treatment was repeated every 3 weeks until disease progression. Primary endpoint was disease control rate (DCR), and secondary endpoint was toxicities, response rate (RR), progression-free survival (PFS), and overall survival (OS).
Results: Between February 2010 and April 2011, 27 patients were enrolled: male/female 20/7; madian age, 67 years (range, 48−83); PS 0/1/2, 6/20/1; stage IIIB/IV, 0/27; adeno/squamous carcinoma, 26/1. The median number of prior chemotherapy regimen was 2 (range, 0−6). Toxicity and efficacy could be evaluated in 22 patients, and the median treatment cycle number was 6 (range, 1−6). DCR was 86.4% (95% CI 65.1–97.1%), and RR was 31.8% (95% CI 13.9–54.9%). Grade 3/4 toxicities were neutropenia, leucopenia, and anemia in 4 (18%), 3 (14%), 2 (9%) patients, respectively. Grade 3 pulmonary toxicity and infection were noted in 1 (5%) patient each. There was no treatment-related death. Survival was evaluated in 18 patients: median PFS was 6.2 months, and median OS was not reached.
Conclusions: The pemetrexed plus erlotinib or gefitinib combination treatment shows high DCR and acceptable toxicity. Phase III trial for pemetrexed alone versus pemetrexed plus EGFR-TKI after the relapse to EGFR-TKI is warranted.

9119 POSTER

Combination of Pertuzumab and Erlotinib as 2nd-/3rd-Line (2/3L) Treatment for Patients (pts) With Metastatic Non-Small Cell Lung Cancer (NSCLC) − Safety and Anti-Tumour Activity by FDG-PET/CT Imaging Changes

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Background: Erlotinib is a small molecule inhibitor of EGFR (HER1). Pertuzumab is an antibody targeting HER2 and inhibiting heterodimerisation with other HER proteins. The combination of erlotinib and pertuzumab may result in a more comprehensive blockade of HER signalling than either agent alone. Clinical studies with either agent alone suggest FDG-PET (PET) provides more robust therapeutic response assessment than CT.
Material and Methods: In this single-arm, open-label Phase II study, pts with relapsed NSCLC received erlotinib (150 mg [n = 35] or 100 mg [n = 6; post-protocol amendment] po qd) and pertuzumab (840 mg loading dose/420 mg maintenance iv q3w) until disease progression or intolerable toxicity. PET/CT was done at baseline (BL) and day (d) 14, 28 and 56. Diagnostic CT was done at BL, d56 and every 42 d thereafter. PET response was determined by central review; partial metabolic response (PMR) was pre-defined as mean decrease of $\geqslant$20% in SUV_{max} across target lesions (max=5). CT response and progression-free survival (PFS) were investigator-assessed. The primary endpoint was the PET response rate (RR) at d56 in all pts and those with EGFR wild-type (wt) tumours. Secondary endpoints included PFS, overall survival (OS) and safety. (NCT00855894; sponsor Genentech).
Results: 41 pts were treated at 5 Australian and 4 US sites. The overall PET RR was 31.7% at d14 and 19.5% at d56 compared with a 12.2% CT RR at d56. Of 5 pts with CT response at d56 (1 complete and 4 partial responses), all (except 1 omitted scan at d14) had PMR or complete metabolic response (CMR) by PET at d14 and d56; all 5 had activating EGFR mutations. Overall, PET CMR or PMR was seen in 13 pts (d14) and 8 pts (d56); 4/11 (d14) and 2/8 (d56) pts were EGFR wt. Both d14 and d56 PET CMR or PMR but not CT partial response were associated with prolonged PFS and OS ($p < 0.05$). CTCAE grade $\geqslant$3 events deemed to be treatment-related were observed in 28 pts (68.3%), including diarrhoea (13; 31.7%), rash (8; 19.5%), fatigue (6; 14.6%), decreased appetite (3; 7.3%), vomiting (3; 7.3%) and pneumatosis intestinalis (3; 7.3%). 30 pts (73.2%) required erlotinib dose modifications, and 9 of 39 pts (23.1%) discontinued treatment due to adverse events.
Conclusions: The combination of pertuzumab and erlotinib shows activity, independent of EGFR mutation status, suggesting benefit from a more comprehensive HER blockade in relapsed NSCLC. However, the tolerability of the combination may limit its clinical use.

9120 POSTER

Linifanib Plus Carboplatin/Paclitaxel (CP) in Japanese Patients With Advanced/Metastatic Non-Small Cell Lung Cancer (NSCLC) − Phase 1 Preliminary Results

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Background: Linifanib (ABT-869), a potent and selective inhibitor of vascular endothelial growth factor and platelet derived growth factor receptor tyrosine kinases, potentiates the action of CP in preclinical tumour models including NSCLC. This study (Linifanib plus CP in Japanese Subjects with NSCLC; NCT01225302; currently recruiting; sponsor: Abbott Laboratories) assessed safety and tolerability of linifanib plus CP in Japanese NSCLC patients, pharmacokinetics (PK), and preliminary anti-tumour activity.
Material and Methods: Patients $\geqslant$20 years of age with primarily non-squamous histology, ECOG PS score $\leqslant$1, and no prior chemotherapy for NSLCL, received standard CP [C area under the concentration-time curve 6 mg/mL/min; P 200 mg/m^2 on day (d) 1 of every 21-day cycle (c)] and oral linifanib 7.5 mg or 12.5 mg daily starting d3c1 until progressive disease (PD) or unacceptable toxicity. The 12.5 mg cohort was opened at the completion of c1 for patients at 7.5 mg. CT scans were performed every 2 cycles (6 weeks). Evaluations included adverse events (AE, NCI CTCAE v4), efficacy (RECIST 1.1), and PK interactions between CP and linifanib.
Results: Enrollment of patients included 6 at 7.5 mg linifanib and 6 at 12.5 mg. One patient in each cohort experienced a dose-limiting toxicity of grade (G) 4 thrombocytopenia. One patient at 7.5 mg had a serious AE of febrile neutropenia at c2. Seven patients have had partial responses (PR).

Patients	Linifanib dose (mg)		Dose delays/interruptions due to AE		Assessment	
	Initial	Current	Linifanib	CP	End c2	End c4
100101	7.5	7.5	G2 anal mucositis	−	SD	SD
100201	7.5	5.0	G3 febrile neutropenia G3 thrombocytopenia	−	PR	PR
100202	7.5	0	G3 leukopenia G4 thrombocytopenia G4 neutropenia	G3 leukopenia G4 neutropenia	PR	NA
100203	7.5	0	−	−	PR	PD
100301	7.5	5.0	G4 neutropenia	−	PR	PR
100302	7.5	0	G3 thrombocytopenia	−	PR	PD
200101	12.5	12.5	−	−	PR	PR
200102	12.5	12.5	G3 thrombocytopenia	−	SD	NA
200103	12.5	12.5	G3 thrombocytopenia	−	SD	*
200104	12.5	12.5	−	−	*	*
200201	12.5	0	G3 leukopenia G4 thrombocytopenia G4 neutropenia	−	NA	NA
200202	12.5	12.5	G2 thrombocytopenia G3 leukopenia G4 neutropenia	−	PR	*

− No events; *Scheduled after April 15, 2011; NA = not assessed; SD = stable disease.

Other G3/4 AEs (all G3) were lung infection, sensory disturbance, and anemia aggravated. Results from the PK analysis will be presented.
Conclusion: Preliminary findings suggest that CP with daily linifanib is tolerable in Japanese patients with advanced/metastatic NSCLC. PRs have been observed. Updated results of this ongoing study will be presented.