

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

Cappuzzo F¹, Pasello G², Delmonte A³, Landi L¹, Benetti B², Metro G⁴, D'Andrea MR⁵, Gori S⁶, Borra G⁷, Mazzoni F⁸, Verusio C⁹, Pagano M¹⁰, Giannarelli D¹⁴, Bonetti A¹¹, Maio M¹², Scimone A¹³, Adamo V¹³

1. Istituto Nazionale Tumori Regina Elena, Roma 2. Istituto Oncologico Veneto IRCCS & Università of Padova, Padova 3. Istituto Romagnolo per lo Studio dei Tumori Dino Amadori – IRCCS, Meldola (FC) 4. Azienda Ospedaliera di Perugia, Perugia 5. Ospedale San Paolo, Civitavecchia (RM) 6. IRCCS Ospedale Sacro Cuore Don Calabria, Negrar di Valpolicella (VR) 7. Azienda Ospedaliero-Universitaria Maggiore della Carità, Novara 8. Azienda Ospedaliero-Universitaria Careggi, Firenze 9. AO Busto Arsizio PO Saronno, Saronno (VA) 10. IRCCS – Arcispedale Santa Maria Nuova, Reggio Emilia 11. Azienda ULSS 9 Scaligera - Ospedale Mater Salutis Legnago, Legnago (VR) 12. Azienda Ospedaliero-Universitaria Senese, Siena 13. Università di Messina & AO Papardo, Messina 14. Fondazione Policlinico Universitario A. Gemelli, Roma

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.

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).

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	q3w	x 6 cycles
TEDOPI	q3w	
TEDOPI	q6w	From cycle 7 until year 1*
TEDOPI	q12w	After year 1
* since treatment start		

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

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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Registration number

EudraCT: 2020-005170-10

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Trial contacts

federico.cappuzzo@ifo.it, lorenza.landini@ifo.it
combi-ted@cr-technology.com

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