Summary attachment

Study title	**An open label, dose escalation followed by dose expansion, safety and tolerability trial of CAN04, a fully humanized monoclonal antibody against IL1RAP, in subjects with solid malignant tumours.**
Study number	CAN04CLIN001
Study Short Code	CANFOUR
EUDRACT number	2017-001111-36

According to the document *EudraCT & EU CTR Frequently asked questions* only the most important endpoints, corresponding to those ones initially defined by the sponsor in section *E.5 END POINT(S)* of the CTA, need to be reported in EudraCT through the full data set section. Unfortunately, all endpoints specified in the protocol, including primary, secondary and exploratory endpoints have been defined in section *E.5 END POINT(S)* of the CTA. Sponsor have thus taken a decision to only report primary and secondary endpoints in the full data set since these are the endpoints considered as the important endpoints and expected to be initially defined in the CTA.

Due to technical limitations to provide all information and results through the full data set in EudraCT, complementary trial information and results for efficacy endpoints for some subject analysis sets are provided in this summary attachment for transparency. In addition, a summary of the immunogenicity and quality of life endpoints that cannot be reported through the full data set section are provided.

1. TRIAL INFORMATION

Subject number per country

In addition to the countries and numbers presented in full data set in EudraCT, Poland was also regulatory activated for the study although no patients were enrolled.

Note: Due to technical issues in EudraCT, despite following instructions in the system, it was not possible to include Poland since no patients were enrolled. For transparency this is clarified in this document.

2. END POINTS

2.1. Efficacy: immune Duration of Response (iDoR) by iRECIST

Statistical Analyses	
No statistical analyses for this end point	
Secondary: Efficacy: immune Duration of Response (iDoR) by iRECIST	
End point title	Efficacy: immune Duration of Response (iDoR) by iRECIST
End point description: Duration of immune Response (iDOR) is defined as the time from first time the criteria for confirmed response (iCR or iPR) are met to disease progression assessed by immune Response Evaluation Criteria in Solid Tumours (iRECIST) or death from any cause or censoring	
End point type	Secondary
End point timeframe: At screening followed by 8-week intervals after first CAN04 dose (Arm NCP: 6-week intervals for 36 weeks, thereafter every 9 weeks) while on trial treatment until confirmed disease progression, start of new line of systemic anti-cancer therapy or death.	

End point values	Part II Combination therapy Arm C 5 mg/kg mITT	Part II Combination therapy Arm C 2.5 mg/kg mITT	Part II Combination therapy Arm NCP mITT	Part II Combination therapy Arm D 5 mg/kg mITT
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6	2	6	5
Units: months				
Median (confidence interval 95%)	7.0 (3.4 to -)	14.8 (5.7 to -)	9.5 (4.4 to -)	11.1 (5.5 to -)

End point values	Part II Combination therapy Arm D 7.5 mg/kg mITT	Part II Combination therapy Arm PDEX2.5 mITT		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	3	6		
Units: months				

Median (confidence interval 95%)	3.9 (3.7 to -)	8.5 (3.7 to -)		

Note: No upper limit for the 95% confidence interval for the median was possible to be estimated for subject analysis set included in table above. Results for the other subject analysis sets is reported in the full data set in EudraCT.

2.2. Efficacy: Duration of Response (DoR) by RECIST 1.1

Statistical Analyses				
No statistical analyses for this end point				
Secondary: Efficacy: Duration of Response (DoR) by RECIST 1.1				
End point title	Efficacy: Duration of Response (DoR) by RECIST 1.1			
End point description: Duration of response (DOR) is defined as the time from first confirmed response (CR or PR) to disease progression assessed by Response Evaluation Criteria in Solid Tumours (RECIST version 1.1) or death from any cause or censoring.				
End point type	Secondary			
End point timeframe: At screening followed by 8-week intervals after first CAN04 dose (Arm NCP: 6-week intervals for 36 weeks, thereafter every 9 weeks) while on trial treatment until confirmed disease progression, start of new line of systemic anti-cancer therapy or death.				
End point values	Part II Combination therapy Arm C 5 mg/kg mITT	Part II Combination therapy Arm C 2.5 mg/kg mITT	Part II Combination therapy Arm NCP mITT	Part II Combination therapy Arm D 5 mg/kg mITT
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6	2	6	5
Units: months				
Median (confidence interval 95%)	7.0 (3.4 to -)	13.0 (5.7 to -)	9.5 (4.4 to -)	11.1 (5.5 to -)

End point values	Part II Combination therapy Arm D 7.5 mg/kg mITT	Part II Combination therapy Arm PDEX2.5 mITT		

Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	3	6		
Units: months				
Median (confidence interval 95%)	3.9 (3.7 to -)	7.4 (3.7 to -)		

Note: No upper limit for the 95% confidence interval for the median was possible to be estimated for subject analysis set included in table above. Results for the other subject analysis sets is reported in the full data set in EudraCT.

2.3. Efficacy: immune related Progression-Free Survival (irPFS) at 6 months by irRC

Statistical Analyses				
No statistical analyses for this end point				
Secondary: Efficacy: immune related Progression-Free Survival (irPFS) at 6 months by irRC				
End point title	Efficacy: immune related Progression-Free Survival (irPFS) at 6 months by irRC			
End point description: Probability for subjects for immune related Progression Free Survival (irPFS) assessed by immune related Response Criteria (irRC) at 6 months after first CAN04 dose.				
End point type	Secondary			
End point timeframe: At screening followed by 8-week intervals after first CAN04 dose while on trial treatment until confirmed disease progression, start of new line of systemic anti-cancer therapy or death.				
End point values	Part I – Dose escalation 1.5 mg/kg mITT	Part I – Dose escalation 3 mg/kg mITT	Part I – Dose escalation 6 mg/kg mITT	Part I – Dose escalation 10 mg/kg mITT
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	3	7	6
Units: %				
Number (confidence interval 95%)	0 (- to -)	0 (- to -)	0 (- to -)	0 (- to -)

End point values	Part II Monotherapy Arm A mITT	Part II Monotherapy Arm B mITT	Part II Monotherapy Arm E mITT	Part II Monotherapy mITT
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	10	10	6	26
Units: %				
Number (confidence interval 95%)	0 (- to -)	0 (- to -)	0 (- to -)	0 (- to -)

Note: For above included subject analysis sets, no patients reached the endpoint timepoint, hence the corresponding 95% confidence interval for the Kaplan Meier estimate at the timepoint could not be estimated. Results for the other subject analysis sets is reported in the full data set in EudraCT.

2.4. Efficacy: Progression-Free Survival (PFS) at 6 months by RECIST 1.1

Statistical Analyses	
No statistical analyses for this end point	
Secondary: Efficacy: Progression-Free Survival (PFS) at 6 months by RECIST 1.1	
End point title	Efficacy: Progression-Free Survival (PFS) at 6 months by RECIST 1.1
End point description: Probability for subjects for Progression Free Survival (PFS) assessed by Response Evaluation Criteria in Solid Tumours (RECIST version 1.1) at 6 months after first CAN04 dose.	
End point type	Secondary
End point timeframe: At screening followed by 8-week intervals after first CAN04 dose (Arm NCP: 6-week intervals for 36 weeks, thereafter every 9 weeks) while on trial treatment until confirmed disease progression, start of new line of systemic anti-cancer therapy or death.	

End point values	Part I – Dose escalation 1.5 mg/kg mITT	Part I – Dose escalation 3 mg/kg mITT	Part I – Dose escalation 6 mg/kg mITT	Part I – Dose escalation 10 mg/kg mITT
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	3	7	6

Units: %				
Number (confidence interval 95%)	0 (- to -)	0 (- to -)	0 (- to -)	0 (- to -)

End point values	Part II Monotherapy Arm A mITT	Part II Monotherapy Arm B mITT	Part II Monotherapy Arm E mITT	Part II Monotherapy mITT
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	10	10	6	26
Units: %				
Number (confidence interval 95%)	0 (- to -)	0 (- to -)	0 (- to -)	0 (- to -)

Note: For above included subject analysis sets, no patients reached the endpoint timepoint, hence the corresponding 95% confidence interval for the Kaplan Meier estimate at the timepoint could not be estimated. Results for the other subject analysis sets is reported in the full data set in EudraCT.

2.5. Efficacy: immune related Progression-Free Survival (irPFS) at 12 months by irRC

Statistical Analyses	
No statistical analyses for this end point	
Secondary: Efficacy: immune related Progression-Free Survival (irPFS) at 12 months by irRC	
End point title	Efficacy: immune related Progression-Free Survival (irPFS) at 12 months by irRC
End point description: Probability for subjects for immune related Progression Free Survival (irPFS) assessed by immune related Response Criteria (irRC) at 12 months after first CAN04 dose.	
End point type	Secondary
End point timeframe: At screening followed by 8-week intervals after first CAN04 dose while on trial treatment until confirmed disease progression, start of new line of systemic anti-cancer therapy or death.	

End point values	Part I Dose escalation mITT	Part I – Dose escalation 1 mg/kg mITT	Part I – Dose escalation 1.5 mg/kg mITT	Part I – Dose escalation 3 mg/kg mITT
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	22	3	3	3
Units: %				
Number (confidence interval 95%)	0 (- to -)	0 (- to -)	0 (- to -)	0 (- to -)

End point values	Part I – Dose escalation 6 mg/kg mITT	Part I – Dose escalation 10 mg/kg mITT	Part II Monotherapy Arm A mITT	Part II Monotherapy Arm B mITT
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	6	10	10
Units: %				
Number (confidence interval 95%)	0 (- to -)	0 (- to -)	0 (- to -)	0 (- to -)

End point values	Part II Monotherapy Arm E mITT	Part II Monotherapy mITT		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	6	26		
Units: %				
Number (confidence interval 95%)	0 (- to -)	0 (- to -)		

Note: For above included subject analysis sets, no patients reached the endpoint timepoint, hence the corresponding 95% confidence interval for the Kaplan Meier estimate at the timepoint could not be estimated. Results for the other subject analysis sets is reported in the full data set in EudraCT.

2.6. Efficacy: immune Progression-Free Survival (iPFS) at 12 months by iRECIST

Statistical Analyses				
No statistical analyses for this end point				
Secondary: Efficacy: immune Progression-Free Survival (iPFS) at 12 months by iRECIST				
End point title	Efficacy: Efficacy: immune Progression-Free Survival (iPFS) at 12 months by iRECIST			
End point description: Probability for subjects for immune Progression Free Survival (iPFS) assessed by immune Response Evaluation Criteria in Solid Tumours (iRECIST) at 12 months after first CAN04 dose.				
End point type	Secondary			
End point timeframe: At screening followed by 8-week intervals after first CAN04 dose (Arm NCP: 6-week intervals for 36 weeks, thereafter every 9 weeks) while on trial treatment until confirmed disease progression, start of new line of systemic anti-cancer therapy or death.				
End point values	Part II Combination therapy Arm D 7.5 mg/kg mITT			
Subject group type	Subject analysis set			
Number of subjects analysed	8			
Units: %				
Number (confidence interval 95%)	0 (- to -)			

Note: For above included subject analysis sets, no patients reached the endpoint timepoint, hence the corresponding 95% confidence interval for the Kaplan Meier estimate at the timepoint could not be estimated. Results for the other subject analysis sets is reported in the full data set in EudraCT.

2.7. Efficacy: Progression-Free Survival (PFS) at 12 months by RECIST 1.1

Statistical Analyses
No statistical analyses for this end point
Secondary: Efficacy: Progression-Free Survival (PFS) at 12 months by RECIST 1.1

End point title	Efficacy: Progression-Free Survival (PFS) at 12 months by RECIST 1.1

End point description:

Probability for subjects for Progression Free Survival (PFS) assessed by Response Evaluation Criteria in Solid Tumours (RECIST version 1.1) at 12 months after first CAN04 dose.

End point type	Secondary

End point timeframe:

At screening followed by 8-week intervals after first CAN04 dose (Arm NCP: 6-week intervals for 36 weeks, thereafter every 9 weeks) while on trial treatment until confirmed disease progression, start of new line of systemic anti-cancer therapy or death.

End point values	Part I Dose escalation mITT	Part I – Dose escalation 1 mg/kg mITT	Part I – Dose escalation 1.5 mg/kg mITT	Part I – Dose escalation 3 mg/kg mITT
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	22	3	3	3
Units: %				
Number (confidence interval 95%)	0 (- to -)	0 (- to -)	0 (- to -)	0 (- to -)

End point values	Part I – Dose escalation 6 mg/kg mITT	Part I – Dose escalation 10 mg/kg mITT	Part II Monotherapy Arm A mITT	Part II Monotherapy Arm B mITT
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	6	10	10
Units: %				
Number (confidence interval 95%)	0 (- to -)	0 (- to -)	0 (- to -)	0 (- to -)

End point values	Part II Monotherapy Arm E mITT	Part II Monotherapy mITT	Part II Combination therapy Arm D 7.5 mg/kg mITT	

Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	6	26	8	
Units: %				
Number (confidence interval 95%)	0 (- to -)	0 (- to -)	0 (- to -)	

Note: For above included subject analysis sets, no patients reached the endpoint timepoint, hence the corresponding 95% confidence interval for the Kaplan Meier estimate at the timepoint could not be estimated. Results for the other subject analysis sets is reported in the full data set in EudraCT.

2.8. Efficacy: immune related Progression-Free Survival (irPFS) by irRC

Statistical Analyses				
No statistical analyses for this end point				
Secondary: Efficacy: immune related Progression-Free Survival (irPFS) by irRC				
End point title	Efficacy: immune related Progression-Free Survival (irPFS) by irRC			
End point description: immune related Progression Free Survival (irPFS) from first CAN04 dose until confirmed disease progression by immune related Response Criteria (irRC), start of new line of systemic anti-cancer therapy or death.				
End point type	Secondary			
End point timeframe: At screening followed by 8-week intervals after first CAN04 dose while on trial treatment until confirmed disease progression, start of new line of systemic anti-cancer therapy or death.				
End point values	Part I – Dose escalation 1 mg/kg mITT	Part I – Dose escalation 1.5 mg/kg mITT	Part I – Dose escalation 3 mg/kg mITT	Part I – Dose escalation 6 mg/kg mITT
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	3	3	7
Units: months				
Median (confidence interval 95%)	3.8 (1.8 to -)	1.9 (1.8 to -)	3.5 (1.8 to -)	1.9 (0.9 to -)

End point values	Part I – Dose escalation 10 mg/kg mITT	Part II Monotherapy Arm E mITT		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	6	6		
Units: months				
Median (confidence interval 95%)	1.9 (0.8 to -)	2.3 (1.2 to -)		

Note: No upper limit for the 95% confidence interval for the median was possible to be estimated for subject analysis set included in table above. Results for the other subject analysis sets is reported in the full data set in EudraCT.

2.9. Efficacy: immune Progression-Free Survival (iPFS) by iRECIST

Statistical Analyses				
No statistical analyses for this end point				
Secondary: Efficacy: immune Progression-Free Survival (iPFS) by iRECIST				
End point title	Efficacy: immune Progression-Free Survival (iPFS) by iRECIST			
End point description: immune Progression Free Survival (iPFS) from first CAN04 dose until confirmed disease progression by immune Response Evaluation Criteria in Solid Tumours (iRECIST), start of new line of systemic anticancer therapy or death.				
End point type	Secondary			
End point timeframe: At screening followed by 8-week intervals after first CAN04 dose (Arm NCP: 6-week intervals for 36 weeks, thereafter every 9 weeks) while on trial treatment until confirmed disease progression, start of new line of systemic anti-cancer therapy or death.				
End point values	Part II Combination therapy Arm C 2.5 mg/kg mITT	Part II Combination therapy Arm NCP mITT		
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	10		

Units: months				
Median (confidence interval 95%)	7.6 (3.7 to -)	9.7 (2.6 to -)		

Note: No upper limit for the 95% confidence interval for the median was possible to be estimated for subject analysis set included in table above. Results for the other subject analysis sets is reported in the full data set in EudraCT.

2.10. Efficacy: Progression-Free Survival (PFS) by RECIST 1.1

Statistical Analyses				
No statistical analyses for this end point				
Secondary: Efficacy: Progression-Free Survival (PFS) by RECIST 1.1				
End point title	Efficacy: Progression-Free Survival (PFS) by RECIST 1.1			
End point description: Progression Free Survival (PFS) from first CAN04 dose until confirmed disease progression by Response Evaluation Criteria in Solid Tumours (RECIST version 1.1).				
End point type	Secondary			
End point timeframe: At screening followed by 8-week intervals after first CAN04 dose (Arm NCP: 6-week intervals for 36 weeks, thereafter every 9 weeks) while on trial treatment until confirmed disease progression, start of new line of systemic anti-cancer therapy or death.				
End point values	Part I – Dose escalation 1 mg/kg mITT	Part I – Dose escalation 1.5 mg/kg mITT	Part I – Dose escalation 3 mg/kg mITT	Part I – Dose escalation 6 mg/kg mITT
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	3	3	7
Units: months				
Median (confidence interval 95%)	3.8 (1.8 to -)	1.8 (1.7 to -)	1.9 (1.8 to -)	1.9 (0.9 to -)

End point values	Part I – Dose escalation 10 mg/kg mITT	Part II Monotherapy Arm E mITT	Part II Combination therapy Arm C 2.5 mg/kg mITT	Part II Combination therapy Arm NCP mITT

Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6	6	3	10
Units: months				
Median (confidence interval 95%)	1.9 (0.8 to -)	2.3 (1.2 to -)	7.6 (3.7 to -)	9.1 (2.6 to -)

Note: No upper limit for the 95% confidence interval for the median was possible to be estimated for subject analysis set included in table above. Results for the other subject analysis sets is reported in the full data set in EudraCT.

2.11. Efficacy: Overall Survival (OS) at 12 months

Statistical Analyses				
No statistical analyses for this end point				
Secondary: Efficacy: Overall Survival (OS) at 12 months				
End point title	Efficacy: Overall Survival (OS) at 12 months			
End point description: Probability for subjects to be alive 12 months after first CAN04 dose.				
End point type	Secondary			
End point timeframe: Follow-up for Overall Survival was performed 12, 24 and 36 months after End of Treatment visit.				
End point values	Part I – Dose escalation 1.5 mg/kg mITT	Part I – Dose escalation 6 mg/kg mITT	Part II Monotherapy Arm A mITT	Part II Monotherapy Arm E mITT
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	7	10	6
Units: %				
Number (confidence interval 95%)	0 (- to -)	0 (- to -)	0 (- to -)	0 (- to -)

Note: For above included subject analysis sets, no patients reached the endpoint timepoint, hence the corresponding 95% confidence interval for the Kaplan Meier estimate at the timepoint could not be estimated. Results for the other subject analysis sets is reported in the full data set in EudraCT.

2.12. Efficacy: Overall Survival (OS) at 24 months

Statistical Analyses				
No statistical analyses for this end point				
Secondary: Efficacy: Overall Survival (OS) at 24 months				
End point title	Efficacy: Overall Survival (OS) at 24 months			
End point description: Probability for subjects to be alive 24 months after first CAN04 dose.				
End point type	Secondary			
End point timeframe: Follow-up for Overall Survival was performed 12, 24 and 36 months after End of Treatment visit.				
End point values	Part I – Dose escalation mITT	Part I – Dose escalation 1 mg/kg mITT	Part I – Dose escalation 1.5 mg/kg mITT	Part I – Dose escalation 3 mg/kg mITT
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	22	3	3	3
Units: %				
Number (confidence interval 95%)	0 (- to -)	0 (- to -)	0 (- to -)	0 (- to -)

End point values	Part I – Dose escalation 6 mg/kg mITT	Part I – Dose escalation 10 mg/kg mITT	Part II Monotherapy Arm A mITT	Part II Monotherapy Arm E mITT
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	6	10	6
Units: %				
Number (confidence interval 95%)	0 (- to -)	0 (- to -)	(- to -)	0 (- to -)

Note: For above included subject analysis sets, no patients reached the endpoint timepoint, hence the corresponding 95% confidence interval for the Kaplan Meier estimate at the

timepoint could not be estimated. Results for the other subject analysis sets is reported in the full data set in EudraCT.

2.13. Efficacy: Overall Survival (OS) at 36 months

Statistical Analyses				
No statistical analyses for this end point				
Secondary: Efficacy: Overall Survival (OS) at 36 months				
End point title	Efficacy: Overall Survival (OS) at 36 months			
End point description: Probability for subjects to be alive 36 months after first CAN04 dose.				
End point type	Secondary			
End point timeframe: Follow-up for Overall Survival was performed 12, 24 and 36 months after End of Treatment visit.				
End point values	Part I – Dose escalation mITT	Part I – Dose escalation 1 mg/kg mITT	Part I – Dose escalation 1.5 mg/kg mITT	Part I – Dose escalation 3 mg/kg mITT
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	22	3	3	3
Units: %				
Number (confidence interval 95%)	0 (- to -)	0 (- to -)	0 (- to -)	0 (- to -)

End point values	Part I – Dose escalation 6 mg/kg mITT	Part I – Dose escalation 10 mg/kg mITT	Part II Monotherapy Arm A mITT	Part II Monotherapy Arm E mITT
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	6	10	6
Units: %				
Number (confidence interval 95%)	0 (- to -)	0 (- to -)	0 (- to -)	0 (- to -)

End point values	Part II Combination therapy Arm D 7.5 mg/kg mITT			
Subject group type	Subject analysis set			
Number of subjects analysed	8			
Units: %				
Number (confidence interval 95%)	0 (- to -)			

Note: For above included subject analysis sets, no patients reached the endpoint timepoint, hence the corresponding 95% confidence interval for the Kaplan Meier estimate at the timepoint could not be estimated. Results for the other subject analysis sets is reported in the full data set in EudraCT.

2.14. Efficacy: Overall Survival (OS)

Statistical Analyses				
No statistical analyses for this end point				
Secondary: Efficacy: Overall Survival (OS)				
End point title	Efficacy: Overall Survival (OS)			
End point description: Overall Survival (OS) from first CAN04 dose until death of any cause.				
End point type	Secondary			
End point timeframe: Follow-up for Overall Survival was performed 12, 24 and 36 months after End of Treatment visit.				
End point values	Part I – Dose escalation 1 mg/kg mITT	Part I – Dose escalation 1.5 mg/kg mITT	Part I – Dose escalation 3 mg/kg mITT	Part I – Dose escalation 10 mg/kg mITT
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	3	3	6
Units: months				

Median (confidence interval 95%)	14.4 (7.2 to -)	5.0 (2.4 to -)	14.1 (3.7 to -)	5.3 (1.1 to -)

End point values	Part II Monotherapy Arm E mITT	Part II Combination therapy Arm C 2.5 mg/kg mITT	Part II Combination therapy Arm NCP mITT	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	6	3	10	
Units: months				
Median (confidence interval 95%)	3.3 (1.2 to -)	18.3 (11.1 to -)	11.3 (5.8 to -)	

Note: No upper limit for the 95% confidence interval for the median was possible to be estimated for subject analysis set included in table above. Results for the other subject analysis sets is reported in the full data set in EudraCT.

2.15. Immunogenicity

Secondary endpoint: Anti-Drug Antibodies (ADA) against CAN04.

Assay development of an ADA assay is currently ongoing. Blood samples to assess the formation of ADAs against CAN04 were collected as specified in the schedule of assessments of the protocol. The planned immunogenicity measurements were not performed at the time of this report. Samples are stored and will be analysed when a validated assay is available.

2.16. Quality of Life

Secondary endpoint (Part II only):

- Health-related quality of life as assessed using EORTC-QLQ - C30; version 3.0.
- Only for subjects with NSCLC, health-related quality of life as assessed using additional EORTC QLQ - LC13.

Due to the nature of how data was collected and analyzed for this endpoint it was not feasible to report it through the structure used in EudraCT.

In Part II, quality of life was assessed using the EORTC QLQ-C30 self-administered cancer specific questionnaire. Differences from baseline of at least 10 points were considered clinically meaningful. Changes of more than 20 points were classified as large effects.

Subjects with NSCLC were additionally asked to complete the EORTC QLQ - LC13 questionnaire.

There were no strong or consistent trends in quality-of-life assessments over the study period.

In patients with NSCLC receiving CAN04 in combination with SoC chemotherapy, the QLQ-C30 global health status score remained unchanged at month 6 in 15 (56%) patients, had worsened in 4 patients (15%), and improved or largely improved in 5 (19%).

QLQ-LC13 scores for cough, dyspnoea and pain had improved in 22–44% of patients at month 6, haemoptysis, sore mouth and dysphagia remained unchanged in a majority, and peripheral neuropathy and alopecia largely worsened in 37%.

In patients with PDAC receiving CAN04 in combination with SoC chemotherapy, the QLQ-C30 global health score remained unchanged at month 6 in 15 (44%) patients, had worsened or largely worsened in 6 patients (18%), and improved or largely improved in 13 (38%).