Abstract #TPS9140: Combi-TED: A Multicenter, Phase II, Open Label, Randomized Trial Evaluating Efficacy Of TEDOPI Plus Docetaxel Or TEDOPI Plus Nivolumab As Second-Line Therapy In Metastatic NSCLC Progressing After First-Line Chemo-Immunotherapy

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Background/Methods:

- **First line combination of chemotherapy and immune checkpoint inhibitors (ICIs) improves overall survival (OS) compared with chemotherapy alone in non-small cell lung cancer (NSCLC) patients. [1-3]**
- **Few options are available at chemoimmunotherapy failure, with docetaxel representing the standard of care.[4]**
- **Tedopi is a cancer vaccine which stimulates killer T cells, currently under development for the therapy of HLA-A2+ lung cancer. In the ATALANTE-1 Phase III trial (EudraCT no. 2015-003183-36), Tedopi provided clinical benefits in patients with advanced NSCLC who failed to respond to checkpoint inhibitors. [5]**
- **Given the need for new therapeutic options in patients failing first-line chemo-immunotherapy and the encouraging preliminary data with Tedopi, there is a strong rationale for investigating the activity of Tedopi plus nivolumab or Tedopi plus docetaxel in patients with metastatic NSCLC failing standard first-line therapy.**

Trial design

KEY ELIGIBILITY CRITERIA

Locally advanced or metastatic NSCLC relapsed after at least 4 cycles of first-line chemoimmunotherapy

HLA-A2 positive

ECOG PS 0-1

EGFR, ALK, ROS WT

Patients with primary resistance or adjuvant resistance to immunotherapy are excluded

RANDOMIZATION

ARM A - TREATMENT		
DRUG	**FREQUENCY**	**DURATION**
Docetaxel TEDOPI	q3w q3w	x 6 cycles
TEDOPI	q6w	From cycle 7 until year 1*
TEDOPI	q12w	After year 1
* since treatment start		

ARM B - TREATMENT		
DRUG	**FREQUENCY**	**DURATION**
Nivolumab TEDOPI	q3w	x 6 cycles
Nivolumab TEDOPI	q3w q6w	From cycle 7 until year 1*
Nivolumab TEDOPI	q3w q12w	After year 1
* since treatment start		

ARM C - TREATMENT		
DRUG	FREQUENCY	DURATION
Docetaxel	q3w	x 6 cycles

Primary end point:
- **1-year Survival Rate**

Secondary end points:
- **Overall Survival (OS) (median, 1 and 2-year OS)**
- **Progression-free survival (PFS) (1 and 2-year PFS)**
- **Objective Response Rate (ORR)**
- **Safety**

Exploratory:
- **Correlation of outcome with biomarkers in tumor tissue or blood.**

Statistical plan

The sample size will be calculated assuming a 1-year OS rate in the standard arm (Arm C) of 20%. The sample size will be determined according to the single-stage design based on the binomial exact test. In both arms A and B we assume a 1-year OS rate of 20%, which if true would imply that treatment does not warrant further investigation, and a 1-year OS rate of 40%, which if true would imply that treatment has a sufficient activity; setting the significance level (one-sided) = 5% and power = 80%, a total number of 105 patients (35 per treatment arm) need to be enrolled. The arm treated only with Docetaxel will be considered a calibration arm and the sample size will be the same as the experimental arms (35 patients).

Study update

The study is currently recruiting in 9 Italian centers.
From October 2021, 15 of planned 105 patients have been enrolled.

References

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COMBI-TED

FoRT

Registration number
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NCT 04884282
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