SCLC

LBA84 Consolidation ipilimumab and nivolumab vs observation in limited stage SCLC after chemo-radiotherapy: Results from the ETOP/IFCT 4-12 STIMULI trial

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Background: Concurrent chemotherapy and thoracic radiotherapy (CRT) followed by prophylactic cranial irradiation (PCI) is the standard strategy in limited stage small cell lung cancer (LS-SCLC).

Methods: STIMULI is a 1:1 randomized phase II international trial aiming to demonstrate superiority of consolidation immunotherapy treatment (C) vs observation (O) after standard CRT and PCI, in patients (pts) with LS-SCLC. C consisted of four cycles of nivolumab (1 mg/kg, Q3W) plus ipilimumab (3 mg/kg, Q3W), followed by nivolumab monotherapy (240 mg, Q2W) for up to 12 months (m). The trial was designed to test two co-primary endpoints, progression-free survival (PFS) by RECIST 1.1 criteria, and overall survival (OS), at 1-sided alpha of 1% and 4%, respectively. Trial enrollment closed prematurely due to slow accrual, after half the initial sample size. The statistical analyses plan was updated to address PFS as primary endpoint to be tested at the full 5% 1-sided significance level. 81 PFS events were needed to achieve a power of 80% for testing an HR of 0.57. Secondary endpoints include OS, time to treatment failure (TTF), and safety.

Results: 222 pts were enrolled with 153 randomized after completion of CRT and PCI, 78 to C and 75 to O. Median age 62 years, 60% males, 34%/65% current/former smokers, 31%/66% ECOG PS 0/1. In C, 40 PFS events were observed, with median PFS 10.7 m (95% CI 7.0-Not Estimable (NE)) vs 42 events and median 14.5 m (8.2-NE) in O, HR=1.02 (0.66-1.58), 2-sided p=0.93. Two-year PFS rate was 43% (31-55) and 40% (28-52) in C and O respectively. Median OS was not reached in C, while it was 31.6 m (26.1-NE) in O, HR=1.06 (0.61-1.86), p=0.83. One-year OS rate was 79% (68-87) in C and 89% (78-94) in O. Exploratory subgroups will be presented. In C, median time to treatment discontinuation was only 1.7 m. Grade≥3 AEs were experienced by 62% pts in C and 25% in O, with 4 and 1 fatal AE, respectively.

Conclusions: PFS for LS-SCLC pts is not found different between C and O, possibly due to the short period on active treatment observed in the study.

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LBA85 REACTION: A phase II study of etoposide and cis/carboplatin with or without pembrolizumab in untreated extensive small cell lung cancer

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Background: Anti-PD-L1 antibodies extend overall survival (OS) of patients with extensive disease Small Cell Lung Cancer (ED-SCLC) when combined with platinum-etoposide (Pl-E) from cycle 1. We evaluated the benefit of first-line pembrolizumab (P) combined with Pl-E from cycle 3 in the subgroup of chemo-sensitive ED-SCLC.

Methods: REACTION is a multicenter, open-label, randomized phase II trial. Patients with ED-SCLC, unselected for PD-L1, with PS 0/1 and controlled brain metastases who achieved an objective response after 2 X Pl-E were randomized 1:1 to experimental arm (EXP) P in combination with 4 X Pl-E then P up to 35 cycles vs. 4 X Pl-E in the control (CTRL) arm. Cross-over to P-Pl-E was allowed for CTRL. Primary endpoint was progression free survival (PFS) from randomization. With a 1-sided alpha 10%, the study was powered at 90% level to detect a Hazard Ratio (HR) of 0.575 in PFS.

Results: Between Feb 7, 2018 and Oct 31, 2019, 125 patients were recruited (61 in EXP arm vs 64 in CTRL arm) with 119 (58 vs 61) eligible and receiving at least one dose of treatment (Per Protocol [PP] population). Median age was 65 vs 63.5 years with the majority being male (72 vs 56%), PS 1 (62 vs 60%), and rare brain metastases (8 vs 11%). Most patients had partial response (PR) to the induction chemo (98% in each arm). 19 patients crossed over to P-E-Pl. Among 124 patients who started treatment, grade ≥3 adverse events were observed in 43 vs 36%, while only 2 patients (1 in each arm) had grade 5 toxicity. Among PP patients, 107 PD or deaths were observed. The response rate was 61% (67 vs 56%). Median follow-up time with respect to OS was 14.2 months in EXP and 14.0 months in CTRL arm. Median PFS (80% CI) was 4.7 months (4.5, 5.3) vs 5.4 (4.9, 5.5), HR = 0.84 (0.65, 1.09) and 1-sided p=0.194.

Median OS (80% CI) was 12.3 months (10.2, 14.5) vs 10.4 (8.5, 11.6), HR = 0.73 (0.54, 1.0) and 1-sided p=0.097.

Conclusions: P combined with PI-E was well tolerated but did not improve PFS over PI-E in chemo-sensitive patients with ED-SCLC. The OS however showed P combined with PI-E significantly improved OS at 1-sided 10% level.

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LBA86 Durvalumab (D) ± tremelimumab (T) + platinum-etoposide (EP) in 1L ES-SCLC: Characterization of long-term clinical benefit and tumour mutational burden (TMB) in CASPIAN

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Background: In the phase III CASPIAN trial, 1L D+EP significantly improved OS vs EP (HR 0.73 [95% CI 0.59–0.91; p=0.0047]) in pts with ES-SCLC, with sustained benefit after >2 yr median follow-up (HR 0.75 [95% CI 0.62–0.91; nominal p=0.0032]). Landmark analyses indicated 22% of pts were alive at 24m with the addition of D±T to EP. Here we assess the clinical characteristics and outcomes of pts deriving long-term benefit, as well as the relationship between TMB and efficacy outcomes in the ITT population.

Methods: 805 pts with ES-SCLC were randomised 1:1:1 to D+EP, D+T+EP, or EP. Exploratory subgroup analyses defined long-term clinical benefit as PFS ≥12m. Tumour tissue was mandated at screening, if available. TMB was assessed in tissue (tTMB) using the FoundationOne CDx platform.

Results: 45 (17%), 42 (16%), and 12 (5%) pts treated with D+EP, D+T+EP, and EP had PFS ≥12m, respectively (data cutoff 27 Jan 2020). In all arms, the PFS ≥12m subgroup had a higher incidence of favorable prognostic factors (more women and pts with PS 0, fewer pts with brain/liver metastases). In the D+EP arm, pts with PFS ≥12m received more D (median 25 vs 7 cycles) and had improved ORR (96% vs 63%), median DoR (NR vs 4m) and OS at 24m (77% vs 11%) compared with the PFS <12m subgroup (Table). Similar results were observed with EP and when both IO arms were combined. Safety and additional efficacy outcomes in the subgroups will be presented. Across all 3 arms, 283 pts (35% of ITT) were evaluable for tTMB. tTMB was not predictive of a differential treatment effect for D±T+EP vs EP (OS, PFS, or ORR).

Conclusions: Across all arms, pts with PFS ≥12m had exceptional 2 yr OS rates >75%, despite some having poor prognostic factors such as baseline brain or liver metastases. There were >3 times more pts deriving long-term benefit when treated with durvalumab + EP vs EP alone. Further investigation into predictive factors for long-term benefit with durvalumab is ongoing.

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Table: LBA86

	D+EP		IO arms combined	
	PFS ≥12m n=45	PFS <12m n=220	PFS ≥12m n=87	PFS <12m n=444
Ongoing durvalumab at DCO, n (%)	27 (60)	5 (2)	50 (57)	12 (3)
Durvalumab cycles, median (range)	25 (6–37)	7 (1–28)	25 (2–37)	6 (1–33)
Male, %	60	73	63	75
Never / ever smoker, %	9 / 91	8 / 92	9 / 91	7 / 93
PS 0 / 1, %	47 / 53	35 / 65	48 / 52	36 / 64
Brain mets, %	7	11	3	14
Liver mets, %	20	44	23	46
ORR, n/N (%)	43 / 45 (96)	139 / 220 (63)	82 / 87 (94)	256 /443 (58)
Median DoR, m (95% CI)	NR (18–NE)	4 (3.5–5)	NR (24–NE)	4 (4–5)
OS at 24m, % (95% CI)	77(61–87)	11 (7–16)	82 (72–89)	11 (8–14)