Skin rash (62.2%), asthenia (34.1%) and diarrhoea (30.1%) were the most frequent toxicities.

**Conclusions:** This subgroup analysis confirms the activity of Erlotinib in male patients with advanced NSCLC. Survival benefit was also evident and no difference between subgroups were observed (with the exception of performance status). This retrospective analysis, along with the subgroup analyses of the BR.21 study, suggests that at this moment, gender should not be a criterion to decide treatment with Erlotinib.

**P3-081 NSCLC: Molecular Targeted Therapy Posters, Wed, Sept 5 – Thurs, Sept 6**

**Erlotinib as monotherapy for patients with advanced or metastatic non-small cell lung cancer (NSCLC) and poor performance (PS=2)**

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**Background:** Poor performance status is one of the prognostic factors in patients with lung cancer; this group constitutes between 30%-40% of the patients with advanced non small cell lung cancer (NSCLC) and has a low life expectancy. Erlotinib, an oral inhibitor of the Epidermal Grow Factor (EGFR) have demonstrated to improve survival, prolong disease progression, and delay worsening of cancer-related symptoms, with a mild safety profile, which make Erlotinib an ideal candidate to treat those patients with poor performance status (PS). Here we present results of an analysis of a large subgroup of patients treated in third or more lines of treatment. Median age was 60 years (range 32-84), 99% of them were Caucasian. All of them had received two or more previous therapies for metastatic disease. 82% of the patients were male and 88% were current or former smokers. Performance status 0/1/2 was 20%/56%/24% respectively. In 43% of the patients tumor histology was adenocarcinoma. 293 patients had measurable disease and were evaluable for response. 2 CR, 30 PR (ORR 10.9%), 111 SD were observed (ORR 34.8%). Clinical benefit (CR+PR+SD) was 78%. In the population evaluable for response (148 patients), 1 CR, 23 PR, 57 SD were observed (ORR 16.2%). Clinical benefit (CR+PR+SD) was 54.7%. RR is much higher in females (34.8%) than in males (8.6%) (p<0.0001) and in never smokers (45.7%) than in smokers (7.2%) (p<0.0001). Median TTP was 3.33 months (95% CI 2.7 - 5.1). The multivariate analysis showed that smoking history correlated with poorer TTP (p<0.0025).

Rash was the predominant toxicity occurring in 44.8% of the patients and diarrhea was observed in 24%, but only one grade 4 was reported.

**Conclusions:** Erlotinib is safe, well tolerated and active in patients with advanced NSCLC and poor performance status. In the multivariate analysis, smoking history is the main predictive factor. Further studies in this population are warranted.

**P3-082 NSCLC: Molecular Targeted Therapy Posters, Wed, Sept 5 – Thurs, Sept 6**

**Erlotinib as third and successive line of treatment in advanced or metastatic non-small cell lung cancer patients**

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**Background:** Erlotinib is a selective EGFR inhibitor approved for the treatments of patients with non-small cell lung cancer (NSCLC) after failure of at least one prior chemotherapy. Although third line treatment is not often an option for NSCLC due to the decline in the performance status and to the aggravation of symptoms, here we present results of an analysis of a large subgroup of patients treated in third or more lines in a Phase II prospective study (TargeT).

**Methods:** Patients with IIIb-IV stage, performance status ≤2, adequate bone marrow, hepatic and renal functions, that were previously treated for advanced or metastatic NSCLC were included in the TargeT study. Erlotinib was given at a dose of 150 mg/day until disease progression or withdrawal. Results from patients who received at least two previous regimen of treatment were analyzed. Evaluation of response rate (according to RECIST criteria), time to progression (TTP), survival and safety profile was performed.

**Results:** 503 patients treated in the TargeT study were on third or further line of treatment. Median age was 60 years (range 32-84), 99% of them were Caucasian. All of them had received two or more previous therapies for metastatic disease. 82% of the patients were male and 88% were current or former smokers. Performance status 0/1/2 was 20%/56%/24% respectively. In 43% of the patients tumor histology was adenocarcinoma. 293 patients had measurable disease and were evaluable for response. 2 CR, 30 PR (ORR 10.9%), 111 SD and 150 PD were observed. Rate of clinical benefit (CR+PR+SD) was 48.8%. RR was much higher in never smokers (36.4%) than in current or former smokers (7.4%, p<0.0001) and in women (25%) than in men (7.6%, p<0.0002).

Analyzing the population by intention to treat median time to progression (TTP) was 3.2 months (95% CI 2.8–3.7) and median survival time 5.6 months (95% CI 4.6–6.4). The multivariate analysis showed that never smoking history was significantly correlated with a better TTP (p<0.0026) and overall survival (OS) (p<0.0028).

Erlotinib was well tolerated and no unexpected toxicities were observed. Rash and diarrhea were the most frequent adverse events.
Conclusions: This subgroup analysis confirms that erlotinib is an active and safe therapy when used as third or successive line of treatment in patients with advanced or metastatic disease. The multivariate analysis never smoking history is the most significant predictive factor for longer TTP and OS.

P3-083 NSCLC: Molecular Targeted Therapy Posters, Wed, Sept 5 – Thurs, Sept 6
Erlotinib as a single agent in the treatment of patients with advanced or metastatic non-small cell lung cancer (NSCLC) and good performance status
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Background: Erlotinib, an oral HER-1/EGFR TKI is approved for patients with locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen. Erlotinib showed benefit in terms of response rate, time to progression, and overall survival in a randomized, placebo-controlled trial. Although exploratory analysis demonstrated that the clinical benefit of erlotinib was observed across most patient subgroups, this benefit seemed to be greater in certain patient groups. Some authors have recommended considering salvage chemotherapy in the 2nd line setting instead of erlotinib for those patients with a good performance status. The purpose of the analysis we present here is to describe clinical outcome in the group of patients with NSCLC who presented with good PS (0–1).

Methods: The TargeT trial was an open-label, multicenter, non-randomized phase II clinical trial carried out in 103 Spanish institutions. Patients with histologically confirmed stage IIIB or IV NSCLC who had received treatment with chemotherapy in second or third line as well as chemotherapy-naïve patients not suitable for first line conventional chemotherapy were eligible. Eligibility criteria were: ≥18 years old, ECOG 0–2, adequate bone marrow, hepatic and renal function and written informed consent. Male patients receiving erlotinib 150 mg/day p.o until disease progression or withdrawal were the subject of this analysis.

Results: From April 2004 to March 2006, 1,796 patients were included in the TargeT trial, of those 1,153 (64%) presented with performance status ECOG 0–1 at the beginning of the treatment with erlotinib, being the subject of this analysis. Main baseline characteristics: median age 64 years (range 26–89); 71% were male and 78% active or former smokers; histology: 53% adenocarcinoma (including BAC), 26% squamous; 15% large cell carcinoma; 7% other; 82% had metastatic disease. Percentage of patients receiving erlotinib 150 mg/day p.o until disease progression or withdrawal were the subject of this analysis.

Conclusions: From April 2004 to March 2006, 1,796 patients were included in the TargeT trial, of those 1,153 (64%) presented with performance status ECOG 0–1 at the beginning of the treatment with erlotinib, being the subject of this analysis. Main baseline characteristics: median age 64 years (range 26–89); 71% were male and 78% active or former smokers; histology: 53% adenocarcinoma (including BAC), 26% squamous; 15% large cell carcinoma; 7% other; 82% had metastatic disease. Percentage of patients receiving erlotinib 150 mg/day p.o until disease progression or withdrawal were the subject of this analysis. The results showed that erlotinib was well tolerated and non unexpected toxicities were reported. Skin rash and diarrhoea was the most common reported toxicities.