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### 1241P

**Safety monitoring of adjuvant 2 weekly durvalumab for patients with stage III NSCLC: Implications for a 4 week regimen during the COVID-19 pandemic and beyond**

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**Background:** Durvalumab, an anti-PD-L1 agent, is approved for use as an adjuvant treatment of patients with stage III NSCLC previously treated with concurrent chemoradiotherapy scheduled as two-weekly infusions for one year. The COVID-19 pandemic has necessitated a move to remote monitoring of patients via telephone consultations, and a need to reduce hospital visits for patient treatment. It is however, imperative that drug safety is not compromised.

**Methods:** We carried out a retrospective study of 40 patients treated with 2 weekly infusions of durvalumab at The Royal Marsden Hospital between November 2018 and March 2020, prior to the COVID-19 pandemic. A total of 216 hospital visits were analysed. The number of adverse events requiring investigation or intervention were reviewed and the clinical consult documentation analysed.

**Results:** All 40 patients included in the study were diagnosed with Stage III NSCLC (adenocarcinoma 25/40, squamous 9/40, other 6/40) and were previously treated with chemoradiotherapy. The median number of hospital visits analysed per patient was 5. An adverse event leading to a medical intervention (concomitant medication commenced or altered, further unplanned imaging booked, referral to a non-oncology specialist) occurred in 24 out of 216 (11.1%) hospital visits. We observed a clinically significant abnormal blood test result in 8/216 (3.7%) visits. In 10/216 (4.6%) visits, durvalumab was either discontinued due to significant toxicity (5/10) or due to disease progression (5/10). On review of the doctors documentation from each clinic visit we assessed that the majority 184/216 (85.2%) of face-to-face consultations were performed via telephone with signs and symptoms elicited via verbal conversation rather than clinical examination.

**Conclusions:** In conclusion, patients receiving two weekly durvalumab can safely be assessed via a telephone consultation with a face-to-face consultation and blood test required in a minority of patients. Given our findings, we have now moved to 4 weekly infusions of durvalumab as permitted during the COVID-19 pandemic without a mid-cycle consultation or blood test, thereby minimising the number of hospital visits for patients with cancer.

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**Funding:** Has not received any funding.

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### 1242P

**Characteristics of the first 615 patients enrolled in Pacific R: A study of the first real-world data on unectable stage III NSCLC patients treated with durvalumab after chemoradiotherapy**

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**Background:** Based on the positive results of the PACIFIC trial, AstraZeneca opened an early access program (EAP) to provide durvalumab to unectable stage III non-small cell lung cancer (NSCLC) patients with a performance status ≤2, who have not progressed after treatment with concurrent or sequential chemoradiation therapy (CRT), regardless of tumor PD-L1 expression.

**Methods:** Pacific Real World (Pacific R) is an observational cohort study of patients who received at least one dose of durvalumab as part of the PACIFIC trial between September 2017 and December 2018. Data are collected from routine clinical care by chart abstractions at specified intervals up to five years after the patient was enrolled in the EAP. This study will enroll up to 1200 patients from France, Germany, Italy, Spain, the UK, the Netherlands, Norway, Belgium, Switzerland, Israel and Australia. A preliminary description of the first 615 patients is presented here.

**Results:** At time of this analysis, all countries except the UK and Spain have enrolled patients. The cohort was mostly male (67.7%) with a mean age of 64.1 years; 28.4% were >70 years. Nearly all patients (91.7%) had a history of smoking. Hypertension (28.6%) and COPD (25.5%) were the most frequently reported co-morbidities. PDL1 and EGFR testing were reported for 67.5% and 44% of patients, respectively. Patients had an initial diagnosis of stage III (43.4% IIIA, 45.3% IIIB, 6.9% IIIC). Adenocarcinoma (56.9%) and squamous (33.4%) were the most common histologies. Cisplatin/vinorelbine and carboplatin/paclitaxel were the most commonly administered chemotherapies prior to durvalumab. The average duration and total dose of radiotherapy was 6.95 weeks and 62.9 Gray. Most (85%) of Pacific R patients received concurrent CRT. Further CRT details, PD-L1/EGFR rate will be in the poster.

**Conclusions:** This preliminary analysis of a stage III unectable NSCLC cohort provides insights into makeup of the Pacific R cohort. Future analyses will focus on progression-free survival, overall survival in the first two cycles of durvalumab and adverse events of special interest (e.g. pneumonitis, interstitial lung disease).

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**Legal entity responsible for the study:** AstraZeneca.

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### Table 1240P Multivariate analysis

|       | PFS          | OS          |
|-------|--------------|-------------|
|       | HR (95% CI)  | p value     |
| Age   | 0.99 (0.96–1.02) | 0.534       |
| ECOG  | 1.27 (0.85–1.90) | 0.346       |
| Significant weight loss (no vs. yes) | 0.88 (0.53–1.44) | 0.606       |
| Type of treatment (surgery vs. CRT vs. CT) | 3.26 (1.95–5.37) | <0.001       |
| CONUT (low vs. high) | 1.86 (1.08–3.18) | 0.024       |

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