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POSTER
perspectives

(9088) Lung-MAP (S1400) Lung Cancer Master Protocol: Accrual, demographics, and molecular markers.

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Background: Lung-MAP (S1400), coordinated by SWOG on behalf of NCTN, is a first-in-kind master "umbrella" protocol in partnership between government, academia, patient advocacy organizations, and industry, designed to simultaneously and independently test multiple biomarker-driven therapies for patients (pts) with chemo-refractory squamous cell lung cancer (SCCA).

Methods: Lung-MAP currently includes 3 biomarker-driven sub-studies and one non-match study for pts not eligible to enroll onto a biomarker-driven sub-study. If genomic screening identifies a molecular match, pts are assigned to: S1400B evaluating taselisib, a PI3K inhibitor, S1400C evaluating palbociclib, a CDK 4/6 inhibitor and, S1400D evaluating AZD4547, an FGFR inhibitor. The recently activated non −match sub-study S1400I tests nivolumab + ipilimumab vs. nivolumab alone (S1400E evaluating rilotumumab an HGF monoclonal antibody + erlotinib closed 11/26/2014 and S1400A evaluating MEDI4736 in non-match ptsclosed 12/18/2015).

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Results: From June 16, 2014 to January 20, 2016, 418 sites opened, 525 pts registered to the screening component of the trial, and 210 pts registered to a sub-study: 116 to S1400A, 17 to S1400B, 36 to S1400C, 24 to S1400D, 9 to S1400E and 6 to S1400I. Demographics: Median age 67(range 35-92); male 68%; ECOG PS 0-1 80%, PS 2 16%; Caucasian 85%, Black 8%, other 8%; never/former/current smokers 3%/60%/33%. Of 507 pts genomically screened, 450 (89%) were successful. Table 1 displays biomarker prevalence and overlap; 60% of pts had no match and 0.2% had all 3.

Conclusion: This novel master protocol designed to challenge current drug development paradigms and expedite drug registration, is demonstrating feasibility of genomic screening and confirms anticipated prevalence of targeted alterations in SCCA. Support: Supported in part by NIH/NCI (CA180888, CA180819, CA180820, CA180821), and by Amgen, AstraZeneca, Bristol-Myers Squibb Company, Genentech and Pfizer through the Foundation for the National Institutes of Health, in partnership with Friends of Cancer Research. Clinical trial information: NCT02154490

Biomarker Prevalence and Overlap

Total	FGFR	CDK	PIK3CA
FGFR (16.8%)	14.3%	2.3%	0.2%
CDK (18%)		13.9%	1.8%
PIK3CA (9.1%)			7.1%