Background OSE2101 (Tedopi®) is an anticancer vaccine with HLA-A2+ restricted modified epitopes targeting five tumor-associated antigens (TAAs) frequently expressed in lung cancer (CEA, HER2, MAGE2, MAGE3, P53). Step 1 results of the phase III, randomized, open-label ATALANTE-1 study comparing Tedopi® vs standard treatment (SoC) showed a favorable benefit/risk of Tedopi® over SoC (HR 0.71 for overall survival) in HLA-A2+ NSCLC patients in 2nd or 3rd line treatment after progression on immune checkpoint blockers (ICB). We analyze available tumor biopsies at initial diagnosis from some patients treated with Tedopi® to determine the expression of the 5 TAAs and to identify other tumor factors associated with long-term survival.

Methods Tumor biopsies were available for 8 HLA-A2+ (blood test) stage IV NSCLC patients included in the trial. Primary (<12 weeks) and secondary (blood test) stage IV NSCLC patients included in the trial.

Results HLA-class I was expressed in all tumor samples. IHC chemistry (IHC). NanoString gene expression profiling was performed using the Pan Cancer Immune gene set. Transcriptional data in the patients that benefited from Tedopi® showed activated macrophage pathway, high IFN-gamma and Expanded Immune Gene Signatures scores. These data will be validated on larger number of patients treated with Tedopi® after the step 2 analysis.

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Trial Registration EudraCT number: 2015-003183-36; NCT number: NCT02654387

REFERENCE


Ethics Approval The study protocol and its related documents (including the patient information and informed consent form) received approval from the Institutional Review Board (IRB), and the Competent Authority prior to study initiation.

Consent Each patient gave his/her written informed consent prior to study enrolment.

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CEA Carcinoembryonic antigen; HER2: Human Epidermal Growth Factor Receptor-2; ICB: Immune checkpoint blocker; IHC: Immunohistochemistry; ND: Not determined; OS: Overall Survival; Patient ID: Patient identification; PDL1: Programmed death-ligand 1; PFS: Progression-free survival; ssGSEA: Single-sample Gene Set Enrichment Analysis. Blue bars = Length of overall survival; Green bars = Gene Signature upregulation; Red bars = Gene Signature downregulation.

Conclusions This study shows that all HLA-A2+ patients (blood test), expressed HLA class I in the tumors at initial diagnosis. Transcriptionomic data in the patients that benefited from Tedopi® showed activated macrophage pathway, high IFN-gamma and Expanded Immune Gene Signatures scores. These data will be validated on larger number of patients treated with Tedopi® after the step 2 analysis.