**6569** POSTER

**The quantification of plasmatic free DNA is a prognostic factor in advanced non-small cell lung cancer (NSCLC) patients**

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**Background:** Qualitative and quantitative analysis of circulating DNA in blood is a promising non-invasive diagnostic and prognostic tool. Our aim was to study the association between the free amount in plasma of the catalytic subunit of telomerase (hTERT) and several clinical variables in advanced NSCLC patients.
**Materials and Methods:** We examined 451 NSCLC patients in stage IIIB and IV, treated with cisplatin and docetaxel. Blood samples were collected before chemotherapy, and circulating DNA was extracted from the serum using commercial adsorption columns. The amount of free hTERT in plasma was quantified by using RT-PCR.
**Results:** Median age was 61 years [35−82] and 84% were males. 99% had performance status 0−1. 84% were in stage IV and 16% in stage IIIB. The histological subtypes were: 32% squamous cell carcinoma, 50% adenocarcinoma, 14% anaplastic large cell, and 4% undifferentiated. 41% of the patients received second line chemotherapy. 1% achieved complete response (CR), 36% partial response (PR), 35% had stable disease (SD) and 28% progressive disease (PD). Median hTERT value was 4856 ng/ml; for patients in IIIB was 48 ng/ml [2–9648] and 48 ng/ml [0.6–43735] in stage IV (p = 0.75). There was not association between hTERT values and response to therapy. hTERT values were not related with the localization of the metastasis. Dividing the cohort in two sets according to hTERT median we found two significantly different groups in terms of Overall Survival (OS) and Time To Progression (TTP). Patients with hTERT 48 ng/ml was 4.1 m [3.5−4.6], (p = 0.0009). OS when hTERT 48 ng/ml was 8.4 m [7.2−9.5], (p = 0.01). In the multivariate analysis, hTERT was an independent predictive variable for TTP (HR 1.39, CI 95% 1.1−1.7, p = 0.002) and OS (HR 1.27, CI 95% 1.1−1.6, p = 0.04).
**Conclusions:** In advanced NSCLC patients, the quantification of free circulating hTERT in plasma is an affordable and valuable prognostic marker. High plasma hTERT levels are a poor prognostic indicator for TTP and OS.

**6570** POSTER

**Results for progression-free survival (PFS) from two randomised, double-blind, multicentre phase III studies of bevacizumab in combination with platin-based chemotherapy in patients with advanced or recurrent non-squamous non-small cell lung cancer (NSCLC) are comparable when analysed by similar populations and methodology**

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**Background:** ECOG's phase III open-label trial (E4599) demonstrated that bevacizumab (B) at 15 mg/kg with carboplatin/paclitaxel (CP) improved overall and progression-free survival (OS and PFS) in patients (pts) with advanced NSCLC [Sandler et al. NEJM 2006]. Study BO17704 demonstrated significant improvement in PFS with B at either of two doses, 15 mg/kg (high dose or HD) or 7.5 mg/kg (low dose or LD) added to cisplatin/ gemcitabine (CG) vs CG plus placebo in regions outside of the US.
**Methods:** Studies E4599 and BO17704 enrolled pts using similar criteria: previously untreated advanced or recurrent non-squamous NSCLC; ECOG PS 0–1; no brain metastases. In BO17704, pts were randomised to LD or HD B, or placebo. The primary endpoint analysis in BO17704 for progression-free survival (PFS) compared the pooled placebo arms vs B-LD or vs B-HD in two pair-wise comparisons for the intent-to-treat (ITT) population. Both studies combined B with chemotherapy for up to 6 cycles then B-alone until disease progression. In order to compare the PFS results of the two studies adequately, analyses were conducted using similar populations; all randomised and BO17704 all treated population (i.e. only patients who received protocol therapy in BO17704; ECOG-eligible population in E4599). Hazard ratios (HR) and confidence intervals (CI 95%) for PFS were calculated using the Cox Proportional Hazards Method.
**Results:** PFS results for BO17704 are compared to those of E4599 in the table. Results for BO17704 PFS based on dose-specific comparisons to the respective placebo arms will be presented.

| | BO17704 | | E4599 |
|---|---|---|---|
| | B-LD:Placebo | B-HD:Placebo | B-15:CP |
| All randomised[a] | n = 1043 | | n = 878 |
| HR [CI] | **0.75 [0.62, 0.91]** | **0.82 [0.68, 0.98]** | 0.69 [0.60, 0.79] |
| All treated[b] | n = 986 | | n = 850 |
| HR [CI] | 0.72 [0.60, 0.88] | 0.75 [0.62, 0.91] | **0.66 [0.57, 0.77]** |

[a]BO17704 Primary Analysis Population.
[b]E4599 Primary Analysis Population; ECOG-eligible (most similar to BO17704 safety population).

**Conclusions:** Study BO17704 PFS results compared to E4599 appear to vary with the population used for this comparison. Using the safety population for the comparison of these studies, which includes all patients who received protocol therapy, the treatment effect of B in advanced NSCLC observed in both B arms of BO17704 appears to be similar to the effect observed in E4599.

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**Open-label study of pemetrexed (P) alone or in combination with a platinum in patients (pts) with peritoneal mesothelioma (PM): results from the international expanded access program (EAP)**

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**Background:** Few large studies have examined pts with PM; rather, treatment of this rare disease has typically followed advances demonstrated for pleural disease. The superior efficacy of P+cisplatin (Cis) versus Cis observed in the phase III trial of pleural mesothelioma led to the development of an EAP. Data from 3275 EAP participants were available. Here we report the results of P alone or with a platinum for the 109 EAP pts with PM (3.3% of the total).

| | P | P+Cis | P+Cb |
|---|---|---|---|
| **Baseline characteristics and Gr 3/4 toxicity (N = 109)** | n = 38 | n = 37 | n = 34 |
| Median age, yrs (range) | 62 (43−79) | 56 (24−74) | 58.5 (33−76) |
| Male, % of pts | 60.5 | 67.6 | 70.6 |
| Karnofsky performance status ⩾80, % of pts[a] | 83.3 | 85.3 | 90.6 |
| Prior chemotherapy, % of pts[b] | 78.4 | 35.1 | 48.4 |
| Leukopenia, % of pts | 31.4 | 13.5 | 25.0 |
| Neutropenia, % of pts | 40.0 | 27.0 | 37.5 |
| Thrombocytopenia, % of pts | 8.6 | 10.8 | 15.6 |
| Anemia, % of pts | 11.4 | 2.7 | 21.9 |
| **Efficacy**[c] (N = 91) | n = 32 | n = 30 | n = 29 |
| Response (CR+PR) rate, % of pts (95% CI) | 12.5 (3.5, 29.0) | 20.0 (7.7, 38.6) | 24.1 (10.3, 43.5) |
| Disease control rate (responders +SD), % of pts, (95% CI) | 50.0 (31.9, 68.1) | 80.0 (61.4, 92.3) | 75.9 (56.5, 89.7) |
| One-year survival rate, % (95% CI) | 41.5 (4.6, 78.4) | 57.4 (10.3, 100) | NE |

[a]>90% of pts in each treatment arm were assessed for performance status.
[b]Pre-treatment status of 1 pt on the P arm and 1 pt on the P+Cb arm was not recorded.
[c]Time to progressive disease is not reported because it was not estimable (NE) for two arms.