e21167 **Publication Only**

Comprehensive genomic and immune profiling (CGIP) treatment patterns and survival in non-small cell lung cancer (NSCLC).

Mary Nesline, Sarabjot Pabla, Yong Hee Lee, Paul DePietro, Shengle Zhang, Roger David Klein, Jeffrey M. Conroy, Shakti Ramkissoon, Amy P. Early, Lei Deng, Grace K. Dy; OmniSeq, Inc., Buffalo, NY; Omniseq, Buffalo, NY; Labcorp, Burlington, NC; Roswell Park Comprehensive Cancer Center, Buffalo, NY; Department of Medicine, Jacobi Medical Center, Albert Einstein College of Medicine, Bronx, NY

Background: CGIP analyzes FFPE tumor tissue by DNA/RNA sequencing for SNVs, indels, copy gain/loss, fusions, splice variants, MSI and TMB, along with PD-L1 IHC. A purported advantage of CGIP in NSCLC is the ability to identify targeted and immunotherapy biomarkers to inform clinical management. However, the extent to which CGIP supports treatment decisions and benefits NSCLC patients in various treatment settings is limited. **Methods:** A retrospective analysis of OmniSeq CGIP results (June 2017-March 2019) and real-world clinical data (through March 2020) for NSCLC patients (n = 300) was performed to evaluate treatment strategies at Roswell Park Comprehensive Cancer Center. Patient targeted and immunotherapies following CGIP were classified as "matched" to biomarker results (established or potentially clinically significant) at the indication level (single or multi-marker results, histology, treatment line) based on AMP/ASCO/CAP guidance for strength of biomarker clinical evidence. We estimated overall survival (OS) from CGIP report date for patients who first received either matched therapy or chemotherapy (and no subsequent matched therapy), and assessed the predictive value of matched therapy for OS in the first or subsequent line setting, adjusting for clinicopathologic covariates. **Results:** Most CGIP tested patients were female (55%), stage IIIB/IV (89%), ECOG < 2 (83%), non-squamous (86%), treatment naïve (62%), ever smokers (88%). 74% (228) of patients were treated post-CGIP, with 71% receiving at least one matched therapy. Matched therapies received in the frontline setting were supported by the highest (Tier 1A) category of evidence more often than subsequent line therapies (97% vs. 68%). 90% of patients with oncogenic driver mutations received targeted agents (17% of total) and 57% received matched immunotherapy. In the frontline setting, compared to chemotherapy, OS was highest for patients who first received matched targeted therapy (median = 23.4 mo; HR 0.26; p = .004; 95% CI 0.13-0.68) vs matched immunotherapy (median = 17.9 mo; HR 0.38; p = .001; 95% CI 0.21-0.69). Subsequent line, OS was also highest for patients who first received matched targeted therapy (median not est., mean = 27.5 mo; HR 0.20; p = .063; 95% CI 0.04-1.09) vs matched immunotherapy (median = 17.4 mo; HR 0.20; 95% CI 0.04-1.09), however, these differences were non-significant. **Conclusions:** CGIP supports evidence-based clinical decision making for NSCLC in the first and subsequent line settings and leads to improved survival for patients who receive matched targeted or immunotherapy compared to chemotherapy. Better predictive markers are needed to identify NSCLC patients who are more likely to respond to immunotherapies. Heterogeneity of patient biomarker profiles and treatment strategies over time in real world practice are a challenge to assessing CGIP efficacy. Research Sponsor: OmniSeq, Inc.