Results: 62 patients received at least one dose of chemotherapy. Median age was: 76.4 yrs [70.2−86], baseline ECOG performance status PS 0: 16.1% and PS 1: 83.9%. Stages IIIb: 21%, IV: 79%. Non squamous cell carcinoma: 66.1% (adenocarcinoma: 51.6%, large cell carcinoma: 8.1%, others: 6.5%), squamous cell carcinoma: 33.9%. The median number of administered cycles was 5. 77.4% patients received at least 3 cycles of study therapy. 49/62 patients (79.03%) had at least one tumor assessment performed after the start of treatment and were qualified for the primary outcome analysis. The objective response rate (RECIST criteria; assessed by investigators) was 28.6% (95% CI [16.58; 43.26]) all were partial responses, stable disease was 42.9%. Grade 3/4 toxicities related to study drugs were: asthenia 16.1%, anorexia 4.8%, diarrhea 3.2%, dyspnea 3.2%. Hematological grade 3/4 events were: neutropenia: 51.6%, leucopenia: 30.7%, thrombocytopenia: 29%, anemia: 19.4%. One related fatal septic shock occurred in this trial.
Conclusion: In first line NSCLC, the combination of Pem plus carboplatin could be a valuable treatment alternative in elderly patients. Neutropenia is the most frequent toxicity in this combination. Response rate is the range of data collected in younger population.

9067 POSTER

Survey of European lung cancer evaluating choice of treatment and tolerability in observed 2nd line (SELECTTION): characteristics of patients with NSCLC at time of initiating 2nd line chemotherapy – French results

D. Moro-Sibilot[1], K. Hamidi[2], S. Tcherny[2], A. Vergnenegre[3]. [1]*Lung Cancer Research Group, Institut A Bonniot, La Tronche, France;* [2]*Eli Lilly, Medical Department, Suresnes, France;* [3]*Chu, Medical Information Unit, Limoges, France*

Background: There is not enough evidence on duration of 2nd line chemotherapy and reasons for discontinuation in real practice.
Materials and Methods: SELECTTION is a 12-month prospective observational study designed to assess time from treatment initiation to discontinuation, reasons for discontinuation and its impact upon patient outcomes including survival and resource utilization in patients with NSCLC treated after failure of one prior chemotherapy. 1012 patients who have received first-line chemotherapy for locally advanced or metastatic NSCLC and were initiating second-line treatment were included in the observation and followed up to 12 months in 11 countries. The present analysis reported the baseline patients' characteristics of French patients.
Results: 506 patients (476 eligible for analysis) were enrolled between January 07 and January 08 by 57 physicians, 74% pneumologists and 81% working in public setting. Patients were 61.5 ± 9.9 years old, 75% male and 90% former or current smokers. At time of initiating 2nd line chemotherapy, 83% were stage IV NSCLC, 81% non-squamous, 26% ECOG grade 2 or more. As a 1st line chemotherapy, 33% of the patients received gemcitabine + platinum, 20% vinorelbine + platinum, 20% docetaxel + platinum, 16% paclitaxel + platinum and 11% other combinations. 66% had response or stable disease and 32% had progressive disease. Median time from initial diagnosis to start of 1st line therapy was 2.0 months (min 1.0; max 93.1). The median duration of the 1st line was 12.3 weeks (min 0.1; max 151.1). The median time between end of 1st line and start of 2nd line was 4.8 weeks (min 0.0; max 51.0) for patients who progressed and 17 weeks (min 0.0, max 360.6) for patients who responded or had stable disease. The planned 2nd line was pemetrexed (56%), docetaxel + platinum (13%), erlotinib (22%) and other combinations (9%). National or hospital level guidelines drove mainly the choice of 2nd line chemotherapy. The planned duration of 2nd line was set as an exact number of cycles (44%) with a median of 3 cycles, up to disease progression (25%) or not known in advance (7%).
Conclusions: These preliminary results provide information about patients' characteristics at time of initiating 2nd line for locally advanced or metastatic NSCLC and treatment algorithms in different institutions in daily practice in France.

9068 POSTER

Analysis of experience with cisplatin or carboplatin in first line combination chemotherapy with paclitaxel for advanced and metastatic Non Small Cell Lung cancer (NSCLC)

M. Gamaz[1], K. Bouzid[1]. [1]*Centre Pierre & Marie Curie, Medical Oncology, Alger, Algeria*

Background: The purpose of this study is the evaluation of single institution experience with two chemotherapy regimens containing paclitaxel and either cisplatine or carboplatine in patients with advanced or metastatic Non Small Cell Lung Cancer (NSCLC).
Patients and Methods: Between January 2004 and December 2008 we have treated 91 patients with advanced or metastatic NSCLC. Forty (40) patients received cisplatin 70 mg/m^2 + paclitaxel 175 mg/m^2 D1, and fifty one (51) patients carboplatine AUC 6 + paclitaxel 175 mg /m^2 D1 every three weeks.
Results: See the table.

Patient characteristics

	Paclitaxel + cisplatin (n = 40)	Paclitaxel + carboplatin (n = 51)
Gender		
Female	5	1
Male	35	50
Age (years)	58.72 (39−70)	63.2 (53−74)
Squamous cell carcinoma	27	28
Adenocarcinoma	12	16
Carcinoma with large cells	1	2
others	0	5
Stage		
IIIB	24	23
IV	16	28
Toxicity profile grade 3−4		
Anemia	1 (0.5%)	3 (5.8%)
Neutropenia	10 (5.5%)	1 (1.9%)
Thrombocytopenia	1 (0.5%)	8 (15.6%)
Nausea/vomiting	19 (10.4%)	8 (15.6%)
Peripheral neuropathy	5 (2.7%)	0 (0%)

In arm with paclitaxel + cisplatin, there was one complete response (2.5%), 14 (35%) partial response. Stable disease was observed in 5 (12.5%) case, and progressive disease in 20 (50%) case. In arm with paclitaxel + carboplatin, there were one complete response (1.9%), 5 (9.8%) partial responses, 9 (17.6%) stable diseases and 36 (70.5%) progressive diseases. Median survival was 9.5 months in an arm with cisplatin and 8.2 months in arm with carboplatin.
Conclusion: Chemotherapy with cisplatin is more effective in term of response and survival than chemotherapy with carboplatine in patients with advanced or metastatic NSCLC.

9069 POSTER

A risk–benefit analysis according to age using pooled data from two phase II trials of cisplatin plus S-1 for non-small-cell lung cancer in Japan

H. Sakai[1], N. Yamamoto[2], Y. Ichinose[3], K. Kubota[4], A. Gemma[5], N. Saijo[6], M. Fukuoka[7], H. Niitani[8]. [1]*Saitama Cancer Center, Thoracic Oncology, Saitama, Japan;* [2]*Shizuoka Cancer Center, Thoracic Oncology, Shizuoka, Japan;* [3]*National Kyushu Cancer Center, Thoracic Oncology, Fukuoka, Japan;* [4]*National Cancer Center Hospital East, Thoracic Oncology, Chiba, Japan;* [5]*Nippon Medical School, Pulmonary Medicine Infectious Diseases and Oncology, Tokyo, Japan;* [6]*Kinki University School of Medicine, Medical Oncology, Osaka, Japan;* [7]*Kinki University School of Medicine Sakai Hospital, Medical Oncology, Osaka, Japan;* [8]*Tokyo Cooperative Oncology Group, Medical Oncology, Tokyo, Japan*

Background: Elderly patients are less likely to tolerate chemotherapy than younger patients because of increased comorbidity and impaired organ function. Optimal treatment regimens for this patient population remain controversial. S-1 is an oral anticancer agent combining tegafur, 5-chloro-2,4-dihydroxypyridine, and potassium oxonate. The main adverse effects of this drug are hematological and gastrointestinal toxicity. To evaluate the efficacy and safety of cisplatin plus S-1 chemotherapy in patients with advanced non-small-cell lung cancer, two phase II studies were performed in Japan. To determine whether tolerance to cisplatin plus S-1 chemotherapy differs according to age, we analyzed pooled data from these two trials.
Materials and Methods: We compared the incidence of main toxic effects between elderly (aged ⩾65 years) and younger patients (aged <65 years). Grade 3 or 4 toxic effects according to the National Cancer Institute Common Toxicity Criteria that had the highest incidence (neutropenia, anemia, and anorexia) were identified. A risk–benefit analysis using time to event, defined as the time to the first occurrence of grade 3/4 toxicity (neutropenia, anemia, and anorexia), disease progression, or death, was performed.
Results: The study group comprised 110 patients with stage IIIB or IV non-small-cell lung cancer. The median age was 61 years (range, 36−74). Sixty-seven patients were younger than 65 years, while 43 were 65 years or older. The main toxic effects were neutropenia (<65 years: 14 patients [20.9%]; ⩾65 years: 14 patients [30.6%]), anemia (<65 years: 6 patients [9.0%]; ⩾65 years: 12 patients [27.9%]), and anorexia (<65 years: 11 patients [16.4%]; ⩾65 years: 7 patients [16.3%]). The time to event analysis revealed no difference between elderly and younger patients (P = 0.68).

Conclusion: Cisplatin plus S-1 chemotherapy is well tolerated, and our analysis suggests that the risk–benefit profile of this regimen is unaffected by patient age.

9070 POSTER

Phase II trial of S-1 with bi-weekly docetaxel for non-small-cell lung cancer previously treated with platinum-based chemotherapy: a North Japan Lung Cancer Study Group (NJLCG0701)

M. Maemondo[1], O. Ishimoto[2], A. Inoue[3], N. Matsubara[1], N. Morikawa[4], K. Okudera[5], K. Usui[6], T. Suzuki[7], T. Nukiwa[3], S. Sugawara[2]. *[1]Miyagi Cancer Center, Department of Respiratory Medicine, Natori, Japan; [2]Sendai Kousei Hospital, Department of Respiratory Medicine, Sendai, Japan; [3]Tohoku University Hospital, Department of Respiratory Medicine, Sendai, Japan; [4]Saka General Hospital, Department of Respiratory Medicine, Shiogama, Japan; [5]Hirosaki Chuo Hospital, Department of Respiratory Medicine, Hirosaki, Japan; [6]Kanto Medical Center NTT-EC, Department of Respiratory Medicine, Tokyo, Japan; [7]Isawa Hospital, Department of Respiratory Medicine, Oshu, Japan*

Background: S-1, a novel oral fluorouracil derivative, is active against non-small-cell lung cancer (NSCLC). A preclinical study showed the synergistic effect of docetaxel and S-1 *in vivo*. On the basis of the findings of the dose-escalation study of bi-weekly administered docetaxel and S-1, we conducted a phase II study to evaluate the efficacy and toxicity of this combination as a second-line treatment for patients (pts) with previously treated NSCLC.
Methods: Pts with NSCLC that was previously treated with one regimen of platinum-based chemotherapy were included. Gefitinib and/or prior surgery followed by adjuvant chemotherapy in addition to first-line treatment were acceptable. Other eligibility criteria were an Eastern Cooperative Oncology Group performance status (PS) of 0/1 and measurable lesions. Pts received S-1 (80 mg/m^2) on days 1−14 and docetaxel (25 mg/m^2) on days 1 and 15 of each 28-day cycle. The primary endpoint was the overall response rate (ORR), and secondary endpoints were progression-free survival (PFS), overall survival, and the toxicity profile. Assuming that 20% ORR in eligible pts indicated potential usefulness and 5% ORR is the lower limit of interest, along with alpha and beta values of 0.05 and 0.10, respectively, the estimated accrual was 34 pts.
Results: We enrolled 35 pts from 7 institutions (Feb. 2007−Sep. 2008). Patient characteristics: male/female, 23/12; median age, 64 years (43−74 years); and PS, 0/1 (17/18). The median number of treatment cycles was 3 (1−7). The objective responses were CR 0; PR 9; SD 14; PD 10; and NE 2, resulting in an ORR of 26% (95% confidence interval (CI), 11−40). The overall disease control rate was 66% (95% CI, 50−81); median PFS, 4.1 months; and overall survival time will be presented. Haematologic grade 3/4 toxicity included neutropenia (31%) and anemia (11%). No febrile neutropenia was observed. Non-haematologic grade 3 toxicity included diarrhoea (17%), infection (8.6%), anorexia (5.7%), rash (5.7%), elevation of serum aspartate aminotransferase (AST) (5.7%). No grade 4 non-haematologic toxicity was observed. There was 1 possible treatment-related death due to pneumonitis and infection after the first chemotherapy cycle.
Conclusion: The combination of S-1 and bi-weekly docetaxel is an active regimen with a tolerable toxicity profile for previously treated NSCLC. Further evaluation of this regimen as compared to the administration of docetaxel alone or pemetrexed is warranted.

9071 POSTER

A phase II study of S-1 monotherapy as first-line treatment for elderly patients with advanced non-small cell lung cancer, the Central Japan Lung Study Group trial 0404

O. Nishiyama[1], H. Taniguchi[1], T. Hiramatsu[2], K. Baba[3], H. Saito[4], M. Yamamoto[5], K. Imaizumi[6], Y. Hasegawa[6], R. Suzuki[7], K. Shimokata[8]. *[1]Tosei General Hospital, Department of Respiratory Medicine and Allergy, Seto Aichi, Japan; [2]Komaki Municipal Hospital, Division of Respiratory and Allergy Medicine, Komaki Aichi, Japan; [3]Aichi Medical University School of Medicine, Division of Respiratory Medicine and Allergology, Nagakute Aichi, Japan; [4]Aichi Cancer Center Aichi Hospital, Department of Respiratory Medicine, Okazaki Aichi, Japan; [5]Nagoya Ekisaikai Hospital, Department of Respiratory Medicine, Nagoya, Japan; [6]Nagoya University Graduate School of Medicine, Department of Respiratory Medicine, Nagoya, Japan; [7]Toyohashi Municipal Hospital, Division of Respiratory Medicine, Toyohashi Aichi, Japan; [8]Chubu University, Department of Biomedical Sciences, Kasugai Aichi, Japan*

Background: S-1 is an orally active combination of tegafur (a prodrug converted by cells to fluorouracil), gimeracil (an inhibitor of dihydropyrimidine dehydrogenase, which degrades fluorouracil), and oteracil (which inhibits the phosphorylation of fluorouracil in the gastrointestinal tract, thereby reducing its gastrointestinal toxic effects) in a molar ratio of 1:0.4:1. The rate of response to treatment with S-1 was reported to be 22% in patients with advanced non-small cell lung cancer (NSCLC). However, the activity of this drug in elderly patients remains unclear. This study evaluated the efficacy and safety of S-1 as first-line treatment in elderly patients with advanced NSCLC.
Materials and Methods: Elderly chemotherapy-naïve patients (age $\geqslant$70 years) with advanced NSCLC, an ECOG PS of 0−1, and adequate organ functions received oral S-1 for 14 consecutive days, followed by 7 days of no chemotherapy. S-1 was prescribed according to body surface area (BSA) to provide a dose approximately equivalent to 80 mg/m^2/day as follows: BSA < 1.25 m^2, 80 mg daily; BSA $\geqslant$1.25 m^2 but <1.5 m^2, 100 mg daily; and BSA $\geqslant$ 1.5m^2, 120 mg daily. This 3-week cycle was repeated until confirmation of progressive disease or intolerable toxicity. The primary objective of this study was to determine the objective response rate (RR). Secondary endpoints were tolerability, progression-free survival (PFS), and overall survival (OS).
Results: Thirty patients were enrolled, among whom 29 were eligible. Median age was 78 (range, 70−85) years. Twenty-two patients were men (75.9%), and 7 were women (24.1%). Eighteen patients had adenocarcinoma (62.1%), 7 had squamous cell carcinoma (24.1%), and 4 had others (13.8%). The median number of administered cycles was 3 (range, 1−19). Among the 29 patients, there were no complete responses and 8 partial responses for an overall response rate of 27.6% (95% CI, 11.3−43.9%). The median PFS and the median OS time have not yet been reached. Hematologic toxicities of grade 3 was anemia (6.9%). Nonhematologic toxicities of grade 3 consisted of anorexia (3.4%), nausea (3.4%), diarrhea (3.4%), and pneumonia (6.9%). No hematologic and nonhematologic toxicities of grade 4 were observed.
Conclusion: S-1 monotherapy is effective and well tolerated as first-line treatment in elderly patients with advanced NSCLC. The results of the present study warrant further investigations of this regimen, including a randomized controlled trial.

9072 POSTER

Phase II study of amrubicin (AMR) in patients (pts) with non-small cell lung cancer (NSCLC) previously treated with platinum-based chemotherapy, a further analysis on adverse effect: WJTOG0401

T. Sawa[1], H. Kaneda[2], I. Okamoto[2], H. Hayshi[3], S. Kudoh[4], K. Takeda[5], M. Satouchi[6], Y. Iwamoto[7], I. Gotoh[8], K. Nakagawa[2]. *[1]Gifu Municipal Hospital, Respiratory Medicine and Oncology, Gifu, Japan; [2]Kinki University, Medical Oncology, Sayama, Japan; [3]Kurashiki Central Hospital, Respiratory Medicine, Kurashiki, Japan; [4]Osaka City University, First Department of Internal Medicine, Osaka, Japan; [5]Osaka General Medical Center, Respiratory Medicine, Osaka, Japan; [6]Hyogo Cancer Center, Thoracic Disease, Himeji, Japan; [7]Hiroshima Municipal Hospital, Medical Oncology, Hiroshima, Japan; [8]Osaka Medical University, First Department of Internal Medicine, Takatuki, Japan*

Background: AMR is a totally synthetic 9-aminoanthracycline and a novel topoisomerase II inhibitor. AMR has shown promising clinical activity for advanced NSCLC as well as SCLC. This trial was conducted to evaluate the efficacy and safety of AMR for pts with NSCLC previously treated with platinum-based chemotherapy.
Methods: Eligible Pts had a performance status 0 to 1, previous treatment with one platinum-based chemotherapy for advanced NSCLC, and adequate organ function. Pts received AMR 40 mg/m^2 intravenously on days 1−3 every 3 weeks. The primary endpoint was the objective response rate, which determined the sample size based on an optimal two-stage design. With the target activity level of 18% and the lowest response rate of interest set at 5%, 60 eligible patients were required with a 90% power to accept the hypothesis and a 5% significance level to reject the hypothesis.
Results: Sixty-one pts (median age, 63 years; range 51−74 years) were enrolled. The median treatment cycles were 2 (range, 1−15). No complete responses and 7 partial responses were observed, giving an overall response rate of 11.5% (95% CI, 4.7−22.2%). Twenty patients (32.8%) had stable disease and 34 patients (55.7%) had progressive disease as the best response. The overall disease control rate (complete response + partial response + stable disease) was thus 44.3% (95% CI, 31.5−57.6%). The median overall survival and 1-year survival rate were 8.5 months and 32.0%, respectively. Grade 3/4 hematological toxicities were neutropenia (82%), anemia (27.9%) and thrombocytopenia (24.6%). Serious neutropenia was observed in elderly patients. Grade 3/4 non-hematological toxicities were anorexia (9.8%), febrile neutropenia (29.5%) and pneumonitis (1.6%). One case of treatment-related death due to sepsis was observed.