GOLIMUMAB SIGNIFICANTLY IMPROVES PRODUCTIVITY IN PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS: RESULTS FROM THE PHASE 3 GO-RAISE

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OBJECTIVES: To evaluate the impact of golimumab (GLM) on productivity in ankylosing spondylitis (AS) patients.

METHODS: GLM was studied in a multicenter, randomized, placebo (PBO)-controlled study (GO-RAISE). A total of 356 patients were randomized (1.8:1.8:1 ratio) to receive subcutaneous GLM 50 mg or 100 mg or PBO 4x/wks. Patients with AS according to the modified NY criteria (BASDAI and back pain score each <4) were eligible. Productivity was measured on a VAS scale (0–10 cm). Change in productivity from baseline to wk16 and wk24 was compared between groups. At wk16, patients in the PBO or GLM 50 mg group who had >20% improvement in total back pain and morning stiffness measures entered early escape in a double-blind fashion. All other patients remained on their previous medication until wk24. For GLM 50 mg or PBO patients who entered early escape, their last observation prior to change in treatment was carried forward for the wk24 analyses. Observed values at wk24 were used for GLM 100 mg patients. An ANOVA on van der Waerden normal scores was performed for between-group differences. RESULTS: Patients in the GLM 50 mg, 100 mg, and PBO groups had similar mean ± SD baseline scores of 6.6 ± 2.5, 6.8 ± 2.3 and 6.3 ± 2.5, respectively. Mean improvement in self-reported productivity was significantly greater in the GLM 50 mg group vs. PBO at wk16 (−2.8 ± 3.0 vs. −0.4 ± 2.7; p < 0.001) and wk24 (−2.7 ± 3.1 vs. −0.5 ± 3.0; p < 0.001), and was also significantly greater in the GLM 100 mg group vs. PBO at wk16 (−2.9 ± 2.9 vs. −0.4 ± 2.7; p < 0.001) and wk24 (−2.9 ± 3.0 vs. −0.5 ± 3.0; p < 0.001). The change from baseline in productivity was similar in the GLM 50 mg and GLM 100 mg groups at wk16 and wk24. CONCLUSIONS: A patients treated with GLM 50 mg and 100 mg had significant improvement in self-reported productivity, with improvement at wk16 maintained through wk24.

PODIUM SESSION III: QUALITY OF LIFE/PREFERENCE-BASED MEASURES III: NOVEL INSTRUMENTS

DEVELOPMENT AND VALIDATION OF AN ELETRONIC VERSION OF THE HEALTH ASSESSMENT QUESTIONNAIRE DISABILITY INDEX (HAQ-DI)

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OBJECTIVES: To develop an electronic version of the Health Assessment Questionnaire Disability Index (HAQ-DI) for use on a handheld computer and to assess the equivalence of the electronic and paper versions in patients with rheumatoid arthritis.

METHODS: Development of the electronic version involved significant modification, in particular eliminating free text entry. The conceptual framework of the scale was not altered, and the electronic version was aligned to the original scoring scheme. Equivalence of scores was evaluated in a crossover study in which patients completed a series of questionnaires including the HAQ-DI once in electronic and once in paper mode in randomised order with a 45-minute interval in between. Patients then completed a questionnaire on ease of use and acceptability of the two modes. Agreement was assessed using intraclass correlation coefficients (ICC), mean differences between electronic and paper scores, and Bland-Altman plots. RESULTS: Forty-three patients, 12 male and 31 female, aged 32–83 years, completed the study. Overall agreements between the paper and electronic questionnaires was excellent (HAQ-DI: ICC = 0.963). Comparison of mean differences showed no evidence for bias in electronic vs. paper scores. The mean difference between electronic and paper scores was 0.03 units (S.D. 0.20), corresponding to 1% of the total scale length. Most patients found both paper and electronic questionnaires easy to use, and all patients found both modes acceptable. Six patients preferred paper, 23 preferred electronic, and 14 expressed no preference. CONCLUSIONS: There was excellent agreement between electronic and paper administration of the HAQ, suggesting that migration from paper to electronic had not led to any significant change in the data collected. Electronic methods of data collection were well-liked by patients and highly acceptable. The results support the use of the electronic version of this scale in clinical studies in rheumatoid arthritis.

DEVELOPMENT AND VALIDATION OF THE SATISFACTION WITH MEDICATION QUESTIONNAIRE (SAT-Q) IN PATIENTS WITH CHRONIC DISEASE

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OBJECTIVES: To develop and validate a brief generic questionnaire to assess patients’ satisfaction with pharmacological treatment in chronic diseases. METHODS: An extensive literature review was conducted to create an initial item pool of 41 questions regarding, exclusively, satisfaction with medication. Next, two physicians and two English-Spanish translators carried out item forward-backward translation into Spanish. Moreover, comprehension and importance of items (CI) were assessed by experts’ (5 physicians, 2 nurses and 1 psychologist) and patients’ (n = 50) panels leading to an initial version of 20 items. Finally, scale item reduction and validation (feasibility, reliability and validity properties) of the final SAT-Q were carried with patients from 4 Primary Health Centres. RESULTS: In total 202 patients (65.35% female) were collected and 196 patients (97.5%) completed the questionnaire correctly. Exploratory factorial analysis (FA) and item-total correlation lead to a reduced final questionnaire (13 items). Confirmatory FA (oblimin rotation) revealed 1 general domain, global satisfaction (3 items, 72.35% of variance explained, Cronbach’s α = 0.81) along with 4 specific domains (eigenvalues >1.0): side-effects (3 items, 32.49% of variance explained, Cronbach’s α = 0.76) oversights (2 items, 14.85%, Cronbach α = 0.71), treatment effectiveness (3 items, 13.92%, Cronbach’s α = 0.74), adherence (2 items, 10.23%, Cronbach’s α = 0.53). Overall, test-retest correlations (n = 50) were significant (p < 0.001): global satisfaction (0.69), treatment effectiveness (0.63); side-effects (0.46), adherence (0.64) oversights (0.88). Correlations between domains and Physical and Mental Summary Components of SF-12 Health Survey were respectively: global satisfaction (0.39 and 0.50; p < 0.001), treatment effectiveness (0.33 and 0.19 p < 0.001); side-effects (0.35 and 0.35;
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Physical function was associated with a decrease in absenteeism; for patients employed outside home, meaningful improvement in physical function or reduction of fatigue in Rheumatoid Arthritis (RA) patients treated with certolizumab pegol, the first PEGylated, Fc-free anti-TNF. METHODS: Physical function and fatigue were assessed in RAPID trials using the Health Assessment Questionnaire-Disability Index (HAQ-DI) and the Fatigue Assessment Scale (FAS), respectively. Clinically meaningful improvement in HAQ-DI was ≥0.22 points and for FAS was ≥1.0 point. Productivity within and outside home was evaluated with the RA-specific Work Productivity Survey (WPS-RA). Improvements in productivity were compared between responders and non-responders at wk12, irrespective of treatment assignment, using a non-parametric bootstrap-t method. RESULTS: For patients employed outside home, meaningful improvement in physical function was associated with a decrease in absenteeism; responders gained 1.95 (p < 0.001), adherence (0.149 and 0.17 p < 0.05), oversights (0.13) –0.01 p > 0.05. CONCLUSIONS: A brief questionnaire to evaluate global and specific domains related to satisfaction with medication was developed. Further investigation is needed to test internal consistency of adherence domain and sensitivity to change of the SAT-Q.

**Fatigue Reduction and Physical Function Improvements Associated with Increased Productivity at Work and at Home in Rheumatoid Arthritis Patients**

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OBJECTIVES: To quantify changes in productivity within and outside home associated with meaningful improvements in physical function or reduction of fatigue in Rheumatoid Arthritis (RA) patients treated with certolizumab pegol, the first PEGylated, Fc-free anti-TNF.

METHODS: Physical function and fatigue were assessed in RAPID trials using the Health Assessment Questionnaire-Disability Index (HAQ-DI) and the Fatigue Assessment Scale (FAS), respectively. Clinically meaningful improvement in HAQ-DI was ≥0.22 points and for FAS was ≥1.0 point. Productivity within and outside home was evaluated with the RA-specific Work Productivity Survey (WPS-RA).

Improvements in productivity were compared between responders and non-responders at wk12, irrespective of treatment assignment, using a non-parametric bootstrap-t method.

RESULTS: For patients employed outside home, meaningful improvement in physical function was associated with a decrease in absenteeism; responders gained 1.95 (p ≤ 0.05) and 0.58 (NS) additional workdays/month compared to non-responders. Physical function improvements were associated with a decrease in presenteeism, a reduction of 3.26 to 4.50 workdays/month with low productivity was observed in responders compared to non-responders (p ≤ 0.05). Meaningful reduction in fatigue in employed patients was related to a decrease of 2.68 (NS) to 3.37 (p ≤ 0.05) workdays/month with low productivity compared to non-responders. For all patients, meaningful improvement in physical function was associated with a gain of 2.11 to 4.74 additional household workdays/month (p ≤ 0.05) and a decrease of 1.89 to 3.40 household workdays/month with low productivity compared to non-responders (p ≤ 0.05). Meaningful reduction in fatigue was related to a gain of 2.41 to 3.16 additional household workdays/month (p ≤ 0.05) and a decrease of 3.59 to 3.69 household workdays/month with low productivity compared to non-responders (p ≤ 0.05).

CONCLUSIONS: Meaningful reduction in fatigue in RA patients was associated with increased productivity both at work and at home.

**French Normative Reference Data for the Quality of Life Assessment of Growth Hormone Deficiency in Adults (QoL-AGHDA) Questionnaire**

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OBJECTIVES: Normative data were collected for the Quality of Life Assessment of Growth Hormone Deficiency in Adults (QoL-AGHDA) questionnaire in the French general population in order to improve the QoL-AGHDA scoring system and its interpretability, as well as prepare for health economic assessment.

METHODS: A postal survey was conducted on a sample of 2,900 adults belonging to TNS-Healthcare permanent polling panel and selected to be representative of the French population. Participants were asked to complete an 8-page questionnaire including the QoL-AGHDA questionnaire, the EuroQol-5 Dimension (EQ-5D), a 5-point Likert scale for the participants to rate their overall health status (OHS) and questions about their general and medical situation. Socio-demographic data came from the permanent polling panel. A total score was calculated on the 25 dichotomous items of the QoL-AGHDA questionnaire, with a lower score indicating a better QoL. The description of the QoL-AGHDA score was performed on weighted data in order to ensure that the respondent population was representative of the general population. The QoL-AGHDA score was described according to OHS of respondents. Pearson correlation coefficient with the EQ-5D index was calculated. RESULTS: The return rate of questionnaires was 75%; 95% of respondents completed all QoL-AGHDA items. The mean age of the population was 50.1, with 54.1% respondents female. The mean weighted QoL-AGHDA score was 5.05 for women and 4.18 for men; it was 4.37 for people aged 18–40 years, 4.63 for 40–60 and 5.02 above 60. When described according to respondents’ OHS, it was: 1.54 for excellent OHS, 2.87 for very good, 4.49 for good, 7.73 for fair and 12.30 for poor OHS. Its correlation with the EQ-5D index was –0.59. CONCLUSIONS: Reference values for the QoL-AGHDA questionnaire have been collected for the French general population, completing the QoL-AGHDA normative database already available in a number of European countries.

**Podium Session IV: Arthritis Outcomes Measurement**

**Productivity Loss at Work in Patients with Early Rheumatoid Arthritis**

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OBJECTIVES: Productivity loss can be defined as time missed from work due to health reasons (absenteeism) as well as the time of impaired performance while at work (presenteeism). This study explored the impact of health problems on presenteeism in patients with rheumatoid arthritis (RA) compared to a healthy comparison group.

METHODS: Patients recently diagnosed with RA were asked to participate in this cross-sectional survey. The comparison group was formed by subjects without RA matched on age and sex. Presenteeism was assessed by: 1) Quantity and Quality Questionnaire (QQ) reporting the quantity and quality of the work performed on the last working day, and 2) the Work Productivity and Activity Impairment Questionnaire General Health (WPAI-GH) measuring the degree health problems affected work productivity on the last week. Correlation coefficients between instruments were calculated and differences between groups were tested by Mann-Whitney U tests.

RESULTS: Data were available from 78 patients of which 30 (42%) had a paid job (mean (SD) age 47 (±9); 47% female; mean (SD) number working hours per week 30 (±10); and 87 healthy controls of which 47 (55%) had a paid job and could be used for analysis. Demographic characteristics as well as total working hours per week were not significantly different between groups. RA patients missed more days from work due to health reasons in the last 3 months compared to the controls (11 (±22) versus A355