tolerance if the benefits are changed. However, DCE seems to be more sensitive for a change in benefits and risks while the MAR estimates obtained through BWS have considerably lower uncertainty than DCE.

PMS50

RAPID IMPROVEMENTS IN PATIENT-REPORTED OUTCOMES WITH CERTOLIZUMAB PEGOL IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS, INCLUDING ANKYLOSING SPONDYLITIS AND NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: 24-WEEK RESULTS OF A PHASE 3 DOUBLE BLIND RANDOMIZED PLACEBO-CONTROLLED STUDY

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OBJECTIVES: RAPID-axSpA (NCT01087762) investigated the impact of certolizumab pegol (CZP) on patient reported outcomes (PRO) in axial spondyloarthritis (axSpA), including ankylosing spondylitis (AS) and non-radiographic axSpA (nr-axSpA, axSpA with no definitive sacroiliitis on X-ray). **METHODS:** The ongoing 158-week (Wk) RAPID-axSpA trial was double blind and placebo-controlled to Wk24. Recruited patients had adult-onset active axSpA, including AS and nr-axSpA. Patients were randomized 1:1:1 to placebo, or 400mg CZP at Wk0, two and four followed by either 200mg CZP every two weeks (Q2W) or 400mg CZP every four weeks (Q4W). PRO endpoints included, physical function (BASFI), total spinal pain, daily pain diary to Wk4, fatigue (from BASDAI), Ankylosing Spondylitis Quality of Life (AsQoL), Sleep Problems Index II domain of the MOS Sleep scale, and SF-36. Change from baseline in PRO was analyzed in full analysis set with LOCF imputation. **RESULTS:** A total of 325 patients were randomized. Baseline characteristics were similar between groups. Compared to placebo, improvements at Wk24 in CZP 200mg Q2W and 400mg Q4W treated groups were observed in pain (-1.3 vs. -3.3 and -3.2), fatigue (-0.9 vs. -2.6 and -2.8), BASFI (-0.5 vs. -2.4 and -2.2) and AsQoL (-1.7 vs. -5.1 and -5.1). Improvements were seen from Wk1, and in spinal pain from day 2. CZP-treated patients also had greater improvements in sleep, and SF-36 components and domains. More CZP patients reached population norms for SF-36. CZP impact on pain, fatigue and AsQoL in AS and nr-axSpA patients was similar. Relative to placebo, CZP-treated nr-axSpA patients demonstrated greater improvements in BASFI and sleep compared to AS, and were more likely to reach population norms for SF-36. **CONCLUSIONS:** Both dosing regimens of CZP rapidly improved all PRO including pain, fatigue, physical function and QoL of axSpA, in both AS and nr-axSpA patients.

PMS51

EFFECT OF CERTOLIZUMAB PEGOL ON THE MULTIPLE FACETS OF PSORIATIC ARTHRITIS AS REPORTED BY PATIENTS: 24-WEEK PATIENT REPORTED OUTCOME RESULTS OF A PHASE 3 DOUBLE BLIND RANDOMIZED PLACEBO-CONTROLLED STUDY

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OBJECTIVES: To report the effect of certolizumab pegol (CZP), a PEGylated Fc-free anti-TNF, on patient reported outcomes (PRO) in psoriatic arthritis (PsA), as investigated in RAPID-PsA (NCT01087788). **METHODS:** The ongoing 158 week (Wk) RAPID-PsA trial is double blind and placebo-controlled to Wk24. Recruited patients had active PsA and had failed ≥1 DMARD. Patients could have received 1 previous anti-TNF. Patients were randomized 1:1:1 to placebo, or 400mg CZP at Wk 0, 2 and 4 (loading dose) followed by either 200mg CZP every 2 weeks (Q2W) or 400mg CZP every 4 weeks (Q4W). PRO measures evaluated: fatigue assessment scale (FAS), patient assessment of pain (VAS), health assessment questionnaire-disability index (HAQ-DI), SF-36, PsAQoL, and the Dermatology Life Quality Index (DLQI). Change from baseline for PRO was analyzed for the randomized population, with LOCF imputation. **RESULTS:** A total of 409 patients were randomized. 20% of patients had received a prior anti-TNF. Baseline demographics were similar between groups. From baseline to Wk24, differences in pain (-11.2 vs. -28.6 and -28.4), fatigue (-0.6 vs. -2.2 and -1.9), HAQ-DI (-0.19 vs. -0.54 and -0.46), SF-36 physical component summary (2.14 vs. 8.43 and 7.58) and mental component summary (0.73 vs 5.49 and 3.49), PsAQoL (-1.27 vs. -4.43 and -3.30), and DLQI (-1.4 vs. -6.3 and -5.2) were observed in placebo vs. CZP 200mg Q2W and 400mg Q4W arms (p<0.001). Differences were observed from Wk1 and were irrespective of prior anti-TNF exposure. More patients on CZP reached SF-36 general population norms than placebo patients. **CONCLUSIONS:** CZP effectively improved multiple PROs in PsA patients across many disease facets. The benefits of CZP treatment on physical and emotional components of HRQoL were seen across generic, PsA-specific and dermatology-specific measures. These benefits were seen in patients regardless of prior anti-TNF exposure.

PMS52

THE IMPORTANCE OF MANAGING ARTHRITIS IN PATIENTS WITH BOTH MODERATE-TO-SEVERE PSORIASIS AND PSORIATIC ARTHRITIS

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OBJECTIVES: To determine the impact of improvements in skin and musculoskeletal components on quality of life (QoL), we studied patients with *both* moderate-to-severe psoriasis and psoriatic arthritis (PsA) treated with etanercept (ETN). **METHODS:** Ad hoc analyses were performed on pooled data from the PRESTA trial in which patients were randomized to ETN 50 mg once weekly (QW) for 12 weeks or ETN 50 mg twice weekly for 12 weeks, followed by ETN 50 mg QW for 12 weeks. Dermatologists evaluated skin disease using the Psoriasis Activity and Severity Index (PASI) endpoints PASI50 (50% improvement) and PASI75 (75% improvement). Rheumatologists evaluated arthritis using the American College of Rheumatology (ACR) endpoints of ACR20 and ACR50 (≥20% and ≥50% improvement in ACR core criteria, respectively). To measure QoL, patients completed the EuroQoL-5 Dimension (EQ-5D) utility (scale 0–1, higher scores=better QoL, minimal important difference [MID]=0.05) and Visual Analog Scale (VAS; scale 0–100, higher scores=better health state, MID=5) questionnaire. **RESULTS:** Improvements from baseline at week 24 in EQ-5D utility and VAS scores for patients achieving ACR50 but not PASI75 (n=89) were significantly and clinically meaningfully greater than patients achieving PASI75 but not ACR50 (n=193; EQ-5D utility Δ=0.327 vs. 0.199, P<0.001; EQ-5D VAS Δ=23.7 vs. 15.1, P=0.002). Similarly, improvements for patients achieving ACR20 but not PASI50 (n=55) were significantly greater than those achieving PASI50 but not ACR20 (n=163; EQ-5D utility Δ=0.385 vs. 0.134, P<0.001; EQ-5D VAS Δ=19.3 vs. 10.4, P=0.005). **CONCLUSIONS:** Patients with both moderate-to-severe psoriasis and PsA showing greater improvements in arthritis than psoriasis reported more QoL gains compared with those with greater improvements in psoriasis than arthritis. Although the ACR response and PASI measures are formed of different components, the magnitude of the QoL gain with improvement in arthritis shows that the arthritis component of psoriatic disease contributes significantly to reduced QoL.

PMS53

IMPACT OF RHEUMATOID ARTHRITIS (RA) ON QUALITY OF LIFE (QOL) IN A NATIONALLY REPRESENTATIVE POPULATION IN THE UNITED STATES

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OBJECTIVES: To assess the physical component score (PCS), mental component score (MCS), and EuroQol (EQ5D) score of RA and non-RA patients. **METHODS:** Retrospective analysis of civilian non-institutionalized Medical Expenditures Panel Survey (MEPS) data for the year 2006. 20,434 respondents had positive weight, had complete information, and who were atleast 18 years were included in the analysis. Clinical Classification Code 202 identified RA respondents. RA and Non-RA respondents were matched on age, gender, race, education, marital status, income, region, insurance, and comorbidity index score. Since the MEPS 2006 consists of only PCS and MCS, a mapping algorithm was used to derive EQ-5D score. Proc surveyfreq, and proc surveymeans to describe the demographic characteristics. T-tests were used to measure statistical differences in QOL scores between the 2 groups. **RESULTS:** Among adults with RA, 86.75% were whites with mean (SE) age of 59.83 (1.18) years and 80% were females. The mean (SE) PCS scores for the RA and Non-RA group was 34.25 (1.35) and 45.46 (1.30). The mean (SE) MCS scores for the RA and Non-RA group was 47.49 (1.09) and 51.14 (0.86). The mean (SE) EQ-5D index score for the RA and Non-RA groups was 0.74 (0.02) and 0.86 (0.01). The results were significant at an apriori alpha value of 0.05. **CONCLUSIONS:** Since the disease conditions were self-reported and institutionalized persons were not included, the true prevalence of RA may be underestimated. All QOL scores for RA patients were lower in the 2006 MEPS data indicating that respondents with RA have reduced QOL. RA significantly impairs QOL in the U.S. population. The study trengthens the importance of treating RA. This study did not differentiate QOL by severity of RA. RA-specific QOL measures were unavailable in MEPS.

PMS54

USTEKINUMAB IMPROVES ARTHRITIS-RELATED AND SKIN-RELATED QUALITY OF LIFE IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS: PATIENT REPORTED OUTCOMES FROM RANDOMIZED AND DOUBLE BLINDED PHASE III PSUMMIT I TRIAL

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OBJECTIVES: Examine impact of ustekinumab treatment on general &disease-specific patient reported outcomes (PROs) of patients with active PsA using PSUMMIT1 data. **METHODS:** Adult PsA patients (n=615) with active disease despite DMARD&/or NSAID therapy were randomized to ustekinumab 45mg, 90mg, or PBO at wks0, 4, &q12wks, thereafter. Patients treated with prior anti-TNF agents were excluded. At wk16, patients with <5% improvement in SJC/TJC entered blinded EE (PBO→ustekinumab 45mg; ustekinumab 45mg→90mg; 90mg→90mg). PROs were measured with HAQ, DLQI, SF-36, &VAS for impact of PsA on work productivity (0-10), patient assessment of pain (0-10)& disease activity (0-10). ANOVA on van der Waerden normal scores was used for continuous variables & chi-square or the Cochran-Mantel-Haenszel (CMH) test for binary variables between groups. **RESULTS:** Baseline PRO measures indicated the study population had severe physical disability& impaired HRQoL, with mean HAQ score of 1.25 &mean DLQI score of ≥10. At wk24, greater improvements in: HAQ (0.31&0.4 vs. 0.1, P<0.001), DLQI (6.6&7.5 vs. 1.4, P<0.001), SF-36 PCS (4.9 &6.2 vs. 1.4, P<0.001)& MCS (3.4&4.8 vs. 1.5, p<0.01 90 mg only) were observed in ustekinumab 45mg &90mg groups vs PBO, respectively. Proportions of patients who achieved clinical meaningful improvements in HAQ ≥0.3 (47.8% &47.5% vs. 28.2%, P<0.001), DLQI ≥5 (58.6% &63.1% vs. 32.9%, P<0.001), &SF-36 PCS ≥5(46.5% &53.3% vs. 26.0%, P<0.001) &MCS ≥5(37.0% &47.7% vs. 33.7%, p<0.01 90mg only) were greater in ustekinumab 45mg &90mg group vs PBO,