received: adalimumab 40 mg every other week (eow) + MTX; adalimumab 40 mg eow; or MTX monotherapy. The Short Form 36 (SF-36) was used to assess 8 domains of HRQOL at baseline, and after 12, 26, 42, 52, 76, and 104 weeks of therapy (higher scores indicate improvement). Scores for 4 physical and 4 mental health concepts were aggregated into Physical Component Summary (PCS) and Mental Component Summary (MCS) scores. A minimum clinically important difference (MCID) is 2.5–5.0 for PCS and MCS. Criteria-based interpretation of the PCS evaluated relationships between clinically and socially meaningful variables. **RESULTS:** Baseline scores for the 799 patients were comparable between all 3 groups, and post-baseline results were comparable for the 2 monotherapy groups. Mean baseline PCS for the adalimumab + MTX (n = 256) and MTX monotherapy (n = 247) groups were 31.7 and 32.2. Mean PCS for the combination therapy group at Week 12 had improved to 42.2 vs. 38.2 for the MTX group. The 4.5 difference in mean change from baseline was clinically meaningful and sustained through 2 years (5.1) ($p < 0.0001$). Based on criteria-based interpretation of the SF-36, differences in PCS scores between the 2 groups indicate patients on MTX alone had an increased likelihood of using more health resources and not being able to work. **CONCLUSIONS:** Adalimumab + MTX were superior to MTX alone in providing significant and clinically meaningful improvements in HRQOL in early RA. Significantly lower PCS at 2 years in the MTX group may mean patients on MTX alone have greater health care utilization and substantially greater job loss than patients on combination therapy.

PAR20

EFFECTS OF LONG-TERM ADALIMUMAB THERAPY ON HEALTH UTILITY AND FATIGUE IN PATIENTS WITH LONG-STANDING, SEVERE RHEUMATOID ARTHRITIS (RA)—RESULTS FROM A 3-YEAR FOLLOW-UP STUDY

Mittendorf T[1], Sterz R[2], Von der Schulenburg J[1], Kupper H[2], Cifaldi M[3], Dietz B[2]

[1]University of Hannover, Hannover, Germany; [2]Abbott GmbH and Co KG, Ludwigshafen, Germany; [3]Abbott Laboratories, Abbott Park, IL, USA

OBJECTIVES: To investigate the ability of adalimumab therapy to provide simultaneous, sustained long-term improvement in two important patient-reported outcomes (health utility and fatigue) in patients with severe RA who had failed at least one DMARD. **METHODS:** The Health Utilities Index Mark 3 (HUI3) and Fatigue (FACIT-F, validated in RA) were simultaneously measured in a health economics companion trial to an adalimumab pivotal study (DE011). For the first 26 weeks patients were followed under double-blind, randomized conditions before rolling over into a long-term, open-label extension (OLE) (n = 99). A subset of patients receiving adalimumab 40 mg every other week was evaluated for up to 170 weeks. The HUI3 scale is 0–1, with "1" denoting perfect health and "0" denoting death. FACIT-F scores range from 0–52, with higher scores representing less fatigue. Changes in HUI3 of ≥0.03 and FACIT-F of ≥4 are considered clinically meaningful. **RESULTS:** Baseline patient characteristics were: female, 80%; age, 53 years; duration of disease, 10 years; TJC (0–68), 34; SJC (0–66), 21; HAQ score, 1.9; C-reactive protein (mg/L), 54; number of previous DMARDs: 4 (all mean values except % female). RA patients' baseline utility and fatigue scores were comparable (vs. placebo) and approximately one-third of the population norm. At week 26, mean changes from baseline in adalimumab-treated patients were 0.18 for HUI3, and 8.54 for FACIT-F (both $p < 0.001$ vs. baseline). These improvements were sustained through out week 170. **CONCLUSIONS:** Adalimumab provided clinically important, simultaneous improvements in health utility and fatigue in patients with severe, active RA who had failed at least one DMARD. These improvements were sustained over the 3-year observation period.

ASTHMA

PAS1

COMPARISON OF TREATMENT WITH BUDESONIDE/FORMOTEROL (BUD/FM) PLUS BUD/FM PRN AS SINGLE INHALER TREATMENT VERSUS REGULAR BUD AND FM PLUS FM PRN AS MONOPRODUCTS IN PATIENTS WITH ASTHMA IN GREECE

Papageorgiou M[1], Loukides S[2], Gaga M[3], Zervas L[3], Christodoulopoulou A[1], Georgatou N[3]

[1]AstraZeneca SA, Athens, Athens, Greece; [2]401 Military Hospital, Athens, Athens, Greece; [3]Sotiria Hospital, Athens, Athens, Greece

OBJECTIVE: To compare the efficacy of regular treatment with BUD/FM plus BUD/FM prn versus regular treatment with budesonide (BUD) and formoterol (FM) plus FM prn in the treatment of asthmatic patients in Greece. **METHODS:** Moderate asthmatic (mean FEV1 76% pred.) patients were recruited from 14 centers in Greece to participate in an open-label, randomized prospective clinical trial. The duration of the study was seven months with four scheduled visits: baseline, first month, third month and seventh month. Patients were randomized in 2 groups: Group A: BUD/FM 160/4.5 ìg bid plus BUD/FM prn and Group B: BUD 200 ìg and FM 9 ìg bid plus FM prn. Outcome measures included lung function, number of exacerbations and relief inhalations, symptom control using the Asthma Control Questionnaire (ACQ) and quality of life using the Asthma Quality of Life Questionnaire (AQLQ). In addition, the use of health services and side effects were recorded. **RESULTS:** A total of 133 patients were recruited, 68 in Group A, and 65 in Group B. Both groups showed a significant improvement in ACQ at the end of the study ($p < 0.0001$). Relief inhalations were significantly less in Group A ($p < 0.0001$) during the last study period, between 3rd and 7th month. No statistically significant differences were found in the other outcome measures. **CONCLUSIONS:** BUD/FM therapy plus BUD/FM as needed demonstrated similar effectiveness in asthma control and quality of life compared to treatment with BUD and FM plus FM as needed. Since fewer relief inhalations were recorded in Group A, BUD/FM plus BUD/FM prn treatment seems preferable for patients with asthma.

PAS2

FLUTICASONE PROPIONATE/SALMETEROL COMBINATION IMPROVES HEALTH OUTCOMES AND QUALITY OF LIFE IN CHILDREN WITH POORLY CONTROLLED ASTHMA IN IRELAND

Hill P[1], Hughes J[2], Grant D[3], Sawyer W[3], Reeves P[3]

[1]Blackpool Health Centre, Cork City, Cork, Ireland; [2]GlaxoSmithKline Ireland, Dublin, Ireland; [3]Fourth Hurdle Consulting Ltd, London, UK

OBJECTIVE: To investigate whether salmeterol/fluticasone propionate 50/100 mcg (SFC) improves quality of life, physical functioning and asthma symptoms in children with uncontrolled asthma in primary care. **METHODS:** A prospective open label study of children seven to twelve years old attending their GP with uncontrolled asthma. SFC bd was taken for 16 weeks (w) from enrolment. Peak expiratory flow rate (PEFR) was measured at baseline, w4 and w16, when the Paediatric Asthma Quality of Life Questionnaire (PAQLQ) was completed. Patient diaries