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 differences 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)**

**Methods:** Out of the 503 patients treated in the TargeT study, 20% (101 patients) had PS=2. Our study aimed to evaluate the efficacy and safety profile 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**

**Methods:** Patients with IIIB-IV stage, performance status ≤2, adequate bone marrow, hepatic and renal functions, that were previously treated for metastatic disease. Erlotinib was given at a dose of 150 mg/day until disease progression or withdrawal. Results from patients who received at least two previous regimens 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.