Early Oligoarticular Psoriatic Arthritis Responds to Treatment With Apremilast: Week 16 Results From FOREMOST – a Phase 4 Randomized Controlled Trial

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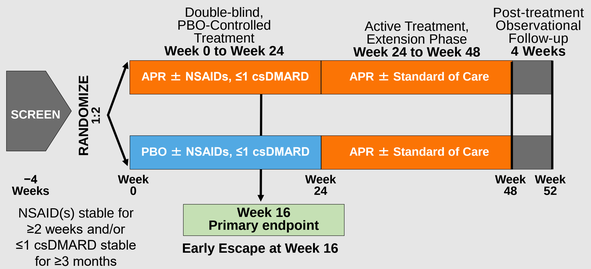
Introduction and Objectives

- Dermatologists may encounter early PsA because up to 30% of patients with psoriasis have PsA[1]
- PsA is underdiagnosed in dermatology practice
  - Dermatologists may encounter PsA before rheumatologists because PsA typically presents 10 years after skin symptoms[2]
- Oligoarticular PsA affects ≤4 joints, is very common, and is underrepresented in clinical trials as most pivotal studies exclude patients with <3 swollen and tender joints[3,4]
- We report the efficacy and safety of apremilast 30 mg BID (APR) vs PBO for the treatment of early oligoarticular PsA

Study Design and Patient Population

- **Design:** Phase 4, multicenter, randomized, double-blind, PBO-controlled, parallel-group study

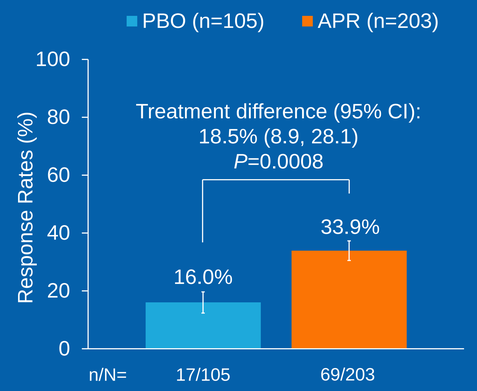


- **Patients:** PsA duration ≤5 years and >1 to ≤4 swollen and >1 to ≤4 tender joints despite treatment with NSAIDs and/or ≤2 csDMARDs
- **Primary endpoint (week 16):** MDA-Joints, a composite measure derived from MDA,[5] mandating low articular disease (TJC ≤1 and SJC ≤1) plus achieving 3 of the following: psoriasis-involved BSA ≤3%, patient pain VAS (0–100 mm) ≤15, PtGA VAS (0–100 mm) ≤20, HAQ-DI ≤0.5, and enthesitis count ≤1 based on LEI
  - MDA is accepted as a treatment target in PsA
- **Secondary endpoints reported in this poster (week 16):** cDAPSA REM (≤4) or LDA (>4 to ≤13), SJC ≤1, TJC ≤1, PtGA ≤20, patient assessment of pain ≤15, PASDAS good or moderate response, change from baseline in PsAID-12, and TEAEs (*scan QR code for pain, PASDAS, and TEAEs*)
- **Exploratory endpoints (week 16):** Nail VAS, BSA=0
- Primary and secondary analyses were based on sentinel joints (those affected at baseline), and exploratory analyses were performed for all joints

Key Takeaways

- **FOREMOST is the first global randomized controlled trial exclusively studying early oligoarticular PsA**
- **We report the first results of FOREMOST, which show that better disease control is achievable with APR, with twice the MDA-Joints response rate compared with PBO at week 16**
- **Findings show that treatment of early oligoarticular PsA with APR improves skin and nail involvement and may inform optimal management of these patients**

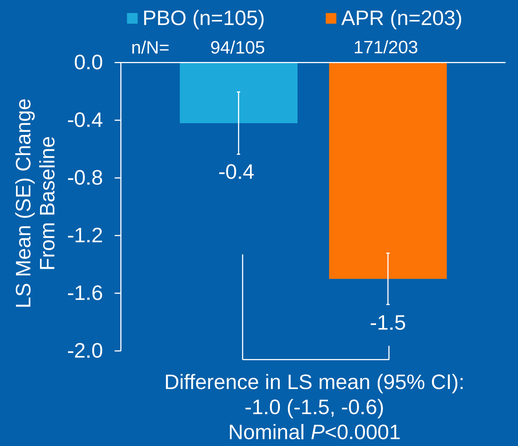
The MDA-Joints response rate was 2 times greater with APR vs PBO at week 16



Error bars represent standard error. Based on sentinel joints (those affected at baseline). Patients who discontinued the study prior to week 16 due to adverse event or lack of efficacy were imputed as non-responders. The remaining missing values at week 16 were imputed by multiple imputation. The number of responders was rounded based on the value given by multiple imputations. *P* value is based on the CMH test, adjusting for prior/concomitant use of csDMARD and baseline glucocorticosteroid use, that is normalized via the Wilson-Hilferty transformation.

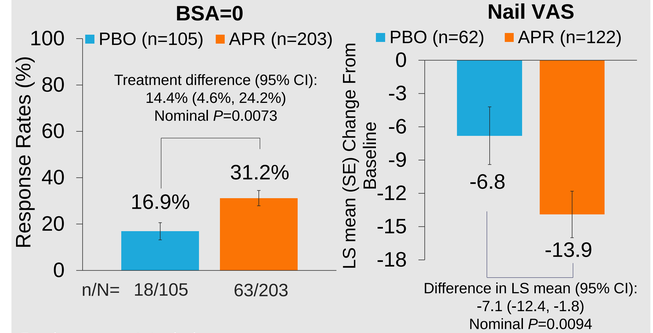
Scan the QR code for baseline characteristics.

Change from baseline in PsAID-12 was greater with APR vs PBO at week 16



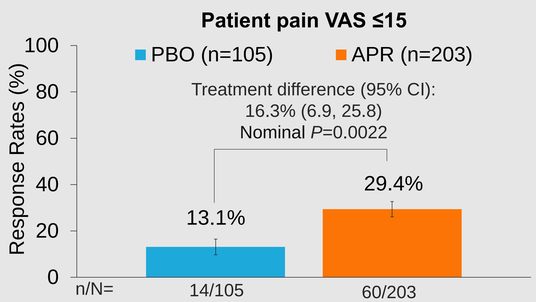
Patients with non-missing data. Based on an MMRM of the change from baseline. The model includes treatment group, time, treatment group by time interaction, prior/concomitant use of csDMARD (naive, prior use only, both prior and concomitant use) and baseline glucocorticosteroids use (yes/no) per IWRS data as factors, and baseline value as a covariate.

Greater reduction in the impact of disease was observed with APR vs PBO at week 16



Error bars represent standard error.
Left: Patients who discontinued the study prior to week 16 due to adverse event or lack of efficacy were imputed as non-responders. The remaining missing values at week 16 were imputed by multiple imputation. The number of responders was rounded based on the value given by multiple imputations. *P* value is based on the CMH test, adjusting for prior/concomitant use of csDMARD and baseline glucocorticosteroid use, that is normalized via the Wilson-Hilferty transformation.
Right: Patients with non-missing data. Based on a mixed model for repeated measures of the change from baseline. The model includes treatment group, time, treatment group by time interaction, prior/concomitant use of csDMARD (naive, prior use only, both prior and concomitant use), and baseline glucocorticosteroids use (yes/no) per interactive web response system data as factors, and baseline value as a covariate.

Greater improvements in pain were seen with APR vs PBO at week 16



Error bars represent standard error. Patients who discontinued the study prior to week 16 due to adverse event or lack of efficacy were imputed as non-responders. The remaining missing values at week 16 were imputed by multiple imputation. The number of responders was rounded based on the value given by multiple imputations. *P* value is based on the CMH test, adjusting for prior/concomitant use of csDMARD and baseline glucocorticosteroid use, that is normalized via the Wilson-Hilferty transformation.

Abbreviations: APR, apremilast 30 mg BID; BID, twice daily; BSA, body surface area; cDAPSA, Clinical Disease Activity in Psoriatic Arthritis; CI, confidence interval; CMH, Cochran-Mantel-Haenszel; csDMARD, conventional synthetic disease-modifying antirheumatic drug; HAQ-DI, Health Assessment Questionnaire Disability Index; IWRS, Interactive Web Response System; LDA, low disease activity; LEI, Leeds Enthesitis Index; LS, least squares; MDA, minimal disease activity; NSAID, nonsteroidal anti-inflammatory drug; PASDAS, Psoriatic Arthritis Disease Activity Score; PBO, placebo; PsA, psoriatic arthritis; PsAID-12, PsA Impact of Disease; PtGA, Patient's Global Assessment of Disease Activity; REM, remission; SE, standard error; SJC, swollen joint count; TEAE, treatment-emergent adverse event; TJC, tender joint count; VAS, visual analog scale.

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For additional data and safety results, scan the QR code or click the link

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