Improvements in anxiety and depression among patients with moderate to severe plaque psoriasis treated with certolizumab pegol: Three-year results from two phase 3 trials (CIMPASI-1 and CIMPASI-2)

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OBJECTIVES:

- To investigate the overall impact of certolizumab pegol (CZP) treatment over three years on Hospital Anxiety and Depression Scale (HADS) scores for patients with moderate to severe anxiety or depression and moderate to severe plaque psoriasis
- To evaluate the proportion of patients with psoriasis and moderate to severe anxiety or depression at baseline who report scores indicating no anxiety or depression during treatment with CZP over three years

Background:

- Psoriasis is associated with an increased risk of depression and anxiety[1]
- We report 3-year data on anxiety and depression (assessed by HADS) in patients with moderate to severe plaque psoriasis (Psoriasis Area and Severity Index [PASI] ≥12, ≥10% body surface area [BSA] affected and Physician's Global Assessment [PGA] ≥3) treated with CZP[2–4]

Hospital Anxiety and Depression Scale

Scores for each questionnaire range from 0–21

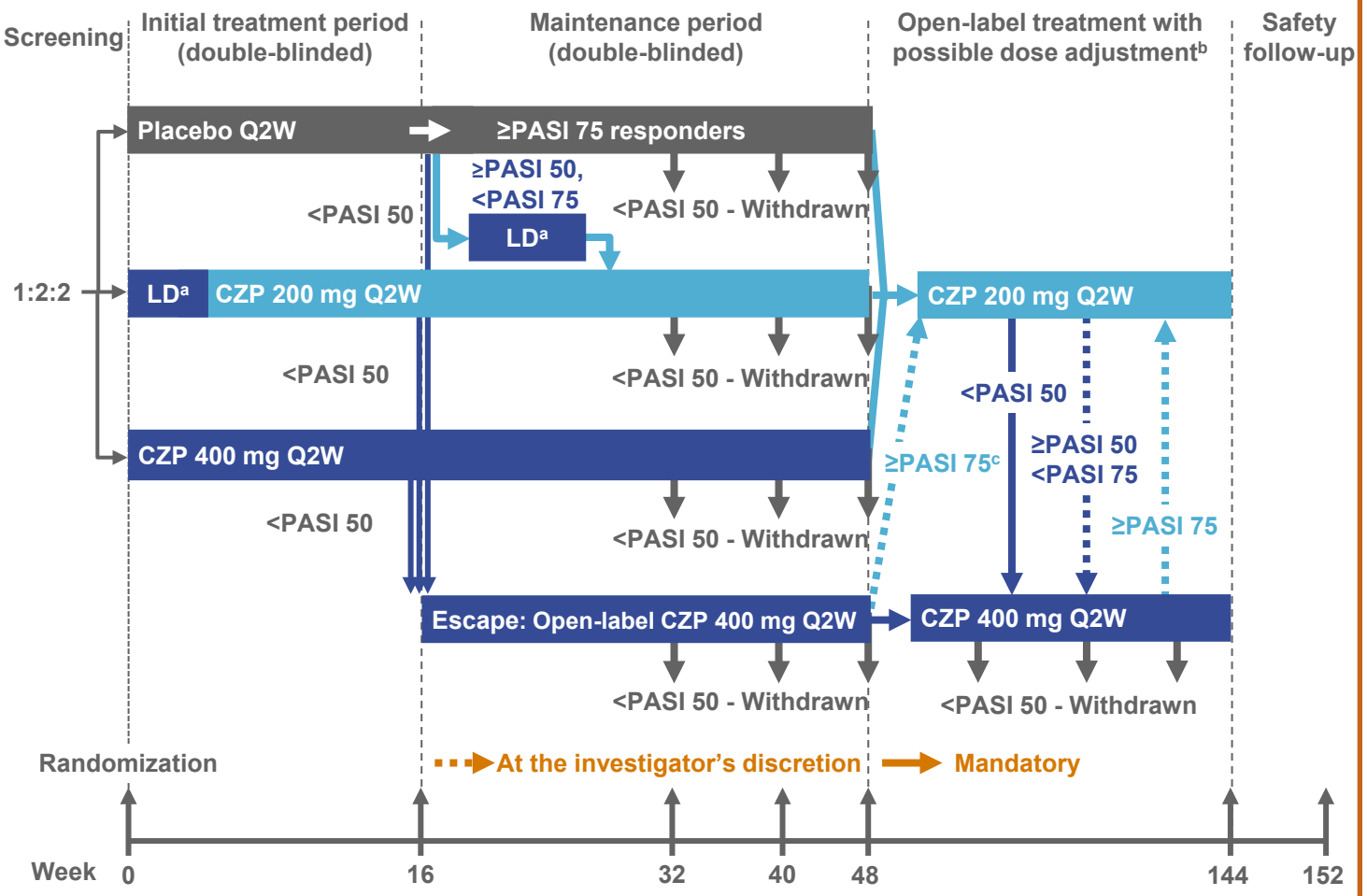
≤7 = no anxiety or depression
8–10 = mild anxiety or depression
11–14 = moderate anxiety or depression
15–21 = severe anxiety or depression

Methods:

- Data were pooled from the identically designed CIMPASI-1 and CIMPASI-2 phase 3 trials[2–4]
- For patients with moderate to severe anxiety or depression at baseline (HADS-Anxiety/HADS-Depression ≥11), we report change from baseline and the proportion who achieved no anxiety or depression (HADS-Anxiety/HADS-Depression ≤7) to Week 144
- The HADS questionnaire consists of two self-assessment subscales that measure anxiety and depression, with scores ranging from 0–21 for each scale; higher scores indicate more severe symptoms, with a minimal clinically important difference of 1.7[5,6]

1. Kurd SK et al. Arch Dermatol 2010;146(8):891–895; **2.** CIMPASI-1: https://clinicaltrials.gov/ct2/show/NCT02326298; **3.** CIMPASI-2: https://clinicaltrials.gov/ct2/show/NCT02326272; **4.** Gordon KB et al. Br J Dermatol 2021;184(4):652–662; **5.** Stern AF. Occup Med 2014;64(5):393–394; **6.** Lemay KR. J Cardiopulm Rehabil Prev 2019;39(6):E6–E11. BSA: body surface area; CZP: certolizumab pegol; HADS: Hospital Anxiety and Depression Scale; PASI: Psoriasis Area and Severity Index; PGA: Physician's Global Assessment.

CIMPASI-1 and CIMPASI-2 Study Design[1]



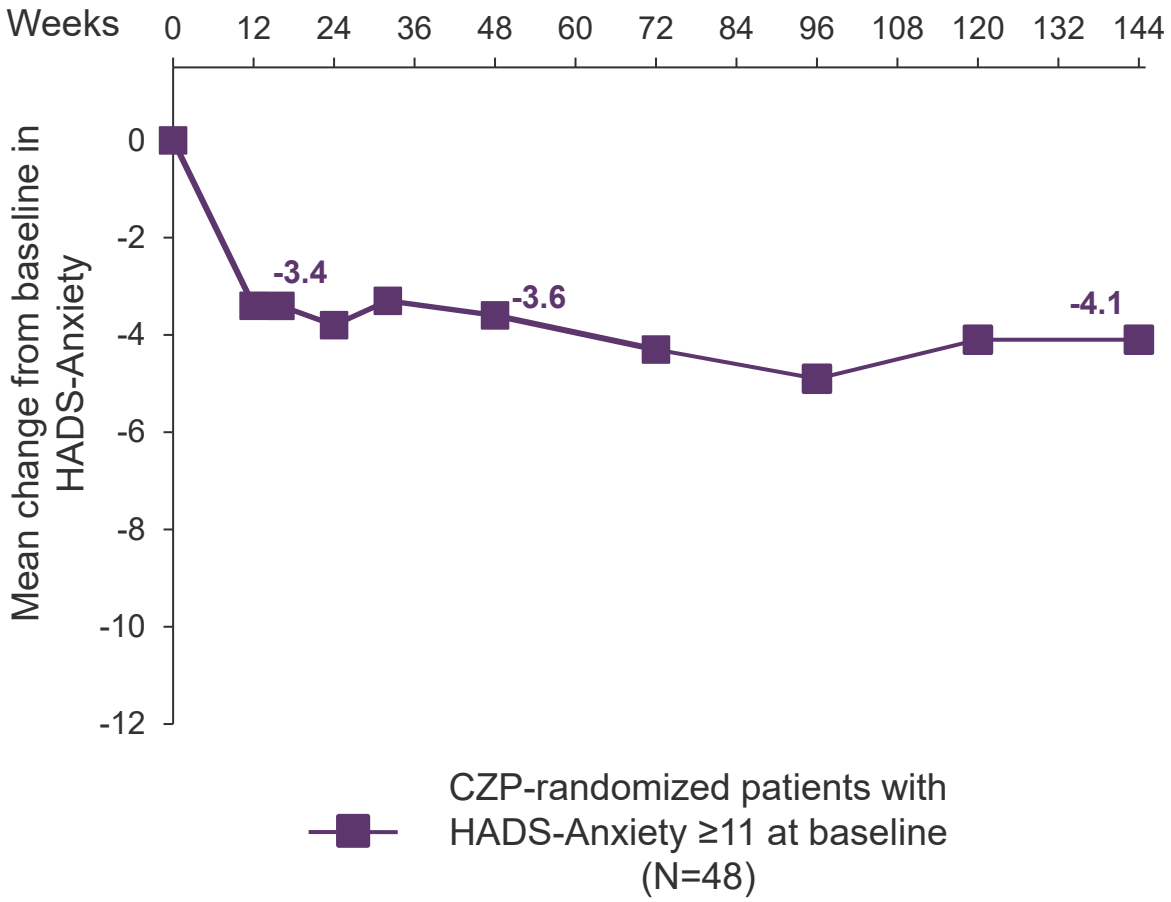
Demographics and Baseline Characteristics

	All CZP (N=361)	CZP 200 mg Q2W[a] (N=186)	CZP 400 mg Q2W (N=175)
Age (years), mean ± SD	45.3 ± 13.0	45.6 ± 13.2	45.0 ± 12.9
Male, n (%)	228 (63.2)	125 (67.2)	103 (58.9)
BMI, kg/m^2, mean ± SD	31.6 ± 7.8	32.0 ± 7.8	31.2 ± 7.9
Weight (kg), mean ± SD	93.6 ± 24.1	95.1 ± 23.4	92.0 ± 24.8
Duration of psoriasis (years), mean ± SD	18.1 ± 12.7	17.7 ± 12.9	18.5 ± 12.6
PASI, mean ± SD	19.4 ± 7.3	19.2 ± 7.2	19.6 ± 7.3
BSA (%), mean ± SD	23.5 ± 14.6	23.5 ± 14.9	23.6 ± 14.3
PGA, n (%)			
3: moderate	254 (70.4)	128 (68.8)	126 (72.0)
4: severe	107 (29.6)	58 (31.2)	49 (28.0)
DLQI total, mean ± SD	14.0 ± 7.1	14.3 ± 7.4	13.7 ± 6.9
Concomitant PsA, n (%)	73 (20.2)	32 (17.2)	41 (23.4)
HADS-Anxiety, mean ± SD	6.2 ± 3.9	6.0 ± 3.9	6.5 ± 3.8
HADS-Depression, mean ± SD	4.9 ± 3.8	4.9 ± 3.8	5.0 ± 3.8
HADS-Anxiety ≥11, n (%)	48 (13.3)	25 (13.4)	23 (13.1)
HADS-Depression ≥11, n (%)	35 (9.7)	18 (9.7)	17 (9.7)

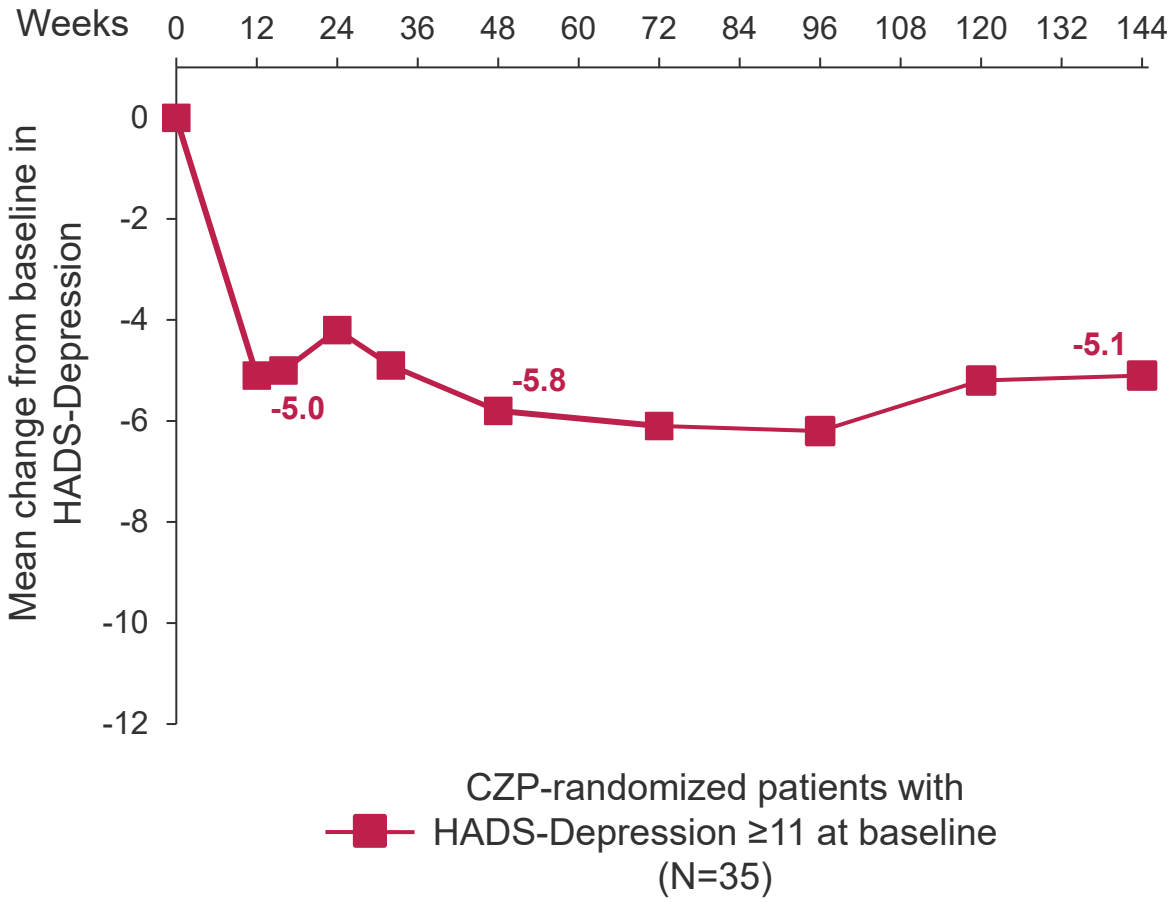
[a] Patients randomised to CZP 200 mg received a loading dose of CZP 400 mg at Weeks 0, 2 and 4 or Weeks 16, 18 and 20; [b] Dose adjustments were permitted through Weeks 60–132; dose escalation was mandatory in patients not achieving PASI 50, and at the investigator's discretion in patients achieving PASI 50 but not PASI 75; patients who had received CZP 400 mg Q2W for at least 12 weeks could have had their dose reduced, at the investigator's discretion, if they achieved PASI 75, and were mandatorily withdrawn in they did not achieve PASI 50; [c] Patients entering the open-label period from the CZP 400 mg Q2W escape arm continued to receive CZP 400 mg Q2W but may have had their dose reduced to CZP 200 mg Q2W at Week 48, at the discretion of the investigator, if they achieved PASI 75. **1.** Gordon KB et al. Br J Dermatol 2021;184(4):652–662. BSA: body surface area; BMI: body mass index; CZP: certolizumab pegol; DLQI: Dermatology Life Quality Index; HADS: Hospital Anxiety and Depression Scale; LD: loading dose; PASI: Psoriasis Area and Severity Index; PASI 50/75: ≥50%/75% improvement from baseline PASI; PGA: Physician's Global Assessment; PsA: psoriatic arthritis; Q2W: every 2 weeks; SD: standard deviation.

Change from Baseline in Anxiety and Depression Through Week 144 in Patients with Moderate to Severe Anxiety or Depression at Baseline (LOCF)

HADS-Anxiety Change from Baseline



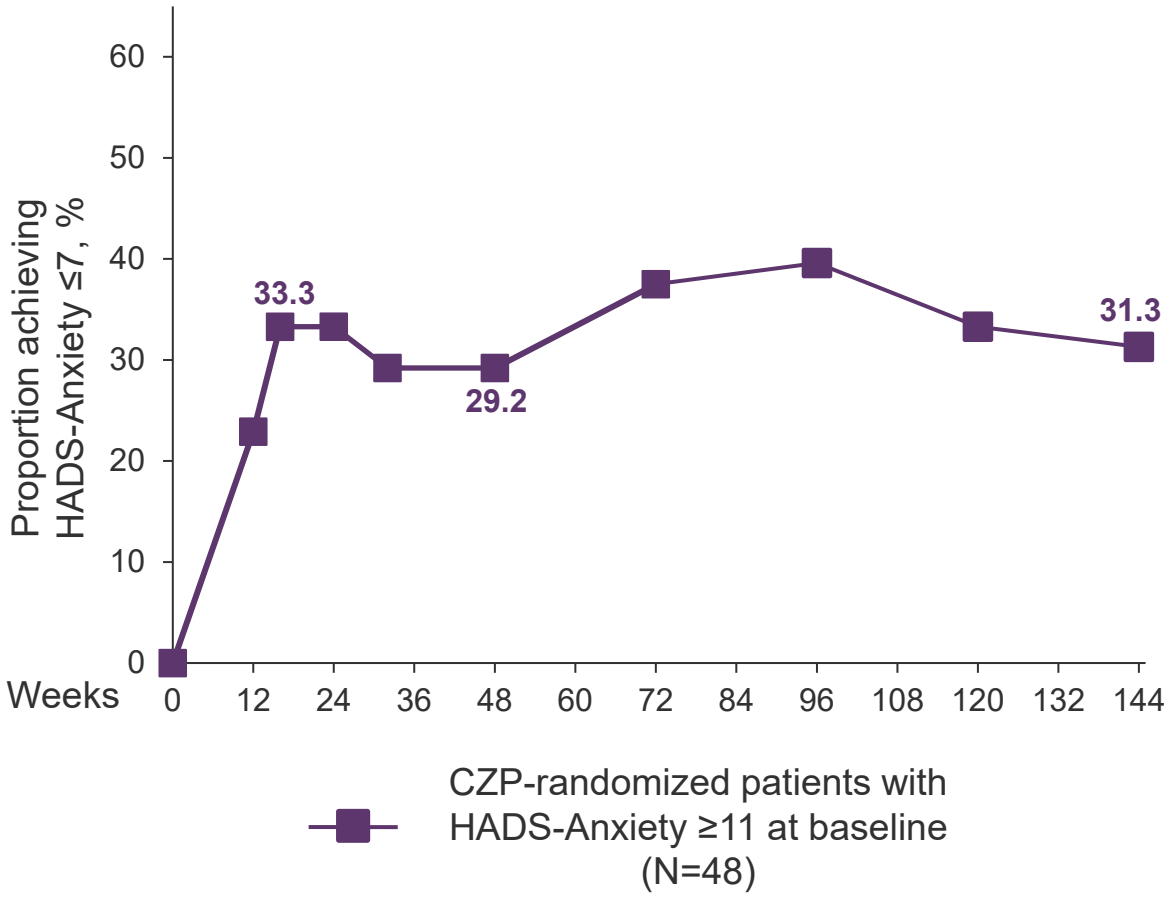
HADS-Depression Change from Baseline



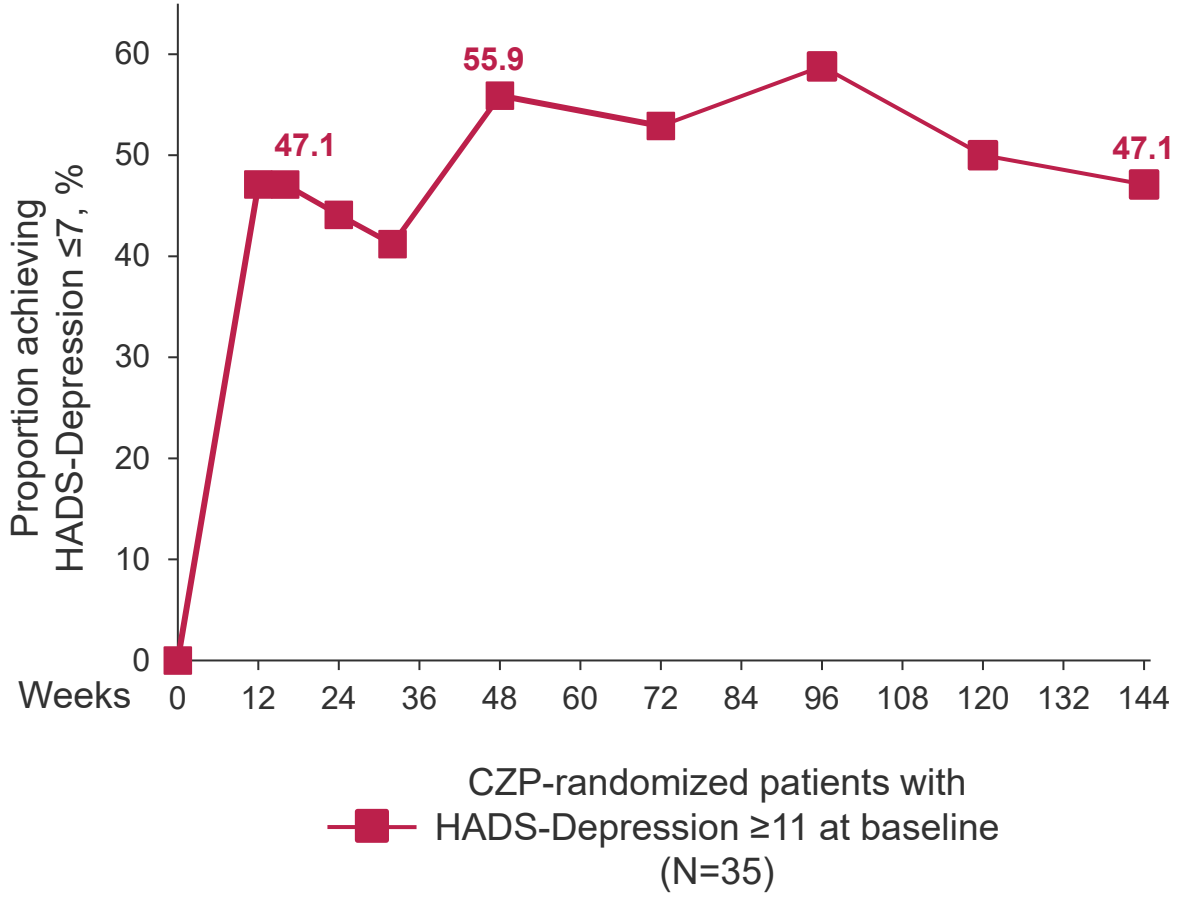
HADS-Anxiety change from baseline SD: 4.4 (Week 48); 4.1 (Week 144). HADS-Depression change from baseline SD: 3.8 (Week 48); 4.8 (Week 144). CZP: certolizumab pegol; HADS: Hospital Anxiety and Depression Scale; LOCF: last observation carried forward; SD: standard deviation.

Patients Achieving No Anxiety or Depression Through Week 144 in Patients with Moderate to Severe Anxiety or Depression at Baseline (LOCF)

HADS-Anxiety ≤7



HADS-Depression ≤7



CZP: certolizumab pegol; HADS: Hospital Anxiety and Depression Scale; LOCF: last observation carried forward.

CONCLUSIONS:

- CZP treatment was associated with improvement in anxiety and depression (assessed by HADS) at Week 48 and Week 144 for patients with moderate to severe anxiety or depression at baseline
- In CZP-treated patients with moderate to severe anxiety or depression at baseline, approximately 1 in 3 achieved no anxiety and almost half achieved no depression at Week 144
- These analyses were limited by the small number of patients enrolled with moderate to severe anxiety or depression

Author Contributions: Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **AA, SM, LS, PFP, PR, GM, NT, JMLP, CP, SH, DMT**; Drafting of the publication or revising it critically for important intellectual content: **AA, SM, LS, PFP, PR, GM, NT, JMLP, CP, SH, DMT**; Final approval of the manuscript: **AA, SM, LS, PFP, PR, GM, NT, JMLP, CP, SH, DMT**. **Disclosures: AA:** Data safety monitoring board member for Boehringer Ingelheim/Parexel; received research funding from Bristol Myers Squibb, Dermavant, Dermira Inc., Eli Lilly, Galderma, Janssen, Kyowa Hakko Kirin, LEO Pharma, Pfizer, and UCB Pharma; has been a research investigator without compensation for Sanofi Genzyme; has been scientific investigator for AbbVie, Bristol Myers Squibb, Dermavant, Eli Lilly, Janssen, LEO Pharma, Modernizing Medicine, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sanofi Genzyme, and Sun Pharma; speaker for AbbVie, Regeneron, and Sanofi Genzyme; **SM:** Consultancy and/or speakers' fees from AbbVie, Almirall, Amgen, Eli Lilly, Novartis, Janssen, Celgene, and UCB Pharma; grant/research support from: AbbVie and Celgene; **LS:** Consultant, and/or scientific adviser, and/or investigator, and/or scientific officer, and/or speaker for Amgen, Anacor, AbbVie, Ascend, Astellas, AstraZeneca, Blaze Bioscience, Bristol Myers Squibb, Boehringer Ingelheim, Botanix, Celgene, Dermira Inc., Eli Lilly, Galderma, Genentech, GSK, Hexima, Janssen, LEO Pharma, Mayne, Medimmune, Merck (MSD), Merck-Serono, Novartis, Otsuka, Pfizer, Phosphagenics, Photon MD, Regeneron, Roche, Samumed, Sanofi/Genzyme, SHR, Sun Pharma ANZ, Trius, UCB Pharma, and Zai Lab; **PFP:** Advisory committee for AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly, Janssen, LEO Pharma, Merck, MSD, Novartis, Roche, Sanofi, and Sun Pharma; educational lectures for AbbVie, Amgen, Avene, Eli Lilly, Galderma, Janssen, La Roche Posay, LEO Pharma, Merck, Novartis, Pfizer, Roche, Sanofi, Schering Plough, Sun Pharma, and UCB Pharma; clinical trials for AbbVie, Amgen, Arena, AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb, CSL, Dermira Inc., Eisai, Eli Lilly, Galderma, GSK, Janssen, Jiangsu Hengrui, Kyowa Hakko Kirin, LEO Pharma, miRagen, Novartis, OncoSec, Pfizer, Regeneron, Roche, Sun Pharma, UCB Pharma, and Xoma; **PR:** Principal investigator, clinical trials: AbbVie, Arcutis, Bristol Myers Squibb, Dermavant, Eli Lilly, Janssen, Novartis, Sun Pharma, and UCB Pharma; **GM:** Taken part in scientific advisory boards for AbbVie, Almirall, Bausch Health, Bristol Myers Squibb, Dermavant, Galderma, Horizon, Janssen, LEO Pharma, Pfizer, Sun Pharma, Trevie, and UCB Pharma; consultant for AbbVie, Almirall, Arcutis, Bausch Health, Bristol Myers Squibb, Dermavant, Eli Lilly, Galderma, LEO Pharma, Pfizer, Sun Pharma, Trevie, and UCB Pharma; speaker for Almirall, LEO Pharma, and UCB Pharma; **NT, JMLP, CP, SH:** Employees of UCB Pharma; **DWT:** Advisor and/or received speakers' honoraria or travel expense reimbursements and/or received grants and/or participated in clinical trials of the companies AbbVie, Almirall, Amgen, Beiersdorf, Biogen, Boehringer Ingelheim, Celgene, Forward Pharma, GSK, Janssen, LEO Pharma, Eli Lilly, Medac, Merck, Novartis, Pfizer, UCB Pharma, and VBL.

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CZP: certolizumab pegol; HADS: Hospital Anxiety and Depression Scale.