

respectively. Ustekinumab 45mg&90mg -treated patients achieved greater improvements in patient assessment of pain (25.9% &29.6% vs. 4.5%, $P<0.001$), patient assessment of disease activity (25.4% &27.6% vs. 7.6%, $P<0.001$) & greater reduction in impact of disease on work productivity (1.82& 2.64 vs. 0.78, $P<0.001$) versus PBO-treated patients, respectively. **CONCLUSIONS:** Ustekinumab improves general as well as arthritis &skin-related QoL, &reduces the impact of disease on work productivity in patients with active PsA.

PMS55

A EUROPEAN ASSESSMENT OF THE IMPACT OF INADEQUATE PAIN RELIEF (IPR) ON HEALTH-RELATED QUALITY OF LIFE (QOL) IN PATIENTS WITH KNEE OSTEOARTHRITIS (OA) IN THE SURVEY OF REAL WORLD THERAPIES (SORT)

Black CM¹, Stokes L², Phillips C³, Peloso PM⁴, Mavros P⁴, Everett SV⁴, Moore A⁵, Conaghan P⁶, Sen S⁴, Taylor SD⁴

¹St. John's University, Queens, NY, USA, ²Merck & Co., Inc., Whitehouse Station, NJ, USA, ³Swansea University, Swansea, Wales, UK, ⁴Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Whitehouse Station, NJ, USA, ⁵Oxford University, Oxford, UK, ⁶University of Leeds, Leeds, UK

OBJECTIVES: To describe inadequate pain relief (IPR) and evaluate its impact on QOL in patients with knee osteoarthritis. **METHODS:** SORT, a 12-month prospective study across 6 EU countries (N=1,260), enrolled participants >50 years old with knee OA who were prescribed pain medications. Clinical history and QOL (generic and disease-specific) were collected at baseline and months 1, 3, 6, 9 and 12. Inadequate Pain Relief (IPR) was defined as a Brief Pain Inventory (BPI) pain score of "moderate or greater pain" (score >4). Statistical analyses of baseline data were conducted. **RESULTS:** Evaluable baseline data are presented for 1217 participants: 67.6% women; mean age 68 (SD=9.4) years; mean duration of OA 5.9 years (SD=6.2) and 83.4% reported taking oral pain medications. IPR comprised 54% of the cohort (656 of 1217). IPR participants reported more disability (14.3% vs. 9.3%, $p=0.013$), greater number of co-morbidities ($p<0.0001$) and were taking more opioid-containing medications (27.1% vs. 16.3%, $p<0.001$) than those with pain relief. IPR participants had worse WOMAC scores: stiffness (56.9 vs. 33.6, $p<0.001$), pain (53.2 vs. 28.4, $p<0.001$) and physical function (54.9 vs. 29.9, $p<0.001$). IPR participants reported significant worse scores for pain severity (5.8 vs. 2.7, $p<0.001$) and pain interference (5.3 vs. 2.4, $p<0.001$) as measured by BPI. General health status was lower for IPR participants with 51.2% vs. 29.0% ($p<0.001$) reporting fair/poor health. IPR participants scored worse on all SF-12 domains with differences for the physical component summary (PCS) (35.1 vs. 41.4, $p<0.001$) and mental component summary (MCS) (45.7 vs. 52.0, $p<0.001$). **CONCLUSIONS:** SORT found over half of participants reported inadequate pain relief (i.e., moderate to severe pain). IPR participants experienced more co-morbidities and significant QOL impairments as demonstrated by poorer health status, greater pain, physical limitations and stiffness than participants with pain relief. The presented SORT baseline data support the relationship between IPR and reduced QOL.

PMS56

SENSITIVITY AND SPECIFICITY OF A QUALITY OF LIFE QUESTIONNAIRE QUALEFFO-41

Tadic I¹, Vujanovic Stupar N², Tasic L³, Stevanovic D⁴, Dimic A⁵, Stamenkovic B⁵, Stojanovic S⁶, Milenkovic S⁶

¹University of Belgrade Faculty of Pharmacy, Belgrade, Serbia and Montenegro, ²University of Belgrade School of Medicine, Belgrade, Serbia and Montenegro, ³University of Belgrade - Faculty of Pharmacy, Belgrade, Serbia and Montenegro, ⁴General Hospital Sombor, Sombor, Serbia and Montenegro, ⁵University of Nis Faculty of Medicine, Nis, Serbia and Montenegro, ⁶Rheumatology Institute Niska Banja, Nis, Serbia and Montenegro

OBJECTIVES: International Osteoporosis Foundation Quality of Life questionnaire (QUALEFFO-41) is the specific questionnaire for the postmenopausal women with osteoporosis and vertebral fractures. Reliability of the questionnaire could be confirmed by sensitivity and specificity. The objective of this study is to test the sensitivity and specificity of the QUALEFFO-41 questionnaire. **METHODS:** A case-control study was conducted during the period of June 2010 - October 2011 to test the main characteristics of the questionnaire. The study included 100 patients with osteoporosis (50 cases with vertebral fractures and 50 controls without fractures). The questionnaire EQ-5D (with direct-scoring) was used for comparison of the results with the QUALEFFO-41 (with reverse-scoring). The study was performed in two medical centers in Serbia. **RESULTS:** The results of the ROC curve analysis (between the case and control group of patients) indicated that the AUC ranges for all five dimensions of the QUALEFFO-41 questionnaire and the total score were 0.62-0.69. The QUALEFFO-41 had a better prediction of the value of HRQOL of cases compared to the generic questionnaire EQ-5D (the AUC difference of the total scores was 0.099, $p=0.013$). Correlations between the total scores of the QUALEFFO-41 and the EQ-5D health state value, for both groups, were negative and statistically significant ($r=-0.78$, $p<0.001$ and $r=-0.73$, $p<0.001$, respectively). **CONCLUSIONS:** The QUALEFFO-41 has the ability to detect the patients with osteoporosis and vertebral fractures among the osteoporosis patients. This questionnaire is more specific for the osteoporosis patients with fractures in relation to the EQ-5D questionnaire.

PMS57

THE PERSONAL DISEASE AND TREATMENT BURDENS OF KOREAN ELDERLY WOMEN WITH OSTEOPOROTIC FRAGILITY FRACTURES: A QUALITATIVE STUDY

Kim J¹, Kim S¹, Lee E¹, Yoo W², Bae H¹

¹Seoul National University, Seoul, South Korea, ²Daegu Haany University, Gyeongsangbuk-do, South Korea

OBJECTIVES: To explore the personal experiences of Korean elderly women who have sustained osteoporotic fragility fractures regarding their disease and treatment burdens. **METHODS:** The research design was a qualitative descriptive

study. Open-ended questions were asked of twelve Korean elderly women who experienced at least two osteoporotic fractures. They participated in an in-depth face-to-face interview. Data were analyzed using qualitative content analysis method, which is an inductive process following eight steps developed by Downe-Wamboldt. **RESULTS:** Five themes were identified: 1) physically living with pain and disability following unexpected fractures; 2) financially facing a penniless old age and unaffordable treatment cost; 3) emotionally feeling the unbridgeable gap between desired life and the present; 4) cognitively having health illiteracy and medical ignorance; and 5) socially and spiritually coping with pain and trying to be free from their suffering lives. **CONCLUSIONS:** The interview participants described how they have suffered from chronic pains and a dysfunctional body after unexpected and recurrent fractures, which made their quality of life decrease. Since most women in this older generation have had low educational attainment and minimal financial preparations for their retirement years, they perceive the medical treatment cost of osteoporosis and their dependency on their own adult children as burdens. Therefore, Korean health care policy stakeholders and professionals need to develop medical assurance and osteoporotic fracture disease specific guidelines that are tailored to this generation.

PMS58

IMPROVEMENTS IN PRODUCTIVITY AT PAID WORK AND WITHIN HOUSEHOLD, AND INCREASED PARTICIPATION IN DAILY ACTIVITIES AFTER 24 WEEKS OF CERTOLIZUMAB PEGOL TREATMENT OF PATIENTS WITH PSORIATIC ARTHRITIS: RESULTS OF A PHASE 3 DOUBLE BLIND RANDOMIZED PLACEBO-CONTROLLED STUDY

Kavanaugh A¹, Gladman D², van der Heijde D³, Purcaru O⁴, Mease P⁵

¹University of California, San Diego, La Jolla, CA, USA, ²University of Toronto, Toronto, ON, Canada, ³Leiden University Medical Centre, Leiden, The Netherlands, ⁴UCB Pharma, Brussels, Belgium, ⁵Swedish Medical Center, Seattle, WA, USA

OBJECTIVES: To report the effect of certolizumab pegol (CZP), a PEGylated Fc-free anti-TNF, on productivity of paid and household work, and daily activities, in psoriatic arthritis (PsA). **METHODS:** Patients had active PsA and had failed ≥ 1 DMARD. Patients were randomized 1:1:1 to placebo, or CZP 400mg at Week (Wk) 0, 2 and 4 followed by either 200mg CZP every 2 weeks (Q2W) or 400mg CZP every 4 weeks (Q4W). The arthritis-specific Work Productivity Survey (WPS, administered Q4W) was used to assess the impact of PsA on productivity at work, at home and daily activities. WPS responses (LOCF imputation) were compared between treatment arms using a non-parametric bootstrap-t method. **RESULTS:** A total of 409 patients were randomized. 56.6%, 60.1%, and 61.5% of patients in the placebo, CZP 200mg Q2W, and CZP 400mg Q4W groups were employed outside home at study baseline. Baseline workplace and household productivity was comparable between treatment arms. At baseline, PsA impacted workplace absenteeism, and presenteeism; however, PsA burden on household productivity and participation in social activities was greater. Compared to placebo, employed patients in both CZP groups reported a greater decrease in absenteeism (mean 1.6 vs. 0.2 and 0.6 days per month) and presenteeism (mean 3.5 vs. 1.3 and 2.1 days per month) at Wk24. Improvements were observed as early as Wk4. CZP groups also reported larger improvements in household productivity as early as Wk4 and continued up to Wk24, compared to placebo. **CONCLUSIONS:** CZP improved workplace productivity in patients with PsA by reducing absenteeism and presenteeism. CZP also improved household productivity and increased participation in social and daily activities.

PMS59

IMPROVEMENTS IN PRODUCTIVITY AT PAID WORK AND WITHIN HOUSEHOLD, AND INCREASED PARTICIPATION IN DAILY ACTIVITIES AFTER 24 WEEKS OF CERTOLIZUMAB PEGOL TREATMENT OF AXIAL SPONDYLOARTHRITIS PATIENTS, INCLUDING PATIENTS WITH ANKYLOSING SPONDYLITIS: RESULTS OF A PHASE 3 DOUBLE-BLIND RANDOMIZED PLACEBO-CONTROLLED STUDY

van der Heijde D¹, Braun J², Rudwaleit M³, Purcaru O⁴, Kavanaugh A⁵

¹Leiden University Medical Centre, Leiden, The Netherlands, ²Rheumazentrum Ruhrgebiet, Herne, Germany, ³Endokrinologikum Berlin, Berlin, Germany, ⁴UCB Pharma, Brussels, Belgium, ⁵University of California, San Diego, La Jolla, CA, USA

OBJECTIVES: Investigate the effect of certolizumab pegol (CZP), a PEGylated Fc-free anti-TNF, on paid and household work productivity, and daily activities, in patients with axial spondyloarthritis (axSpA), including patients with ankylosing spondylitis (AS) and non-radiographic axSpA (nr-axSpA, axSpA with no definitive sacroiliitis on X-ray). **METHODS:** Recruited patients had adult-onset active axSpA, including AS and nr-axSpA. Patients were randomized 1:1:1 to placebo, or CZP 400mg at Week (Wk) 0, 2 and 4 followed by either CZP 200mg every two weeks (Q2W) or CZP 400mg every four weeks (Q4W). The arthritis-specific Work Productivity Survey (WPS, administered Q4W) assessed the impact of axSpA on workplace and household productivity. WPS responses (LOCF imputation) were compared between treatment arms using a non-parametric bootstrap-t method. **RESULTS:** A total of 325 patients were randomized. At baseline, 63.2%, 69.4%, and 74.8% of placebo, CZP 200mg Q2W, and CZP 400mg Q4W group patients were employed outside the home. Baseline workplace and household productivity was similar between groups. Baseline burden of axSpA on workplace and household productivity was high. Compared to placebo, employed patients in CZP 200mg Q2W and 400mg Q4W groups reported reduced absenteeism (mean 2.0 vs 1.1 and 0.6 days per month) and presenteeism (mean 4.4 vs 2.4 and 2.7 days per month) at Wk24. Improvements were observed as early as Wk4. CZP groups reported greater reductions vs placebo in lost days of household work and of family/social/leisure activities per month, in days with reduced household productivity and in axSpA interference with household duties as early as Wk4 through to Wk24. Similar improvements were reported in both AS and nr-axSpA populations. **CONCLUSIONS:** CZP improved workplace productivity in patients with axSpA by reducing absenteeism and presenteeism.