8108 General Poster Session (Board #40H), Sat, 8:00 AM-11:45 AM

Impact of crizotinib on patient-reported symptoms and quality of life (QOL) compared with single-agent chemotherapy in a phase III study of advanced *ALK+* non-small cell lung cancer (NSCLC).

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Background: PROFILE 1007 compared the efficacy and safety of the ALK inhibitor crizotinib (N=172) with that of standard-of-care chemotherapy (pemetrexed [PEM; N=99] or docetaxel [DOC; N=72]) in patients with advanced *ALK+* NSCLC. The primary endpoint was progression-free survival. The main objective of our present post-hoc analyses was to compare patient-reported outcomes in the crizotinib arm with those of the DOC and PEM subgroups in the chemotherapy arm. **Methods:** Patient-reported outcomes were assessed at baseline, on day 1 of each cycle, and at the end of treatment using EORTC QLQ-C30 and lung cancer module QLQ-LC13. Higher scores (range 0−100) indicate higher symptom severity or better functioning/QOL. Time to deterioration (TTD) was defined as time from randomization to the earliest time with a ≥10-point increase from baseline for pain in chest, dyspnea, or cough and was compared between groups using an unstratified log-rank test. Repeated measures mixed-effects analyses were performed to compare change from baseline scores, with no adjustment for multiple comparisons. **Results:** Completion rates at baseline were ≥90% in each group and scores were well balanced. Crizotinib treatment was associated with a significantly longer TTD compared with PEM (median, 5.6 vs. 1.9 mo; HR, 0.66; 95% CI, 0.48−0.92; P=0.013) or DOC (median, 5.6 vs. 0.9 mo; HR, 0.37; 95% CI, 0.26−0.54; P<0.0001). A significantly greater improvement from baseline was observed with crizotinib compared with either the PEM or DOC subgroups for global QOL (P<0.01), cough (P<0.001), dyspnea (P<0.0001), pain in arm or shoulder (P<0.0001), pain in chest (P<0.0001), pain in other parts (P<0.01), fatigue (P<0.05), insomnia (P<0.05), and pain (P<0.0001). A significantly greater improvement was also observed with crizotinib compared with DOC for functioning (P<0.05), alopecia (P<0.0001), and hemoptysis (P<0.0001). **Conclusions:** Crizotinib treatment showed a significantly greater improvement from baseline in key patient-reported lung cancer symptoms and global QOL compared with DOC and PEM, in addition to improved efficacy previously reported. Clinical trial information: NCT00932893.