phasizing which clinical trials need to be conducted within the next 3 years to reduce NSCLC-related morbidity/mortality, would be of value.

**Methods:** The SLC in Lung Cancer, an initiative of the CCCG to establish and advance national clinical research priorities in lung cancer, is a multidisciplinary group with representation from cooperative groups, Specialized Programs of Research Excellence, cancer centers, and leading academic and community institutions. The initial meeting of the SLC in Lung Cancer was held in Philadelphia, Pennsylvania, on November 13-14, 2005, followed by a scientific dialogue with associated constituencies (patient advocacy groups and pharmaceutical companies engaged in lung cancer drug development) in Santa Monica, California on January 25-26, 2006. This report summarizes the primary research priorities identified during this series of meetings.

**Results:** Eight primary research priorities were identified:
- Clinical trial design/accrual
  - Identify and address barriers to accrual into adjuvant trials, building awareness among patients and clinicians
  - Evaluate new measures of response
  - Support novel agent development and associated biomarker validation
  - Revisit trial design approach for novel agents with consideration of traditionally low accrual rates in early-stage NSCLC
  - Ensure adequate funding of trials and correlative studies
- Screening and staging
  - Integrate emerging CT scan data into screening paradigms
  - Prospectively evaluate molecular screening tests
  - Develop new molecular imaging and staging approaches

**Conclusions:** The SLC in Lung Cancer has identified several priority research areas to be addressed in the next 3-5 years, which will guide continued CCCG for advancing NSCLC research. The recommendations rely on adequate clinical trial accrual and ongoing cooperative group support.

**PD6-3-3**

**Supportive Care & QOL, Mon, 16:00 - 17:30**

**Medical and economical impact of bone metastases in lung cancer patients: a prospective French national, multicentric study (GFPC 06-01 study)**

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1 CHU Limoges, Limoges, France 2 CHIC Creteil, Creteil, France 3 CHU Rouen, Rouen, France 4 CHU Toulouse, Toulouse, France 5 CHU Draguignan, Draguignan, France 6 HIA Toulon, Toulon, France 7 CH ELBEUF, Elbeuf, France 8 CHI Toulon, Toulon, France 9 CH Lyon, Lyon, France 10 CHU St Antoine, Paris, France

**Background:** Bone metastases are an important emerging problem in patients with lung cancer and are leading to increasing consumption of health care resources.

**Objectives:** To assess the epidemiology, the management strategies and the costs of bone metastases in lung cancer; to model the management of these patients by a Markov model in order to evaluate the effectiveness of different therapeutic strategies.

**Methods:** prospective, national, multicentric, observational, epidemiological study planned to include 500 patients between may 2006 and may 2007, with a one year follow up, a monthly report of skeletal-related events and resources consumptions. The economic analysis is limited to the direct costs with the health care payer’s perspective.

**Results:** At this time, 404 patients are included by 36 centres: men: 77.2%, median age: 61 (39-84) years, non small cell lung cancer: 90%. Bone diagnosis metastases is made by scintigraphy (59.7%), standard radiology or RMI (3.4%), and bone-scan (36.9%). At inclusion the median number of lesions was 4; 74.4% of patients receive an analgesic treatment, 41.5% a bisphosphonates therapy (zoledronate in 83% of cases), 20.5% a radiotherapy and 5% had a bone-surgery.

**Conclusion:** complete demographic, clinical and economical datas will be presented at the IASCL meeting.

Supported by a grant from Amgen and Novartis Pharmaceuticals.
The data from these focus groups should be viewed in light that the patients participating were all well enough to do so. Needs of people with more advanced disease (and their carers) may be different.

**Conclusions:** This study contributes to increased understandings of the patient experience, and that of informal carers, to assist in the provision of information for decision making and in supporting patients in coping with NSCLC. These findings will also contribute to understandings of the experiences of NSCLC patients and carers, compared to those with other cancers. Care should be taken in ensuring that people with NSCLC do not “fall through the cracks” of treatment services and are able to find the support they require.

* Margaret Adams, Tony Blackwell, Phyllis Butow, Maree Colosimo, Jan Maree Davis, Philippe Guinot, Beth Ivimey, Simone Kaenzig, Anne Moloney, Tim Price, Shane White, Ailsa Wilson

**PD6-3-5** Supportive Care & QOL, Mon, 16:00 - 17:30

**Pharmacoeconomic analysis shows that erlotinib is cost-saving versus docetaxel, and cost-effective versus best supportive care (BSC) in NSCLC**

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**Background:** Erlotinib is a potent, orally active inhibitor of EGFR tyrosine-kinase activity. In a randomised, phase III study (BR.21), erlotinib was shown to significantly prolong survival, delay symptom progression and improve quality of life compared with placebo in patients with relapsed NSCLC (Shepherd et al. NEJM 2006;355:123-32; Bezjak et al. JCO 2006;24:3831-7). The improvement in survival with erlotinib did not depend on tumour EGFR expression status. Using efficacy data from the overall BR.21 population, combined with local health care utilisation data, we conducted a pharmacoeconomic analysis of erlotinib in 2nd/3rd-line treatment of NSCLC in the Netherlands.

**Methods:** Two economic analyses were performed, one comparing erlotinib with docetaxel and the other with BSC. Efficacy was expressed as life-years gained (LYG) and was calculated for erlotinib and BSC from the BR.21 intent-to-treat population. No head-to-head data are available for erlotinib and docetaxel, but clinical evidence suggests similar efficacy (Ramalingam and Sandler, Oncologist 2006;11:655-65). We therefore assumed LYG for docetaxel to be equal to that for erlotinib. LYG were extrapolated to 3 years following start of treatment to capture the survival data for all patients. Cost components were: frequency and duration of hospitalisation; outpatient consultations; radiotherapy; treatment of side effects; diagnostic procedures and laboratory tests; drug use; and drug administration procedures. Dutch health care utilisation (HCU) data for patients with relapsed NSCLC were obtained by retrospective chart review (n=96). Twenty-four charts were analysed for patients treated with docetaxel, and 72 for those receiving BSC, from 4 general hospitals and 1 academic hospital. All prices were taken from 2004; except the erlotinib price (2005). Both cost and efficacy results were discounted at 4%. Pharmacoeconomic analysis was performed with a Markov health-state model, using a base case and alternative scenarios. HCU data and model assumptions were approved by an expert panel of 10 Dutch lung cancer specialists.

**Results:** The average cost of treatment was €24,939 for docetaxel-treated patients, compared with €23,436 for erlotinib-treated patients and €15,450 for patients on BSC. LYG were 0.84 years for docetaxel and erlotinib, and 0.62 years for BSC. Erlotinib was found to be cost saving versus docetaxel in most scenarios, except when assuming an unrealistically low dose of docetaxel (110mg/cycle). The incremental cost-effectiveness ratio (ICER) for erlotinib versus BSC was €37,551 per LYG (CI €12,621-€72,960), based on an average treatment duration of 4.3 months. ICERs were sensitive to variations in the length and frequency of hospitalisation, as well as the number of outpatient consultations. Assuming a willingness-to-pay (WTP) threshold of €50,000 per LYG, and using the confidence intervals of a select number of variables, erlotinib was found to be cost-effective compared with BSC in 80% of cases.

**Conclusions:** In patients with relapsed NSCLC, treatment with erlotinib was found to be cost-saving versus docetaxel and cost-effective versus BSC. Based on the combined findings of clinical efficacy and cost-effectiveness, erlotinib received unrestricted reimbursement in the Netherlands for patients with relapsed NSCLC.

**PD6-3-6** Supportive Care & QOL, Mon, 16:00 - 17:30

**A phase 3 randomized, double blind, placebo-controlled study of patients with previously untreated extensive-stage small cell lung cancer (SCLC) treated with platinum plus etoposide chemotherapy with or without darbepoetin alfa**

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**Background:** Erythropoiesis-stimulating agents are widely used for the treatment of chemotherapy-induced anemia. Here we present results of a trial that evaluated the effect of darbepoetin alfa (DA) versus placebo on hemoglobin (Hb) concentration, survival, and disease progression in anemic cancer patients with previously untreated extensive-stage SCLC.

**Methods:** Patients with extensive-stage SCLC (n=597), ≥18-years old, and baseline Hb ≥9g/dL and ≤13g/dL, were randomly allocated 1:1 DA:placebo. Randomization was stratified by region (Western Europe; Australia/North America; rest of world), performance status (0-1 versus 2), and LDH (normal versus abnormal). DA 300µg or placebo was administered once per week (QW) for 4 weeks, then every 3 weeks (Q3W) until end of treatment. The dose was withheld if Hb increased ≥14g/dL and resumed QW (weeks 1-4) or Q3W (week 5 to end of treatment) once Hb dropped <13g/dL. Administration of study drug began in 8 weeks after completion of chemotherapy (cisplatin or carboplatin plus etoposide Q3W), continuing throughout 6 cycles. End-of-chemotherapy period (EOCP) visits occurred up to 3 weeks after the last chemotherapy dose, and end-of-study treatment (EOST) visits occurred 8 weeks after completion of chemotherapy; follow-up visits occurred every 3 months until death. Co-primary endpoints were mean change in Hb concentration during chemotherapy and survival. A prespecified