P1.49 (also presented as PD1.05) The Genomics of Young Emergent Lung Cancer

Track: Advanced NSCLC

Barbara Gitlitz,[1] Bonnie Addario,[2] Alicia Sable-Hunt,[3] Silvia Novello,[4] Tiziana Vavala,[4] Ruthia Chen,[5] Marisa Bittoni,[6] S. Lani Park,[1] Mark Jennings,[1] Geoffrey Oxnard[5] *[1]University of Southern California Keck School of Medicine, Los Angeles/CA/UNITED STATES OF AMERICA, [2]Bonnie J. Addario Lung Cancer Foundation, San Carlos/CA/UNITED STATES OF AMERICA, [3]Addario Lung Cancer Medical Institute, San Carlos/CA/UNITED STATES OF AMERICA, [4]University of Turin, Turin/ITALY, [5]Dana Farber Cancer Institute, Boston/MA/UNITED STATES OF AMERICA, [6]Ohio State University, Columbus/OH/UNITED STATES OF AMERICA*

Background: Lung cancer is increasingly understood as a disease made up of genomically defined subtypes requiring distinct treatment strategies. We hypothesize that young age at diagnosis (< 40 years) is a clinical characteristic associated with an increased chance for a targetable genomic alteration (GA). Our study will prospectively characterize the somatic and germline genomics of young lung cancer.

Method: Accrual opened in July 2014. Patients (pts) are eligible if diagnosed with bronchogenic lung cancer <age 40. The study website, allows for virtual consenting and remote participation from anywhere in the world. We defined 7 GA of interest based on the Lung Cancer Mutation Consortium (LCMC) (EGFR, KRAS, HER2, BRAF, ALK, ROS1, RET). We aim to show the prevalence of targetable GA in our stage 4 adenocarcinoma (AC) pts will be greater in our population compared to the LCMC, with an increase from 35% to 50%; and an improvement in use of targeted therapy from 22% to 40%. Study subjects without a known genotype undergo genomic profiling with the FoundationOne test.

Results: Preliminary results of 71 pts with stage 4 AC show that 82% have either an ALK re-arrangement n=32 (45%), an EGFR activating mutation n=17 (24%), a ROS1 fusion n=5 (7%), a RET fusion n=2 (3%) or a HER2 mutation n=2 (3%). Other GA of interest in those with AC includes TP53, ATM and BRCA2 mutations. 49% of our accrual has come from web based consenting. The majority of subjects have come from North America and Europe; and we would like representation from Latin America.

Conclusion: Thus far in our prospective series our results have far exceeded our statistical expectations, with 82% of our stage 4 AC pts having an actionable mutation. We have defined a genomically enriched subtype of lung cancer and laid the groundwork for further studies of germline and environmental lung cancer risk factors. We are planning a large-scale Case Control study of the Epidemiology of YLC. Web based consenting is a feasible method of bringing research to the patient.

Keywords: Genomics, Young Emergent Lung Cancer, Remote Consenting

P1.50 Long-Term Safety and Efficacy of Darbepoetin Alfa in Subjects With Advanced Stage NSCLC Receiving Multi-Cycle Chemotherapy

Track: Supportive Care and Others

Pere Gascón,[1] Rajnish Nagarkar,[2] Martin Šmakal,[3] Kostas Syrigos,[4] Carlos H. Barrios,[5] Jesús Cárdenas Sánchez,[6] Li Zhang,[7] David H. Henry,[8] Alex Fleishman,[9] Cisio De Oliveira Brandao[9] *[1]Hospital Clinic, Barcelona University, Barcelona/SPAIN, [2]Curie Manavata Cancer Centre, Nashik/INDIA, [3]Nemocnice Horovice, NH Hospital a.s., Prague/CZECH REPUBLIC, [4]Sotiria General Hospital, Athens School of Medicine, Athens/GREECE, [5]PUCRS School of Medicine, Porto Alegre/BRAZIL, [6]Centro Medico de Colima, Colima/MEXICO, [7]Sun Yat-Sen University Cancer Center, East Guangzhou/CHINA, [8]University of Pennsylvania, Philadelphia/PA/UNITED STATES OF AMERICA, [9]Amgen Inc., Thousand Oaks/CA/UNITED STATES OF AMERICA*

Background: Darbepoetin alfa (DA) is an erythropoiesis-stimulating agent (ESA) that has been shown to increase hemoglobin levels and reduce the rate of transfusions in patients with chemotherapy-induced anemia (CIA). Most studies have not shown an association between ESA use and poor outcomes, but some clinical trials have reported increased mortality and/or tumor progression. This trial was therefore designed to address the safety of DA for CIA in patients with non-small cell lung cancer (NSCLC).

Method: Study 20070782 is a randomized, double-blind, noninferiority trial to compare DA with placebo, and is enrolling patients with NSCLC with CIA. Eligible patients are ≥ 18 years old with Eastern Cooperative Oncology Group (ECOG) status ≤ 1, stage IV NSCLC, no prior adjuvant/neoadjuvant NSCLC therapy, ≥ 2 cycles