

APREMILAST NELLE SEDI SPECIALI

Maria Esposito
Università degli Studi dell'Aquila



- Le localizzazioni di psoriasi in sedi speciali rappresentate da **unghie, scalpo, volto, aree genitali e palmoplantari** hanno una prevalenza variabile ed elevata di circa:
 - 50% per la psoriasi ungueale^{1,2,3}
 - 80% per la psoriasi dello scalpo^{1,2,3}
 - 60% per la psoriasi del volto (PF/MF)⁴
 - 60 % per la psoriasi genitale^{1,2,3}
 - 15% per la psoriasi palmoplantare^{1,2,3}
- Definite aree **“difficult to treat”** per le problematiche terapeutiche
- Peggiorano in modo significativo la QoL del paziente e possono rappresentare un aspetto della malattia poco condiviso con il clinico

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**PASI
DLQI**



**LOCALIZZAZIONE
IN SEDI SPECIALI:**

Unghie
Cuoio capelluto
Volto
Genitali
Palmo-plantare

INDICATORI DI SEVERITA' nelle SEDI SPECIALI



	Cuoio capelluto	Unghie	Volto	Palmo- plantare	Genitali
INDEX	sc-PGA ss-IGA PSSI	NAPSI f-PGA	f-PASI f-PLASI	hf-PGA ppPASI	s-PGA-G Itch NRS GenPS-SFQ

“DIFFICULT TO TREAT AREAS”



	Unghie	Cuoio capelluto	Volto	Genitali	Palmo- plantare
Terapia topica	Top: CCS Ret/Ditr Vit D Deriv K IntraLes: CCS/ MTX	CCS Vit D Deriv Tar/Antr K UVB	TIM Vit D Deriv CCS	Vit D Deriv TIM CCS Anti-Micr	CCS K Ret Tar/Antr UVB PUVA
Terapia sistemica tradizionale	MTX/Ret/Cs	Cs/MTX/Ret	Cs/MTX/Ret	Cs/MTX/Ret MMof/ Dapsone	Cs/MTX/Ret
Terapia biologica	Anti-TNF Anti-IL12/23 Anti-IL17 APR	Anti-TNF Anti-IL12/23 Anti-IL17 APR	Anti-TNF Anti-IL12/23 Anti-IL17 APR	Anti-TNF Anti-IL12/23 Anti-IL17 APR	Anti-TNF Anti-IL12/23 Anti-IL17 APR

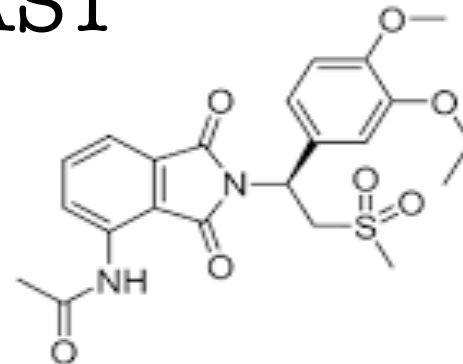
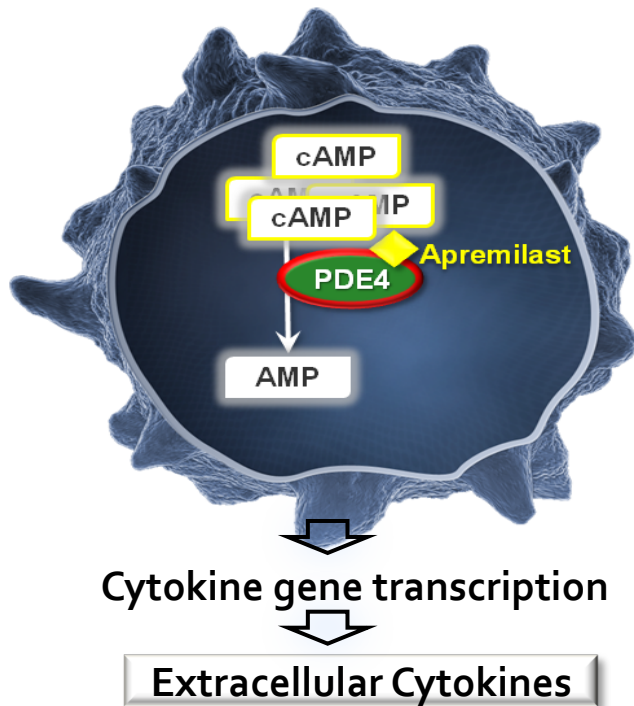
In epoca precedente lo sviluppo di nuove molecole biologiche e small molecole per la psoriasi l'efficacia delle terapie sulle sedi speciali rappresentava interesse minimo ed in letteratura erano presenti descrizioni limitate, casi aneddotici e studi RW

...solo recentemente l'analisi dell'efficacia dei farmaci in sedi speciali è stata inserita nei RCT aprendo il campo ad un maggiore approfondimento e comprensione

APREMILAST



Intra-cellular



Small-molecule con azione inibente la
fosfodiesterasi 4-PD4

Agisce a livello intracellulare modulando il
network di alcuni mediatori pro/
antinfiammatori

Non ha azione immunosoppressiva

Apremilast, an oral phosphodiesterase 4 inhibitor, in patients with difficult-to-treat nail and scalp psoriasis: Results of 2 phase III randomized, controlled trials (ESTEEM 1 and ESTEEM 2)

Phoebe Rich, MD,^a Melinda Gooderham, MD,^b Hervé Bachelez, MD, PhD,^c Joana Gonçalves, MD,^d Robert M. Day, PhD,^e Rongdean Chen, PhD,^f and Jeffrey Crowley, MD^g
Portland, Oregon; Peterborough, Ontario, Canada; Paris, France; Warren, New Jersey; and Bakersfield, California

Background: In the phase III double-blind Efficacy and Safety Trial Evaluating the Effects of Apremilast in Psoriasis (ESTEEM) 1 and 2, apremilast, an oral phosphodiesterase 4 inhibitor, demonstrated efficacy in moderate to severe psoriasis.

Objective: We sought to evaluate efficacy of apremilast in nail/scalp psoriasis in ESTEEM 1 and 2.

Methods: A total of 1255 patients were randomized (2:1) to apremilast 30 mg twice daily or placebo. At week 16, placebo patients switched to apremilast through week 32, followed by a randomized withdrawal phase to week 52. A priori efficacy analyses included patients with nail (target nail Nail Psoriasis Severity Index score ≥ 1) and moderate to very severe scalp (Scalp Physician Global Assessment score ≥ 3) psoriasis at baseline.

Results: At baseline, 66.1% and 64.7% of patients had nail psoriasis; 66.7% and 65.5% had moderate to very severe scalp psoriasis in ESTEEM 1 and 2. At week 16, apremilast produced greater improvements in Nail Psoriasis Severity Index score versus placebo; mean percent change: -22.5% versus +6.5% (ESTEEM 1; $P < .0001$) and -29.0% versus -7.1% (ESTEEM 2; $P = .0052$). At week 16, apremilast produced greater NAPS-50 response (50% reduction from baseline in target nail Nail Psoriasis Severity Index score) versus placebo (both studies $P < .0001$) and sPGA response (Scalp Physician Global Assessment score 0 or 1) versus placebo (both studies $P < .0001$). Improvements were generally maintained over 52 weeks in patients with Psoriasis Area and Severity Index response at week 32.

From the Oregon Health and Science University;^a SKIN Centre for Dermatology and Probiy Medical Research, Peterborough;^b Sorbonne Paris Cité Université Paris Diderot, Assistance Publique-Hôpitaux de Paris Hôpital Saint-Louis;^c Celgene Corporation, Warren;^d and Bakersfield Dermatology.^e

These studies were sponsored by Celgene Corporation.

Disclosures: Dr Bachelez received honoraria/research funding as an advisory board member and/or consultant for AbbVie, Amgen, Boehringer Ingelheim, Celgene Corporation, Eli Lilly and Company, Janssen Pharmaceuticals, LEO Pharma, Novartis, Pfizer, Merck Sharp & Dohme, and Pierre Fabre. Dr Crowley received honoraria/research funding as a consultant for AbbVie, Amgen, Celgene Corporation, and Eli Lilly and Company; was an investigator for AbbVie, Amgen, Celgene Corporation, Eli Lilly and Company, Janssen Pharmaceuticals, Merck, and Pfizer; and was a speaker for AbbVie, Amgen, and Celgene Corporation. Drs Gonçalves, Day, and Chen are employees of Celgene Corporation. Dr Gooderham received honoraria/research funding as a consultant for Janssen Pharmaceuticals; was a data safety monitoring board member for Kyowa Hakko Kirin Pharma; was an investigator for AbbVie, Amgen, Celgene Corporation, Dermira, Dr Reddy, Eli Lilly and Company, Forward Pharma, Galderma Laboratories, Kyowa

Hakko Kirin Pharma, Kythera, LEO Pharma, MedImmune, Merck & Co Inc, Novartis, Pfizer, Regeneron, Roche Laboratories, and Takeda Pharmaceuticals USA Inc; and was a speaker for AbbVie, Actelion, Amgen, Astellas Pharma US Inc, Celgene Corporation, Eli Lilly and Company, Galderma Laboratories, LEO Pharma, and Novartis. Dr Rich received honoraria/research funding as an advisory board member for Eli Lilly and Company and Sandoz; was a consultant for Polychem, and was an investigator for AbbVie, Amgen, Celgene Corporation, Eli Lilly and Company, Janssen, Merck & Co Inc, Novartis, and Pfizer.

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Table I. Demographic and clinical characteristics of patients with nail psoriasis (Nail Psoriasis Severity Index score ≥ 1) at baseline

Characteristics	ESTEEM 1		ESTEEM 2	
	Placebo n = 195	Apremilast 30 mg BID n = 363	Placebo n = 91	Apremilast 30 mg BID n = 175
Age, mean (SD), y	46.2 (12.33)	45.9 (11.94)	45.7 (12.82)	46.2 (12.80)
Male, n (%)	148 (75.9)	266 (73.3)	77 (84.6)	124 (70.9)
Duration of plaque psoriasis, mean (SD), y	18.57 (11.662)	20.48 (12.324)	19.35 (11.685)	18.80 (10.810)
History of psoriatic arthritis, n (%)	38 (19.5)	88 (24.2)	7 (7.7)	27 (15.4)
PASI score (0-72), mean (SD)	20.33 (8.026)	19.52 (8.131)	20.63 (7.621)	19.39 (7.373)
PASI score >20 , n (%)	72 (36.9)	117 (32.2)	36 (39.6)	56 (32.0)
BSA, mean (SD), %	26.52 (15.300)	25.21 (16.185)	28.07 (15.223)	26.14 (16.592)
BSA $>20\%$, n (%)	108 (55.4)	166 (45.7)	57 (62.6)	92 (52.6)
sPGA score of 3 (moderate), n (%)	128 (65.6)	244 (67.2)	55 (60.4)	123 (70.3)
sPGA score of 4 (severe), n (%)	67 (34.4)	119 (32.8)	36 (39.6)	51 (29.1)
NAPSI score in target nail, mean (SD)	4.3 (2.16)	4.3 (2.00)	4.4 (2.05)	4.2 (2.13)
No. of nails involved, mean (SD)	7.1 (3.25)	6.5 (3.54)	6.7 (3.48)	6.3 (3.47)

The n reflects the number of randomized patients; actual number of patients available for each parameter may vary. Data for patients with nail psoriasis include patients with target nail NAPSI score ≥ 1 .

BID, Twice daily; **BSA**, body surface area; **ESTEEM**, Efficacy and Safety Trial Evaluating the Effects of Apremilast in Psoriasis; **NAPSI**, Nail Psoriasis Severity Index; **PASI**, Psoriasis Area and Severity Index; **sPGA** static Physician Global Assessment.

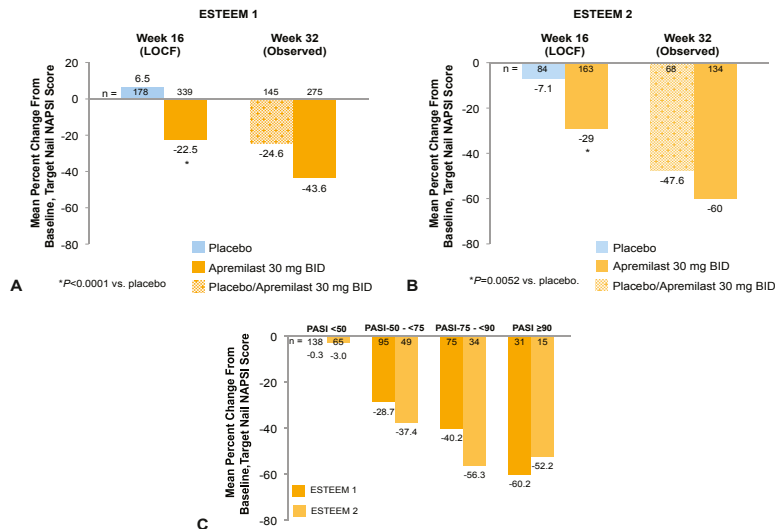
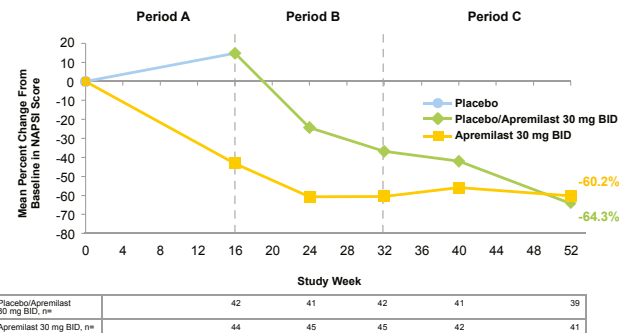
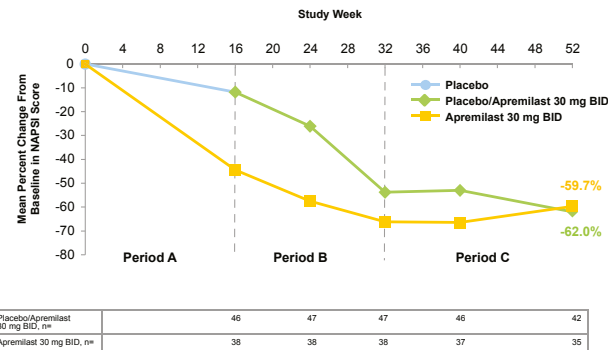


Fig 2. For patients with nail psoriasis at baseline, mean percent change from baseline in target Nail Psoriasis Severity Index (NAPSI) score at week 16 (placebo-controlled phase, period A) and week 32 (maintenance phase, period B) in Efficacy and Safety Trial Evaluating the Effects of Apremilast in Psoriasis (ESTEEM) 1 (A) and ESTEEM 2 (B), and mean percent change in target nail NAPSI score by Psoriasis Area and Severity Index (PASI) response at week 16 (period A) in patients treated with apremilast 30 mg twice daily (BID) in ESTEEM 1 and ESTEEM 2 (C). Missing values at week 16 were imputed using the last observation carried forward (LOCF) methodology. Patients without an observation at week 32 were considered nonresponders. * $P < .0001$ versus placebo in ESTEEM 1 and * $P = .0052$ versus placebo in ESTEEM 2, both based on the χ^2 test. $PASI-50$, $\geq 50\%$ reduction from baseline in PASI score; $PASI-75$, $\geq 75\%$ reduction from baseline in PASI score; $PASI-90$, $\geq 90\%$ reduction from baseline in PASI score.



A

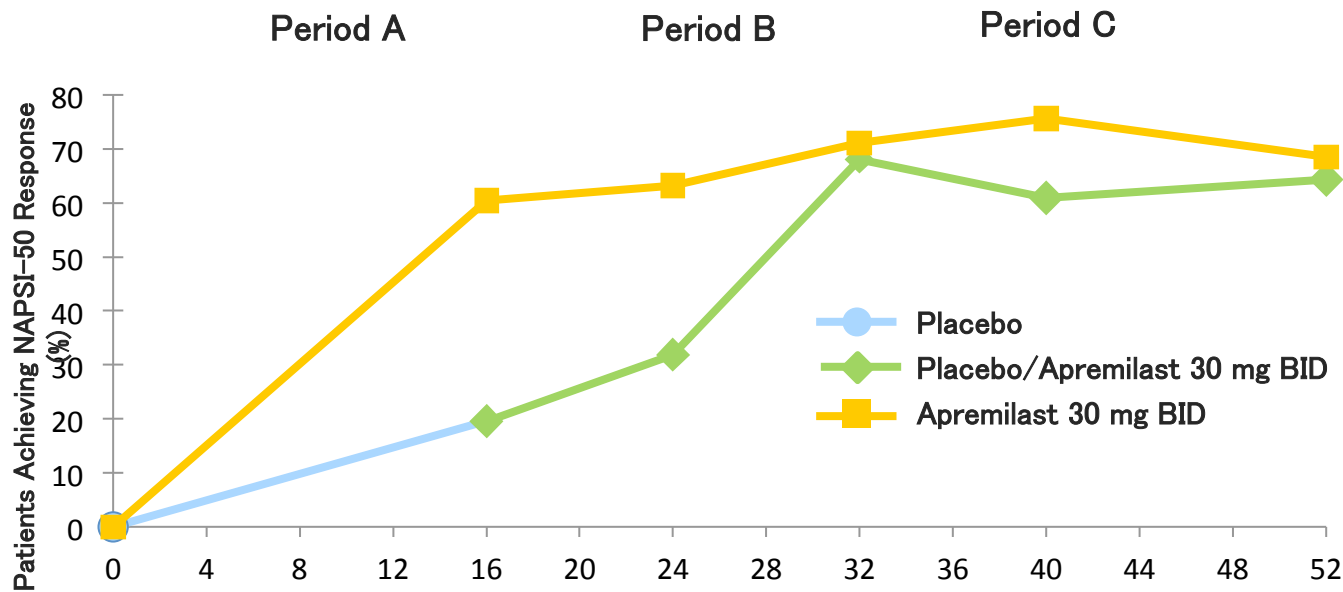


B

Fig 5. Mean percent change from baseline in Nail Psoriasis Severity Index (NAPSI) score over 52 weeks in patients with nail psoriasis (NAPSI score ≥ 1) at baseline and Psoriasis Area and Severity Index response at week 32 in Efficacy and Safety Trial Evaluating the Effects of Apremilast in Psoriasis (ESTEEM) 1 (A) and ESTEEM 2 (B). BID, Twice daily.

NAPSI-50

achievement was generally maintained for up to 52 weeks in patients who received apremilast or placebo at baseline who were PASI-50 responders at Week 32



*In patients with NAPSI score ≥ 1 at baseline (BL).

§Patients who were initially randomized to apremilast 30 mg BID at Week 0, were PASI-50 responders at Week 32, and were re-randomized to continued apremilast 30 mg BID in Period C.

*Patients who were initially randomized to placebo at Week 0, were PASI-50 responders at Week 32, and entered Period C.

APREMILAST nella PSORIASI del CUOIO CAPELLUTO



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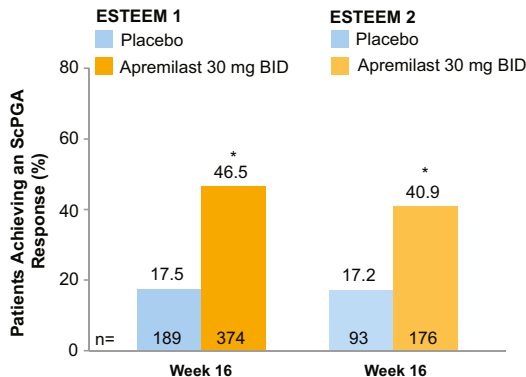
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* $P < 0.0001$ vs. placebo.

Fig 3. Percentage of patients with moderate to very severe scalp psoriasis at baseline (Scalp Physician Global Assessment [ScPGA] score ≥ 3) achieving ScPGA score of 0 or 1 at week 16 in Efficacy and Safety Trial Evaluating the Effects of Apremilast in Psoriasis (ESTEEM) 1 and ESTEEM 2. Missing values at week 16 were imputed using the last observation carried forward methodology. * $P < .0001$ versus placebo, based on the χ^2 test. BID, Twice daily.

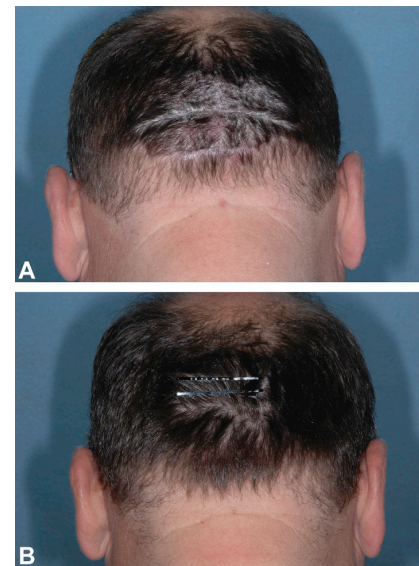
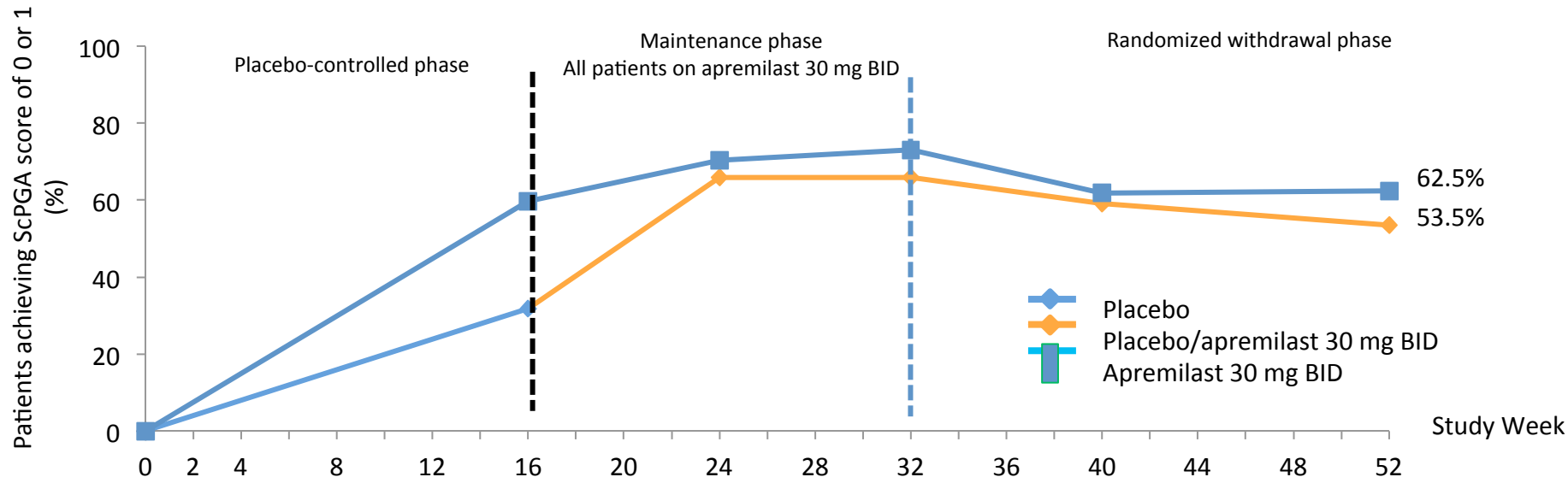


Fig 4. Effect of apremilast 30 mg twice daily in a patient with scalp psoriasis at baseline (Scalp Physician Global Assessment [ScPGA] score = 5) (A) and week 16 (ScPGA score = 0) (B).

APREMILAST nella PSORIASI del CUOIO CAPELLUTO



ScPGA score of 0 or 1 maintenance for up to **52 weeks** in patients randomized to apremilast 30 mg BID or placebo at baseline who were PASI-50 responders at Week 32



Full analysis set

Patients with moderate to very severe scalp psoriasis at baseline (ScPGA score ≥ 3)

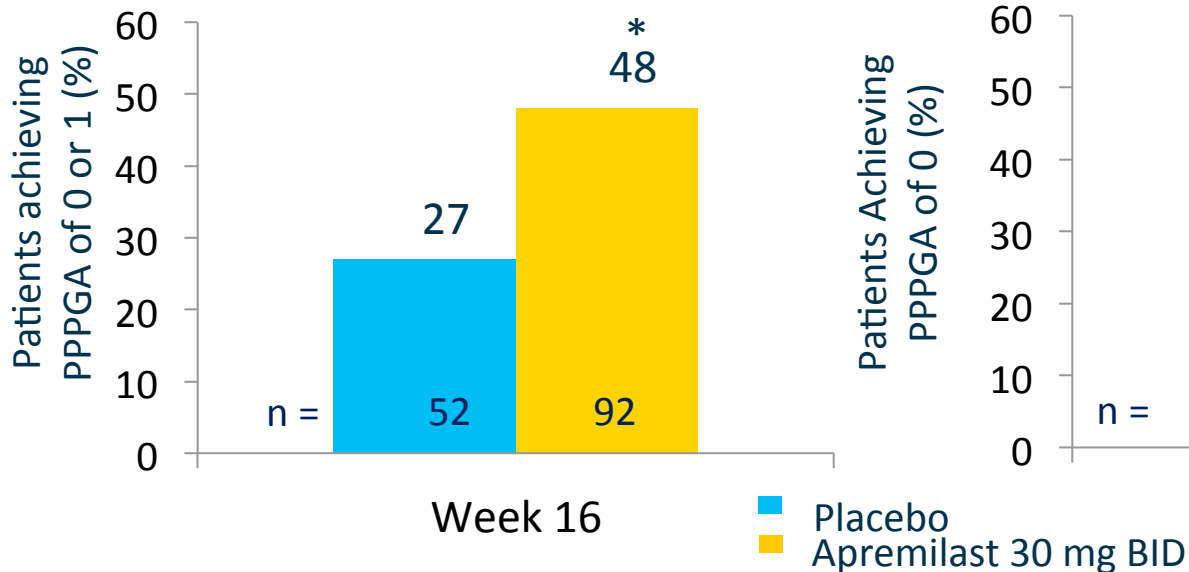
BID=twice daily; ScPGA=Scalp Physician Global Assessment; PASI=Psoriasis Area and Severity Index

Crowley J A et al. Poster presented at the 73rd Annual Meeting of the American Academy of Dermatology, 20–24 March 2015, San Francisco, CA (894)

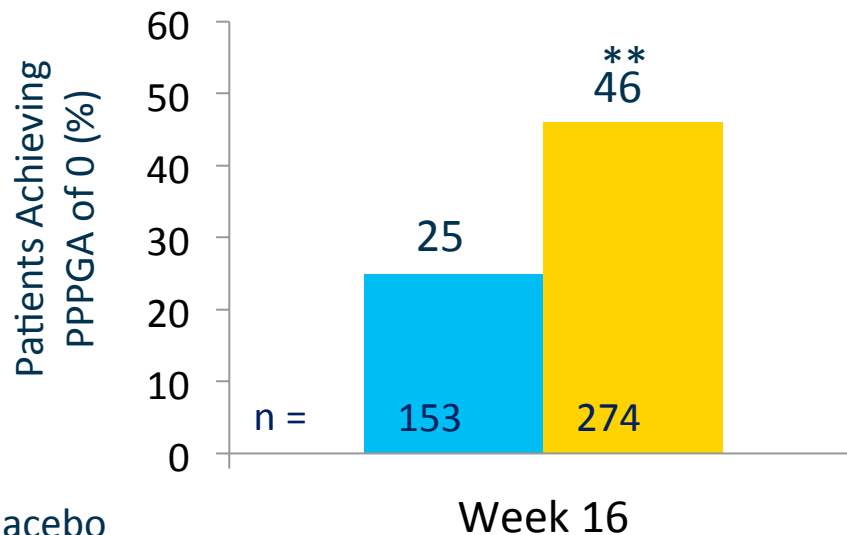
APREMILAST nella PSORIASI PALMO-PLANTARE



Patients with PPPGA ≥ 3 at baseline



Patients with PPPGA ≥ 1 at baseline



Pooled analysis from Phase II PSOR-005, ESTEEM1 and ESTEEM 2.

* P = 0.021 vs placebo; ** P < 0.001 vs placebo; N, number of patients with sufficient data for evaluation. Missing values were handled using NRI. BID, twice weekly; NRI, non-responder imputation; PPPGA, palmoplantar psoriasis physician global assessment.

Ad oggi non esistono dati della letteratura di riferimento sull'uso di Apremilast nella psoriasi genitale

Apremilast - Protocol CC-10004-PSOR-025 Celgene Corporation

A PHASE 3, MULTICENTER, RANDOMIZED, PLACEBO-CONTROLLED,
DOUBLE-BLIND STUDY OF THE EFFICACY AND SAFETY OF
APREMILAST (CC- 10004) IN SUBJECTS WITH MODERATE TO
SEVERE GENITAL PSORIASIS

APREMILAST in Real Life

ORIGINAL ARTICLE

Real-world data on the efficacy and safety of apremilast in patients with moderate-to-severe plaque psoriasis

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Abstract

Background Psoriasis is a chronic inflammatory skin disease, which requires long-term, safe and effective treatment. Apremilast, a small-molecule PDE4 inhibitor, has been introduced as psoriasis (and psoriatic arthritis) treatment in Europe in 2015.

Objective We analysed and report the efficacy and safety of apremilast in the first 51 patients with psoriasis that have undergone treatment with this novel small molecule in our outpatient clinic.

Method Our primary endpoint was the evaluation of clinical response to apremilast according to the percentage of Psoriasis Area Severity Index (PASI) reduction (ΔPASI) at 16 weeks after treatment initiation. Secondary endpoints were the evaluation at week 16 of (i) PASI; (ii) Dermatology Life Quality Index (DLQI); (iii) Physician Global Assessment (PGA); (iv) Psoriasis Scalp Severity Index (PSSI); and (v) the percentage of patients who achieved ΔPASI50, ΔPASI75, ΔPASI90 and ΔPASI100; (vi) adverse events (AE); (vii) reasons for drug discontinuation; and (viii) drug survival.

Results About 59.3% of the patients who remained on apremilast achieved at least ΔPASI75 at week 16, while 11.1% achieved combined 50% ≤ PASI < 75% and DLQI ≤ 5 (satisfactory response) adequate enough to maintain treatment. Five patients (18.5%) also achieved ΔPASI100. Patients discontinued apremilast (28%), mostly during the first 4 weeks due to adverse events (12%) with gastrointestinal symptoms being the most common, and later due to lack of efficacy (16%). A statistically significant improvement of PASI, DLQI, PGA and PSSI scores was observed after 4 and 16 weeks of treatment relative to pretreatment measurements.

Conclusion Apremilast is a safe and efficacious treatment for psoriasis patients as it produces ΔPASI75 and ΔPASI50 responses combined with DLQI ≤ 5 in 16 weeks in 70.4% of the patients. These results, from a real-world setting, confirm the efficacy and safety of apremilast which has been demonstrated in large phase III clinical trials.

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Conflicts of interest

Evangelia Papadavid has received consultancy fees, payment for lectures and support for travel to scientific meetings from GENESIS PHARMA, SA; NOVARTIS, JANSSEN and ABBVIE. Natalia Rompoti has received payment for lectures from JANSSEN and NOVARTIS and support for travel to scientific meetings and congresses from ABBVIE, JANSSEN and NOVARTIS. Konstantinos Theodoropoulos has received payment for lectures from GENESIS PHARMA, SA and NOVARTIS, payment as a subinvestigator for observational studies from ABBVIE and JANSSEN and support for travel to scientific meetings from ABBVIE. Georgios Kokkalis has no conflict of interest. Dimitrios Rigopoulos has received consultancy fees, payment for lectures and support for travel to scientific meetings from CELGENE, NOVARTIS, JANSSEN and ABBVIE.

Funding sources

No funding sources supported this project.

Introduction

Psoriasis is a chronic inflammatory disease that requires long-term use of safe and efficacious therapeutic agents. Several biologic agents and the novel, small-molecule PDE4 inhibitor

apremilast, introduced in Europe in 2015 and in Greece in 2016, have been used in the treatment of psoriasis. Randomized controlled trials (RCTs) have shown the superiority of apremilast over placebo with an excellent safety profile, comparable to placebo during the placebo-controlled phase of the trials^{1,2} and long-term maintenance of efficacy.^{3,4}

Real-world data on efficacy and safety of apremilast

3

Table 1 Baseline patient characteristics among those who took at least 1 dose of apremilast (n = 50 patients)

Characteristics	No. of patients with available data/Total no. of patients	No.	%
Total patients with >1 dose	50/50	50	
Age (year), mean (min–max)	37/50	55.0 (25–82)	
Age (year) at disease first diagnosis, mean (min–max)	33/50	32.8 (5–65)	
Males	35/35	35	70.0
Females	15/15	15	30.0
BMI, mean (min–max)	31/50	28.4 (17.6–49.6)	
Waist circumference (cm)	31/50	96.7 (52–131)	
Dose			
30 mg PO BID		46	92.0
Changed dosage		4	8.0
30 mg BID to 30 mg OD		2	4.0
30 mg OD to 30 mg BID		1	2.0
30 mg OD		1	2.0
Treatment combinations		2	4.0
Apremilast with CyA		1	2.0
Apremilast with MTX		1	2.0
Prior systemic therapy	33/50	28	
Biologic therapy		7	21.2
Conventional therapy		26	78.8
Type of psoriasis			
Chronic plaque psoriasis and palmoplantar plaque psoriasis	50/50	4	8.0
Chronic plaque psoriasis		46	92.0
PASI score mean (median, range)		10.8 (9, 0–49)	
Special location			
Psoriasis with scalp involvement	36/50	30	83.3
Psoriasis with nail involvement	32/50	16	50.0
PsA	34/50	4	11.8

[†]The first two authors have equally contributed to this article.

Table 3 Clinical response to apremilast

Primary endpoints	No. of patients	%	
APASI > 75	16/27	59.3	
APASI 50 and DLQI < 5	3/27	11.1	
Total	19/27	70.4	
Secondary endpoints			
APASI 50	9/27†	33.3	
APASI 75	9/27	33.3	
APASI 90	2/27	7.4	
APASI 100	5/27	18.5	
APASI 75 cumulative	16/27	59.3	
Scores, mean (median/range)	T0	T4 weeks‡	T16 weeks‡
PASI	10.8 (9, 0–49)	4.9 (4.2, 0–13.6)	4.3 (1.8, 0–16.8)
PSSI	7.4 (3.0, 0–60)	3.4 (3.0, 0–14)	2.8 (0, 0–12)
DLQI	11.1 (12, 0–24)	6.0 (6, 0–17)	3.9 (2, 0–14)
PGA	2.7 (3, 0–5)	1.7 (2, 0–3)	1.3 (1, 0–3)

[†]In another four patients, Δ PASI50 was achieved, but Δ PASI75/PASI90/PASI100 could not be evaluated due to drug discontinuation within the first 16 weeks (these patients were excluded from Δ PASI50 evaluation).

[‡]Where applicable.

PASI, Psoriasis Area Severity Index; PSSI, Psoriasis Scalp Severity Index; DLQI, Dermatology Life Quality Index; PGA, Physician Global Assessment score (5 point ranked scale; 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate, 4 = severe).

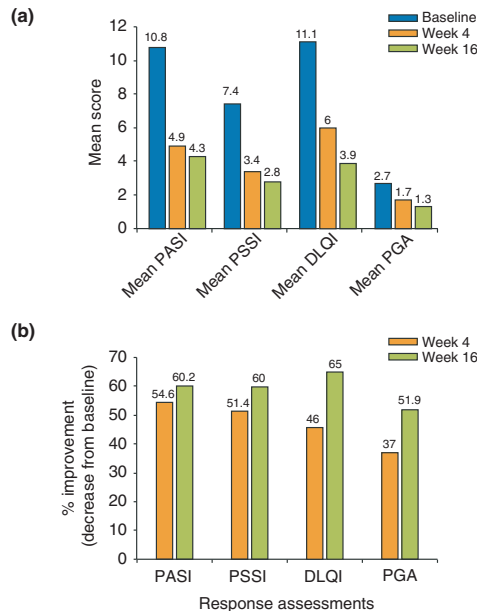


Figure 3 (a) Mean scores from baseline to week 16. (b) Mean percentage improvement from baseline to week 16 ('as observed' analysis).

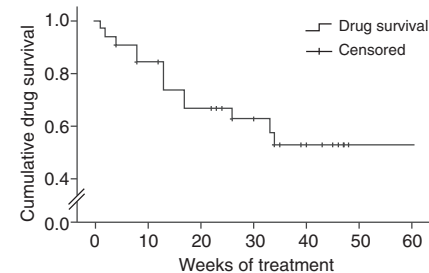


Figure 1 Drug survival curve among patients who received apremilast treatment.



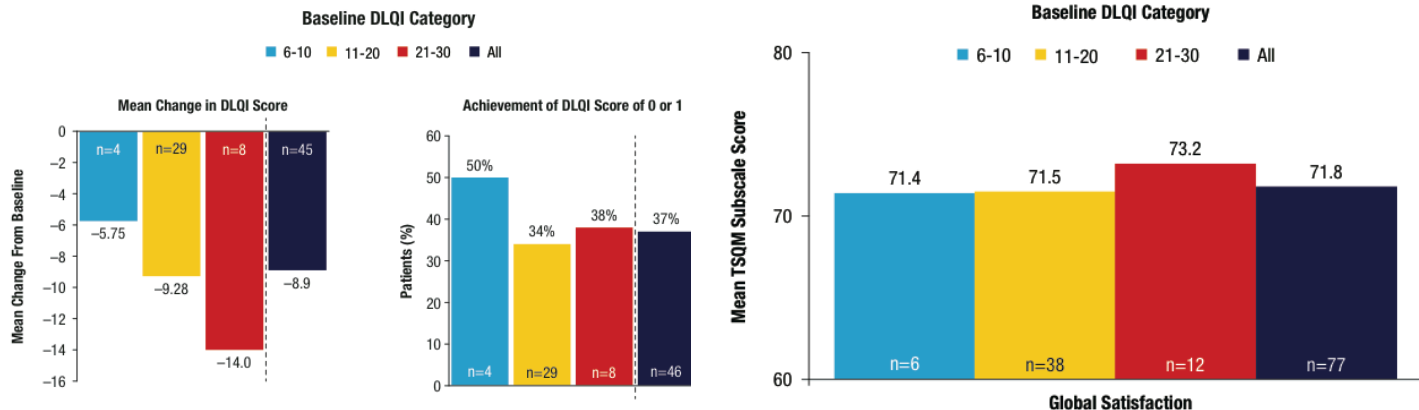
APREMILAST in Real Life

PSS74

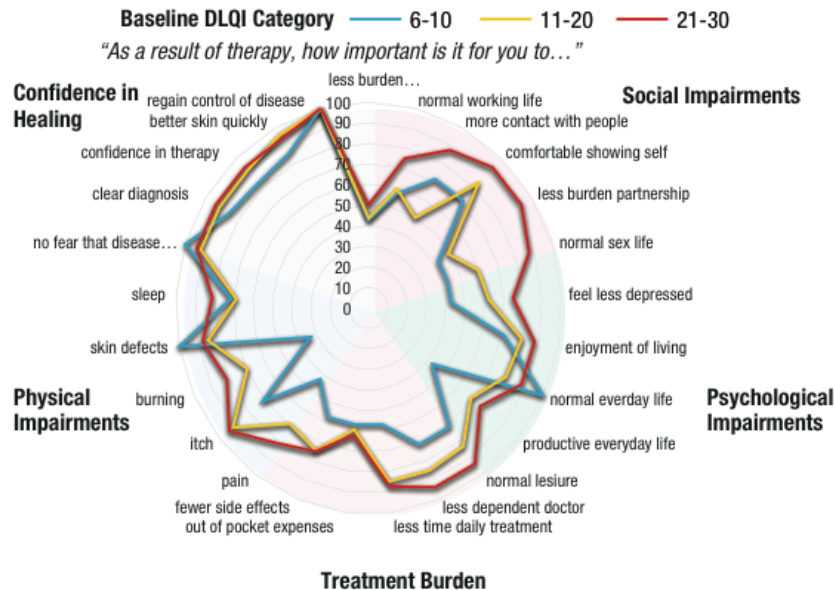
Patient Quality of Life and Satisfaction in an Apremilast-Treated Psoriasis Population: Analysis of 126 Patients From the APPRECIATE Study in the United Kingdom and Ireland

Lindsey Yeo,¹ Kave Shams,² Philip Laws,³ Emilia Duarte Williamson,⁴ Janet Eccles,⁵ Myriam Cordey,⁶ Volker Koscielny,⁷ Christopher E.M. Griffiths⁸

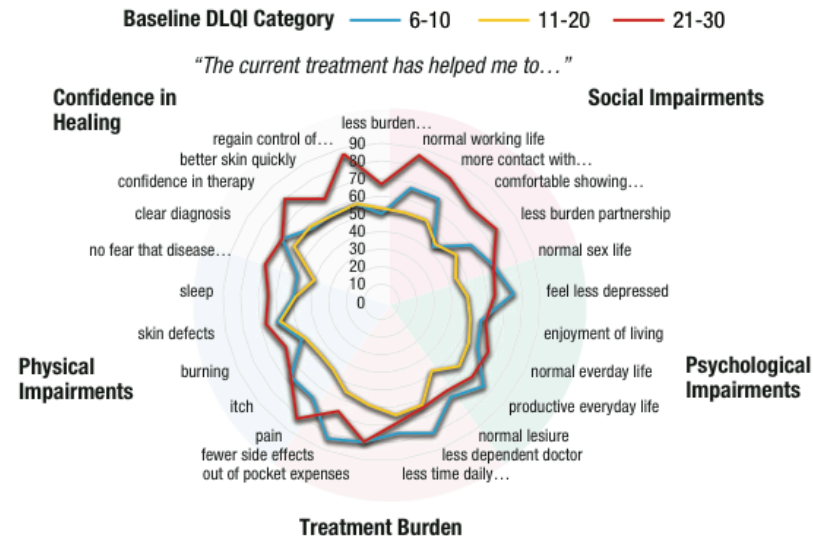
¹Dumfries and Galloway Royal Infirmary, Dumfries, UK; ²University of Leeds St James' University Hospital, Leeds, UK; ³Department of Dermatology, Leeds Teaching Hospitals, Leeds, UK; ⁴East Kent Hospitals University NHS Foundation Trust, Canterbury, UK; ⁵Calderdale L&G, Uxbridge, UK; ⁶Cellgene International, Boudry, Switzerland; ⁷The Dermatology Centre, The University of Manchester, Manchester Academic Health Science Centre, Manchester, UK



The Apremilast Clinical Treatment Experience in Psoriasis (APPRECIATE) study (NCT02740218), a multinational, retrospective, cross-sectional, observational study of psoriasis patients (tot 126) treated with apremilast, in real-world clinical practice, aims to describe patient needs, treatment patterns, and outcomes among patients treated with apremilast.



Domains and needs question

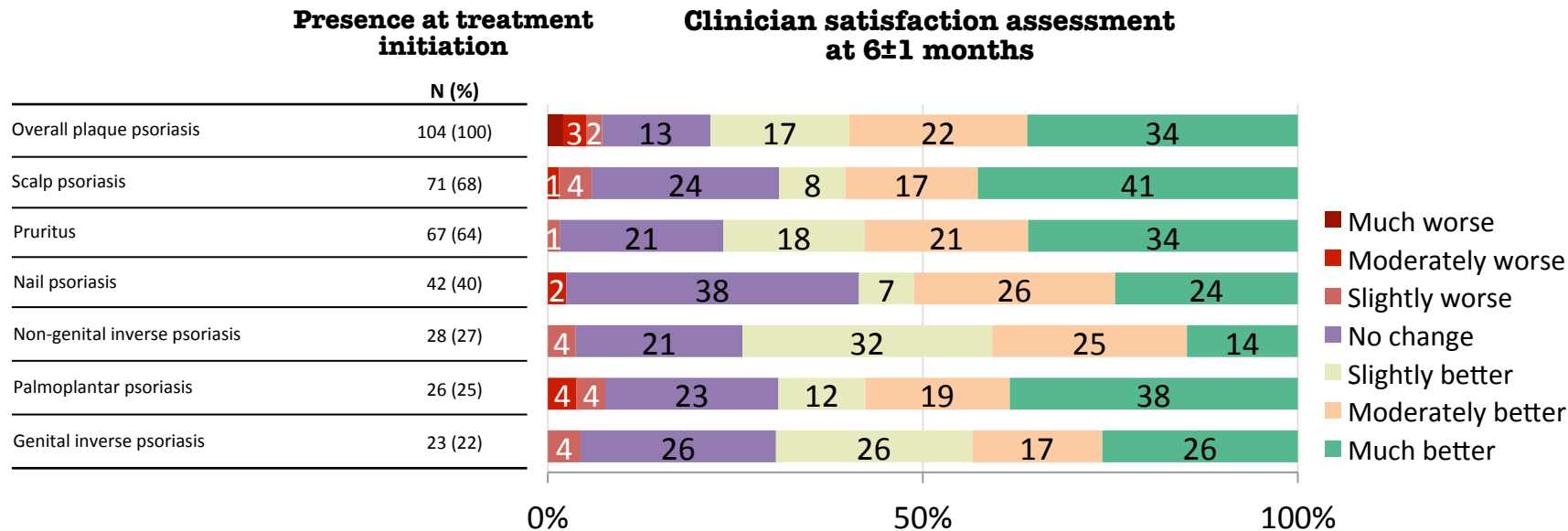


Treatment Satisfaction
by Baseline DLQI Category

CLINICIAN RATINGS OF APREMILAST EFFECTIVENESS



APPRECIATE interim analysis



N = 104; clinician questionnaire completed at 6±1 months for each patient with sign(s) present at treatment initiation. Numbers in bar graph may be less than or greater than 100 because of rounding.

Kleyn CE, et al. Psoriasis: from Gene to Clinic. London, UK; 1 December 2017. FC21.

In pratica clinica...

LOCALIZZAZIONE PSORIASI IN SEDI SPECIALI

- ① Esame clinico
- ② Valutazione relativa al quadro generale (isolata/ associata)
- ③ Gravità relativa rispetto al PASI generale
- ④ DLQI
- ⑤ Risposta a precedenti terapie per psoriasi (mirate/generali)
- ⑥ Localizzazione residua (PASI/DLQI)

APREMILAST negli studi RCT, nelle evidenze della real life e nella nostra esperienza ha dimostrato particolare e specifica efficacia nelle sedi speciali

In particolare a livello di:

Psoriasi ungueale

Psoriasi del cuoio capelluto

Psoriasi palmoplantare

Con risultati soddisfacenti anche su:

Psoriasi del volto

Psoriasi genitale

Particolare Utilità nel paziente **lieve moderato** con localizzazioni speciali

Indicazione anche nel paziente **severo** con localizzazioni speciali/localizzazioni residue in **monoterapia** o anche in **terapia combinata**



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MARIA CONCETTA FARGNOLI

