

Table. LIBERATE Efficacy Outcomes

Pts Achieving Response, % (LOCF)	PBO n=84	APR n=83	ETN n=83
Week 16			
PASI-75	11.9	39.8*	48.2*
sPGA 0 or 1 [§]	3.6	21.7*	28.9*
ScPGA 0 or 1 [¶]	25.9	44.4**	50.0 [†]
NAPSI-50 ^{§§}	10.9	25.0 ^{¶¶}	48.0*
Percent change from BL in NAPSI ^{¶¶}	-10.1	-18.7	-37.7
Week 104			
PASI-75	50.7	45.9	51.9
sPGA 0 or 1 [§]	27.4	18.9	26.6
ScPGA 0 or 1 [¶]	50.0	59.2	56.6
NAPSI-50 ^{§§}	48.6	60.4	65.2
Percent change from BL in NAPSI ^{¶¶}	-48.1	-48.2	-51.1

APR=apremilast 30 mg BID; ETN=etanercept 50 mg QW; LOCF=last observation carried forward; NAPSI=Nail Psoriasis Severity Index; NAPSI-50=50% or greater reduction from baseline in NAPSI score; PASI=Psoriasis Area and Severity Index; PASI-75=75% or greater reduction from baseline in PASI score; PBO=placebo; ScPGA=Scalp Physician Global Assessment; sPGA=static Physician's Global Assessment

*P<0.0001; †P=0.0005; ‡P≤0.0021; **P=0.0458; ††P=0.0083; ¶¶P=0.0701 vs. PBO (LOCF). Italics indicate values are nominally significant due to hierarchical testing of study end points.

[§]With ≥2-point reduction from baseline.

[¶]In pts with ScPGA ≥3 (moderate to very severe) at baseline (exploratory); PBO n=58; APR n=54; ETN n=54 at Week 16 and PBO/APR n=50; APR/APR n=49; ETN/APR n=53 at Week 104.

^{§§}In pts with NAPSI ≥1 at baseline: PBO n=46; APR n=52; ETN n=50 at Week 16 and PBO/APR n=37; APR/APR n=48; ETN/APR n=46 at Week 104.

^{¶¶}PBO n=42; APR n=50; ETN n=50 at Week 16; PBO/APR n=33; APR/APR n=48; ETN/APR n=45 at Week 104.

Disclosure of Interest: K. Reich Consultant for: AbbVie, Amgen, Biogen, Boehringer Ingelheim, Celgene Corporation, Centocor, Covagen, Eli Lilly, Forward Pharma, GlaxoSmithKline, Janssen-Cilag, LEO Pharma, Medac, Merck Sharp & Dohme, Novartis, Ocean Pharma, Pfizer (Wyeth), Regeneron, Takeda, UCB Pharma, and Xenoport, Speakers Bureau: AbbVie, Amgen, Biogen, Boehringer Ingelheim, Celgene Corporation, Centocor, Covagen, Eli Lilly, Forward Pharma, GlaxoSmithKline, Janssen-Cilag, LEO Pharma, Medac, Merck Sharp & Dohme, Novartis, Ocean Pharma, Pfizer (Wyeth), Regeneron, Takeda, UCB Pharma, and Xenoport, M. Goodfield: None declared, L. Green Consultant for: AbbVie, Amgen, Celgene Corporation, LEO Pharma, Novartis, Pfizer, and Valeant, Speakers bureau: AbbVie, Amgen, Celgene Corporation, LEO Pharma, Novartis, Pfizer, and Valeant, K. Nograles Employee of: Celgene Corporation, R. Chen Employee of: Celgene Corporation, E. Levi Employee of: Celgene Corporation, R. Langley Speakers bureau: AbbVie, Amgen, Celgene Corporation, Eli Lilly, LEO Pharma, Merck, Novartis, and Pfizer

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AB0772 SECUKINUMAB PROVIDES SUSTAINED IMPROVEMENT IN FUNCTION, QUALITY OF LIFE AND FATIGUE OVER 2 YEARS IN PATIENTS WHO ACHIEVED LOW DISEASE ACTIVITY RELATED TO PSORIATIC ARTHRITIS DISEASE ACTIVITY SCORE (PASDAS)

L.C. Coates^{1,2}, T.K. Kvien³, P. Nash⁴, L. Gossec⁵, V. Strand⁶, L. Pricop⁷, L. Rasouliyan⁸, K. Ding⁷, S. Jugl⁹, C. Gaillez⁹ on behalf of the FUTURE 2 study group. ¹University of Leeds; ²Leeds Teaching Hospitals NHS Trust, Leeds, United Kingdom; ³Diakonhjemmet Hospital, Oslo, Norway; ⁴University of Queensland, Brisbane, Australia; ⁵UPMC Université Paris 06, Paris, France; ⁶Stanford University School of Medicine, Palo Alto; ⁷Novartis Pharmaceuticals Corporation, East Hanover, United States; ⁸RTI Health Solutions, Barcelona, Spain; ⁹Novartis Pharma AG, Basel, Switzerland

Background: PASDAS is a composite index measuring disease activity in psoriatic arthritis (PsA), well correlated with HAQ and health related quality of life¹.

Objectives: To report the impact of secukinumab on individual core components of PASDAS and its relationship with function (HAQ-DI), health related quality of life (SF36-PCS and MCS, DLQI, PsAQoL) and fatigue in patients (pts) who achieved PASDAS low disease activity (LDA) vs. high disease activity (HDA) through Week (Wk) 104 using *post-hoc* analysis from FUTURE 2 trial.

Methods: 397 pts with active PsA were randomised to s.c. secukinumab (300, 150, or 75mg) or placebo in FUTURE 2 study.² PASDAS is derived from physician's global VAS, pts global VAS, SF-36 PCS, tender and swollen joints (TJC68 and SJC66), Leeds enthesitis count, dactylitis count and CRP level and has cut-points for HDA (≥5.4), LDA (<3.2) and remission (REM≤1.9).³ PASDAS was assessed at Wks 16, 52 and 104 and reported as observed using non-mutually exclusive categories at group level. Additionally, the SF-36 PCS, SF-36 MCS, HAQ-DI, FACIT-Fatigue, PsAQoL, and DLQI were assessed by PASDAS LDA and HDA at Wks 16, 52 and 104 using MMRM analyses.

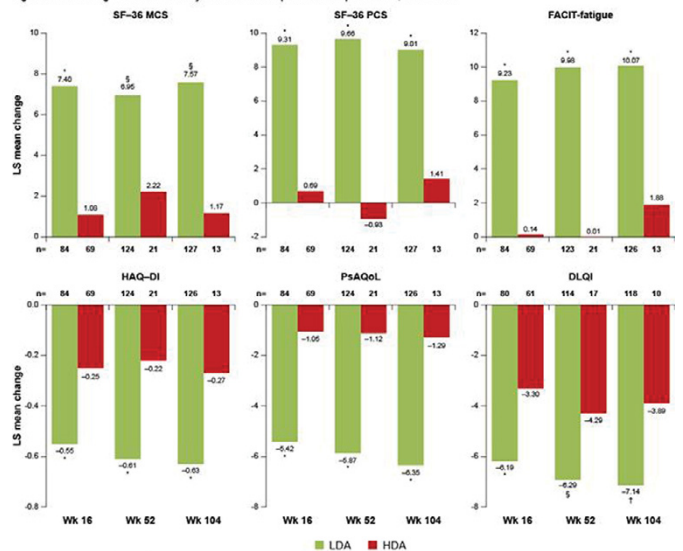
Results: Pts presented similar baseline characteristics. Mean±SD score of each PASDAS component among pts reaching LDA and HDA at Wk 16 for each treatment group are shown in table and were similar at Wk 104. Secukinumab treated pts achieving PASDAS LDA had significantly greater improvements in function, physical and mental health quality of life and fatigue compared to HDA through Wk 104 (Figure).

Conclusions: In pts treated with secukinumab, the most improved individual components with PASDAS LDA were related to dactylitis, enthesitis, SF36-PCS, Physician global VAS and SJC at Wk 16 and Wk 104. PASDAS LDA was associated with better improvement in function, quality of life and fatigue than

Table 1. Scores of PASDAS components at Wk 16

Core components, Mean ± SD	Secukinumab/PBO (s.c.), mg	LDA 300mg: n=37; 150mg: n=34; PBO: n=14	HDA 300mg: n=12; 150mg: n=23; PBO: N=34
Physician/Pt Global VAS	300 150 PBO	7.3±7.2/14.6±10.3 8.3±8.7/13.2±10.3 11.4±9.8/16.7±13.4	43.2±10.2/65.7±21.6 55.7±16.2/67.8±14.9 56.7±12.8/64.8±15.6
SF-36 PCS	300 150 PBO	51.5±5.8 51.8±5.5 49.4±6.6	34.9±6.0 34.2±6.5 33.5±8.2
SJC 66/TJC 68	300 150 PBO	2.2±3.0/2.3±3.4 1.9±3.6/2.6±5.0 1.7±2.0/3.4±4.7	12.3±10.0/27.9±16.1 15.9±11.1/32.3±21.7 10.1±6.1/25.4±14.0
Leeds Enthesitis Score	300 150 PBO	0.3±0.8 0.1±0.3 0.2±0.6	3.0±2.5 3.0±2.5 2.4±1.8
Tender Dactylitis count	300 150 PBO	0.03±0.2 0 0.1±0.5	0.9±2.6 1.4±3.1 1.3±2.4
CRP (mg/L)	300 150 PBO	3.3±3.5 3.3±3.5 5.8±15.2	5.0±4.5 8.1±11.6 14.7±19.5

Figure: Mean Change in PRO scores by PASDAS states (LDA vs. HDA) at Wks 16, 52 and 104



*P < 0.0001; †P < 0.001; ‡P < 0.01 versus HDA. DLQI, Dermatology Life Quality Index; FACIT, fatigue; Functional Assessment of Chronic Illness Therapy-Fatigue; HAQ-DI, Health Assessment Questionnaire Disability Index; HDA, high disease activity; LDA, low disease activity; LS, least squares; n, number of pts with measurements; N, number of pts in each group of the specified analysis set; PsAQoL, PsA-specific quality of life; SF-36 MCS, Short Form-36 Mental Component Summary; SF-36 PCS, Short Form-36 Physical Component Summary. Wk 16: n=85 (LDA) and n=69 (HDA); Wk 52: n=125 (LDA) and n=21 (HDA); Wk 104: n=128 (LDA) and n=13 (HDA). Analysis data were pooled across treatment arms; Placebo group not reported at Wk 16.

HDA confirming the importance to reach stringent target in a PsA pts with multifaceted disease.

References:

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