**Online Supplementary Tables**

**Table S1** Primary, secondary, and exploratory efficacy endpoints

|  |  |
| --- | --- |
| **Efficacy endpoints** | |
| **Primary** | Modified ACR20 response\* at week 161 |
| **Key secondary** | Change from baseline in HAQ-DI score† at week 162, 3 |
| **Secondary** | ACR20 response at week 241 |
|  | Change from baseline in HAQ-DI score at week 242, 3 |
|  | Change from baseline in the SF-36v2 Physical Functioning scale score (norm-based) at week 244 |
|  | Modified PsARC response‡ at week 245 |
|  | Change from baseline in the patient assessment of pain at week 24 |
|  | Change from baseline in the MASES at week 24 in patients with enthesitis at baseline6 |
|  | Change from baseline in the dactylitis count§ at week 24 in patients with dactylitis at baseline7 |
|  | Change from baseline in the DAS-28 (CRP) at week 248 |
|  | Change from baseline in the CDAI score at week 249 |
|  | Proportion of patients achieving good or moderate EULAR response‖ at week 2410 |
|  | ACR50 response at week 241 |
|  | ACR70 response at week 241 |
|  | Proportion of patients with enthesitis at baseline whose MASES improves from baseline to 0 at week 246 |
|  | Proportion of patients with dactylitis at baseline whose dactylitis count improves from baseline to 0 at week 247 |
| **Exploratory** | PASI-75 response¶ at week 24 among patients with psoriasis body surface area ≥3% at baseline11 |
|  | PASI-50 response at week 24 among patients with psoriasis body surface area ≥3% at baseline11 |

\*The modified ACR20 response requires ≥20% improvement from baseline in swollen or tender joint counts, based on evaluation of 76 swollen and 78 tender joints, plus ≥20% improvement in three of the following: patient’s global assessment of disease activity1 (0-100 mm VAS); physician’s global assessment of disease activity (VAS)1; patient’s assessment of pain (VAS); HAQ-DI2, 3; or CRP level.

†Proportions of patients achieving minimal clinically important differences on the HAQ-DI (≥0.13 [Kwok] and ≥0.30 [Mease]) were also determined. Pre-specified thresholds were based on the literature at the time of the protocol development.12, 13

‡Modified PsARC response is defined as improvement in at least two of the four measures (swollen joint count, tender joint count, patient’s global assessment of disease activity, physician’s global assessment of disease activity), at least one of which must be swollen or tender joint count, and no worsening in any of the four measures. Improvement or worsening in joint counts is defined as a decrease or increase, respectively, from baseline by ≥30%; improvement or worsening in global assessments is defined as a decrease or increase, respectively, from baseline by ≥20 mm VAS.

§Each digit on the patient’s hand and feet was assessed for presence (score=1) or absence (score=0) of dactylitis. The dactylitis count was the sum of the individual assessments for all 20 digits.

‖A EULAR good response is defined as DAS-28 at the time point ≤3.2 and improvement from baseline >1.2. A EULAR moderate response is defined as DAS-28 at the time point >3.2 and improvement from baseline >1.2, or DAS-28 at the time point ≤5.1 and improvement from baseline >0.6 and ≤1.2.

¶The PASI score was determined only for patients whose psoriasis has a body surface area ≥3%. PASI scores range from 0 to 72, with higher scores reflecting greater disease severity.11

ACR20/50/70, 20%/50%70% improvement in baseline American College of Rheumatology response criteria; CDAI, Clinical Disease Activity Index; CRP, C-reactive protein; DAS-28, 28-joint count Disease Activity Score; EULAR, European League Against Rheumatism; HAQ-DI, Health Assessment Questionnaire-Disability Index; MASES, Maastricht Ankylosing Spondylitis Enthesitis Score; PASI-75/50, 75%/50% reduction from baseline Psoriasis Area and Severity Index score; PsARC, Psoriatic Arthritis Response Criteria; SF-36v2, 36-item Short-Form Health Survey version 2; VAS, visual analog scale.

**References**

1 Felson DT, Anderson JJ, Boers M, *et al*. American College of Rheumatology. Preliminary definition of improvement in rheumatoid arthritis. *Arthritis Rheum* 1995;**38:**727-35.

2 Bruce B, Fries JF. The Stanford Health Assessment Questionnaire: a review of its history, issues, progress, and documentation. *J Rheumatol* 2003;**30:**167-78.

3 Fries JF, Spitz P, Kraines RG, *et al*. Measurement of patient outcome in arthritis. *Arthritis Rheum* 1980;**23:**137-45.

4 Ware JE Jr, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Med Care* 1992;**30:**473-83.

5 Clegg DO, Reda DJ, Mejias E, *et al*. Comparison of sulfasalazine and placebo in the treatment of psoriatic arthritis. A Department of Veterans Affairs Cooperative Study. *Arthritis Rheum* 1996;**39:**2013-20.

6 Heuft-Dorenbosch L, Spoorenberg A, van Tubergen A, *et al*. Assessment of enthesitis in ankylosing spondylitis. *Ann Rheum Dis* 2003;**62:**127-32.

7 Antoni C, Krueger GG, de Vlam K, *et al*. Infliximab improves signs and symptoms of psoriatic arthritis: results of the IMPACT 2 trial. *Ann Rheum Dis* 2005;**64:**1150-7.

8 Mease PJ, Antoni CE. Psoriatic arthritis treatment: biological response modifiers. *Ann Rheum Dis* 2005;**64**(Suppl 2)**:**ii78-ii82.

9 Aletaha D, Smolen J. The Simplified Disease Activity Index (SDAI) and the Clinical Disease Activity Index (CDAI): a review of their usefulness and validity in rheumatoid arthritis. *Clin Exp Rheumatol* 2005;**23:**S100-S108.

10 Fransen J, Van Riel PL. The Disease Activity Score and the EULAR response criteria. *Clin Exp Rheumatol* 2005;**23:**S93-S99.

11 Fredriksson T, Pettersson U. Severe psoriasis--oral therapy with a new retinoid. *Dermatologica* 1978;**157:**238-44.

12 Kwok T, Pope JE. Minimally important difference for patient-reported outcomes in psoriatic arthritis: Health Assessment Questionnaire and pain, fatigue, and global visual analog scales. *J Rheumatol* 2010;**37:**1024-8.

13 Mease PJ, Ganguly R, Wanke L, *et al*. How much improvement in functional status is considered important by patients with active psoriatic arthritis: applying the outcome measures in rheumatoid arthritis clinical trials (OMERACT) group guidelines [abstract SAT0015]. *Ann Rheum Dis* 2004;**63**(Suppl 1)**:**391.

**Table 2S.** Week 16 values for baseline clinical characteristics presented in Table 1: intent-to-treat population (N=504\*)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | | **Apremilast** | |
|  | | **Placebo n=168** | **20 mg BID n=168** | **30 mg BID n=168** |
| Swollen joint count (0-76), mean (SD) | | 10.9 (10.2) | 8.2 (8.7) | 7.5 (8.3) |
| Tender joint count (0-78), mean (SD) | | 21.2 (16.2) | 16.9 (16.3) | 15.8 (14.7) |
| HAQ-DI (0-3), mean (SD) | | 1.1 (0.64) | 0.95 (0.67) | 0.97 (0.68) |
| Patient’s global assessment (0-100 mm VAS), mean (SD) | | 53.8 (24.6) | 46.2 (27.2) | 45.9 (25.7) |
| Physician’s global assessment (0-100 mm VAS), mean (SD) | | 46.8 (24.9) | 37.5 (26.1) | 36.9 (24.7) |
| CRP (mg/dL, normal range <0.5), mean (SD) | | 1.6 (2.0) | 0.79 (1.2) | 0.73 (0.87) |
| Patient’s assessment of pain (0-100 mm VAS), mean (SD) | | 53.4 (23.5) | 44.7 (25.9) | 44.4 (25.3) |
| SF-36v2 PF score, mean (SD) | | 35.9 (10.9) | 38.7 (11.6) | 37.7 (11.0) |
| DAS-28 (CRP), mean (SD) | | 4.6 (1.2) | 4.0 (1.3) | 4.0 (1.3) |
| CDAI (0-76), mean (SD) | | 25.6 (13.7) | 20.3 (13.8) | 20.4 (13.6) |
| PASI score (0-72),† mean (SD) | | 9.1 (10.3) | 5.6 (8.5) | 5.7 (8.0) |
| MASES (0-13),‡ mean (SD) | | 4.3 (3.6) | 3.5 (3.7) | 3.3 (3.2) |
| Dactylitis severity score (0-20),§ mean (SD) | | 2.0 (2.7) | 1.7 (2.8) | 1.5 (1.9) |

\*The n reflects the number of randomized patients; actual number of patients available for each endpoint may vary. Missing data at week 16 were handled using last observation carried forward methodology.

†Examined among patients who had body surface area ≥3% affected at baseline and ≥1 post-baseline value at or prior to week 16 (placebo: n=63; apremilast 20 mg BID: n=71; apremilast 30 mg BID: n=79).

‡Examined among patients who had enthesopathy at baseline and ≥1 post-baseline value at or prior to week 16 (placebo: n=95; apremilast 20 mg BID: n=100; apremilast 30 mg BID: n=108).

§Examined among patients who had dactylitis at baseline and ≥1 post-baseline value at or prior to week 16 (placebo: n=63; apremilast 20 mg BID: n=56; apremilast 30 mg BID: n=66).

CDAI, Clinical Disease Activity Index; CRP, C-reactive protein; DAS-28, 28-joint count Disease Activity Score; HAQ-DI, Health Assessment Questionnaire-Disability Index; PASI, Psoriasis Area and Severity Index score; SF-36v2, 36-item Short-Form Health Survey version 2; VAS, visual analog scale.