Effect of baseline disease severity on achievement of treatment target with apremilast: results from a pooled analysis

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Abstract

Background Treating to absolute treatment targets rather than relative measures such as Psoriasis Area and Severity Index (PASI)-75 is emerging as an important clinical concept included in psoriasis guidelines and clinical practice. Achieving treatment targets is associated with achievement of long-term outcomes.

Objective To evaluate the relationship between psoriasis severity, disease characteristics and achievement of PASI ≤2 with apremilast in a pooled analysis of the phase 3 ESTEEM 1 and 2 (NCT01194219 and NCT01232283), phase 3b LIBERATE (NCT01690299) and phase 4 UNVEIL (NCT02425826) clinical trials.

Methods Pooled data from patients with moderate-to-severe plaque psoriasis randomized to apremilast 30 mg BID were analysed by baseline PASI quartiles (Q1: 2.4–13.1; Q2: 13.2–15.9; Q3: 16.0–20.0; Q4: 20.1–57.8). Assessments included PASI, Dermatology Life Quality Index (DLQI), Scalp Physician’s Global Assessment (ScPGA; ScPGA ≥1) and target (worst) Nail Psoriasis Severity Index (NAPSI; NAPSI ≥1).

Results Of 1062 patients, 963 had ScPGA ≥1 and 643 had NAPSI ≥1; 771 patients with baseline and Week 32 PASI assessments were included in analyses of Week 32 PASI target achievement. Rates of PASI ≤2 at Week 32 were greater in lower PASI quartiles (Q1: 43.5%; Q2: 31.2%; Q3: 26.8%; Q4: 18.4%). Most patients achieving PASI ≤2 target (83.6%) achieved DLQI ≤5 at Week 32; 59.3% of patients who did not achieve PASI ≤2 target achieved DLQI ≤5. At Week 32, mean improvements in ScPGA and NAPSI were similar with more moderate vs. more severe disease (ScPGA, range: 1.1–1.4; NAPSI, range: 1.6–2.5). In a subgroup analysis, achievement of PASI ≤2 target was higher in the lowest PASI quartile and with disease duration <5 years.

Conclusions Greater achievement of PASI ≤2 was observed in patients with more moderate vs. more severe skin disease. Apremilast may be particularly beneficial in more moderate disease early in the treatment paradigm.

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Conflicts of Interest

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Introduction
Psoriasis treatment guidelines and clinical trials often focus on relative improvement from baseline in Psoriasis Area and Severity Index (PASI) as a treatment goal for patients with psoriasis.\(^1\)\(^,\)\(^3\) In real-world clinical practice, selecting a relevant baseline time point is challenging when managing a chronic condition and may be confounded by variability in prior treatment washout periods.\(^2\)\(^,\)\(^4\) Furthermore, using improvement from baseline as an indicator of treatment efficacy may inadequately capture clinically meaningful improvements in patients with more moderate disease because they have lower absolute baseline scores.\(^2\) Expert opinion and national and international psoriasis guidelines are shifting towards treating psoriasis to an absolute treatment target such as target PASI, psoriasis-involved body surface area (BSA) or Dermatology Life Quality Index (DLQI) scores.\(^1,\)\(^2\)\(^,\)\(^4\)\(^,\)\(^6\) Achievement of absolute PASI treatment target may demonstrate stronger correlations with indicators of quality of life (QOL) than relative PASI improvements,\(^4\) and a target PASI ≤2 has been validated as a relevant, practical treatment goal for psoriasis.\(^2\)

Apremilast, an oral phosphodiesterase 4 inhibitor, demonstrated efficacy and tolerability vs. placebo in clinical trials of patients with moderate-to-severe plaque psoriasis.\(^7\)\(^-\)\(^10\) In a recent real-world study, patients initiating apremilast in routine clinical practice generally had more moderate psoriasis (e.g. lower BSA) than those in apremilast clinical trials,\(^11\) underscoring the importance of evaluating apremilast efficacy using measures that adequately capture meaningful improvements in more moderate psoriasis. In clinical studies, apremilast-treated patients with moderate psoriasis\(^10\) had lower PASI-75 response rates (UNVEIL: 21.6%)\(^10\) than those with moderate-to-severe psoriasis (ESTEEM 1: 33.1%; ESTEEM 2: 28.8%).\(^7,\)\(^8\) However, data on achieving target PASI response (defined as PASI ≤2), which may more adequately capture clinically meaningful improvement in patients with more moderate disease,\(^7,\)\(^4\) have not been reported for most apremilast clinical trials.
This analysis evaluated achievement of PASI treatment target with apremilast by baseline disease severity and disease characteristics in a pooled population of patients with moderate-to-severe plaque psoriasis from ESTEEM 1 and 2 (NCT01194219 and NCT0132283) and LIBERATE (NCT01690299) and patients with moderate plaque psoriasis from UNVEIL (NCT0245826).7–10

Materials and methods

Eligibility criteria and study design
Methodologies for ESTEEM 1 and 2,7,8 LIBERATE,9 and UNVEIL10 have been reported. ESTEEM 1 and 2 were similarly designed phase 3 studies including patients with moderate-to-severe plaque psoriasis (PASI ≥12, BSA ≥10%, static Physician Global Assessment [sPGA] score ≥3).7,8 LIBERATE was a phase 3b study including biologic-naive patients with moderate-to-severe plaque psoriasis (PASI ≥12, BSA ≥10%, sPGA score ≥3).9 UNVEIL was a phase 4 study of conventional systemic- and biologic-naive patients with moderate plaque psoriasis (BSA of 5–10%, sPGA score of 3).10

In ESTEEM 1 and 2,7,8 patients were randomized (2:1) to apremilast 30 mg twice daily (BID) or placebo through Week 16; patients received apremilast 30 mg BID from Week 16 to Week 32. In LIBERATE,9 patients were randomized (1:1:1) to apremilast 30 mg BID, subcutaneous etanercept 50 mg once weekly, or placebo up to Week 16; at Week 16, etanercept and placebo patients switched to apremilast 30 mg BID and apremilast patients continued apremilast 30 mg BID up to Week 104. In UNVEIL,10 patients were randomized (2:1) to apremilast 30 mg BID or placebo through Week 16; patients received apremilast 30 mg BID from Week 16 to Week 32.

Assessments and statistical analyses
Efficacy assessments, including PASI, DLQI, Scalp PGA (ScPGA) and target (worst) Nail Psoriasis Severity Index (NAPSI), were summarized descriptively. Logistic regression was performed to evaluate baseline PASI score as a predictor of achieving PASI ≤2 at Week 32. Achievement of PASI ≤2 at Week 32 by baseline PASI quartiles (Q1: 2.4–13.1; Q2: 13.2–15.9; Q3: 16.0–20.0; Q4: 20.1–57.8) was analysed in patients with baseline and Week 32 PASI assessments. Achievement of DLQI total score ≤5 at baseline and Weeks 4, 16 and 32 by PASI response status at Week 32 (PASI ≤2 vs. PASI >2; non-responder imputation) was analysed in patients with baseline PASI >3 and available Week 32 PASI assessments. Mean ScPGA and NAPSI scores at baseline, Week 16 and Week 32 by baseline PASI quartiles were analysed in patients with baseline ScPGA ≥1 and NAPSI ≥1 (data as observed).

A subgroup analysis assessed achievement of PASI ≤2 at Week 32 based on baseline disease severity (PASI ≤13.1 vs. >13.1; patients in Q1 vs. patients in higher quartiles), disease duration (<5 vs. ≥5 years) and treatment history (systemic-naive vs. systemic-experienced) in patients with baseline PASI ≥3, and available disease duration and Week 32 PASI data.

Results

Patients
Of 1062 patients in the pooled population, 963 (90.7%) had ScPGA ≥1 and 643 (60.5%) had NAPSI ≥1. At Week 32, 771 patients were included in analyses of PASI target achievement. Subgroup analyses included 925 patients at Week 16 and 764 patients at Week 32.

Baseline characteristics were generally consistent across PASI quartiles (Table S1). Lower PASI quartiles had greater proportions of patients classified as moderate (lower mean BSA and DLQI), and patients in the lowest PASI quartile had lower prior use of systemic treatments vs. higher quartiles (Table S1). Most patients had ScPGA ≥1 across PASI quartiles, and rates of NAPSI ≥1 were greater in higher quartiles (Table S1).

Achievement of PASI treatment target with apremilast 2411 by Week 32 PASI Target Status (PASI ≤2 vs. >2) in the pooled population, 29.5% of patients achieved PASI ≤2 at Week 32. A 1-point decrease from baseline in PASI was estimated

Figure 1 Proportion of Patients Achieving a PASI ≤2 at Week 32 Based on Baseline PASI Quartiles. Analysis included patients with baseline and Week 32 PASI assessments. Data are presented as observed.

Table 1 Proportion of Patients Achieving a DLQI Total Score ≤5 by Week 32 PASI Target Status (PASI ≤2 vs. >2)

| PASI target status | Patients achieving a DLQI total score ≤5 |
|--------------------|----------------------------------------|
|                    | Baseline | Week 4 | Week 16 | Week 32 |
| PASI ≤2, n/N (%)   | 45/226 (19.9) | 129/226 (57.1) | 176/226 (77.9) | 189/226 (83.6) |
| PASI >2, n/N (%)   | 96/541 (17.7) | 286/541 (52.9) | 346/541 (64.0) | 321/541 (59.3) |

Patients with missing values were considered non-responders. Analysis included patients with baseline PASI >3 and available Week 32 PASI assessments.
to increase the odds of achieving PASI \( \leq 2 \) by 7% at Week 32 (odds ratio [95% CI]: 0.93 [0.91-0.96]). Achievement of PASI \( \leq 2 \) at Week 32 was greater among patients with a mean baseline PASI in the first quartile vs. higher quartiles; 43.5% of patients in the lowest quartile achieved PASI \( \leq 2 \) at Week 32 (Fig. 1).

At baseline, the percentage of patients with a DLQI total score \( \leq 5 \) (no or small effect on QOL) was generally similar, regardless of Week 32 PASI target status (Table 1). Among patients with PASI \( \leq 2 \) at Week 32, 83.6% achieved DLQI total score \( \leq 5 \); however, 59.3% of patients who did not reach PASI \( \leq 2 \) achieved DLQI total score \( \leq 5 \) at Week 32 (Table 1).

Mean improvements from baseline in ScPGA and NAPSI scores at Weeks 16 and 32 were similar across PASI quartiles (Fig. 2).

In the subgroup analysis, patients with shorter disease duration and lower baseline PASI score achieved PASI \( \leq 2 \) at higher rates than those with longer disease duration and higher baseline PASI score at Weeks 16 and 32 (Fig. 3). Among systemic-naive patients with <5-year disease duration, 37.0% with PASI \( \leq 13.1 \) and 30.0% with PASI >13.1 achieved PASI \( \leq 2 \) at Week 16; at Week 32, 45.5% with PASI \( \leq 13.1 \) and 36.6% with PASI >13.1 achieved PASI \( \leq 2 \) (Fig. 3).
In this analysis of pooled apremilast clinical trials, patients with more moderate disease had higher odds of achieving the PASI treatment target (PASI ≤ 2) and higher rates of PASI response with apremilast treatment than those with more severe disease. Most patients who achieved PASI ≤ 2 with apremilast achieved good QOL overall, as measured by DLQI total score ≤ 5, which indicates a small or no effect on QOL.12 More than half of patients who did not reach PASI ≤ 2 also achieved DLQI total score ≤ 5, suggesting that factors other than the extent of skin disease severity influence QOL. This is in line with other analyses showing that improvements in PASI and DLQI do not always correlate well.13,14 Patients with itch or psoriasis in highly visible and sensitive special areas, such as the scalp and nails, often report high disease burden regardless of their level of overall skin involvement.15,16 Apremilast treatment was associated with similar improvements in scalp and nail psoriasis in patients with more moderate vs. more severe skin disease. It is possible that patients who achieved DLQI total score ≤ 5 without achieving PASI ≤ 2 had improvements in itch or special areas of psoriasis (scalp or nails) that substantially reduced their overall disease burden.

**Figure 3** Achievement of the PASI Treatment Target (PASI ≤ 2) at (a) Week 16 and (b) Week 32 by Baseline PASI (PASI ≤ 13.1 vs. >13.1), Disease Duration and Treatment History. Analysis included patients with baseline PASI ≥ 3 and available Week 16 or Week 32 PASI assessments. Data are presented as observed; note that this analysis excluded patients with baseline PASI <3 (n = 4) and those missing disease duration data (n = 3).
Subgroups of patients with lower baseline PASI score and shorter disease duration had greater achievement of PASI ≤2. Among patients with disease duration ≥5 years, systemic-naive patients had a higher rate of achievement of PASI ≤2 than systemic-experienced patients. Our observations are consistent with a pooled post hoc analysis of ESTEEM 1 and 2, in which apremilast-treated patients with moderate psoriasis had higher rates of achievement of absolute treatment targets (PASI ≤3, BSA ≤2%, sPGA 0 or 1) vs. the pooled population of all apremilast-treated patients.17

Study limitations include the post hoc nature of the analyses and the small numbers of patients in some subgroups despite the use of pooled data from 4 clinical trials. Also, PASI responses were not captured between study visits. Real-world studies capturing patient-reported outcomes in daily patient diaries would be beneficial to complement physician-rated assessments of apremilast effectiveness.

This pooled analysis of apremilast studies adds to the literature evaluating systemic psoriasis treatments using absolute PASI treatment goals.18–20 Our findings suggest that apremilast treatment is particularly beneficial in patients with more moderate skin disease who may have psoriasis in special areas, and when used early in the treatment paradigm to achieve treatment targets.

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Data Sharing
Qualified researchers may request data from Amgen clinical studies. Complete details are available at http://www.amgen.com/datasharing.

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Supporting information
Additional Supporting Information may be found in the online version of this article:

Table S1. Demographics and Baseline Disease Characteristics by Baseline PASI Quartiles