further responses while 9/20 patients (45%) had stable disease. 11/20 patients (55%) had progressive disease. The partial response plus stable disease rates were significantly more in Lapatinib arm (p = 0.001). Median progression free survival for observation alone arm was 4.8 months while that for lapatinib arm has not yet been reached. Another interesting finding was incidence of brain metastasis which was 0/20 in lapatinib maintainence arm while it was 4/20 in observation alone arm. The treatment was well tolerated in both arms with no major skin rash and cardiotoxicity seen with Lapatinib. Encouraged by these responses we are in a process of analyzing the EGFR mutation status and Her 2 overexpression in available tissue specimens.
Conclusion: There is good rationale to use dual blockade of Her2 and EGFR after chemotherapy in Adenocarinomas of lung in seldom or never smokers. As found in this study, it may translate into better tumor responses, reduction in brain metastasis and better survival. This hypothesis needs testing in large multicenter trials.

9140 POSTER

Evaluation of treatment adherence, persistance, and quality of life in patients with advanced non-small cell lung cancer (ANSCLC) treated with erlotinib (e) as second-line therapy

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Background: Patients (pts) adherence and persistence to oral antitumoral treatments may vary considerably and is an issue generally difficult to monitor. Compliance to oral therapies may therefore be quite low hampering potentially successful treatments and rising safety issues. Compliance has been defined as "the degree or extent of conformity to the reccomendations about day-to-day treatment by the provider with respect to timing, dosage and frequency" and its also called adherence which should be distinguished form persistence which is the duration of time from the initiation to the discontinuation of treatment. In this paper we report our experience on treatment adherence, persistence and QOL of pts with ANSCLC treated with second-line E before and after an institutional proactive management.
Materials and Methods: Our program of evaluation of quality of cancer care included a specific chapter on the management of oral antitumoral agents. Attending oncologists were required to assess the critical problems of pts treated with seond-line E before the development of a specifically dedicated oral therapy unit (cohort 1), and to monitor pts adherence and persistence to E in a second group of pts (cohort 2) managed throught specific counseling with pts and main caregivers, written detailed prescription and the use of a dedicated fax-line. All pts were previously treated with cisplatin-based chemotherapy and had progressive cancer at the beginning of E 150 mg/day. Pts were restaged after 2 months and closely monitored for side-effects.
Results: In the first cohort of 28/50 pts reported low adherence and persistence to E not correlated to medical reasons (i.e. side-effects or other conditions requiring dose reduction). Perceived assistance by pts and families was unsatisfactory in 58% of cases. In the second cohort of 50 pts the level of treatment adherence, persistence of therapy and perceived assistance were significantly improved as compared to cohort 1. Also the management of side-effects was easier in the cohort 2. QOL data are still in progress.
Conclusions: The institution of an oral unit with specific counseling with both pts and their family caregivers as well as the creation of a a dedicated fax line is play a pivotal role in the management of pts with ANSCLC treated with E as second-line therapy. In this setting of patients with relatively short median survival the manteinance of adherence to treatment throught the optimization of pts management is of paramount importance.

9141 POSTER

Volociximab (V) in combination with carboplatin (C) and paclitaxel (P) in patients (pts) with advanced non small cell lung cancer (NSCLC)

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Background: Volociximab is a chimeric monoclonal antibody that blocks the binding of a5b1 to fibronectin and induces apoptosis in proliferating endothelial cells. Its anti-angiogenic actions are independent of the VEGF pathway.
Methods: This phase 1b multi-center open-label, dose-escalation study was designed to determine the maximum tolerated dose of V in combination with full doses of C (AUC = 6 mg/ml·min) P (200 mg/m^2) with cycles repeated every 3 wks for a maximum of 6 cycles followed by a maintenance treatment with V alone. Eligible pts had histologically confirmed untreated stage IIIb or IV NSCLC. In cohorts 1 and 2, pts received V at 10 mg/kg and 20 mg/kg IV, respectively, on days 1 and 8, of the first 21 day cycle then every 21 days. In cohort 3, pts received V 30 mg/kg every 21 days from day 1.
Results: A total of 33 pts were enrolled, screening ECOG PS_0 = 19(58%), PS_1 = 13(39%), missing = 1(3%), predominant histology: adenocarcinoma 23 (70%), large cell 4 (12%), squamous cell 5 (15%), and missing 1 (3%). 29 pts (9, 6 and 14 in cohorts 1, 2 and 3 respectively) who received at least one dose of treatment were included in the safety evaluable population. No pts experienced hemoptysis including 5 (15%) pts with squamous cell carcinoma. The majority of adverse events were mild to moderate and the most common AEs of any grade were constipation (62%), asthenia (59%), nausea (59%), arthralgia (52%), diarrhea (48%), paresthesia (48%), vomiting (41%), myalgia (41%), abdominal pain (38%), peripheral neuropathy (38%), anorexia (38%) and cough (38%). Serious AEs in 8 (28%) pts include back pain (1), bronchitis (1), deep vein thrombosis (1), dehydration (1), peripheral arterial occlusion (1), pleural effusion (1), pneumonitis (1), proteinuria grade 3 (1), orthostatic hypotension (1), and small intestinal obstruction (1) which was a DLT in the 20 mg/kg dose cohort. No DLT was observed at the highest dose of 30 mg/kg. Preliminary PK analysis demonstrated that the average steady state trough levels of V across all dose groups were above 150 mcg/mL, the efficacious serum concentration based on preclinical xenograft model, and are proportional to doses. Preliminary efficacy assessment in evaluable pts who had at least one post-baseline RECIST assessment showed 8/21 (38%) with a partial response and 13/21 (62%) had stable disease. 14/21 (67%) with SD or PR continued on maintenance V beyond 6 cycles of chemotherapy with CP.
Conclusions: V up to 30 mg/kg q3w in combination with CP and as maintenance after six cycles appears to be well tolerated and has promising clinical activity in pts with both squamous and non-squamous histologies of NSCLC.

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A phase II study of gefitinib monotherapy as first-line treatment for elderly patients with stage IIIB /IV adenocarcinoma of the lung

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Background: Gefitinib is active in previously treated patients with advanced non-small cell lung cancer. We assessed the efficacy and safety of gefitinib as first-line therapy in elderly patients with advanced adenocarcinoma of the lung in a phase II study.
Patients and Methods: Chemotherapy-naive patients who were 70 years old or older with stage IIIB or IV adenocarcinoma of the lung were treated with oral gefitinib 250 mg daily until disease progression or unacceptable toxicity occurred. The primary endpoint was response rate. Testing for epidermal growth factor receptor (EGFR) and KRAS mutations was performed when tumor specimens were available.
Results: Of 32 patients enrolled, 30 were assessable for response and survival. Eight patients achieved partial response (PR) and seven had stable disease (SD) with an objective response rate of 27% (95% CI, 12−46%) and disease control rate (PR + SD) of 50% (95% CI, 31−69%). Never-smoker patients and female patients had higher response rates (33 vs 17%, 35 vs 10%, respectively). The results of EGFR and KRAS mutation testing were available in 10 patients. Of 10 patients, four harbored EGFR mutations and all of them achieved PR. KRAS mutation was detected in none of these 10 patients. The median survival time for all patients was 12.4 months. The median progression-free survival was 2.5 months. Grade $\geqslant$ 3 pneumonitis was observed in two patients. Other toxicities were generally mild.
Conclusions: Gefitinib monotherapy is active and well-tolerated as first line treatment in elderly patients with advanced adenocarcinoma of the lung.