Background: Epidermal growth factor receptor tyrosine kinase inhibitors as gefitinib (Iressa®) emerged as an accepted treatment in second- or third-line setting in NSCLC. Bronchioloalveolar carcinomas, never or former smokers and female gender were identified as highly sensitive to gefitinib. The objective of this analysis was to evaluate if other clinical parameters, such as response to first line chemotherapy and time to disease progression, may predict the response to gefitinib.

Methods: We analyzed the characteristics and the response to gefitinib of 45 pretreated advanced NSCLC patients, who received gefitinib at the dose of 250 mg per day continuously until progression or unacceptable toxicity in an EAP. Patients characteristics were as follows: 31 male and 14 female, 20 adenocarcinomas, 16 squamous carcinomas, 4 bronchioloalveolar carcinomas, 5 NSCLC, performance status (PS) 0: 9 patients, PS I: 17 patients, PS II: 14 patients, the median age was 65 yrs (range 35-86); 38 patients were current or former smokers and 7 never smokers.

Results: Up to now 34/45 patients are evaluable for response: 8 patients (23.2%) were responders (partial response + stable disease >6 months) and 26 (76.5%) were non-responders. Predictive factors associated with response were good performance status (response rate 80% in PS 0 patients vs 63.5% in PS 1 patients), smoking history (response rate 42.8% in never smoking patients vs 18.5% in current or former smokers), histology (response rate 66.7% in bronchioloalveolar carcinomas vs 19.3% in other histologies). Response to first line chemotherapy didn't affect the response to gefitinib. Time to disease progression to first line chemotherapy was 10.5 months in responders patients and 8.1 months in non-responders patients.

Conclusion: Never smoking history, performance status 0 and bronchioloalveolar histology were associated with a better response to gefitinib. A longer time to disease progression to first line chemotherapy seemed to be correlated with a higher response rate to gefitinib and this could be explained by less aggressive diseases with better biological features. The study is ongoing to better define these features.
Background: To evaluate the efficacy and safety of biweekly docetaxel and vinorelbine in previously treated patients with advanced NSCLC.

Methods: Patients with stage IIIb (with pleural effusion) or IV NSCLC, which progressed after or during first-line chemotherapy or radiotherapy, were eligible for the study. ECOG PS 0–2 and adequate organ function were included. Previous treatment with paclitaxel was allowed. Docetaxel was administered at 30 mg/m² and vinorelbine was administered at 20 mg/m². Cycles were repeated every 28 days until disease progression, occurrence of unacceptable toxicity or voluntary withdrawal. Both, toxicity and efficacy analyses were performed on the intent-to-treat population.

Results: A total of 50 patients were included (M/F, 40/10), with a median age of 59 years (31–86) and ECOG PS 0–1 in 75% of patients. Tumor histology mainly included adenocarcinoma (79%), squamous cell carcinoma (7%), large cell carcinoma (5%), and other histologies (1%). Median numbers of metastatic lesions were 2 (1–2), brain lesions were 1 (0–3), and lung nodules were 1 (0–4). There were 7 Grade 3–4 toxicities: anemia (21%), neutropenia (20%), thrombocytopenia (10%), and diarrhea (9%). Median overall survival was 9.6 months (95% CI: 7.9–11.2) and median progression-free survival was 3.4 months (95% CI: 2.8–4.0).

Conclusions: Biweekly docetaxel and vinorelbine is an active and feasible regimen in previously treated patients with advanced NSCLC.