Efficacy of Secukinumab in Patients With Mild to Moderate Psoriasis: A Pooled Analysis of 6 Phase 3 Studies

Bruce Strober,[1,2] Peter van de Kerkhof,[3] Heng Fan,[4] Eugenia Levi,[4] Andrew Blauvelt[5]

[1]Yale University, New Haven, CT; [2]Central Connecticut Dermatology Research, Cromwell, CT; [3]Radboud University Medical Centre, Nijmegen, the Netherlands; [4]Novartis Pharmaceuticals Corporation, East Hanover, NJ; [5]Oregon Medical Research Center, Portland, OR

BACKGROUND

- Secukinumab, a fully human monoclonal antibody that selectively neutralizes interleukin 17A, has demonstrated sustained long-term efficacy across the spectrum of psoriatic disease manifestations, including moderate to severe plaque psoriasis[1]
  - Efficacy of secukinumab in mild to moderate psoriasis, however, has not been rigorously evaluated
- The secukinumab phase 3 clinical trial program included patients with mild to moderate psoriasis among populations with active psoriatic arthritis (EXCEED and FUTURE 2-5; NCT02745080, NCT01752634, NCT01989468, NCT02294227, and NCT02404350) and among patients with moderate to severe palmoplantar psoriasis (GESTURE; NCT01806597)[2-7]

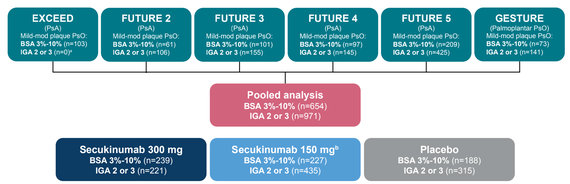
OBJECTIVE

- To report the efficacy and safety of secukinumab in a pooled population of patients with mild to moderate psoriasis

METHODS

- This post hoc analysis included patients from the phase 3 EXCEED, FUTURE 2-5, and GESTURE trials with mild to moderate psoriasis, defined as either a baseline affected body surface area (BSA) of 3% to 10% or a baseline Investigator's Global Assessment modified 2011 (IGA) score of 2 or 3 (**Figure 1**)
- Patients received subcutaneous secukinumab 300 mg, secukinumab 150 mg, or placebo administered once weekly at Weeks 0, 1, 2, 3, and 4, and every 4 weeks thereafter; some patients received secukinumab 150 mg subcutaneously at Week 0 and every 4 weeks thereafter
- Patients were pooled by treatment received through Week 16 (treatment period 1) and from Weeks 16 to 52 (treatment period 2) according to the following groups:
  - Treatment period 1: secukinumab 300 mg, secukinumab 150 mg, or placebo
  - Treatment period 2: secukinumab 300 mg or secukinumab 150 mg

Figure 1. Study Design



BSA, body surface area; IGA, Investigator's Global Assessment modified 2011; mild-mod, mild to moderate; PsA, psoriatic arthritis; PsO, psoriasis.
ª IGA was not measured in EXCEED.
ᵇ Includes patients receiving secukinumab 150 mg with or without loading dose.

- Efficacy was assessed by the proportion of patients achieving 75% improvement in the Psoriasis Area and Severity Index (PASI75), PASI90, and PASI100 among patients with a BSA of 3% to10%; and by IGA 0/1 response with ≥2-point improvement among patients with baseline IGA of 2 or 3
- Descriptive statistics were reported for each outcome using non-responder imputation

RESULTS

Patient Demographics and Baseline Characteristics

- Overall, 654 patients and 971 patients had mild to moderate psoriasis at baseline as defined by a BSA of 3% to 10% or IGA score of 2 or 3, respectively
- Demographics and baseline disease characteristics were similar between populations with mild to moderate psoriasis defined by BSA and by IGA (**Table 1**)
  - This population of patients with mild to moderate psoriasis included a greater proportion of female patients than a population from a representative clinical trial of patients with moderate to severe psoriasis[1] (ERASURE; **Table 1**)

Table 1. Baseline Patient Characteristics by Definition of Mild to Moderate Psoriasis Compared With Moderate to Severe Psoriasis from ERASURE[a]

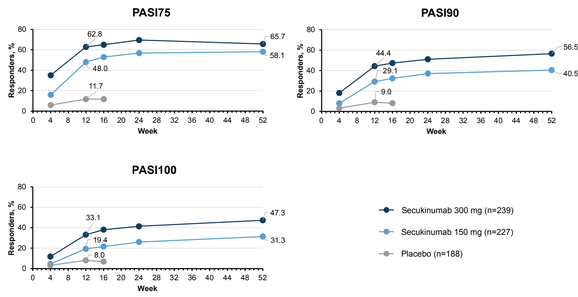
Characteristic	Baseline BSA 3%-10% n=654	Baseline IGA 2 or 3 n=971	ERASURE Overall n=738
Age, mean (SD), years	48.0 (12.4)	48.1 (12.3)	45.1 (13.1)
Sex, n (%)			
Male	318 (48.6)	504 (51.9)	509 (69.0)
Female	336 (51.4)	467 (48.1)	229 (31.0)
Weight, mean (SD), kg	84.1 (18.3)	84.4 (18.4)	88.6 (23.8)
PASI score, mean (SD)	5.2 (2.6)	–	22.1 (9.4)
BSA, mean (SD)	5.8 (2.0)	–	31.9 (18.2)
IGA score[a]			
2	–	303 (31.2)	0
3	–	668 (68.8)	466 (63.1)
4	–	0	272 (36.9)

BSA, body surface area; IGA, Investigator's Global Assessment modified 2011; PASI, Psoriasis Area and Severity Index.
ª IGA was not measured in EXCEED.

Efficacy

- Among patients with a baseline BSA of 3% to 10%, secukinumab resulted in greater achievement of PASI75/90/100 compared with placebo at Week 12, with increased responses at Week 52 (**Figure 2**)

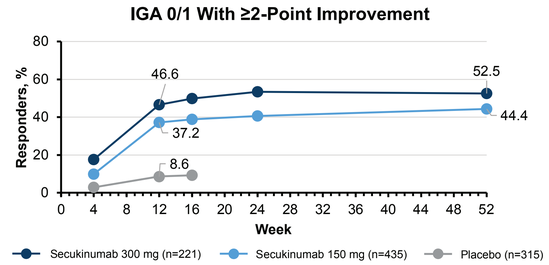
Figure 2. Achievement of PASI Responses by Week Among Patients With Mild to Moderate Psoriasis Defined as a BSA of 3% to 10% at Baseline (non-responder imputation)



BSA, body surface area; PASI, Psoriasis Area and Severity Index.

- In the ERASURE trial of moderate to severe psoriasis,[1] patients achieved PASI90 at Weeks 12 and 52:
  - Secukinumab 300 mg: 59.2% and 60.0%
  - Secukinumab 150 mg: 39.1% and 36.2%
- The proportion of patients with a baseline IGA score of 2 or 3 achieving IGA 0/1 response with ≥2-point improvement was greater among patients receiving secukinumab 300 mg or 150 mg than placebo at Week 12, with increased responses at Week 52 (**Figure 3**)

Figure 3. Achievement IGA 0/1 With ≥2-Point Improvement Among Patients With Mild to Moderate Psoriasis Defined as IGA Score of 2 of 3 at Baseline (non-responder imputation)



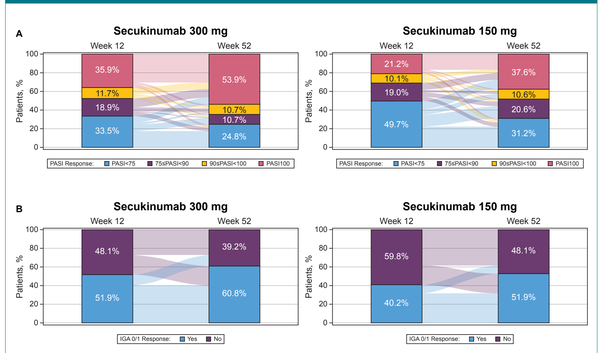
IGA, Investigator's Global Assessment modified 2011.

- In the ERASURE trial of moderate to severe psoriasis,[1] patients achieved IGA 0/1 at Weeks 12 and 52:
  - Secukinumab 300 mg: 65.3% and 60.4%
  - Secukinumab 150 mg: 51.2% and 41.4%

Maintenance of Response

- At the level of individual patients, PASI and IGA clinical responses were generally maintained from Week 12 to Week 52 (**Figure 4**)

Figure 4. Maintenance of (A) PASI and (B) IGA 0/1 Responses From Week 12 to Week 52



IGA, Investigator's Global Assessment modified 2011; PASI, Psoriasis Area and Severity Index.

LIMITATIONS

- In this post hoc analysis, patients had mild to moderate psoriasis in addition to active PsA or moderate to severe palmoplantar psoriasis
  - As such, clinical characteristics and treatment response of these patients may not be representative of patients without these psoriatic comorbidities
- This analysis included trials in which patients were permitted to receive stable doses of methotrexate and/or corticosteroids, which could affect skin efficacy; this is in contrast to secukinumab monotherapy trials in patients with moderate to severe psoriasis[1]

CONCLUSIONS

- Secukinumab led to rapid improvements in measures of disease severity among patients with mild to moderate psoriasis after 12 weeks of treatment vs placebo, with secukinumab 300 mg resulting in numerically greater improvements than secukinumab 150 mg
- Both doses showed increased efficacy from Week 12 to Week 52

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Disclosures

B. Strober is an honoraria consultant for AbbVie, Almirall, Amgen, Arcutis, Arena, Aristea, Asana, Boehringer Ingelheim, Immunic Therapeutics, Bristol Myers Squibb, Connect Biopharma, Dermavant Sciences, EPI Health, Equillium, Evelo Biosciences, Janssen, Leo Pharma, Eli Lilly, Maruho, Meiji Seika Pharma, Mindera Health, Novartis, Pfizer, UCB, Sun Pharma, Regeneron, Sanofi Genzyme, Ventyxbio, and VTV Therapeutics; is a shareholder of Connect Biopharma and Mindera Health; has received speakers fees from AbbVie, Arcutis, Dermavant, Eli Lilly, Incyte, Janssen, Regeneron, and Sanofi Genzyme; receives consulting fees as a scientific codirector for the CorEvitas (formerly Corrona) Psoriasis Registry; is an investigator for Dermavant Sciences, AbbVie, CorEvitas (formerly Corrona) Psoriasis Registry, Dermira, Cara, Novartis; and receives honoraria as the Editor-in-Chief for the *Journal of Psoriasis and Psoriatic Arthritis*. **P. van de Kerkhof** received fees for consultancy service or lectureships from Almirall, AbbVie, Eli Lilly, Novartis, Janssen Pharmaceuticals, Leo Pharma, Bristol Myer Squibb, UCB, Boehringer Ingelheim, and Dermavant Sciences, and is a chief medical officer at International Psoriasis Council. **H. Fan** and **E. Levi** are employees of Novartis. **A. Blauvelt** has served as a speaker (received honoraria) for AbbVie, Bristol Myers Squibb, Eli Lilly and Company, Pfizer, Regeneron, and Sanofi; has served as a scientific adviser (received honoraria) for AbbVie, Abcentra, Aclaris, Affibody, Aligos, Almirall, Alumis, Amgen, Anaptysbio, Apogee, Arcutis, Arena, Aslan, Athenex, Bluefin Biomedicine, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, CTI BioPharma, Dermavant, EcoR1, Eli Lilly and Company, Escient, Evelo, Evommune, Forte, Galderma, HighlightII Pharma, Incyte, InnoventBio, Janssen, Landos, LEO, Lipidio, Merck, Monte Rosa Therapeutics, Nektar, Novartis, Overtone Therapeutics, Paragon, Pfizer, Rani, Rapt, Regeneron, Sanofi Genzyme, Spherix Global Insights, Sun Pharma, Takeda, TLL Pharmaceutical, TrialSpark, UCB Pharma, Union, Ventyx, Vibliome, and Xencor; and has acted as a clinical study investigator (institution has received clinical study funds) for AbbVie, Acelyrin, Allakos, Almirall, Alumis, Amgen, Arcutis, Athenex, Boehringer Ingelheim, Bristol Myers Squibb, Concert, Dermavant, Eli Lilly and Company, Evelo, Evommune, Galderma, Incyte, Janssen, LEO, Merck, Novartis, Pfizer, Regeneron, Sanofi, Sun Pharma, UCB Pharma, and Ventyx.

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