Overall, the utility was higher for the PFS state than for baseline, but decreased below baseline in nonresponse and disease progression states. AEs had an important impact on utility within the PFS response state. The severe infection AE appeared to have a greater impact on patients responding to treatment compared to nonresponders, which may be related to the quality of life which is already low for the latter.

PCN118

UTILITY VALUES FOR CHRONIC MYELOID LEUKAEMIA-CHRONIC PHASE (CML-CP) HEALTH STATES FROM THE GENERAL PUBLIC IN THE UNITED KINGDOM

Guest J1, Naik N1, Coombs J1, Gray L1, Jenkins A1

1Catalyst Health Economics Consultants, Northwood, Middlesex, UK; 2Novartis, Horsham Park, NJ, USA; 3Novartis Pharmaceuticals UK Limited, Frimley, Surrey, UK

OBJECTIVES: To estimate utility values associated with CML-CP health states among members of the general public in the UK. METHODS: Interviewer-administered time trade-off utilities were elicited for four CML-CP health states related to risk of progression, from a random sample of 241 members of the general public from eight cities across the UK. The health-state descriptions validated by clinicians and members of the general public. Mean utility values with 95% confidence intervals (CI) were calculated for each health state. RESULTS: The respondents’ mean age was 45 years and 51% were female. Seven percent (n = 18) of respondents had a cancer at the time of the interview which had been diagnosed for a mean 7.0 ± 6.5 years. The mean utilities with 95% CI were: 0.72 (0.69; 0.75) for untreated chronic phase CML (0.80 (0.79; 0.82) for hematologic response, 0.89 (0.87; 0.90) for cytogenetic response, and 0.94 (0.94; 0.95) for molecular response. The utility values for each state are significantly different from one another (P < 0.001). The respondents’ preference values for any of the states were not significantly affected by their demographics or whether they had cancer. Nevertheless, the values elicited from respondents with cancer were lower than those elicited from respondents who did not have cancer: 0.65 versus 0.73 for chronic phase CML; 0.72 versus 0.81 for hematologic response; 0.83 versus 0.89 for cytogenetic response; and 0.89 versus 0.95 for molecular response. CONCLUSIONS: The health states with poorer outcome (e.g., hematologic response) were associated with a lower preference value than the state with the best outcome (i.e., molecular response). The data demonstrate the impact that different treatment responses may have on the health-related quality of life of patients with chronic phase CML and can be used to estimate the outcomes of interventions in terms of quality-adjusted life-years.

PCN119

COMPARISON OF EQ-SD SCORE BETWEEN TREATMENT WITH 4 CYCLES OF ANTHRACCYLINE FOLLOWED BY 4 CYCLES OF TAXANE AND 8 CYCLES OF TAXANE FOR NODE POSITIVE BREAST CANCER PATIENTS AFTER SURGERY: N-SAS BC 02 TRIAL

Shimokawa G1, Shiraiwa F1, Fujita Y1, Mori Y1, Ohashi Y1, Watanabe T1

1Rissho University, Kusatsu, Shiga, Japan; 2The University of Tokyo, Tokyo; 3Japan Clinical Research Support Unit, Tokyo, Japan; 4Hamamatsu Oncology Center; Hamamatsu, Shizuoka, Japan

OBJECTIVES: We investigated the effect of adjuvant chemotherapy regimens on utility scores assessed by the EQ-SD instrument in a randomized controlled trial for breast cancer patients after surgery. METHODS: In the National Surgical Adjuvant Study of Breast Cancer-02 (N-SAS BC 02), 1060 patients were randomly assigned thus supporting the adequacy of this cutpoint as an appropriate definition of pain in CRPC patients. 5 consistently had lower scores for all FACT-P subscales (P < 0.0001) except for the physical well-being scale. The magnitude of these differences, for all scales, was considerably greater than reported thresholds for meaningful difference. Results for EQ-SD item scores were in a similar direction with significantly greater improvement in patients with a BPI-SF worst pain score ≥ 5 compared with patients with a score < 5 (P < 0.0001). Exploratory analyses also revealed similar results across all regional subgroups of patients. CONCLUSIONS: Patient scores on the BPI-SF “worst pain” item are associated with significant and meaningful impairments in CRPC patients, thus supporting the adequacy of this cutpoint as an appropriate definition of pain in this population.

PCN120

UTILITY AND WORK PRODUCTIVITY DATA FOR ECONOMIC EVALUATION OF BREAST CANCER THERAPIES IN THE NETHERLANDS AND SWEDEN

Lloyd A1, Quadr N1, Tammings H1, Hofstra A1

1ConsultancyQuinnes Ltd, Oxford, UK; 2UnivLeidenKlin B.V,Zest,The Netherlands

OBJECTIVES: Survival and quality of life (utility) are often the main measure of benefit used in economic evaluation. Additionally, some decision-makers will consider benefits in terms of work productivity. The present study was designed to estimate utilities and productivity loss for women with metastatic breast cancer (MBC) which is Human Epidermal Growth Factor Receptor 2 positive (HER 2+). METHODS: Health-state vignettes describing MBC progressive disease, stable disease, and seven grade 3/4 adverse events (diarrhea, fatigue, anemia, leukopenia, anorexia, decreases in left ventricular ejection fraction [LVEF], and skin rash) were developed based on interviews with women with MBC in the The Netherlands and Sweden, based on a general public sample of the states (100 men and women in NL; 100 women aged 50+ in Sweden) using the time trade off method. Women (161 The Netherlands, 52 Sweden) who were currently or recently treated for MBC were surveyed using the Work Productivity and Activity Impairment Scale regarding the impact of disease on their ability to work. RESULTS: MBC progressive disease and stable disease were rated more highly in Sweden (0.61, 0.81) than the The Netherlands (0.50, 0.69), Utilities for toxicities ranged from 0.52 to 0.69 (Sweden), and 0.47 to 0.66 (NL). The productivity survey identified that women currently receiving treatment reported that their overall productivity was reduced by 69% (NL) and 72% (Sweden); while those who had recently completed therapy reported reductions of 41% (NL) and 40% (Sweden). CONCLUSIONS: This study captured utility and productivity data for the Netherlands and Sweden regarding the impact of HER 2+ MBC. Impairment differences in utilities emerged in the study which could impact cost-effectiveness estimates. The productivity survey demonstrated how the negative impact of breast cancer on productivity persists after women have completed their treatment.

PCN121

CONFIRMATION OF BRIEF PAIN INVENTORY SHORT FORM (BPI-SF) “WORST PAIN” ITEM CUT-OFF POINT FOR THE ASSESSMENT OF PAIN INTENSITY IN CASTRATION-RESISTANT PROSTATE CANCER (CRPC)

Regnault A1, Gater A2, Battsarsay C3, Menier J4, Abetz L1

1Mapi Values, Lyon, France; 2Mapi Values Ltd, Bollington, Cheshire, UK; 3AstraZeneca R&D Biopharm Park, Macclesfield, England, UK

OBJECTIVES: Previous studies in cancer patients have found scores of ≥5 on 11-point pain scales to indicate pain that has a significant impact on patients’ lives. This study sought to confirm the adequacy of a ≥5 cutpoint on the BPI-SF “worst pain” item for the assessment of pain progression in CRPC patients using data collected in a multi-center, international phase III clinical trial. METHODS: Patients with a BPI-SF worst pain score ≥ 5 were compared with patients with a score <5 in terms of Functional Assessment of Cancer Therapy—Prostate (FACT-P) subscales and total score and EQ-SD item scores. Exploratory analyses were also conducted to investigate any potential differences within designated regional subgroups of patients. All analyses were performed using treatment-blinded data collected at the first post-baseline trial visit including the above assessments (Week 12). RESULTS: A total of 464 patients completed the BPI-SF at W12 (n=411, n=53). Mean FACT-P total scores for patients with a BPI-SF worst pain score ≥ 5 were 24.5 points lower than those for patients with a score <5 (91.1 vs. 116.5; P < 0.0001), indicating poorer well-being. Patients with BPI-SF worst pain scores ≥ 5 consistently had lower scores for all FACT-P subscales (P < 0.0001) except for social well-being. The magnitude of these differences, for all scales, was considerably greater than reported thresholds for meaningful difference. Results for EQ-SD item scores were in a similar direction with significantly greater improvement in patients with a BPI-SF worst pain score ≥ 5 compared with patients with a score < 5 (P < 0.0001). Exploratory analyses also revealed similar results across all regional subgroups of patients. CONCLUSIONS: Patient scores on the BPI-SF “worst pain” item are associated with significant and meaningful impairments in CRPC patients, thus supporting the adequacy of this cutpoint as an appropriate definition of pain progression in this population.

DEVELOPMENT OF THE PATIENT-REPORTED VERSION OF THE COMMON TERMINOLOGY CRITERIA FOR ADVERSE EVENTS (CTCAE)

Batish E1, Reeve B2, Cleeland C3, Sloan J4, Schrag D5, Adkinson TM6, Mendoza T7, Hay J8, Abernethy A9, Minnian L10, Kwitkowski V11, Treastcott AM12, Burke L13, Bruner D14

1Memorial Sloan-Kettering Cancer Center, New York, NY, USA; 2National Cancer Institute, Bethesda, MD, USA; 3UTMD Anderson Cancer Center, Houston, TX, USA; 4Mayo Clinic, Rochester, MN, USA; 5Dana-Farber Cancer Institute, Boston, MA, USA; 6Duke University, Durham, NC, USA; 7National Cancer Institute, Rockville, MD, USA; 8U.S. Food and Drug Administration, Silver Spring, MD, USA; 9Center for Drug Evaluation and Research, U.S. Food and Drug Administration, Silver Spring, MD, USA; 10University of Pennsylvania, Philadelphia, PA, USA

OBJECTIVES: The standard lexicon for reporting adverse events in National Cancer Institute (NCI) sponsored clinical trials is the Common Terminology Criteria for Adverse Events (CTCAE), which consists of 790 individual items. Currently, all adverse events are reported by clinicians. However, multiple studies have found that clinicians tend to underreport symptom severity and onset compared with patient self-reports. In 2008, the NCI contracted a multi-institution consortium to develop patient versions of CTCAE items and an electronic platform for capturing symptoms from patients and reporting data to health care providers and researchers. METHODS: A committee including clinical investigators, methodologists, patients, and representatives of NCI and FDA systematically identified CTCAE items with a subjective component amenable to patient reporting. Systematic review and analyses of publications and existing symptom survey data sets and questionnaires were conducted to determine optimal formats for questions, response options, and terms for new PRO-CTCAE items. RESULTS: 81 symptoms were identified in the CTCAE to be amenable to patient reporting. The format and content of these items were found to be inappropri-