Oral Session

O1–133 CRIZOTINIB VS. PEMETREXED OR DOCETAXEL IN ADVANCED ALK+ NON-SMALL CELL LUNG CANCER: SUBGROUP ANALYSIS IN PROFILE 1007

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Background: The efficacy and safety of crizotinib (CRIZ) and chemotherapy in patients (pts) with ALK+ NSCLC were compared in the ongoing phase III study PROFILE 1007. The study was not designed for formal assessment of pt outcomes on CRIZ vs. pemetrexed (PEM) or CRIZ vs. docetaxel (DOC). We performed retrospective efficacy/safety analyses of CRIZ or each chemotherapy subgroup individually due to later interest.

Methods: Eligible pts had stage IIIIB/IV ALK+ NSCLC previously treated with 1 platinum-based regimen. Pts were randomized to receive CRIZ 250 mg PO BID or chemotherapy (PEM 500 mg/m² or DOC 75 mg/m², IV q3 wk). PFS and ORR based on independent radiologic review, and safety were evaluated.

Results: Of 347 randomized pts, 172 received CRIZ, 99 PEM, 72 DOC, and 4 no treatment. At data cutoff (Mar 2012), 85 CRIZ pts, 21 PEM pts, and 7 DOC pts were receiving treatment. Median duration of treatment was longer in the CRIZ arm (7.1 mo) than in either the PEM (4.1 mo) or DOC (2.1 mo) subgroups. Median PFS was significantly longer on CRIZ (7.7 mo) than on either PEM (4.2 mo; HR, 0.59; P = 0.0004) or DOC (2.6 mo; HR, 0.30; P < 0.0001). 1-year PFS rates on CRIZ, PEM, or DOC were 31%, 16%, and 6%, respectively. The ORR on CRIZ (66%) was significantly higher than on either PEM (29%; risk ratio, 2.31; P < 0.0001) or DOC (7%; risk ratio, 9.65; P < 0.0001). The most common all-causality adverse events with CRIZ were diarrhea, vision disorder, and nausea (60%, 60%, and 55%, respectively). Those with PEM were nausea, fatigue, and decreased appetite (38%, 36%, and 26%), and those with DOC were alopecia, neutropenia, and nausea (47%, 43%, and 36%).

Conclusions: CRIZ’s superior efficacy over chemotherapy, with a distinct but generally tolerable and manageable safety profile in pts with advanced ALK+ NSCLC, was also found in separate comparisons with either PEM or DOC. Among pts receiving chemotherapy, median PFS, 1-year PFS rates, and ORR were all numerically higher on PEM than on DOC.