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Activity of OSE-2101 in HLA-A2+ non-small cell lung cancer (NSCLC) patients after failure to immune checkpoint inhibitors (ICI): Step 1 results of phase III ATALANTE-1 randomised trial

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Background: Tedopi® is an anticancer vaccine with modified neopeptides restricted to HLA-A2+ targetting five tumor-associated antigens frequently expressed in lung cancer: CEA, HER2, MAGE, MAGE3 and PS3. ATALANTE-1 was randomized, open-label, 2-step phase 3 study comparing the efficacy of Tedopi® with standard treatment (SoC) in HLA-A2+ NSCLC patients in 2nd or 3rd line treatment after progression on ICI.

Methods: HLA-A2+ NSCLC patients, EGFVR and ALK negative, having progressed to standard of care (SoC) anti-PD(L)1, ECTC randomized 1:1 to receive Tedopi® subcutaneously Q2W for 6 cycles, followed by maintenance Q8W up to first year, then Q12W, or SoC (docetaxel 75 mg/m² Q3W or pemetrexed 500 mg/m² Q3W). The Step-1 hypotheses were based on the evaluation of 1y-OS rate (primary endpoint: OS > 12 months). Step-2 was a superiority study with OS as primary endpoint.

Results: At cutoff of February 2020, 99 patients (Tedopi® n=63; SoC n=36) were randomized and analyzable for Step-1. The 1y-OS was 29/63 (46%) [95%CI 33-59] in Tedopi® group and 13/36 (36%) [95%CI 21-54] in SoC. The Step-1 endpoint has shown a lower than the 85% confidence interval above the fullity boundary (25%) with a 90% confidence interval of 10% and subgroup data will be further presented. Grade 3-4 related TEAEs were 11% in Tedopi® group and 43% in SoC. There was no related grade 5 TEAE. Related TEAE leading to withdrawal from the study were also less frequent in Tedopi® group (6% versus 14%). Due to the results obtained, the ATALANTE-2 study is ongoing.

Conclusions: The Step-1 primary endpoint was positively achieved with a 1y-OS rate above the estimate of SoC and a good safety profile. Step-1 results shown a favorable clinical profile of Tedopi® over SoC as 2nd or 3rd line treatment in advanced HLA-A2+ NSCLC patients after failure to ICI.

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Mobocertinib demonstrated antitumor activity in pts with advanced NSCLC with EGFR exon20ins. The safety profile for mobocertinib was consistent with other EGFR TKIs.

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