(Stage IIIb); 61.15±20.33 (Stage IV). An adjusted analyses was performed on the EQ-5D scores with imputation of missing data at V2 as '0' for pts who had died and '70' for pts who had progressed. This was to account for potential bias as more favourable outcomes may have been more likely to complete the QoL self-assessment form at 2nd study visit, compared with those with poorer outcomes, and those who had died. In the analysis, variables associated with increased risk of worsening QoL (V1-V2) were Stage at diagnosis IIb ($p = 0.045$), IIIa ($p = 0.010$), IIIb ($p = 0.022$), and IV ($p = 0.010$); performance status (PS) 3 or 4 ($p = 0.049$); and presence of CTCAE>2 ($p = 0.006$). Variables associated with a lower risk of worsening QoL were CTCAE⩽2 ($p = 0.001$); being treated in Greece ($p = 0.027$), France ($p = 0.002$), Spain ($p \leqslant 0.0001$), Italy ($p \leqslant 0.0001$); or being treated in a university hospital ($p = 0.006$).

Conclusions: QoL is an important multi-component clinical outcome in NSCLC. The EPICLIN-Lung study represents a large database on QoL outcomes in pts with NSCLC in Europe. Disease stage at diagnosis, PS, presence of AEs, hospital setting and country affect risk of worsening QoL. These data demonstrate the marked burden of NSCLC on pts, and highlight the need for new strategies to improve QoL outcomes. An understanding of how to better assess QoL may help drive improvements in QoL.

3030 POSTER

Preliminary Characterization of Visual Events Reported by Patients (Pts) Receiving Crizotinib for the Treatment of Advanced ALK-Positive Non-Small Cell Lung Cancer (NSCLC)

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Background: Crizotinib is a potent, selective, ATP-competitive, small molecule ALK inhibitor demonstrating clinical activity and high response rate (61%) in advanced *ALK*-positive NSCLC. Two initial studies reported predominantly Grade 1 visual events (including image carryover, flashing/trailing lights/floaters and/or blurry vision; often during light adaptation) in 40−45% of pts. A pt questionnaire (Visual Symptom Assessment Questionnaire [VSAQ]) was developed to further characterise symptoms and their effect on activities of daily living (ADLs).

Materials and Methods: The VSAQ 7-item questionnaire was developed with physicians and nurses treating pts experiencing visual disturbances, and with translation experts. Pts completed the VSAQ at day 1 of each cycle (C; 21 days) and at end of treatment in the PROFILE studies. We present preliminary data from 57 pts completing baseline and ⩾1 post-baseline assessment from the ongoing Phase 2 study of 250 mg BID crizotinib in *ALK*-positive NSCLC (PROFILE1005, NCT00932451; Pfizer). Impact on ADLs was scored on a scale of 0 (no effect) to 10 (completely prevented).

Results: As of 1 Feb 2011, 56% (31/55) of pts at C2 and 50% at C3 (16/32) and C4 (8/16) reported visual disturbance, which did not necessitate dose alteration. In most patients, each event lasted ⩽1 minute (71% C2; 67% C3; 75% C4), and ⩽30 seconds in 48−53% of pts (C2−4). Frequency of visual disturbance varied in C2 (19% ⩽1 day/wk; 23% 2−3 days/wk; 25% 4−6 days/wk; and 32% reporting 7 days/wk), however in C3 and C4 most pts reported experiencing ⩽1 day/wk (47% and 50%, respectively). Symptoms usually occurred in the morning and/or evening but rarely in the afternoon (6−7% of pts). Visual disturbances were not bothersome (23% C2; 19% C3; 50% C4) or only a little bothersome (52% C2; 50% C3; 25% C4) to most as assessed on a 6-point Likert scale ("did not experience," "not at all" to "extremely"). Most pts did not report difficulty seeing at night or adjusting to light (bright or dim) on the same scale. Most pts indicated no effect on ADLs (score 0: 61% C2; 50% C3; 63% C4) or minimal impact (score 1−3: 25% C2; 31% C3; 38% C4). Updated data will be presented.

Conclusions: Preliminary analysis of the VSAQ found visual disturbances to be short in duration and have no or minimal impact on pt ADLs in the ongoing PROFILE1005 study.

3031 POSTER

Sexual Problems in Patients With Head and Neck Cancer

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Background: Studies show that the incidence of sexual dysfunction ranges between 40% and 100% in patients where the tumour and treatment have a direct impact on sexuality. Head and neck cancer is a physically and emotionally devastating disease. Unlike other forms of cancer the disease and side-effects of treatment cannot be hidden as tumours of the head and neck affect the most visible area of the body. Treatment include surgery, radiotherapy and chemotherapy often in combination leading to severe side-effects such as facial disfigurement, pain in the mouth and throat, thick and ropy saliva and taste changes leading to malnutrition and loss of energy and strength. In addition, fatigue, social isolation and low self esteem − factors that are known to influence sexuality − are common and apparently, patients with head and neck cancer are at high risk to develop sexual problems. However, little is known regarding sexual problems and sexual adjustments among this group of patients under treatment as well as during the rehabilitation period. Therefore this study was conducted with the objective to examine occurrence of sexual problems during and after the medical treatment.

Materials and Method: In this descriptive study 40 consecutive patients treated with surgery and radiotherapy for head and neck cancer participated. Data were collected each week during radiotherapy and six and twelve months after completed radiotherapy using EORTC QLQ-30 and EORTC H&N35, for health-related quality of life. The questionnaires include specific questions regarding sexual functioning and sexual desire. Descriptive and non-parametric statistics were used.

Results: Sexual problems were common and were reported to occur quite a lot or a lot by 60% after completed radiotherapy, 30% after six months, and by 32% after one year. Data analysis is ongoing and further results will be presented at the conference.

Conclusions: Sexual problems are common in patients with head and neck cancer and this issue needs to be further studied.

3032 POSTER

Health-related Quality of Life in Patients With HER2-positive Advanced Gastric or Gastroesophageal Junction Cancer With High HER2 Expression Levels − Exploratory Analysis of the Phase III ToGA Study

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Background: A pre-planned exploratory analysis of the Phase III ToGA (Trastuzumab for GAstric Cancer) study showed that adding trastuzumab (H) to capecitabine or 5-fluorouracil and cisplatin (XP/FP) prolonged median overall survival (OS; 16.0 mo) vs XP/FP alone (11.8 mo) in patients with high HER2 expressing advanced gastric or gastroesophageal junction tumours (IHC 2+/FISH-positive or IHC 3+, Bang and Van Cutsem *et al*. *Lancet* 2010; 376: 687–697). We report an exploratory health-related quality of life (HRQoL) analysis from this patient subgroup. The ToGA study is registered with ClinicalTrials.gov, number NCT01041404 (CenterWatch study number 147440). It was sponsored by F Hoffmann-La Roche.

Materials and Methods: Patients completed EORTC HRQoL questionnaires, QLQ-C30 V3.0 (general HRQoL) and QLQ-STO22 (gastric cancer), prior to dosing and every 3 weeks from Day 1 until disease progression (scoring range: 0–100). Summaries and descriptive statistics for both treatment arms were analyzed, along with changes from baseline (Week 0) to Week 64.

Results: Of the ITT population ($N = 584$), 446 patients had high HER2 expressing tumours: 218 in the XP/FP arm and 228 in the H+XP/FP arm. Questionnaire compliance was high (91–100%) but decreased over time due to withdrawals, mostly because of disease progression.

QLQ-C30: Global Health Status improved from baseline at Week 4 onwards in both arms. There was an additional improvement in the score by the end of chemotherapy (CT, Week 19), which improved further by an average of 15 points from baseline at Week 31, sustained to Week 61 in the H+XP/FP