First "Real-World" Insights on Apremilast Treatment for Patients With Plaque Psoriasis From the LAPIS-PSO Study: An Interim Analysis

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INTRODUCTION

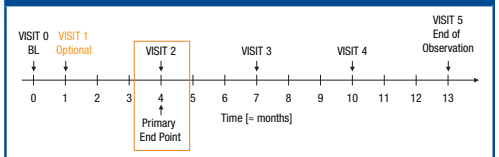
- This national, multicenter, prospective, noninterventional study is assessing long-term treatment with apremilast in patients with plaque psoriasis in Germany (LAPIS-PSO; ClinicalTrials.gov: NCT02626793).
- This study aims to determine patients' quality of life and satisfaction with apremilast 30 mg twice daily (APR) treatment, as well as the clinical efficacy of APR, in a real-world setting of patients who have previously received conventional systemic therapy.
- A subgroup analysis of the LAPIS-PSO interim analysis is presented here.

METHODS

Study Design

- The subgroup analysis was stratified based on the number of prior conventional systemic treatments (≤1 vs. >1) (**Table 1**).
- Scope: Baseline until Visit 2 (~4 months), n=111 (**Figure 1**)
- Patients: Moderate to severe plaque psoriasis (N=500, 100 sites planned)
  - Indication and inclusion according to apremilast Summary of Product Characteristics[1]
  - Patients previously treated with biologics were not observed
- No strict visit schedule was performed; visits were timed according to clinical practice.

Figure 1. Study Design



Stratification

- Two subgroups were defined following stratification:
  - Subgroup 1: Patients with treatment failure (lack of efficacy or intolerance) of ≤1 prior conventional systemic treatment
  - Subgroup 2: Patients with treatment failure (lack of efficacy or intolerance) of >1 prior conventional systemic treatment

End Points

Primary End Point

- The primary end point was the percentage of patients achieving Dermatology Life Quality Index (DLQI) score ≤5 or improvement from baseline in DLQI score by ≥5 points at Visit 2.

Secondary End Points (Interim Analysis at Visit 2)

- Percentage of patients achieving DLQI score ≤5 or improvement from baseline in DLQI score by ≥5 points at all other visits
- Efficacy on skin: Physician's Global Assessment (PGA) and body surface area (BSA) involvement
- In addition, the following were assessed:
  - Scalp involvement
  - Nail involvement
  - Patient's Global Assessment (PaGA)
- Safety and tolerability

RESULTS

Patient Demographics and Disease Characteristics

- Baseline patient demographics and disease characteristics for the full analysis set (FAS) are shown in **Table 1**.

Table 1. Baseline Patient Demographics and Disease Characteristics

Characteristic	Subgroup 1 (≤1 prior conventional systemic) n=43	Subgroup 2 (>1 prior conventional systemic) n=30
Male (%)	51.2	43.3
Age at inclusion, mean (SD), years	49.2 (13.22)	53.3 (12.99)
Body mass index, mean (SD), kg/m²	27.74 (5.21)	28.37 (5.92)
Age at initial diagnosis, mean (SD), years	32.1 (17.01)	27.7 (12.54)
Scalp involvement, n (%)	36 (83.7)	27 (93.1)
Nail involvement, n (%)	21 (48.8)	15 (50.0)
Number of affected nails, mean (SD)	6.6 (3.82; n=17)	6.1 (3.50; n=13)
Palmoplantar involvement, n (%)	11 (26.2)	6 (20.7)
PGA score, mean (SD)	3.1 (0.86)	3.2 (0.63)
PaGA score, mean (SD)	3.0 (0.92)	3.4 (0.57)

RESULTS (cont'd)

DLQI Response

- Characteristics at baseline were comparable (mean [SD] DLQI score was 14.6 [6.31]; n=73).
- The percentage of patients achieving DLQI score of ≤5 or DLQI improvement from baseline by ≥5 (primary end point) was 65.8% in subgroup 1 vs. 61.5% in subgroup 2 (**Table 2**).

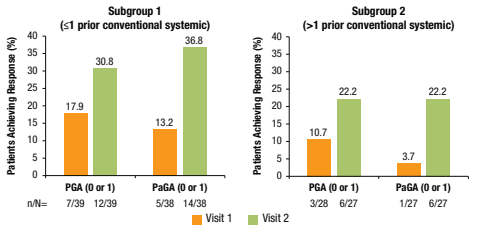
Table 2. DLQI Response at Visit 2: Stratification (FAS)

Stratification	Achievement of DLQI Score ≤5 or DLQI Improvement From BL by ≥5, n/N (%)	Achievement of DLQI Score ≤5, n/N (%)	Change From BL in DLQI Score, Mean (SD)
Subgroup 1 (≤1 prior conventional systemic)	25/38 (65.8)	22/38 (57.9)	–8.3 (8.09)
Subgroup 2 (>1 prior conventional systemic)	16/26 (61.5)	9/26 (34.6)	–6.4 (5.94)

PGA and PaGA Response

- A higher percentage of patients achieved PGA and PaGA scores of 0 or 1 at Visit 2 in subgroup 1 (30.8% and 36.8%, respectively) compared with subgroup 2 (22.2% and 22.2%, respectively) (**Figure 2**).

Figure 2. PGA and PaGA* Response of 0 or 1 at Visits 1 and 2

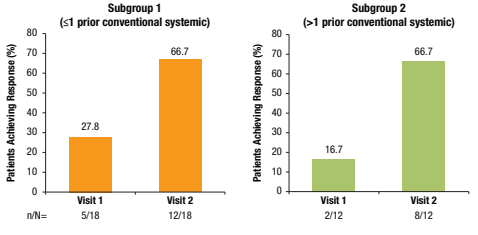


*The PGA and PaGA are 5-point scales ranging from 0 (clear), 1 (almost clear), 2 (mild), 3 (moderate), to 4 (severe).

Efficacy on Nail Psoriasis: Target-Nail Psoriasis Severity Index (Target-NAPSI)

- The mean (SD) Target-NAPSI in subgroup 1 (4.0 [2.06]) was better than that in subgroup 2 (4.6 [2.53]).
- The mean (SD) percentage change in Target-NAPSI was –58.22% (53.423) in subgroup 1 and –48.61% (37.241) in subgroup 2.
- Target-NAPSI-50 response was identical between subgroups at Visit 2 (66.7%) (**Figure 3**).

Figure 3. Target-NAPSI-50 Response



- Scalp manifestation was comparable at baseline and had slightly greater improvements in subgroup 1 at ~4 months.

Safety

- The overall incidence of AEs (**Table 3**) is lower than that in clinical studies.
- Only 1 patient was affected by severe AEs (obstipation, tremor, palpitations).

RESULTS (cont'd)

Table 3. Overview of Adverse Events

Patients, n (%)	Subgroup 1 n=61	Subgroup 2 n=47
≥1 AE	14 (23.0)	13 (27.7)
≥1 AE (APR treatment-related)	11 (18.0)	7 (14.9)
≥1 AE leading to drug withdrawal	6 (9.8)	3 (6.4)
≥1 SAE (APR treatment-related: disorders of the nervous system: tremor and heart diseases: palpitations)	1 (1.6)	0 (0.0)

AE=adverse event; SAE=serious adverse event.

- The most common AE was diarrhea (8.3%) (**Table 4**).

Table 4. Most Common Adverse Events

Patients,* n (%)	SAP n=108
Diarrhea	**9 (8.3)**
Nausea	2 (1.9)
Upper respiratory tract infection	1 (0.9)
Headache	2 (1.9)

*Most common AEs that occurred in ≥5% of patients in phase 3 clinical trials of apremilast. Interim analysis includes total number of SAEs and related AEs. Nonserious AEs were asked to be reported upon termination. SAP=safety analysis population (all patients who received ≥1 dose of APR and fulfilled the inclusion criteria).

CONCLUSIONS

- The LAPIS-PSO interim analysis presents the first data on APR for the treatment of patients with moderate to severe plaque psoriasis under routine clinical care in Germany.
- This interim analysis suggests that the efficacy of APR in daily practice is comparable to clinical trial results and responses may be improved in patients who have received fewer prior conventional systemic therapies.
- Patient quality of life is rapidly and significantly improved by APR (as shown by DLQI response within 4 weeks at Visit 1).
- The safety profile in this real-world setting was consistent with clinical trials of APR in psoriasis.[2,3]
- There was a significant improvement in disease in both subgroups.

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ACKNOWLEDGMENTS

The authors acknowledge financial support for this study from Celgene Corporation. The authors received editorial support in the preparation of this report from Amy Shaberman, PhD, of Peloton Advantage, LLC, Parsippany, NJ, USA, funded by Celgene Corporation, Summit, NJ, USA. The authors, however, directed and are fully responsible for all content and editorial decisions for this poster.

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DISCLOSURES

KR: AbbVie, Amgen, Biogen, Boehringer Ingelheim, Celgene Corporation, Centocor, Covagen, Eli Lilly, Forward Pharma, GlaxoSmithKline, Janssen-Cilag, LEO Pharma, Medac, Merck Sharp & Dohme Corp, Novartis, Ocean Pharma, Pfizer (Wyeth), Regeneron, Takeda, UCB Pharma, and XenoPort – honoraria as a consultant and/or advisory board member and/or acted as a paid speaker and/or participated in clinical trials. **SB:** No conflicts or potential conflicts of interest to disclose. **BK:** No conflicts or potential conflicts of interest to disclose. **MM:** AbbVie, Janssen, and Novartis – paid consultant or study investigator. **US:** AbbVie Deutschland GmbH, Almirall Hermal GmbH, Astellas Pharma GmbH, Beiersdorf Derma Medical GmbH, Celgene GmbH, Janssen Cilag GmbH, Johnson & Johnson GmbH, LEO Pharma GmbH, L´Oréal GmbH, MEDA Pharma GmbH, Merz Pharmaceuticals GmbH, MSD SHARP & DOHME GmbH, Novartis Pharma GmbH, Pfizer GmbH, and Medical Project Design GmbH – paid speaker, advisory board member, investigator, and/or stockholder. **HM, KG & NNG:** Celgene GmbH – employment.

Presented at: the 2017 Fall Clinical Dermatology Conference; October 12–15, 2017; Las Vegas, NV.