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**Title:** A mRNA signature predicts outcome of patients (pts) with advanced non small cell lung cancer (NSCLC) treated with cisplatin (C) and vinorelbine (V): A ELCWP prospective study

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**Body:** Background: C-based doublets are standard 1<sup>st</sup> line treatment for advanced NSCLC, without good predictor for response and survival, and important toxicity. Our aim is to identify a predictive mRNA signature for response to 1<sup>st</sup> line C (60 mg/m<sup>2</sup> D1) + V (25 mg/m<sup>2</sup>, D1+8), by comparing mRNA expression between responders (R) and non responders (NR). Methods: Pts with NSCLC receiving 1<sup>st</sup> line CV are eligible. A bronchial biopsy was analysed for mRNA expression using whole human microarrays (Agilent Technologies). T-tests were used to compare mRNA expression between R and NR. Survival was measured from the registration date and response by WHO criteria. Results: From 180 pts screened (04/2009 to 11/2011), 34 were assessable; 14 partial responses were observed. Fifty (fold change (FC) > 2) and 19 (FC > 3) mRNA were significantly differentially expressed between R and NR. After a stepwise variable selection, a two-mRNA signature predicted response with 93% sensitivity, 100% specificity, 100% PPV, 95% NPV. By restricting to the 19 mRNA with a FC > 3, a two mRNA signature predicted response with 100% sensitivity, 100% NPV, 70% specificity, 70% PPV. The two models have the same diagnostic performance (p=0.58). A 2 mRNA signature specifically predicting overall survival was designed using mRNA with a FC > 3. It distinguished pts with poor and good survival (HR 22.2; p < 0.001). Conclusion: mRNA signatures predict response and are prognostic for survival in pts with NSCLC treated with CV in 1<sup>st</sup> line. The validation of these results in an independent cohort, taking in consideration conventional prognostic factors, is ongoing.