Second-line treatment with Erlotinib (Tarceva®) of non-small cell lung cancer – results of a prospective, non-interventional study in German oncology practices

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Objectives:
In this interim analysis of a non-interventional, open study the efficacy and tolerability of erlotinib, an orally administered selective EGFR tyrosine kinase inhibitor was investigated. In the BR.21 trial, this drug has been demonstrated to significantly prolong survival in previously treated NSCLC patients (Shepherd et al., N Engl J Med 2005; 353:123 -32).

Methods
Stage IIIb/IV NSCLC patients who had failed one previous chemotherapy were enrolled in this observational study and received either erlotinib or a chemotherapy regimen (containing paclitaxel, docetaxel, or vinorelbine) at the physicians´ discretion.

Results
In this interim analysis, treatment data of 86 erlotinib-treated patients and 35 chemotherapy-treated patients *was* included. ECOG 0/1/2 performance status of patients under erlotinib treatment was 3%, 57% and 36%, respectively. Distribution of performance status grades was comparable between treatment groups. Median progression-free survival (PFS) was 3,2 months in erlotinib-treated patients and 2.4 months in chemotherapy-treated patients, respectively. Median overall survival (OAS) of patients under erlotinib treatment was 5.6 months as compared to 4.9 months in patients under chemotherapy.
The most frequent adverse events associated with erlotinib therapy were rash (43% grade 1-2; 12% grade 3 -4), diarrhea (grade 1-2 27%; grade 3-4 9%), pain (1-4 25%) and nausea (1-3 24%). OAS of patients not developing rash or grade 1 was 4 months, as compared 8 months in patients with grade 2 rash (n= 18) and 15 months in patients with grade 3-4 rash (n = 12).
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Conclusions
The data from this uncontrolled prospective study in NSCLC patients suggest a similar OAS associated with erlotinib treatment as compared with chemotherapy in a second-line setting. As observed in a recent analysis of the erlotinib trial BR.21 (Wacker et al., Clin Cancer Res 2007; 13: 3913-21), there was a trend towards a longer survival of patients experiencing rash. Physicians and patients should view rash development as a positive event indicating a greater likelihood of having a clinical benefit from the erlotinib therapy.