



STATISTICAL ANALYSIS PLAN

Study title	A Pilot Study of Sequential ONCOS-102, an Engineered Oncolytic Adenovirus Expressing GM-CSF, and Pembrolizumab in Patients with Advanced or Unresectable Melanoma Progressing after PD1 Blockade
Study No/Code	ONCOS C824
Phase	I
Sponsor	Targovax
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This study was conducted in accordance with GCP.

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LIST OF ABBREVIATIONS

AE	Adverse event
Anti-PD1	anti-Programmed cell death protein 1
AST, SGOT	Aspartate aminotransferase
ALT, SGPT	Alanine aminotransferase
BORR	Best Objective Response Rate
CI	Confidence interval
CPO	Cyclophosphamide
CR	Complete Response
CT	Computed tomography
DLT	Dose limiting toxicity
EAS	Efficacy analysis set
ECOG	Eastern Cooperative Oncology Group
IAS	Immune analysis set
IMP	Investigational medicinal product
irAE	Immune-related adverse events
irRECIST	Modified immunologically relevant RECIST
i.t.	intratumoral
i.v.	intravenous
MedDRA	Medical Dictionary for Regulatory Activities
MRI	Magnetic Resonance Imaging
ORR	Objective response rate
OS	Overall survival
PBMC	Peripheral blood mononuclear cells
PD1	Programmed cell death protein 1
PPR	Protocol Participant Registration
PFS	Progression Free Survival



PR	Partial Response
PT	Preferred term
RA	Research authorization
RECIST	Response Evaluation Criteria In Solid Tumors
RR	Response rate
SAE	Serious adverse event
SAP	Statistical analysis plan
SAS	Safety analysis set
SOC	System organ class
TEAE	Treatment-emergent adverse event
TIL	Tumor infiltrating lymphocytes
TSH	Thyroid stimulating hormone
VP	Viral particles
WHO	World Health Organization



1 INTRODUCTION

This is a statistical analysis plan (SAP) for ONCOS C824 study which is based on the final study protocol version 5.0 (dated 20JUL2018) and protocol version 6.2 (dated 08APR2019, for Norway). This SAP describes the statistical analyses which will be presented in the clinical study report.

This SAP will include safety and clinical data. A separate SAP is prepared to describe the statistical analyses including immune data.

2 STUDY OBJECTIVES AND ENDPOINTS

The nature of the study is exploratory.

The **primary objective** of the study is:

- Part 1: To determine the safety of sequential treatment with ONCOS-102 followed by pembrolizumab.
- Part 2: To determine the safety of an initial treatment phase with ONCOS-102 followed by a treatment phase with ONCOS-102 + pembrolizumab.

The **primary endpoint** of the study is:

- Safety for the duration of the therapy.

The **secondary objectives** are:

- To estimate the objective response rates (ORR) by RECIST 1.1 and irRECIST.
- [Redacted]
- [Redacted]
- To estimate Progression Free Survival (PFS) by RECIST 1.1 and irRECIST.
- To estimate the clinical benefit rate at 27 weeks, defined as any confirmed objective response by RECIST 1.1 or stable disease lasting at least until week 27.
- To estimate the clinical benefit rate at 27 weeks, defined as any objective response by irRECIST criteria or immune-related stable disease lasting at least until week 27.
- To estimate the change in size in individual lesions.

The **secondary endpoints** of the study are:

- Objective responses by RECIST 1.1 and irRECIST criteria.
- [Redacted]
- [Redacted]
- PFS by RECIST 1.1 and irRECIST criteria.
- Clinical benefit rate, defined as subjects who are not in progression by RECIST 1.1 at 27 weeks.
- Clinical benefit rate, defined as subjects who are not in progression by irRECIST at 27 weeks.
- Change in size in individual lesions.

The **exploratory objectives** are the following:

- [Redacted]
- [Redacted]
- [Redacted]

[REDACTED]

The **exploratory endpoints** for the study are:

3 STUDY TYPE AND DESIGN

This study consists of two parts:

Part 1 of this study is a prospective, open-label, pilot safety study of sequential ONCOS-102 injection with cyclophosphamide priming followed by pembrolizumab.

Part 2 of this study is a prospective, open-label, pilot safety study of an initial treatment phase with ONCOS-102 injection primed with CPO, followed by a treatment phase with ONCOS-102 and pembrolizumab.

The study will include patients with advanced or unresectable melanoma who have had progression following PD1 blockade as monotherapy or in combination with ipilimumab with at least 1 cutaneous tumor or lymph node amenable to injection with ONCOS-102.

Part 1: The primary objective is to characterize the safety of the sequential treatment with ONCOS-102 and pembrolizumab starting at baseline and continuing for a 9 week DLT monitoring period.

Part 2: The primary objective is to determine safety of initial treatment phase with ONCOS-102 followed by a treatment phase with ONCOS-102 and pembrolizumab. The DLT monitoring period starts at baseline and continues for [REDACTED]

[REDACTED]

[REDACTED] Suspected DLTs will be assessed continuously by a safety review committee.

Part 1:

Patients will undergo standard radiologic and clinical screening. Following screening, eligible patients will receive a 300 mg/m² i.v. bolus of cyclophosphamide 1-3 days prior to the first of 3 injections of ONCOS-102. 2.5mL of ONCOS-102 will be injected into accessible tumor(s) at outpatient visits on days 1, 4, and 8. The dose at each timepoint will be 3x10¹¹ VP. Pembrolizumab will be administered according to institutional practice (either 2mg/kg or flat dosing at 200mg) starting at Week 3 (day 22) and continue every 3 weeks. The DLT period for this intervention [REDACTED]

[REDACTED] Cross-sectional imaging to document local and systemic responses will be performed at Week 9, 18, and 27. Photographs will be taken to document location, size and possible changes to tumors at baseline and as applicable throughout the study. [REDACTED]

[REDACTED] Safety laboratory variables and vital signs will be evaluated and physical examination performed regularly throughout the study. [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED] Please see Figure 1 for a schematic of the study.



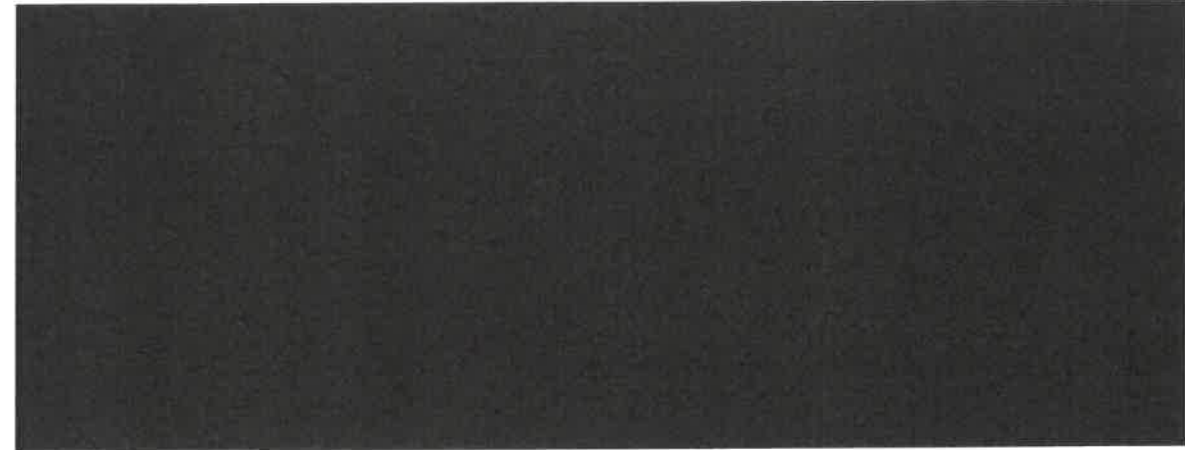
Figure 1 Part 1
BL=Baseline, CPO=Cyclophosphamide, DLT=Dose Limiting Toxicity, Yellow circle indicating Imaging

Part 2:

Patients will undergo standard radiologic and clinical screening. Following screening, eligible patients will receive a 300 mg/m² i.v. bolus of CPO 1-3 days prior to the first of 4 injections of ONCOS-102. 2.5mL of ONCOS-102 will be injected into accessible tumor(s) at outpatient visits on days 1, 4, 8 and 15. The dose at each timepoint will be 3x10¹¹ VP.

Subsequently, ONCOS-102 (3x10¹¹ VP) will be given in combination with pembrolizumab on Day 22/Week 3 and every three weeks thereafter until Day 169/Week 24. Pembrolizumab will be given according to institutional practice (2mg/kg or 200mg flat dose) until Day 190/Week 27. The DLT monitoring period starts at baseline and continues for 9 weeks. Cross-sectional imaging will be done at baseline, Week 9, 18, and 27 to document local and systemic responses. Photographs will be taken to document location, size and possible changes to tumors at baseline and as applicable throughout the study. [REDACTED]

[REDACTED] Safety Laboratory Variables and Vital signs will be evaluated, and Physical examination performed regularly throughout the study. PBMCs will be collected at Baseline, day 1 (Week 1), day 22 (Week 3), day 64 (Week 9), day 127 (Week 18) and day 190 (Week 27). [REDACTED]

**Figure 2 Part 2****BL=Baseline, CPO=Cyclophosphamide, DLT=Dose Limiting Toxicity****4 RANDOMISATION**

Randomization is not applicable.

5 STATISTICAL HYPOTHESES

All the analyses are descriptive; no statistical hypothesis has been defined.

6 ESTIMATION OF SAMPLE SIZE

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

This is applicable for both Part 1 and Part 2.

7 STATISTICAL METHODS**7.1 Analysis sets**

All patients who enrol and receive cyclophosphamide and a minimum of one dose of ONCOS-102 will be included in the Safety Analysis Set (SAS).

All patients with a repeat assessment of tumor burden, including a photograph or cross-sectional imaging, will be included in the Efficacy Analysis Set (EAS).

All patients with a repeat assessment of tumor biopsy/PBMC will be included in the Immune Analysis Set (IAS).

Table 1 Data sets to be used in the analysis

Efficacy variables	Safety variables	Exploratory variables	Demographic and baseline variables
EAS, SAS	SAS	IAS	SAS

7.2 General statistical considerations

All data collected in the CRF will be presented in individual patient data listings. These will be sorted by study part and patient number. Cohort will be presented in disposition and demographics listings.

All endpoints will be summarised by Part 1 and Part 2.

Baseline is defined as the assessment done the day of the first administration of ONCOS-102 (Day 1 pre-treatment and/or the -3 to -1 Day prior the ONCOS treatment). If a baseline assessment is missing, the last non-missing assessment before baseline will be used as baseline assessment.

All categorical variables will be summarized with counts and percentages. Shift tables can be used, if applicable.

All continuous variables will be summarized by number of observations, mean, standard deviation (SD), median, first and third quartiles, minimum and maximum values. In addition, normalized values and/or fold-change and/or absolute change and/or percentage change will be presented.

Table 2 Decimal places for summary statistics

Statistic	Number of digits
Minimum, maximum	Same as original data
Mean, median, q1, q3	1 more than in original data
SD	2 more than in original data
Frequencies (%)	1 decimal place

7.2.1 Definition of derived variables

Efficacy and safety variables

Absolute change from baseline or relative (percentage) change from baseline will be calculated with the following formulas:



Absolute change from baseline = Post-baseline value – Baseline value

Relative change from baseline= (Post-baseline value – Baseline value)/ Baseline value*100

Immune and Exploratory endpoints

Immune and exploratory endpoints will be described in a separate SAP.

7.2.2 Imputing missing values

No imputation of missing values will be done.

7.2.3 Handling of data from discontinued patients

Data from screen failures will be listed. Data from patients enrolled but not treated or only received cyclophosphamide will be listed. Data entered from discontinued patients that have received cyclophosphamide and minimum 1 dose of ONCOS-102 will be used in the analyses.

The study will be deemed complete when the patient returns for end of study assessments at Week 27 (day 190).

7.3 Disposition of patients

The number of enrolled, dosed with ONCOS-102, and CPO, completed or discontinued patients from the study will be tabulated. The reason for study discontinuation will be listed.

Disposition of patients, informed consent signing information, and inclusion/exclusion criteria will also be listed by patient.

Disposition of patients will be shown separately for Part 1 and Part 2.

7.4 Demographic and baseline characteristics

Demographic and baseline characteristics (age, sex, race, weight, height, and ECOG) will be summarised in terms of descriptive statistics in the safety population.

Medical history, disease characteristics and previous cancer history, previous cancer treatments, prior and concomitant medications will be tabulated.

All demographic and baseline data will be presented by Part 1 and Part 2 in the safety population.

7.5 Extent of exposure and compliance

Extent of exposure will be summarized showing:

ONCOS-102 i.t.:

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

CPO:

- number of patients exposed
- total amount administered per patient

Pembrolizumab:

- number of patients exposed
- number of patients exposed per cycle
- total number of cycles per patient
- total amount administered per patient
- number of changed doses

7.6 Analysis of efficacy

Efficacy and immune data will be summarised and analysed in efficacy and immune populations, by Part 1 and Part 2.

7.6.1 Imaging data

Imaging data will be summarized using efficacy population. Imaging will be assessed using RECIST 1.1 and irRECIST criteria.

Objective response rate (ORR)

Objective response rate is defined as the proportion of patients in whom complete response (CR) or partial response (PR) was observed during the study period according to RECIST 1.1 or Immune-Related Complete Response (irCR) or Immune-Related Partial Response (irPR) according to irRECIST.

ORR will be summarized with frequency tables separately for RECIST 1.1 and irRECIST for both best overall response (BORR) and for ORR observed at last timepoint.

Clinical benefit rate

Clinical benefit rate is defined as the proportion of patients with objective response (CR or PR) or stable disease (SD) was confirmed by CT or MRI imaging [REDACTED] For [REDACTED]



Patients [redacted]. Clinical benefit rate will be summarized with frequency table separately for RECIST 1.1 and irRECIST.

Size of lesions

For target lesions, the mean absolute and relative (%) change in size in non-injected and injected lesions will be described by summary statistics and tabulated by organ and time point.

Absolute and relative (%) change in size of lesions (marked with injected and non-injected lesions) from baseline to last time point will be displayed with waterfall plots by patient. Absolute and relative (%) change in size of lesions (marked with injected and non-injected lesions) from baseline to best response will be displayed with waterfall plots by patient. In addition, absolute and relative (%) change in size of lesions (marked with injected and non-injected lesions) from baseline to last time point will be displayed with spaghetti plots by patient and by time point.

The tumor size measured from digital photographs will be listed.

Progression free survival (PFS)

Progression free survival is defined as time from start of IMP (CPO) until progression or death from any cause. If a patient had not had an event (progression or death) before end of trial, then patient will be right-censored at the last date known of non-progression. Analysis will be presented by part 1 and 2.

PFS will be calculated separately for progression per RECIST 1.1 and irRECIST. Number of events, median, maximum and quartiles of follow-up time will be shown, as well as Kaplan-Meier estimates at certain time points. In addition, Kaplan-Meier plot with summary table of number of patients, events, censoring events, median and 95% confidence intervals will be provided.

The SAS-code to be used in its general form is:

```
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
run;
```

7.6.2 Immune data

Analysis of immune data will not be described in the scope of this SAP.

7.6.3 [redacted]

[redacted]

7.6.4 Analysis of explanatory data

All exploratory data will be analysed and reported separately as an addendum to the clinical study report.

7.7 Analysis of safety and tolerability

Safety data will be presented separately by Part 1 and Part 2 in the safety population.

The primary endpoint of the study is the safety for the duration of the therapy.

7.7.1 Adverse events

Adverse events (AEs) will be classified by System Organ Class (SOC) and Preferred Term (PT) using MedDRA dictionary (version 15 or higher). AEs will be divided to treatment-emergent adverse events (TEAE) and pre-treatment AEs. A TEAE is defined as an AE with start date/time on or after the first administration of ONCOS-102 or an AE with start date/time prior to the first administration of ONCOS-102 that worsens after first administration of ONCOS-102. A pre-treatment AE is defined as an AE with start date/time after treatment with CPO but prior to the first administration of ONCOS-102 that does not worsen after first administration of ONCOS-102.

AEs continuing with change in intensity (CTCAE grading) and/or causality will be counted as one event with maximum intensity and/or maximum causality. In case of more than one reported intensity and/or causality the worst outcome is used for reporting subject count, respectively.

Following summary tables will be created for TEAEs, reporting number of events and number of patients with events by MedDRA System Organ Class and Preferred Term after two cycles of pembrolizumab and separately for all TEAEs:

- Overall summary table of AEs
- Patient and event counts of AEs by system organ class (SOC) and preferred term (PT)
- Patient and event counts of related AEs (relationship as possible, probable or define) AE by SOC and PT
- Patient and event counts of AEs by maximum NCI CTCAE grading, SOC and PT
- Patient and event counts of SAEs by SOC and PT
- Patient and event counts of related SAEs by SOC and PT
- Patient and event counts of AEs leading to discontinuation of ONCOS-102 or withdrawal of study by SOC and PT
- AEs leading to death

AE after two cycles of pembrolizumab is defined as an AE with start date/time on or after the start of third cycle of pembrolizumab or an AE with start date/time prior to the third cycle start that worsens on or after the start of third cycle of pembrolizumab. Third cycle start of pembrolizumab will be assessed on individual patient level. In case of missing third cycle start, day 64 is used as the start of third cycle of pembrolizumab.

AEs continuing with changed intensity will be reported only once with worst intensity (by CTCAE grading).

Relationship as possible, probable or definitely will be considered as related. In case of more than one reported intensity and/or causality the worst outcome is used for reporting subject count, respectively. Relationship will be tabulated by IMP as follows:

- CPO only
- ONCOS-102 only
- ONCOS-102 and CPO
- ONCOS-102 and Pembrolizumab
- ONCOS-102 and CPO and Pembrolizumab
- Pembrolizumab only.

Pre-treatment AEs will be summarized only in overall summary table.

7.7.2 Laboratory safety variables

Safety laboratory parameters will be tabulated by descriptive statistics, including means, standard deviations, medians and minimum and maximum by visit or summarized by counts and percentages per categorical result (e.g., for urinalysis results). Absolute change from baseline (if missing, then the last non-missing measurement before first IMP (ONCOS-102) administration will be used as baseline) will be tabulated as well.

7.7.3 Other safety variables

Vital signs (blood pressure, heart rate, body temperature), weight and ECOG/WHO performance status will be summarised by visit, using descriptive statistics and by frequency tables, when applicable. Change from baseline will also be presented for vital signs and weight.

Physical examinations will be tabulated by visit as normal/abnormal (clinical significance will be listed only).

7.8 Other analysis

Details about the correlation analysis (between ORR and TILs) will be described in a separate SAP.

7.9 Interim analysis and data monitoring

No planned interim analysis in this study.

7.10 Changes in the statistical plans from those presented in the study protocol (if applicable)

Not applicable.



7.11 Execution of statistical analysis

Statistical analysis will be performed by [REDACTED]

8 HARDWARE AND SOFTWARE

Statistical analysis, tables, figures and subject data listings will be performed with SAS® for Windows (SAS Institute Inc., Cary, NC, USA) or R programming language.

9 REFERENCES

1. SAS, Institute Inc., Cary, NC, USA.

10 APPENDIX

10.1 List of tables, figures and listings

10.2 List of subject data listings (NA)

10.3 Table shells

11 DOCUMENT HISTORY

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]



STATISTICAL ANALYSIS PLAN ADDENDUM

Study title	A Pilot Study of Sequential ONCOS-102, an Engineered Oncolytic Adenovirus Expressing GM-CSF, and Pembrolizumab in Patients with Advanced or Unresectable Melanoma Progressing after PD1 Blockade
Study No/Code	ONCOS C824
Phase	I
Sponsor	Targovax
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This study was conducted in accordance with GCP.

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C824 Statistical Analysis Plan ONCOS-102 v3.0 – Addendum v1.0

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Signature:	
Date:	3/11/20



LIST OF ABBREVIATIONS

EAS	Efficacy analysis set
irRECIST	Modified immunologically relevant RECIST
RECIST	Response Evaluation Criteria In Solid Tumors
SAP	Statistical analysis plan
SAS	Safety analysis set
SEAS	Sensitivity efficacy analysis set



1 INTRODUCTION

The statistical analysis plan (SAP) addendum serves the purpose to provide more details on some statistical aspects covered in the SAP v3.0.

2 ANALYSIS SETS

In addition to analysis sets described in the SAP v3.0, sensitivity analysis on EAS analysis set will be performed. Patients with major protocol deviations will be excluded from the Sensitivity Efficacy Analysis Set (SEAS).

This additional sensitivity analysis set will be presented in disposition of patients table and all efficacy tables and figures will be done for this analysis set, in addition to SAS and EAS analysis sets.

3 SIZE OF LESIONS

Tumor burden at baseline will be presented by patient in a bar chart, in addition best response per RECIST 1.1 and irRECIST criteria will be shown.

Number of lesions at baseline will be presented by patient in a bar chart, in addition best response per RECIST 1.1 and irRECIST criteria will be shown.

Absolute and relative change from baseline to best response in tumour burden for target lesions will be presented in a waterfall plot.

Comments entered for non-target lesions at imaging visits will be listed by ONCOS-102 injection information for all injected and non-injected lesions.

4 APPENDIX

4.1 List of tables, figures and listings

5 DOCUMENT HISTORY

Version number	Version date	Status	Author
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]