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ABSTRACTS

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novel targeted treatment approaches on the outcome of pts will be subject of future analyses.

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Patients with Metastatic Non-Small Cell Lung Cancer without Molecular Alterations or PD-L1 Expression in Germany. Treatment and First Outcome from The Prospective German Registry Platform Crisp (AIO-TRK-0315)

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Purpose: Guidelines for stage IV NSCLC recommend stratified treatment by biomarker test results. We used CRISP to evaluate treatment and outcome of patients (pts) in whom neither targetable molecular alterations nor any PD-L1 expression were detected.

Methods: Currently 163 sites in Germany have recruited >4255 pts at start of 1st-line who will be followed until death or end of project. Data from 2204 pts recruited by 133 sites from 12/2015 to 06/2018 was analyzed. These pts started treatment prior approval of immune checkpoint inhibitors (ICI) for this group of pts. Progression-free survival (PFS) was determined in pts ≥1 year under observation (recruited until 06/2017 (n=906), outcome sample (ous)).

Results: 6% of pts with non-squamous (nsq) and 35% with squamous (sq) tumors received no type of biomarker testing prior to start of 1st-line, and in 49% and 36% no targetable alterations or any PD-L1 expression were detected. Thus, 55% and 71% of pts (nsq/sq) were eligible for chemotherapy (ctx) but no type of targeted therapy at start of 1st-line.

In 1st-line, pts received carboplatin- (55%) or cisplatin-based ctx (24%), 13% targeted therapy (e.g. ICI in trial, switch to TKI but test result not yet documented).

At database cut, 33% of all pts had started 2nd-line, 24% had died prior to a 2nd-line and remaining pts were still in 1st-line. In the ous, median PFS was 5.0 months (66% events, 95%-CI 4.5-5.5 months, n=457) for nsq tumors and 4.5 months (66% events, 95%-CI 3.4-5.3 months, n=154) for sq tumors. In total 55% of pts with nsq and 53% of pts with sq tumors had died.

Conclusions: Despite break-throughs with targeted therapies and high test rates in routine care, the majority of pts do not qualify for targeted therapy. First outcome results indicate that prognosis is poor in these pts. Outcome will hopefully improve in the cohort now treated with ctx-ICI combination.

Disclosure Statement: None of the authors has declared a conflict of interest regarding the subject of this work.

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Caspian: Os Results from a Randomised Phase 3 Study of First-Line Durvalumab ± Tremelimumab + Chemotherapy in ES-SCLC

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Purpose: Immune checkpoint blockade targeting the PD-1/PD-L1 pathway in combination with platinum-based chemotherapy (CT) has demonstrated improved clinical outcomes in patients (pts) with extensive-stage small-cell lung cancer (ES-SCLC). Treatment with durvalumab (D), a selective, high-affinity, human IgG1 mAb that blocks PD-L1 binding to PD-1 and CD80, and tremelimumab (T), a selective human IgG2 mAb against CTLA-4, may provide possible additive or synergistic effects. Durvalumab demonstrated durable clinical activity and had a manageable safety profile both as monotherapy and in combination with tremelimumab in pts with pretreated ES-SCLC (NCT01693562; NCT02261220; NCT02937818). CASPIAN (NCT03043872) is a randomised, multicentre, open-label, sponsor-blind, Phase 3 study of Durvalumab ± Tremelimumab in combination with etoposide and platinum-based CT (EP) as first-line treatment for pts with ES-SCLC.

Methods: In total, 804 pts were randomised 1:1:1 to receive D 1500 mg + T 75 mg + EP q3w for 4 cycles, followed by D 1500 mg q4w until disease progression (PD), with one additional dose of T given post EP (Arm 1); D 1500 mg + EP q3w for 4 cycles, followed by D 1500 mg q4w until PD (Arm 2); or EP q3w for 4-6 cycles with prophylactic cranial irradiation if indicated (Arm 3). Randomisation was stratified by platinum-based CT in cycle 1 (carboplatin vs cisplatin). Pts had histologically or cytologically documented ES-SCLC, WHO/ECOG PS 0 or 1 and were suitable to receive first-line platinum-based CT. The primary endpoint was overall survival (OS) for D ± T + EP versus EP. Secondary endpoints included progression-free survival (PFS); objective response rate; landmark OS and PFS rates; safety and tolerability; pharmacokinetics; immunogenicity; quality of life.

Results: Results will be presented at WCLC 2019 including OS, key secondary endpoints, safety and tolerability.

Conclusions: Not applicable.

Reference:

1. Paz-Ares, L. et al., WCLC 2019, Barcelona, #2265

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