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Efficacy and Safety of Apremilast for the Treatment of Japanese Patients With Palmoplantar Pustulosis: Results From a Phase 2, Randomized, Placebo-Controlled Study

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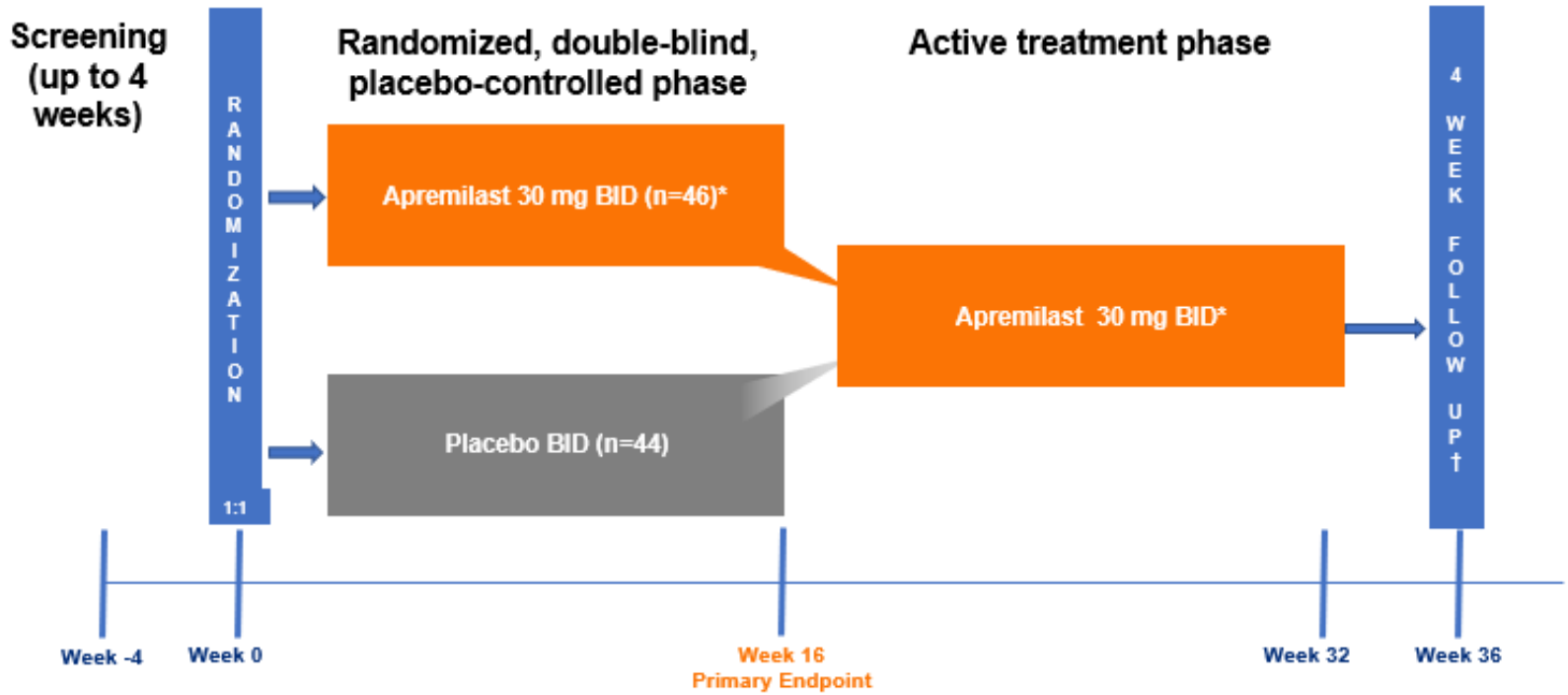
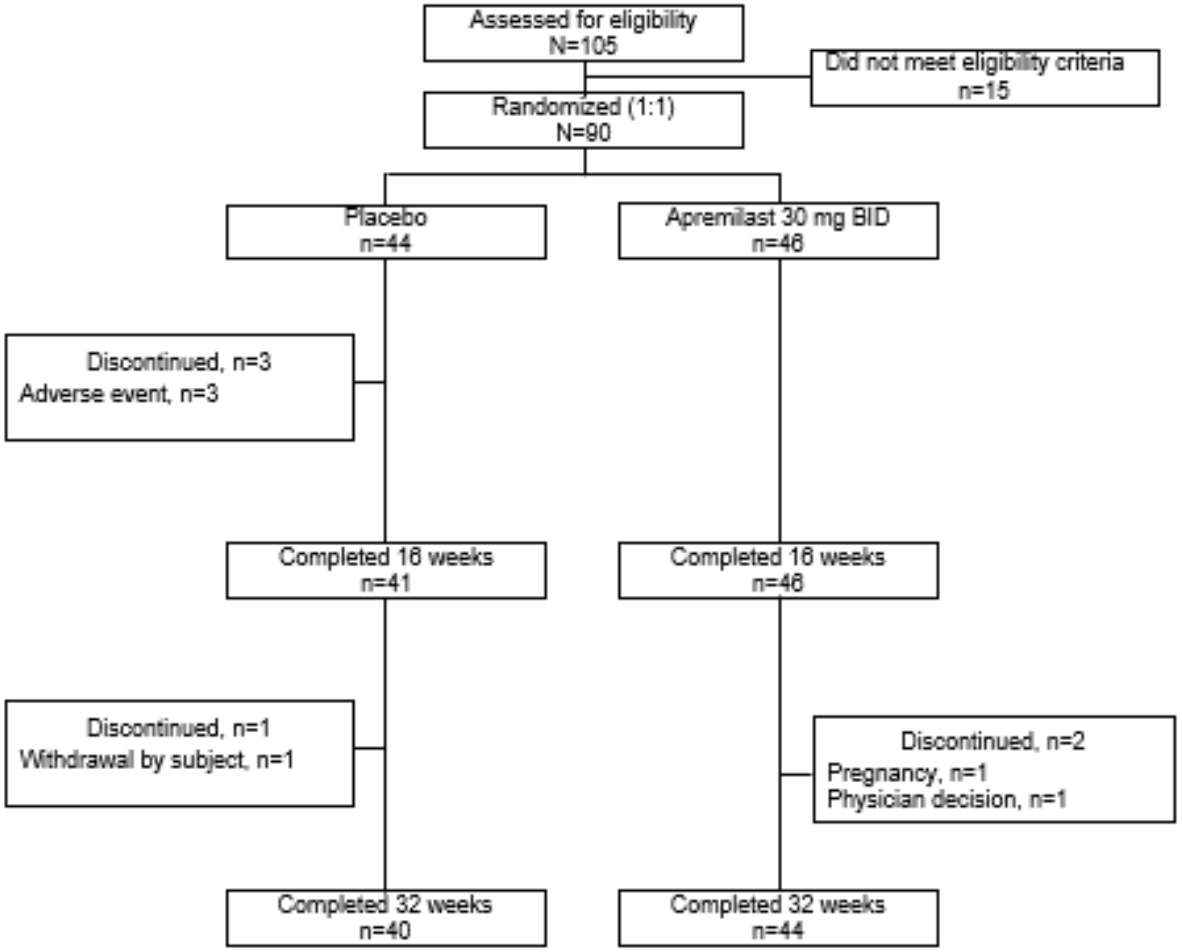
Online Resource 1. Study Design



*Apremilast dose was titrated over a 5-day period at Week 0 for patients initially randomized to apremilast and at Week 16 for patients switched from placebo to apremilast.

†Observational follow-up for all patients who completed the study or discontinued the study early.

Online Resource 2. Patient Disposition



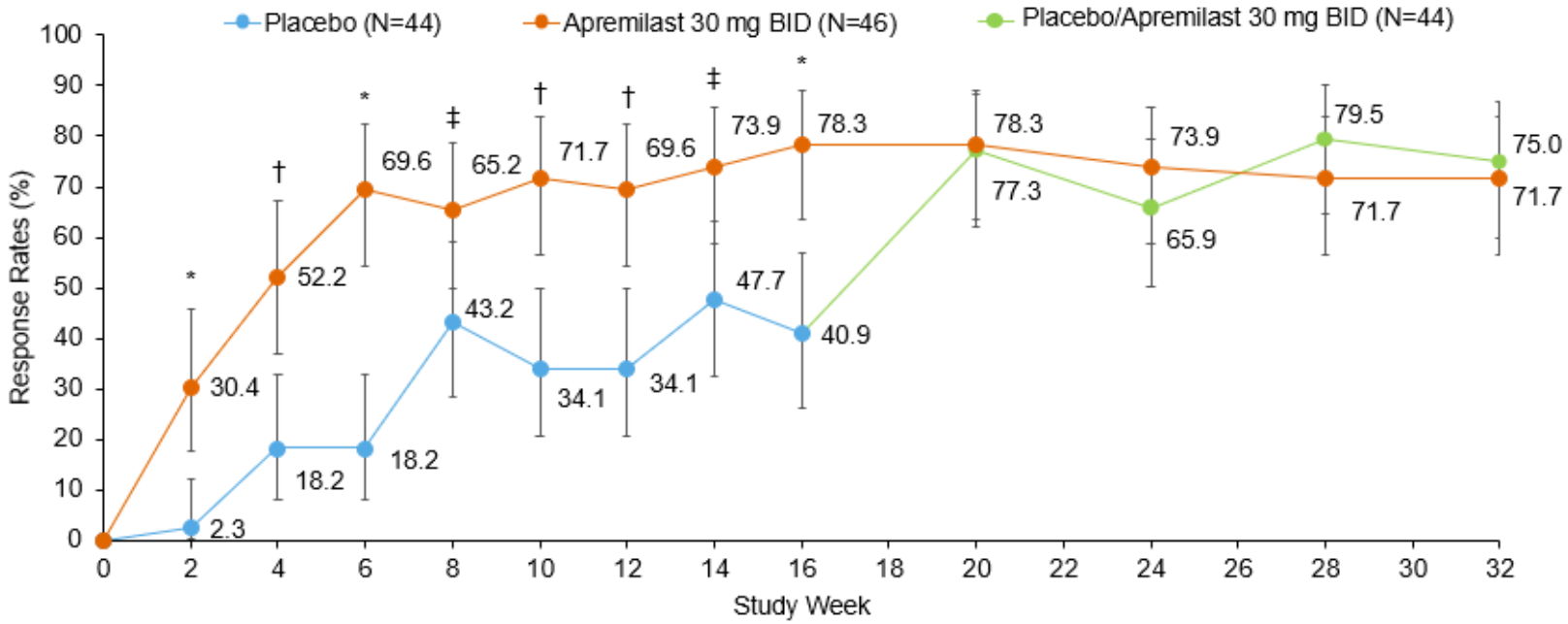
Online Resource 3. Proportion of Patients at Week 16 With PPPASI-50, PPPASI-75, or PPPASI-90 Response

Proportion of Patients	Placebo N=44 n (%)	Apremilast N=46 n (%)	Difference in Proportion % (95% CI)	Nominal *P* value
PPPASI-50	18 (40.9)	36 (78.3)	37.4 (18.6, 56.1)	0.0003
PPPASI-75	7 (15.9)	20 (43.5)	26.3 (8.3, 44.2)	0.0074
PPPASI-90	3 (6.8)	6 (13.0)	6.2 (-6.0, 18.5)	0.3278

Intent-to-treat population. Two-sided CI is based on the Clopper-Pearson method. Two-sided *P* value (nominal) is based on Cochran Mantel-Haenszel test adjusting for baseline PPPASI score range and baseline focal infection status at baseline. Missing data were imputed by nonresponder imputation. CI=confidence interval; PPPASI=Palmoplantar Pustulosis Area and Severity Index; PPPASI-50=≥50% improvement from baseline in PPPASI total score; PPPASI-75=≥75% improvement from baseline in PPPASI total score; PPPASI-90=≥90% improvement from baseline in PPPASI total score. NA=not available

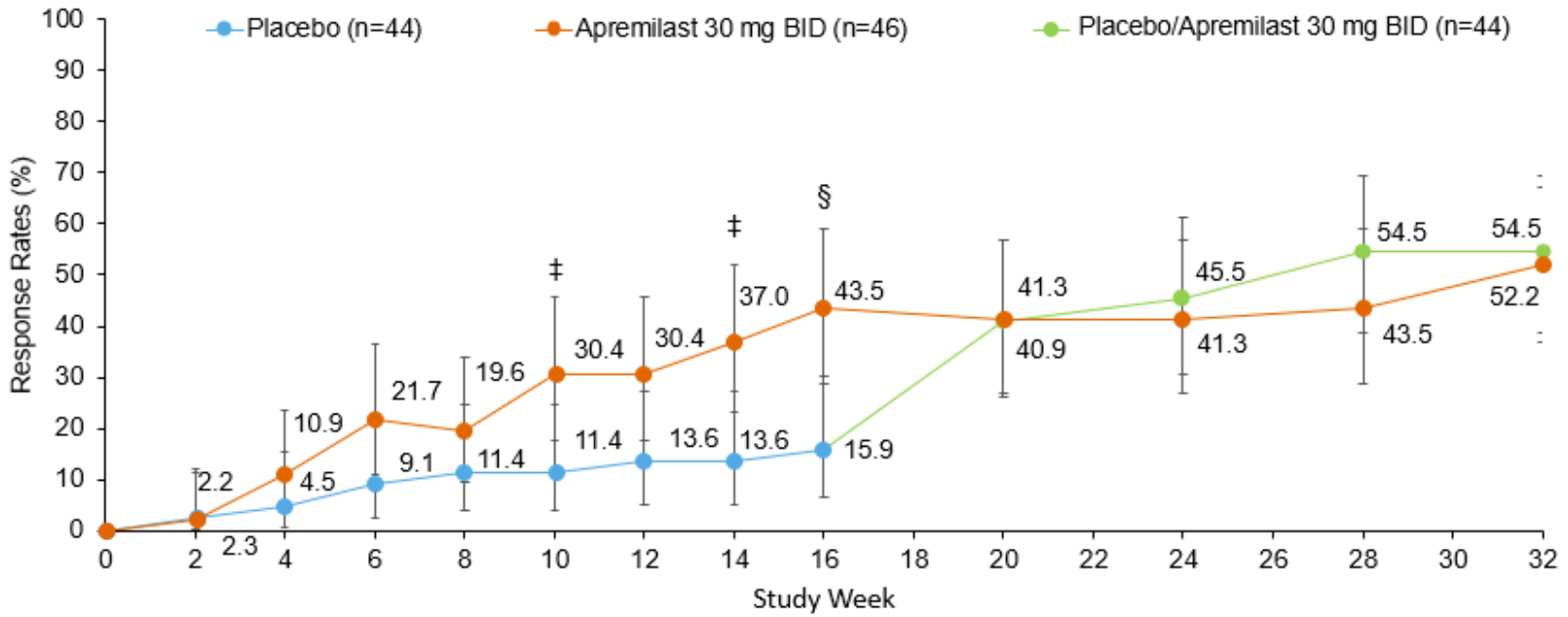
Online Resource 4. Proportion of Patients With a. PPPASI-50 Response; and b. PPPASI-75 Response Over 32 Weeks

a.



Placebo, n/N	0	1/44	8/44	8/44	19/44	15/44	15/44	21/44	18/44	34/44	29/44	35/44	33/44
Apremilast, n/N	0	14/46	24/46	32/46	30/46	33/46	32/46	34/46	36/46	36/46	34/46	33/46	33/46

b.

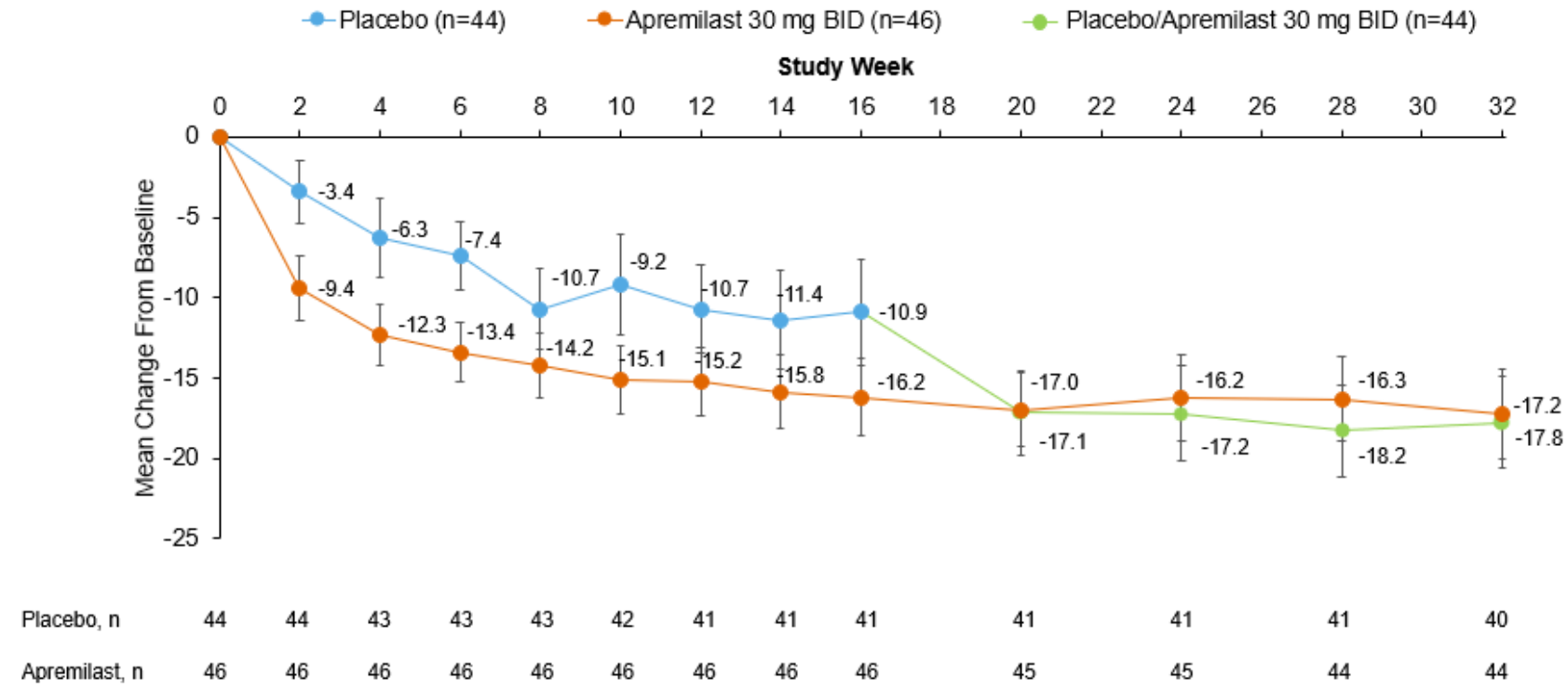


Placebo, n/N	0	1/44	2/44	4/44	5/44	5/44	6/44	6/44	7/44	18/44	20/44	24/44	24/44
Apremilast, n/N	0	1/46	5/46	10/46	9/46	14/46	14/46	17/46	20/46	19/46	19/46	20/46	24/46

*Nominal $P \leq 0.0005$ vs placebo. †Nominal $P < 0.005$ vs placebo. ‡Nominal $P < 0.05$ vs placebo. §Nominal $P = 0.0074$ vs placebo. Intent-to-treat population. Two-sided CI is based on the Clopper-Pearson method. Two-sided *P* value (nominal) is based on the Cochran-Mantel-Haenszel test adjusting for baseline PPPASI score range and baseline focal infection status. Missing data were imputed by nonresponder imputation. CI=confidence interval; PPPASI=Palmoplantar Pustulosis Area and Severity Index; PPPASI-50=≥50% improvement from baseline in PPPASI total score; PPPASI-75=≥75% improvement from baseline in PPPASI total score.

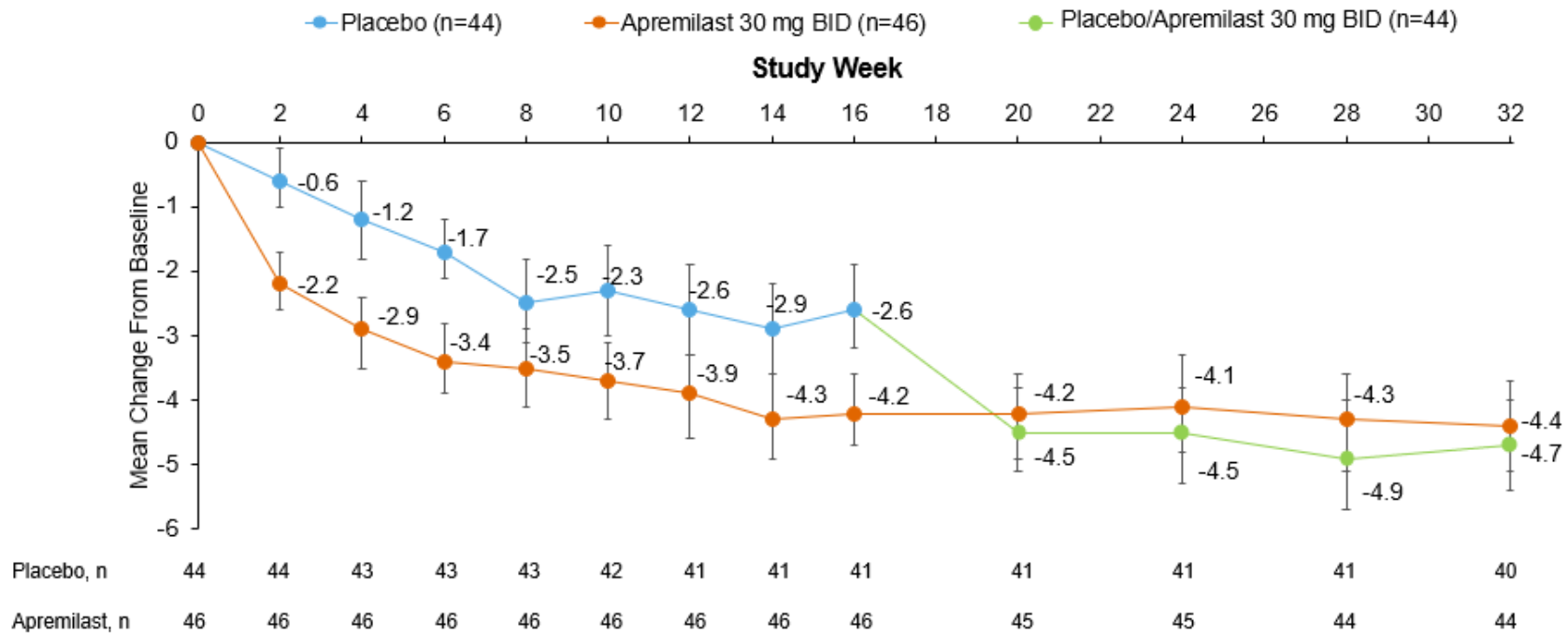
Online Resource 5. Change From Baseline in a. PPPASI; and b. PPSI Score Over Time

a.



Error bars represent 95% CI. Intent-to-treat population.

b.

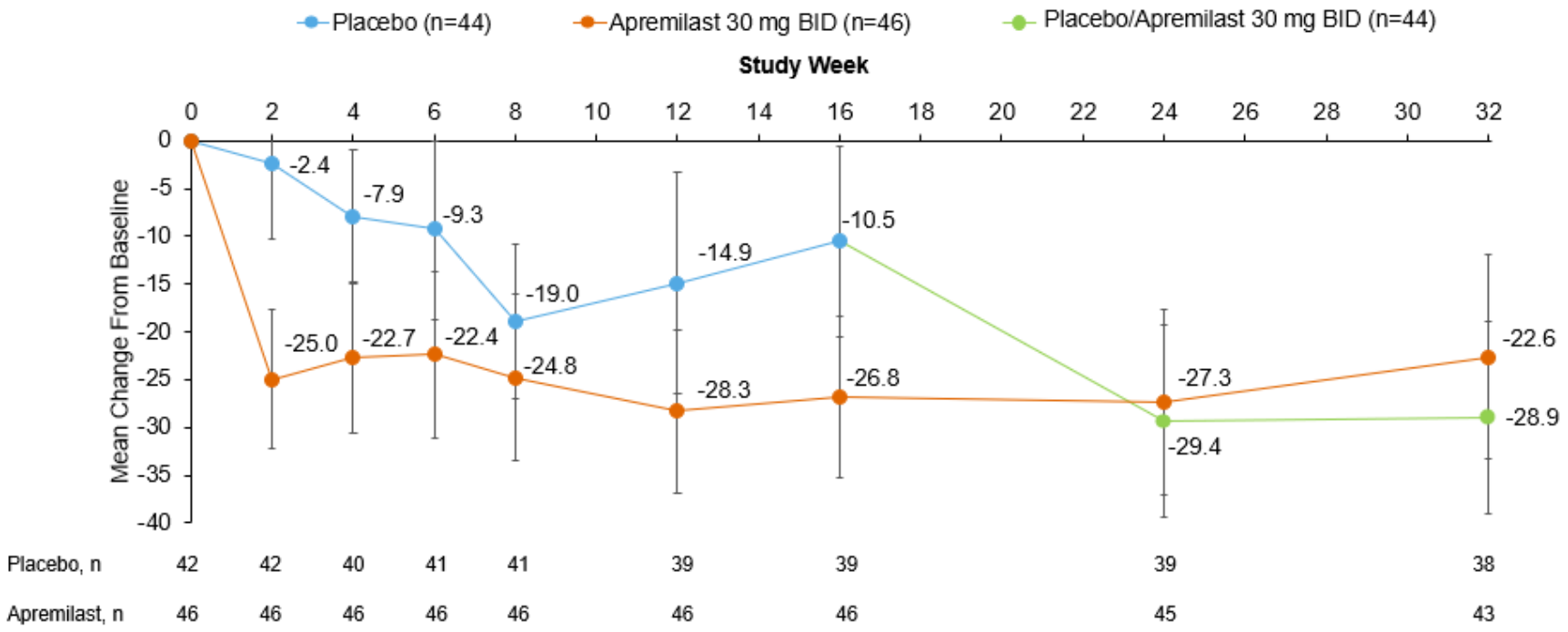


Error bars represent 95% CI. Intent-to-treat population.

CI=confidence interval; PPPASI=Palmoplantar Pustulosis Area and Severity Index; PPSI=Palmoplantar Severity Index.

Online Resource 6. Change From Baseline in a. Pruritus VAS; and b. Skin Discomfort/Pain VAS Over Time

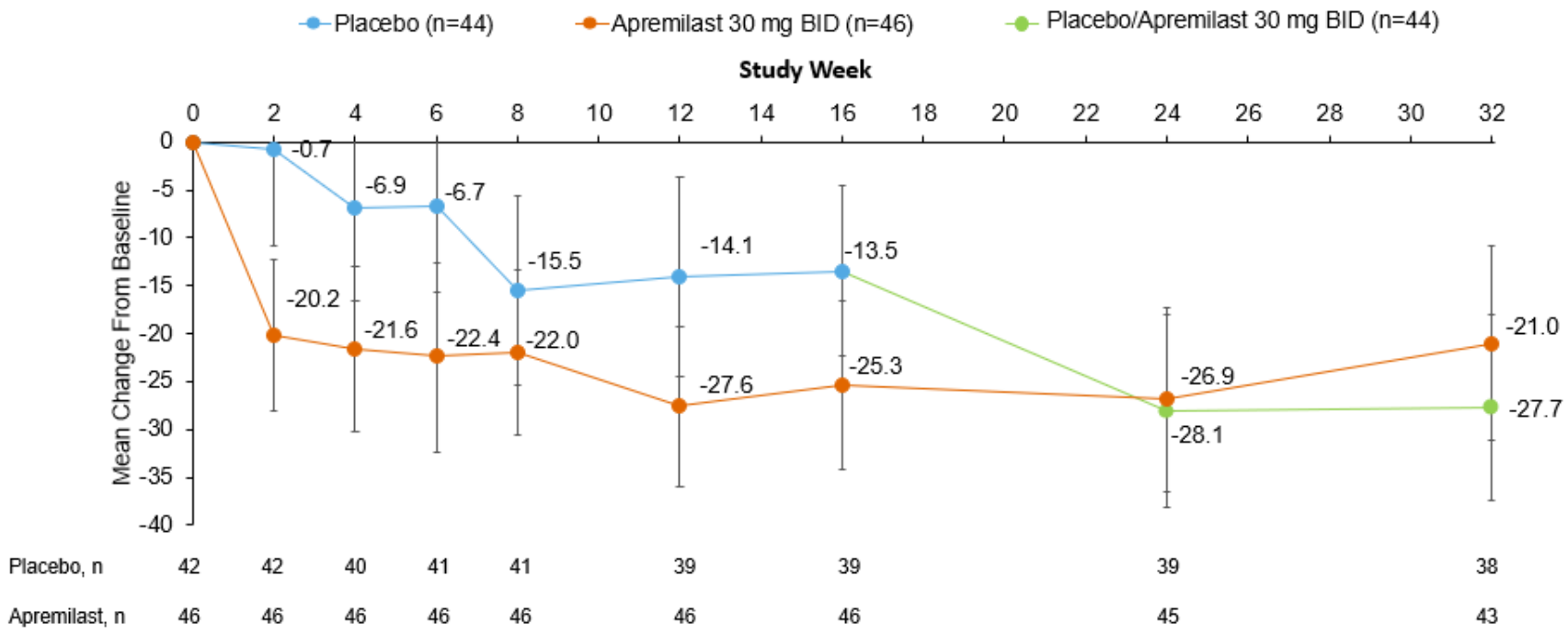
a.



Error bars represent 95% CI. Intent-to-treat population.

CI=confidence interval; VAS=visual analog scale.

b.



Error bars represent 95% CI. Intent-to-treat population.

CI=confidence interval; VAS=visual analog scale.