ABSTRACT NUMBER: 1360

Ultrasound Demonstrates Continued Improvement in Psoriatic Arthritis Synovitis and Enthesitis with Secukinumab: 52-week Results from a Phase III Study

Maria Antonietta D'Agostino[1], Georg Schett[2], Corine Gaillez[3], Carlos Guerrero[4], PETRA HANOVA[5], Tomas Cazenave[6], Maria S. Stoenoiu[7], Marina Backhaus[8], Gael Mouterde[9], Maarten Boers[10], Anne-Marie Duggan[11], Punit Goyanka[12] and Philip Conaghan[13], [1]Rheumatology, Fondazione Policlinico Universitario "Gemelli", IRCCS, Rome, Italy, [2]Universitätsklinikum Erlangen, Department of Internal Medicine 3 – Rheumatology and Immunology, Erlangen, Germany, Erlangen, Germany, [3]Novartis Pharma AG, Basel, Switzerland, [4]Dermatologico Country, Jalisco, Mexico, [5]Department of Rheumatology, Institute of Rheumatology, Prague, Czech Republic, [6]Instituto de Rehabilitación Psicofisica, Buenos Aires, Argentina, Buenos Aires, Argentina, [7]Rheumatology department, Cliniques Universitaires Saint-Luc, Institut de Recherche Expérimentale et Clinique (IREC), Brussels, Belgium, [8]Department of Internal Medicine, Rheumatology and Clinical Immunology, Park-Klinik Weissensee Academic Hospital of the Charité, Berlin, Germany, Berlin, Germany, [9]Rheumatology department, CHU Montpellier, Montpellier, France, [10]Department of Epidemiology and Data Science, and Amsterdam Rheumatology and Immunology Center, Amsterdam UMC, Vrije Universiteit, Amsterdam, Netherlands, [11]Novartis Ireland Limited, Dublin, Ireland, Dublin, Ireland, [12]Novartis Healthcare Pvt Ltd, Hyderabad, India, Hyderabad, India, [13]Leeds Institute of Rheumatic and Musculoskeletal Medicine, University of Leeds, Leeds, United Kingdom

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SESSION INFORMATION

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Session Type: Poster Session C

Title: Spondyloarthritis Including PsA – Treatment Poster II: Psoriatic Arthritis I (1329–1363)

Session Time: 8:30AM-10:30AM

Background/Purpose: Power Doppler ultrasound (PDUS) is a sensitive non-invasive imaging tool to visualize a wide range of articular and periarticular inflammation in psoriatic arthritis (PsA).[1,2] ULTIMATE (NCT02662985) is the first large RCT that used ultrasound with Global OMERACT ultrasound synovitis score (GLOESS) as the primary endpoint, to demonstrate early benefits of secukinumab on synovitis in patients with PsA through 12 weeks.[3] Here we report the responsiveness of ultrasound on synovitis and enthesitis, clinical efficacy, and safety of secukinumab up to 52 weeks.

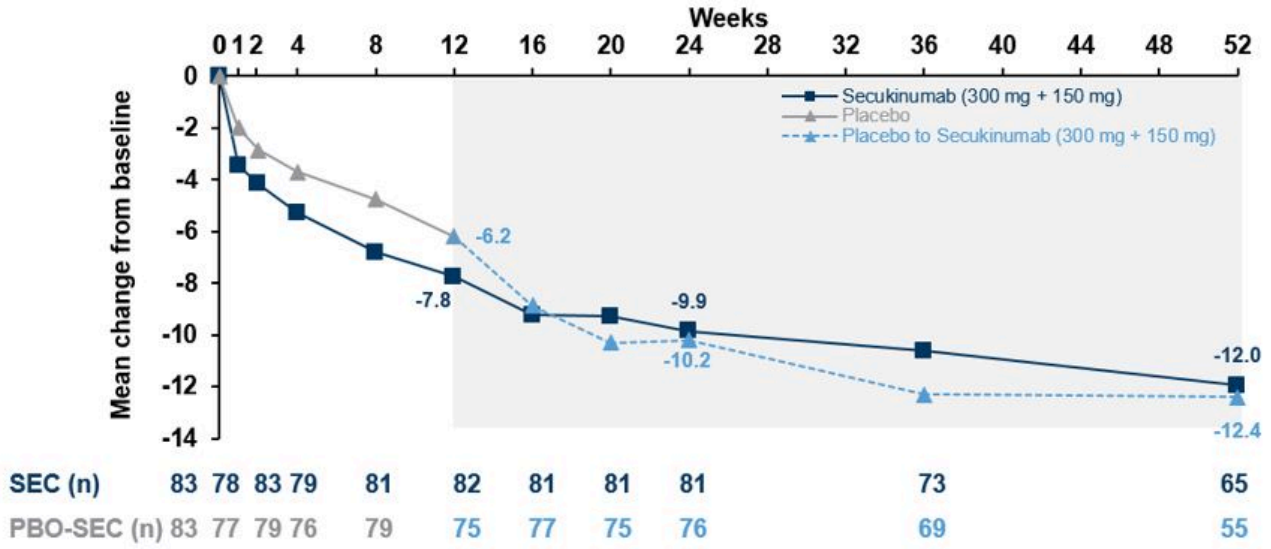
Methods: This was a 52-week study with a 12-week double-blind placebo-controlled treatment followed by 12-week open-label treatment and 6-month open-label extension treatment in all patients. Detailed study design and eligibility criteria have been reported previously.[3,4] Synovitis and ultrasound enthesitis response were measured by GLOESS and Global OMERACT enthesitis Score (Definitions 1 and 2)[4] at patient level, respectively. Other assessments across key PsA manifestations of joints (ACR responses), enthesitis, (SPARCC), skin (PASI responses), dactylitis (LDI) and physical function (HAQ-DI) were also evaluated. Data are presented as observed.

Results: A total of 166 patients were enrolled, of which 90% (75/83) of secukinumab and 83% (69/83) of placebo-secukinumab participants completed 52 weeks. A continued improvement in GLOESS was observed in both secukinumab and placebo-secukinumab group after switch to active therapy at Week 12 through Week 52 (**Figure 1**). A similar trend of improvement in Global OMERACT enthesitis score (Definition 1 and 2) was observed up to 52 weeks in both groups (**Figure 2**). Sustained clinical response rates were observed across multiple facets of disease and physical function up to 52 weeks in both secukinumab and placebo-secukinumab groups (**Table**). There were no new or unexpected safety findings.

Conclusion: ULTIMATE demonstrated the responsiveness of ultrasound on both synovitis and enthesitis outcomes in PsA supporting its use in clinical trials, and confirmed the rapid and continued benefits of secukinumab through 52 weeks. Sustained efficacy was also observed across key clinical PsA manifestations with a safety profile consistent with previous reports.

References:

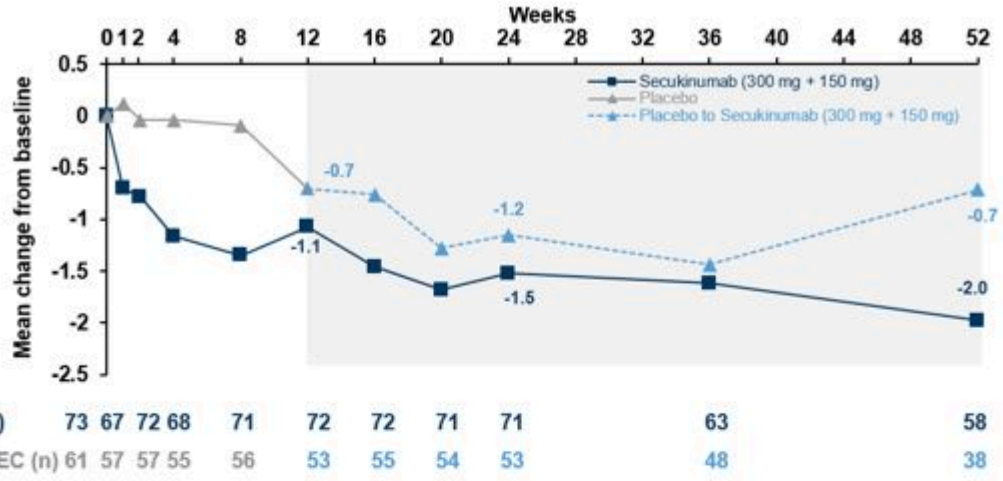
1. D'Agostino MA and Coates LC. *J Rheumatol* 2019;46:337–9
2. Uson J, et al. *Rheumatol Clin* 2018;14:27–35
3. D'Agostino MA, et al. *Arthritis Rheumatol* 2020;72 (suppl 10)
4. Boers M et al. *Ann Rheum Dis* 2021;80:314



Data presented as observed. Open label period from Week 12-52 (shaded area). GLOESS=Global OMERACT-EULAR Synovitis Score using PDUS Composite score of 24 paired joints. The range for the GLOESS score is 0 to 144.
EULAR, European League Against Rheumatism; GLOESS, OMERACT-EULAR global synovitis score; OMERACT, Outcome Measures in Rheumatology; PBO-SEC, placebo-secukinumab; PDUS, power Doppler ultrasound; SEC, secukinumab

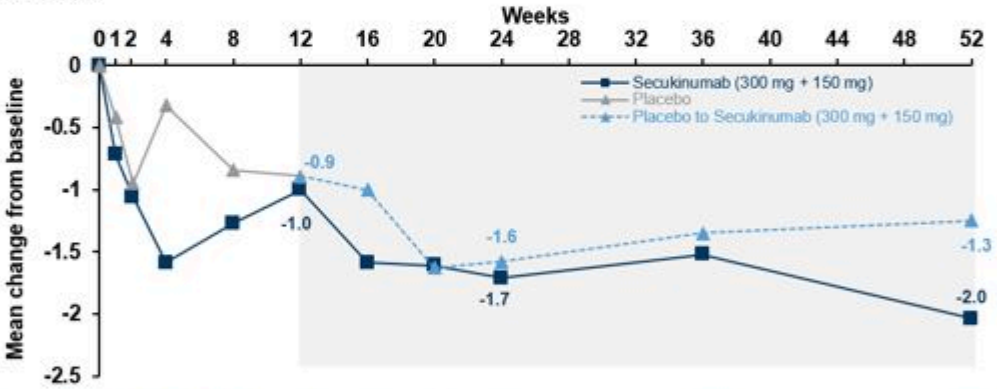
Figure 1: Mean change from baseline in GLOESS by treatment up to Week 52

a. Definition 1



SEC (n)	73	67	72	68	71	72	72	71	71	63	58
PBO-SEC (n)	61	57	57	55	56	53	55	54	53	48	38

b. Definition 2



SEC (n)	34	32	34	32	33	34	34	33	34	31	28
PBO-SEC (n)	20	19	19	19	19	19	19	19	19	17	16

Data presented as observed. Open label period from Week 12-52 (shaded area). Global OMERACT (PDUS) enthesitis score Definition 1 ranges from 0-48 and is the sum of the B-Mode (0 = absence, 1 = presence) and PD signal across 12 enthesitis sites; Definition 2 ranges from 0-36 and is the sum of the PD signal across 12 sites. At each time point, only patients with a value at both baseline and that time point are included. Only patients with positive values (>0 at baseline) were included.

EULAR, European League Against Rheumatism; GLOESS, OMERACT-EULAR global synovitis score; N, total number of randomized patients; n, number of evaluable patients; OMERACT, Outcome Measures in Rheumatology; PBO-SEC, placebo-secukinumab; PDUS, power Doppler ultrasound; SEC, secukinumab

Figure 2: Mean change from baseline Global OMERACT enthesitis score up to Week 52

	Secukinumab (300 mg + 150 mg; N = 83)	Placebo-Secukinumab (N = 83)
Responders, %		
ACR20	89	84
ACR50	68	72
ACR70	48	47
PASI 90*	59	74
PASI 100*	55	48
Resolution of dactylitis (LDI=0)	89	92
Change from baseline, mean (SD)		
SPARCC enthesitis index	–3.0 (2.3)	–3.6 (3.4)
HAQ-DI	–0.8 (0.6)	–0.7 (0.6)

*PASI response was calculated for patients with BSA ≥3 %. At Week 52, m for ACR were 65 and 57, PASI were 22 and 23, and LDI were 18 and 13 for secukinumab and placebo-secukinumab group, respectively.
ACR, American College of Rheumatology; BSA, Body Surface Area; HAQ-DI, Health Assessment Questionnaire Disability Index; LDI, Leeds Dactylitis Index; N, number of randomized patients, m, number of evaluable patients; PASI, Psoriasis Area and Severity Index; SD, standard deviation; SPARCC; Spondyloarthritis research consortium of Canada - enthesitis index.

Table: Clinical efficacy outcomes at Week 52 (Extension period)

Disclosures: M. D'Agostino, Sanofi, 2, 6, Novartis, 2, 6, BMS, 2, 6, Janssen, 2, 6, Celgene, 2, 6, Roche, 2, 6, AbbVie, 2, 6, UCB, 2, 6, Eli Lilly, 2, 6; **G. Schett**, Janssen, 6, Novartis, 6, AbbVie, 6, Bristol Myers Squibb, 6, Celgene, 6, Eli Lilly, 6, UCB, 6, Roche, 6; **C. Gaillez**, Novartis Pharma AG, 3, 11, BMS, 11; **C. Guerrero**, None; **P. HANOVA**, None; **T. Cazenave**, None; **M. Stoenoiu**, AbbVie, 2, 5, 6, UCB, 2, 5, 6, Pfizer, 2, 5, 6, MSD, 2, 5, 6, Roche, 2, 5, 6; **M. Backhaus**, BMS, 2, 5, 6, AbbVie, 2, 5, 6, Gilead, 2, 5, 6, Jonsson, 2, 5, 6, MSD, 2, 5, 6, Novartis, 2, 5, 6, Pfizer, 2, 5, 6, Roche, 2, 5, 6, UCB, 2, 5, 6; **G. Mouterde**, AbbVie, 2, 5, 6, BMS, 2, 5, 6, Celgene, 2, 5, 6, Lilly, 2, 5, 6, Novartis, 2, 5, 6, Pfizer, 2, 5, 6; **M. Boers**, BMS, 2, Novartis, 2, GSK, 2, Pfizer, 2; **A. Duggan**, Novartis, 3; **P. Goyanka**, Novartis, 3; **P. Conaghan**, AbbVie, 2, 6, BMS, 2, 6, Eli Lilly, 2, 6, Galapagos, 2, 6, Gilead, 2, 6, Novartis, 2, 6, Pfizer, 2, 6, AstraZeneca, 2, 6.

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