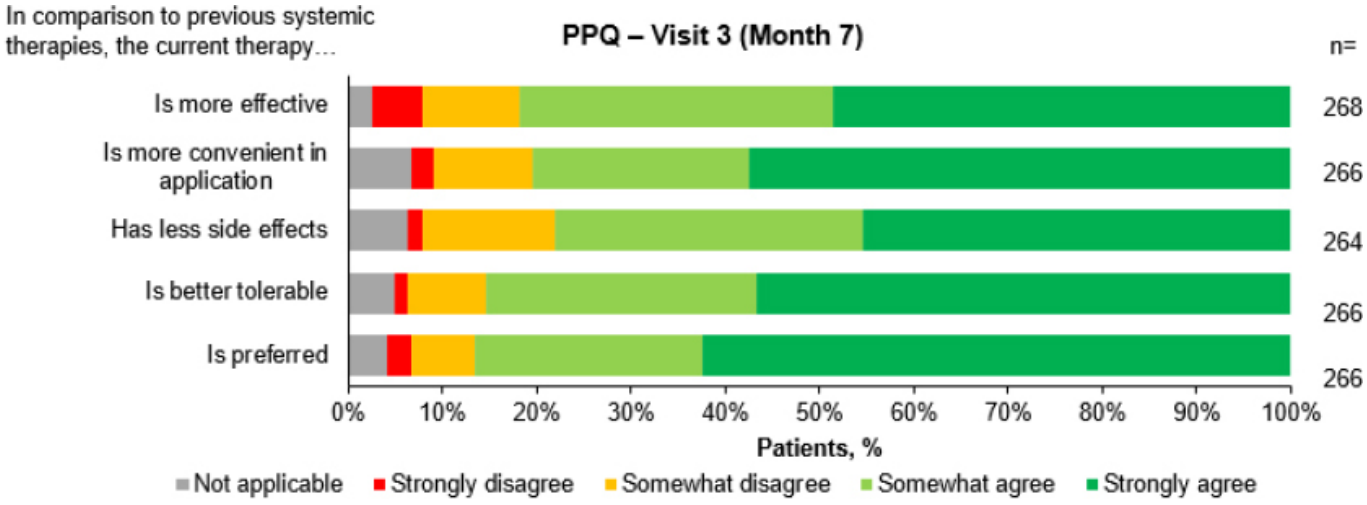
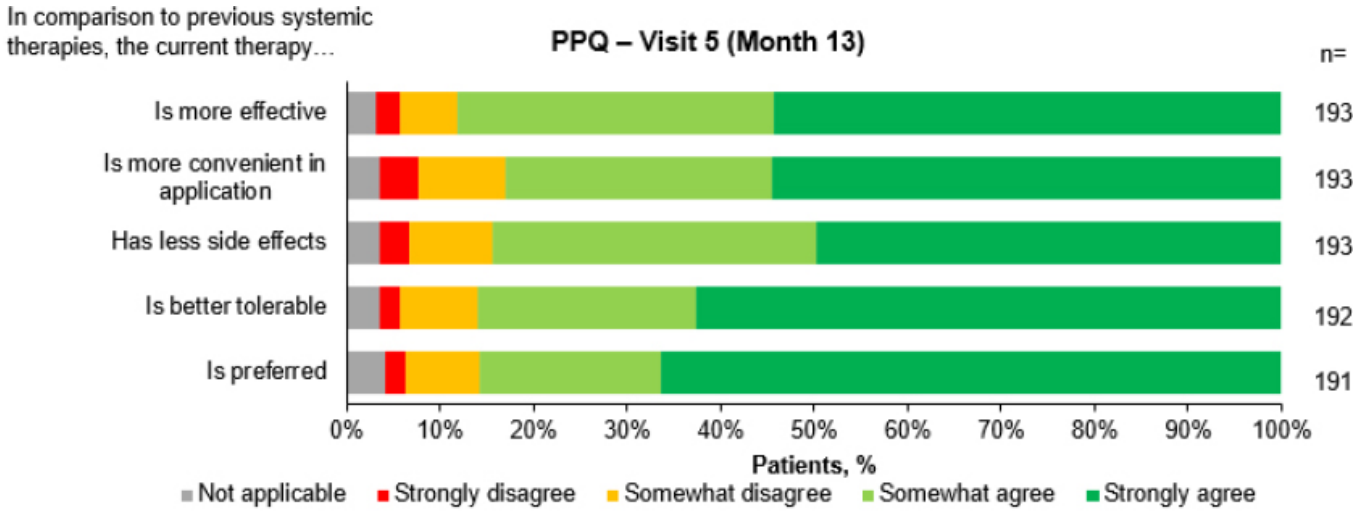


Fig. (S4). Patient-reported outcomes over time in patients with PsA receiving apremilast in German clinical practice.





Full analysis set. Data as observed.
PPQ, Patient Preference Questionnaire.

Fig. (S5). Patient preference for apremilast over previous therapy at visits 3 and 5 as measured by the PPQ.

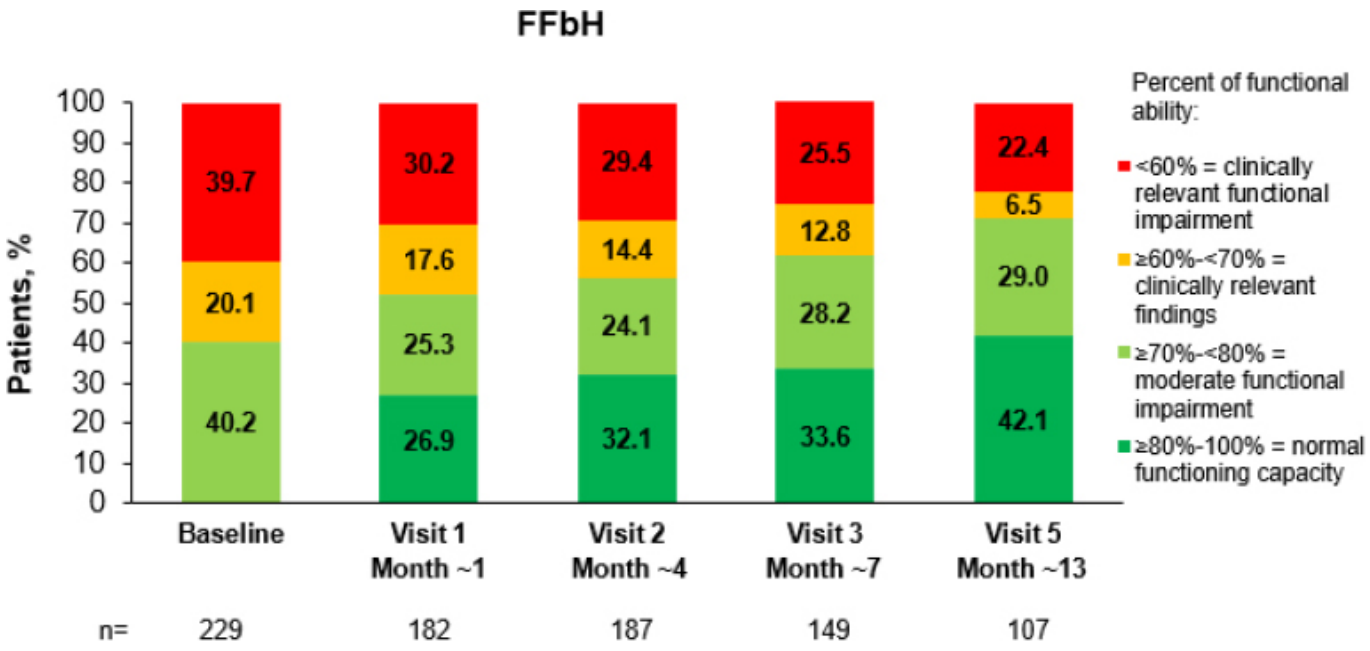


Fig. (S6). Patient functioning over time in patients with PsA receiving apremilast in German clinical practice with FFbH <80% at baseline.
Full analysis set with <80% functional ability at baseline. Data as observed.
FFbH, Hannover Functional Status Questionnaire; PsA, psoriatic arthritis.

Table S3. Mean HAQ-DI values over time in patients with PsA receiving apremilast in German clinical practice.

	Baseline	Visit 1*	Visit 2*	Visit 3*	Visit 5*
HAQ-DI, n Mean (SD)	416 1.06 (0.53)	312 0.99 (0.51)	339 0.92 (0.50)	283 0.86 (0.48)	207 0.82 (0.48)

Full analysis set. Data as observed.
*Visit 1: ~1 month after baseline; visit 2: ~4 months after baseline; visit 3: ~7 months after baseline; visit 5: ~13 months after baseline.
HAQ-DI, Health Assessment Questionnaire-Disability Index; PsA, psoriatic arthritis; SD, standard deviation.

Table S4. Treatment-related SAEs in patients with PsA receiving apremilast in German clinical practice.

	SAS N=484
Drug ineffective	7 (1.4)
Psoriatic arthritis	5 (1.0)
Diarrhea	3 (0.6)
Psoriasis	2 (0.4)
Hospitalization	1 (0.2)
Synovectomy	1 (0.2)
Vomiting	1 (0.2)
Abdominal pain	1 (0.2)
Abducens nerve palsy	1 (0.2)
Bladder cancer recurrence	1 (0.2)
Pneumonia	1 (0.2)
Depression	1 (0.2)
Osteoarthritis	1 (0.2)
Type II diabetes	1 (0.2)

Values are n (%).
PsA, psoriatic arthritis; SAE, serious treatment-emergent adverse event, SAS, safety analysis set.