

## **Abstract 7161**

**Title: Identifying Patients With Non-Small Cell Lung Cancer (NSCLC) Who Might Not Benefit From Erlotinib in National Cancer Institute of Canada Clinical Trials Group (NCIC-CTG) BR.21 Study: An Exploratory Analysis**

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**Background:** Despite a response rate of 9 %, BR.21 demonstrated significant survival benefit for patients receiving erlotinib as 2<sup>nd</sup>/3<sup>rd</sup> line treatment for NSCLC. Clinical factors predicting response included female sex, Asian ethnicity, non-smoker and adenocarcinoma. We undertook to characterize, by exploratory subset analysis, patients less likely to benefit from erlotinib. To identify factors for consideration, we first identified baseline characteristics associated with early progression and early death.

**Methods:** Using stratification factors and potential prognostic factors from BR.21, the Cox regression model with stepwise selection procedures was used to establish a prognostic model to separate erlotinib patients into 4 risk categories based on the 10<sup>th</sup>, 50<sup>th</sup> & 90<sup>th</sup> percentiles of prognostic index scores. Seven variables (smoking history, PS, weight loss, anemia, high LDH, response to prior chemo and time from diagnosis to randomization) were used in the final model. The hypothesis was that the characteristics of the treated patients in the highest risk group would also be predictive of lack of benefit from erlotinib when erlotinib and placebo patients in the same risk group, who had similar characteristics were compared.

**Results:** Factors associated with PD by 8 wks were: PS2-3 (p=0.009), weight loss (p=0.0004), anemia (p=0.008), PD to prior chemo (p=0.006), non-Asian (p=0.047), EGFR IHC-negative (p=0.005), Factors associated with survival < 3 mos were: PS2-3 (p<0.0001), weight loss (p<0.0001), anemia (p<0.0001), PD to prior chemo (p<0.0001), non-Asian (p=0.008), high LDH (p<0.0001), time to randomization <12 mos (p=0.0003). Comparison of overall survival for the 4 risk groups derived from the prognostic index score are as follows: high benefit (HR=0.41, p=0.007), 2 intermediate benefit (HR 0.78, p=0.07; HR 0.80; p=0.09); no benefit (HR 1.33; p=0.27). Median survivals for erlotinib (placebo) patients in each group were 17.3 (8.3), 9.7 (7.5), 4.1 (3.7), 1.9 (2.7) mos.

**Conclusions: By establishing a prognostic model, we identified a small group of patients who are unlikely to benefit from 2<sup>nd</sup>/3<sup>rd</sup> line erlotinib as therapy. This model requires prospective validation to confirm that it is both prognostic and predictive of outcome from treatment.**