NOVARTIS

Clinical Trial Results Website

Sponsor

Novartis Pharmaceuticals

Generic Drug Name

PCA062

Trial Indication(s)

pCAD-positive solid tumors

Protocol Number

CPCA062X2101

Protocol Title

A phase 1 multi-center, open-label dose escalation and expansion study of PCA062 administered intravenously in adult patients with p-CAD positive tumors

Clinical Trial Phase

Phase 1

Phase of Drug Development

Phase I

Study Start/End Dates

Study Start Date: April 2015 (Actual)
Primary Completion Date: July 2018 (Actual)
Study Completion Date: July 2018 (Actual)

Reason for Termination (If applicable)

Due to the limited clinical activity observed with PCA062 with the doses already tested, and because testing of higher doses would result in tolerability issues, Novartis decided to terminate the study before the dose expansion part of the study started.

Study Design/Methodology

This study was a phase I, multi-center, open-label study to determine the MTD/RDE and safety of PCA062 in subjects with pCAD-positive tumors. For the purposes of dose escalation decisions, each cohort consisted of three to six newly enrolled patients who were treated at the specified dose level. The first cohort was treated with the starting dose of 0.4 mg/kg every 14 days. Dose escalation continued until identification of the MTD.
Due to the limited clinical activity observed with PCA062 with the doses already tested, and because testing of higher doses would result in tolerability issues, Novartis decided to terminate the study before the dose expansion part of the study started.

Centers

7 centers in 6 countries: United States(2), Spain(1), Japan(1), Italy(1), Singapore(1), France(1)

Objectives:

Primary
To determine the maximum tolerated dose/recommended dose for expansion (MTD/RDE) of PCA062 in pCAD-positive tumors
Secondary

- To characterize the safety and tolerability of PCA062
- To characterize the pharmacokinetic profile of PCA062
- To assess emergence of anti-PCA062 antibodies following one or more intravenous infusions of PCA062
- To assess the preliminary anti-tumor activity of PCA062 in patients with TNBC, HNSCC and esophageal cancer (squamous and adenocarcinoma)

Test Product (s), Dose(s), and Mode(s) of Administration

PCA062 was available as 50 mg lyophilized powder for infusion.

Statistical Methods

The primary endpoint was the incidence of DLTs during the first two cycles in dose escalation part. Estimation of the MTD/RDE was based upon the estimation of the probability of DLT during the first two cycles for subjects in the dose determining set. An adaptive, 2-parameter Bayesian Logistic Regression Model (BLRM) guided by the escalation with overdose control principle was used to guide the dose escalation and identify the MTD/RDE during the dose escalation part of the study.
Analysis of efficacy endpoints was performed using the full analysis set. Tumor response was determined locally according to RECIST v1.1 per local investigators' assessment. Efficacy endpoints in solid tumor subjects were progression-free survival (PFS), best overall response (BOR), objective response rate (ORR), duration of response (DOR), and disease control rate (DCR).
PK parameters for PCA062 (total Antibody, total ADC and free DM1) were determined by noncompartmental method(s) using Phoenix WinNonlin. The parameters were estimated and reported, as appropriate. PAS was used in all pharmacokinetic data analysis and PK summary statistics.
Collection of safety data included the frequency and severity of AEs/SAEs, laboratory data, vital signs, and electrocardiograms. The safety summary tables included on-treatment events/assessments collected up to 30 days after the date of last study treatment administration. All safety events/assessments data were listed and those collected after 30 days from treatment discontinuation date were flagged.

Study Population: Key Inclusion/Exclusion Criteria

Inclusion criteria:
1. Male or female ≥ 18 years of age
2. Documented pCAD expressing tumor cells with the exception of HNSCC and ESCC. An archived tumor sample collected within 36 months prior to baseline if available, or a new tumor biopsy sample must be available for molecular pre-screening.
3. Consent for a tumor biopsy at screening
4. Progressive disease and no effective therapy exists
5. Measurable disease as per RECIST v1.1 criteria
6. ECOG Performance status of ≤ 2

Exclusion criteria:
1. CNS metastatic involvement
2. Clinically significant cardiac, respiratory, gastrointestinal, renal, hepatic or neurological conditions.
3. A history of serious allergic reactions, which in the opinion of the investigator pose an increased risk of serious infusion reactions.
4. Monocular vision or has media opacities or any other condition that precludes monitoring of the retina or the fundus, or has a history of ophthalmology exam with retina or cornea abnormalities
5. Previously treated with anti-pCAD biologic therapies.
6. Received anti-cancer therapies within the following time frames prior to the first dose of study treatment:
• Conventional cytotoxic chemotherapy: ≤4 weeks
• Biologic therapy (eg, antibodies), other than ADCs: ≤4 weeks
• Non-cytotoxic small molecule therapeutics: ≤5 T1/2 or ≤2 weeks (whichever is longer)
• Other investigational agents: ≤4 weeks
• Radiation therapy (palliative setting is allowed.): ≤4 weeks
• Major surgery: ≤2 weeks
7. Patient has out of range laboratory values defined as:
• Hematological values:
• Absolute neutrophil count (ANC) <1.5 x 109/L
• Hemoglobin (Hgb) <9 g/dL
• Platelets <100 x 109/L
• Hepatic and renal function
• Total bilirubin >1.5 x upper limit of normal (ULN). For patients with Gilbert's syndrome, total bilirubin >2.5 x ULN.
• Aspartate aminotransferase (AST) or alanine aminotransferase (ALT) >3 x ULN for patients without tumor involvement of the liver or >5 x ULN for patients with tumor involvement of the liver.
• Serum creatinine >1.5 x ULN and/or measured creatinine clearance < 40 ml/min

Participant Flow Table

Overall Study

	0.4 mg/kg Q2W	0.6 mg/kg Q2W	0.9 mg/kg Q2W	1.4 mg/kg Q2W	2.1 mg/kg Q2W	3.2 mg/kg Q2W	3.6 mg/kg Q2W	4.4 mg/kg Q2W	4.7 mg/kg Q2W	5.0 mg/kg Q2W	Total
Arm/Group Description	escalation	escalation	escalation	escalation	escalation	escalation	escalation	escalation	escalation	escalation	
Started	3	4	4	5	4	6	9	8	1	3	47

Completed	0	0	0	0	0	0	0	0	0	0	0
Not Completed	3	4	4	5	4	6	9	8	1	3	47
Death	0	0	0	1	0	0	0	1	0	0	2
Adverse Event	0	0	0	1	1	1	1	0	0	0	4
guardian decision	0	0	0	1	0	0	0	0	0	1	2
Physician Decision	0	0	0	0	0	2	0	0	0	0	2
progressive disease	3	4	4	2	3	3	8	7	1	2	37

Baseline Characteristics

	0.4 mg/kg Q2W	**0.6 mg/kg Q2W**	**0.9 mg/kg Q2W**	**1.4 mg/kg Q2W**	**2.1 mg/kg Q2W**	**3.2 mg/kg Q2W**	**3.6 mg/kg Q2W**	**4.4 mg/kg Q2W**	**4.7 mg/kg Q2W**	**5.0 mg/kg Q2W**	**Total**
Arm/Group Description	escalation	escalation	escalation	escalation	escalation	escalation	escalation	escalation	escalation	escalation	
Number of Participants [units: participants]	3	4	4	5	4	6	9	8	1	3	47
Age Continuous (units: years) Mean ± Standard Deviation											
	57.3±14.15	54.5±11.47	56.5±6.35	48.6±11.50	57.5±16.82	58.2±11.05	53.7±14.04	60.5±11.98	50.0±0	63.7±6.43	56.3±11.72

Race/Ethnicity, Customized (units: participants) Count of Participants (Not Applicable)											
Caucasian	1	4	3	1	1	4	5	7	1	2	29
Black	0	0	0	1	0	0	1	0	0	0	2
Asian	2	0	1	3	3	2	3	0	0	1	15
Unknown	0	0	0	0	0	0	0	1	0	0	1
Sex: Female, Male (units: participants) Count of Participants (Not Applicable)											
Female	1	2	4	2	2	4	4	3	0	0	22
Male	2	2	0	3	2	2	5	5	1	3	25

Summary of Efficacy

Primary Outcome Result(s)

Incidence of dose limiting toxicities

(Time Frame: 28 days)

	0.4 mg/kg Q2W	0.6 mg/kg Q2W	0.9 mg/kg Q2W	1.4 mg/kg Q2W	2.1 mg/kg Q2W	3.2 mg/kg Q2W	3.6 mg/kg Q2W	4.4 mg/kg Q2W	4.7 mg/kg Q2W	5.0 mg/kg Q2W
Arm/Group Description	escalation	escalation	escalation	escalation	escalation	escalation	escalation	escalation	escalation	escalation
Number of Participants Analyzed [units: participants]	3	3	4	5	4	5	9	6	0	2
Incidence of dose limiting toxicities										

(units: participants) Count of Participants (Not Applicable)										
	0	0	0	1	0	1	2	1	0	2

Secondary Outcome Result(s)

Pharmacokinetic parameter for PCA062 Cmax

(Time Frame: day 1)

	0.4 mg/kg Q2W	0.6 mg/kg Q2W	0.9 mg/kg Q2W	1.4 mg/kg Q2W	2.1 mg/kg Q2W	3.2 mg/kg Q2W	3.6 mg/kg Q2W	4.4 mg/kg Q2W	4.7 mg/kg Q2W	5.0 mg/kg Q2W
Arm/Group Description	escalation	escalation	escalation	escalation	escalation	escalation	escalation	escalation	escalation	escalation
Number of Participants Analyzed [units: participants]	3	4	4	5	4	6	9	8	1	3
Pharmacokinetic parameter for PCA062 Cmax (units: microgram/mL) Geometric Mean (Geometric Coefficient of Variation)										
	10 (20%)	14 (28%)	19 (5%)	30 (18%)	35 (14%)	65 (10%)	67 (15%)	83 (26%)	80 (0%)	87 (32%)

Overall response rate and disease control rate

(Time Frame: 3 years)

	0.4 mg/kg Q2W	0.6 mg/kg Q2W	0.9 mg/kg Q2W	1.4 mg/kg Q2W	2.1 mg/kg Q2W	3.2 mg/kg Q2W	3.6 mg/kg Q2W	4.4 mg/kg Q2W	4.7 mg/kg Q2W	5.0 mg/kg Q2W
Arm/Group Description	escalation	escalation	escalation	escalation	escalation	escalation	escalation	escalation	escalation	escalation
Number of Participants Analyzed [units: participants]	3	4	4	5	4	6	9	8	1	3
Overall response rate and disease control rate (units: participants) Count of Participants (Not Applicable)										
HNSCC ORR	0	0	1	0	0	0	0	0	0	0
HNSCC DCR	0	0	1	0	0	0	1	0	0	0
Esophageal cancer DCR	0	0	0	0	1	0	0	1	0	0
Other DCR	0	1	0	1	1	1	2	0	0	1

Best overall response

(Time Frame: 3 years)

	0.4 mg/kg Q2W	0.6 mg/kg Q2W	0.9 mg/kg Q2W	1.4 mg/kg Q2W	2.1 mg/kg Q2W	3.2 mg/kg Q2W	3.6 mg/kg Q2W	4.4 mg/kg Q2W	4.7 mg/kg Q2W	5.0 mg/kg Q2W
Arm/Group Description	escalation	escalation	escalation	escalation	escalation	escalation	escalation	escalation	escalation	escalation
Number of Participants Analyzed [units: participants]	3	4	4	5	4	6	9	8	1	3
Best overall response (units: participants) Count of Participants (Not Applicable)										
HNSCC partial response	0	0	1	0	0	0	0	0	0	0

HNSCC stable disease	0	0	0	0	0	0	1	0	0	0
HNSCC progressive disease	0	0	1	0	0	0	0	0	0	0
HNSCC unknown	1	0	0	0	0	0	0	0	0	0
TNBC progressive disease	0	0	0	0	0	1	0	0	0	0
Esophageal cancer stable disease	0	0	0	0	1	0	0	1	0	0
Esophageal cancer progressive disease	0	0	0	0	0	1	0	2	0	0
Esophageal cancer unknown	0	0	0	1	0	1	0	0	0	2
other stable disease	0	1	0	1	1	1	2	0	0	1
other progressive disease	1	3	2	2	2	1	5	2	0	0
other unknown	1	0	0	1	0	1	1	1	1	0

progression free survival (PFS)

(Time Frame: day 1)

	HNSCC	Esophageal cancer	Other
Arm/Group Description	escalation	escalation	escalation
Number of Participants Analyzed [units: participants]	6	9	31

progression free survival (PFS) (units: months) Median (95% Confidence Interval)			
	1.45 (1.28 to 8.36)	1.25 (0.46 to 2.93)	1.30 (0.95 to 2.67)

Pharmacokinetic parameter for PCA062 Tmax

(Time Frame: day 1)

	0.4 mg/kg Q2W	0.6 mg/kg Q2W	0.9 mg/kg Q2W	1.4 mg/kg Q2W	2.1 mg/kg Q2W	3.2 mg/kg Q2W	3.6 mg/kg Q2W	4.4 mg/kg Q2W	4.7 mg/kg Q2W	5.0 mg/kg Q2W
Arm/Group Description	escalation	escalation	escalation	escalation	escalation	escalation	escalation	escalation	escalation	escalation
Number of Participants Analyzed [units: participants]	3	4	4	5	4	6	9	8	1	3
Pharmacokinetic parameter for PCA062 Tmax (units: hour)										
	2.1	2.1	2.1	4.9	3.5	2.4	2.1	2.5	2.0	4.9

Presence of PCA062 anti-bodies

(Time Frame: day 1)

	0.4 mg/kg Q2W	0.6 mg/kg Q2W	0.9 mg/kg Q2W	1.4 mg/kg Q2W	2.1 mg/kg Q2W	3.2 mg/kg Q2W	3.6 mg/kg Q2W	4.4 mg/kg Q2W	4.7 mg/kg Q2W	5.0 mg/kg Q2W
Arm/Group Description	escalation	escalation	escalation	escalation	escalation	escalation	escalation	escalation	escalation	escalation
Number of Participants	3	4	4	5	4	6	9	8	1	3

Analyzed [units: participants]										
Presence of PCA062 anti-bodies (units: participants) Count of Participants (Not Applicable)										
Subjects ADA-negative baseline	2	4	2	4	4	5	7	4	1	0
Subjects ADA-positive baseline	1	0	0	0	0	1	2	1	0	0
Treatment-induced ADA (ADA positive baseline)	0	0	0	0	0	0	0	0	0	0
Treatment-induced ADA (ADA negative baseline)	0	0	0	0	0	0	0	0	0	0

Summary of Safety

Safety Results

All-Cause Mortality

0.4 mg/kg Q2W N = 3	0.6 mg/kg Q2W N = 4	0.9 mg/kg Q2W N = 4	1.4 mg/kg Q2W N = 5	2.1 mg/kg Q2W N = 4	3.2 mg/kg Q2W N = 6	3.6 mg/kg Q2W N = 9	4.4 mg/kg Q2W N = 8	4.7 mg/kg Q2W N = 1	5.0 mg/kg Q2W N = 3	All patients N = 47

Arm/Group Description	0.4 mg/kg Q2W	0.6 mg/kg Q2W	0.9 mg/kg Q2W	1.4 mg/kg Q2W	2.1 mg/kg Q2W	3.2 mg/kg Q2W	3.6 mg/kg Q2W	4.4 mg/kg Q2W	4.7 mg/kg Q2W	5.0 mg/kg Q2W	All patients
Total participants affected	0 (0.00%)	0 (0.00%)	1 (25.00%)	2 (40.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	1 (12.50%)	0 (0.00%)	1 (33.33%)	6 (12.77%)

Serious Adverse Events by System Organ Class

Time Frame	approximately 3 years
Source Vocabulary for Table Default	MedDRA (21.0)
Assessment Type for Table Default	Systematic Assessment

	0.4 mg/kg Q2W N = 3	**0.6 mg/kg Q2W N = 4**	**0.9 mg/kg Q2W N = 4**	**1.4 mg/kg Q2W N = 5**	**2.1 mg/kg Q2W N = 4**	**3.2 mg/kg Q2W N = 6**	**3.6 mg/kg Q2W N = 9**	**4.4 mg/kg Q2W N = 8**	**4.7 mg/kg Q2W N = 1**	**5.0 mg/kg Q2W N = 3**	**All patients N = 47**
Arm/Group Description	0.4 mg/kg Q2W	0.6 mg/kg Q2W	0.9 mg/kg Q2W	1.4 mg/kg Q2W	2.1 mg/kg Q2W	3.2 mg/kg Q2W	3.6 mg/kg Q2W	4.4 mg/kg Q2W	4.7 mg/kg Q2W	5.0 mg/kg Q2W	All patients
Total participants affected	2 (66.67 %)	2 (50.00 %)	2 (50.00 %)	4 (80.00 %)	3 (75.00 %)	3 (50.00 %)	5 (55.56 %)	6 (75.00 %)	1 (100.00 %)	3 (100.00 %)	31 (65.96 %)
Blood and lymphatic system disorders											
Anaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Thrombocytopenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	1 (2.13%)
Gastrointestinal disorders											

Abdominal pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	2 (4.26%)
Ascites	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (4.26%)
Constipation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Gastrointestinal haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Intestinal obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (4.26%)
Oesophageal haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	1 (2.13%)
Pancreatitis acute	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Peptic ulcer	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Small intestinal obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (4.26%)
General disorders and administration site conditions											
Pyrexia	0 (0.00%)	0 (0.00%)	2 (50.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	3 (6.38%)
Hepatobiliary disorders											
Biliary dilatation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Hepatic failure	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Hyperbilirubinaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)

Infections and infestations											
Bronchitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Pneumonia	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (4.26%)
Pulmonary sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Respiratory syncytial virus infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Urinary tract infection	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Viral upper respiratory tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Injury, poisoning and procedural complications											
Fall	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Investigations											
Troponin increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Metabolism and nutrition disorders											
Dehydration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (2.13%)

Hypercalcaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Musculoskeletal and connective tissue disorders											
Back pain	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (4.26%)
Neck pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)											
Tumour haemorrhage	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Nervous system disorders											
Dizziness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Dysarthria	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Somnolence	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Renal and urinary disorders											
Acute kidney injury	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (4.26%)
Hydronephrosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Proteinuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (4.26%)

Respiratory, thoracic and mediastinal disorders											
Dysphonia	1 (33.33 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Dyspnoea	1 (33.33 %)	0 (0.00%)	0 (0.00%)	1 (20.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (4.26%)
Epistaxis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (100.00 %)	0 (0.00%)	1 (2.13%)
Haemoptysis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	1 (2.13%)
Pneumonia aspiration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	2 (4.26%)
Respiratory failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Vascular disorders											
Hypotension	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)

Other Adverse Events by System Organ Class

Time Frame	approximately 3 years
Source Vocabulary for Table Default	MedDRA (21.0)
Assessment Type for Table Default	Systematic Assessment
Frequent Event Reporting Threshold	5%

	0.4 mg/kg Q2W N = 3	0.6 mg/kg Q2W N = 4	0.9 mg/kg Q2W N = 4	1.4 mg/kg Q2W N = 5	2.1 mg/kg Q2W N = 4	3.2 mg/kg Q2W N = 6	3.6 mg/kg Q2W N = 9	4.4 mg/kg Q2W N = 8	4.7 mg/kg Q2W N = 1	5.0 mg/kg Q2W N = 3	All patients N = 47
Arm/Group Description	0.4 mg/kg Q2W	0.6 mg/kg Q2W	0.9 mg/kg Q2W	1.4 mg/kg Q2W	2.1 mg/kg Q2W	3.2 mg/kg Q2W	3.6 mg/kg Q2W	4.4 mg/kg Q2W	4.7 mg/kg Q2W	5.0 mg/kg Q2W	All patients
Total participants affected	3 (100.00 %)	4 (100.00 %)	4 (100.00 %)	5 (100.00 %)	4 (100.00 %)	6 (100.00 %)	9 (100.00 %)	7 (87.50 %)	1 (100.00 %)	3 (100.00 %)	46 (97.87 %)
Blood and lymphatic system disorders											
Anaemia	0 (0.00%)	0 (0.00%)	1 (25.00 %)	2 (40.00 %)	2 (50.00 %)	3 (50.00 %)	4 (44.44 %)	3 (37.50 %)	0 (0.00%)	1 (33.33 %)	16 (34.04 %)
Leukopenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Lymphopenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (4.26%)
Neutropenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Thrombocytopenia	1 (33.33 %)	1 (25.00 %)	0 (0.00%)	1 (20.00 %)	1 (25.00 %)	1 (16.67 %)	4 (44.44 %)	4 (50.00 %)	0 (0.00%)	3 (100.00 %)	16 (34.04 %)
Cardiac disorders											
Bundle branch block right	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Pericardial effusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Tachycardia	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Ear and labyrinth disorders											

Vertigo	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Eye disorders											
Corneal disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Corneal epithelial microcysts	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33 %)	2 (4.26%)
Dry eye	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Foreign body sensation in eyes	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Keratitis	0 (0.00%)	2 (50.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (4.26%)
Ocular toxicity	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Photophobia	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Refraction disorder	0 (0.00%)	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Gastrointestinal disorders											
Abdominal discomfort	0 (0.00%)	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Abdominal pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (33.33 %)	1 (11.11 %)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	4 (8.51%)
Abdominal pain upper	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (25.00 %)	0 (0.00%)	0 (0.00%)	2 (4.26%)
Anal haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Aphthous ulcer	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)

Ascites	1 (33.33 %)	0 (0.00%)	0 (0.00%)	2 (40.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (6.38%)
Constipation	0 (0.00%)	1 (25.00 %)	0 (0.00%)	1 (20.00 %)	0 (0.00%)	0 (0.00%)	2 (22.22 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (8.51%)
Diarrhoea	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	1 (25.00 %)	2 (33.33 %)	1 (11.11 %)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	6 (12.77 %)
Dry mouth	0 (0.00%)	1 (25.00 %)	0 (0.00%)	1 (20.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (4.26%)
Dyspepsia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Dysphagia	0 (0.00%)	0 (0.00%)	1 (25.00 %)	0 (0.00%)	1 (25.00 %)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	1 (33.33 %)	4 (8.51%)
Gastrointestinal inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Nausea	1 (33.33 %)	0 (0.00%)	2 (50.00 %)	1 (20.00 %)	0 (0.00%)	2 (33.33 %)	6 (66.67 %)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	13 (27.66 %)
Odynophagia	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Oesophageal haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33 %)	2 (4.26%)
Oesophageal pain	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Oesophagitis	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Rectal haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Small intestinal haemorrhage	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Stomatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00 %)	0 (0.00%)	1 (11.11 %)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	3 (6.38%)
Subileus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)

Toothache	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Vomiting	1 (33.33 %)	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	2 (33.33 %)	2 (22.22 %)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	7 (14.89 %)
General disorders and administration site conditions											
Asthenia	0 (0.00%)	3 (75.00 %)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	2 (33.33 %)	2 (22.22 %)	1 (12.50 %)	0 (0.00%)	1 (33.33 %)	10 (21.28 %)
Catheter site rash	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Chest discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Early satiety	1 (33.33 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Fatigue	0 (0.00%)	0 (0.00%)	2 (50.00 %)	2 (40.00 %)	3 (75.00 %)	1 (16.67 %)	2 (22.22 %)	0 (0.00%)	0 (0.00%)	1 (33.33 %)	11 (23.40 %)
Hyperpyrexia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Localised oedema	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (4.26%)
Non-cardiac chest pain	0 (0.00%)	2 (50.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (4.26%)
Oedema peripheral	0 (0.00%)	1 (25.00 %)	0 (0.00%)	1 (20.00 %)	2 (50.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33 %)	5 (10.64 %)
Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Pyrexia	0 (0.00%)	2 (50.00 %)	1 (25.00 %)	1 (20.00 %)	2 (50.00 %)	1 (16.67 %)	3 (33.33 %)	3 (37.50 %)	0 (0.00%)	1 (33.33 %)	14 (29.79 %)
Ulcer	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)

Hepatobiliary disorders											
Hepatic function abnormal	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Hyperbilirubinaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Infections and infestations											
Anorectal infection	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Arthritis infective	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Bronchitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Conjunctivitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Gingivitis	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Influenza	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Lung infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33 %)	1 (2.13%)
Oral candidiasis	1 (33.33 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (4.26%)
Otitis media	0 (0.00%)	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Peritonitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33 %)	1 (2.13%)
Urinary tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00 %)	0 (0.00%)	0 (0.00%)	3 (33.33 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (8.51%)

Injury, poisoning and procedural complications											
Fall	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Infusion related reaction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Post procedural inflammation	0 (0.00%)	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Procedural pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Stoma site haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Investigations											
Activated partial thromboplastin time prolonged	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	2 (4.26%)
Alanine aminotransferase increased	0 (0.00%)	0 (0.00%)	1 (25.00 %)	2 (40.00 %)	2 (50.00 %)	1 (16.67 %)	2 (22.22 %)	1 (12.50 %)	1 (100.00 %)	2 (66.67 %)	12 (25.53 %)
Amylase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00 %)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (4.26%)
Aspartate aminotransferase increased	0 (0.00%)	0 (0.00%)	1 (25.00 %)	3 (60.00 %)	2 (50.00 %)	3 (50.00 %)	5 (55.56 %)	4 (50.00 %)	1 (100.00 %)	2 (66.67 %)	21 (44.68 %)
Blood alkaline phosphatase increased	0 (0.00%)	0 (0.00%)	1 (25.00 %)	2 (40.00 %)	1 (25.00 %)	1 (16.67 %)	3 (33.33 %)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	9 (19.15 %)
Blood bilirubin increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (40.00 %)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	1 (12.50 %)	1 (100.00 %)	0 (0.00%)	5 (10.64 %)
Blood creatine phosphokinase increased	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (4.26%)

Blood creatinine increased	0 (0.00%)	1 (25.00 %)	0 (0.00%)	1 (20.00 %)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (6.38%)
Blood ketone body increased	1 (33.33 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Blood lactate dehydrogenase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Electrocardiogram QT prolonged	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Gamma-glutamyltransferase increased	0 (0.00%)	0 (0.00%)	1 (25.00 %)	0 (0.00%)	1 (25.00 %)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (6.38%)
International normalised ratio increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Lipase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00 %)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (4.26%)
Lymphocyte count decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Neutrophil count decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Platelet count decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00 %)	1 (25.00 %)	1 (16.67 %)	3 (33.33 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	6 (12.77 %)
Transaminases increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00 %)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (4.26%)
Troponin I increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Weight decreased	0 (0.00%)	0 (0.00%)	1 (25.00 %)	1 (20.00 %)	1 (25.00 %)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (8.51%)
Metabolism and nutrition disorders											

Decreased appetite	0 (0.00%)	1 (25.00 %)	1 (25.00 %)	1 (20.00 %)	2 (50.00 %)	4 (66.67 %)	2 (22.22 %)	3 (37.50 %)	0 (0.00%)	1 (33.33 %)	15 (31.91 %)
Dehydration	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (40.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (4.26%)
Hypercalcaemia	0 (0.00%)	0 (0.00%)	1 (25.00 %)	1 (20.00 %)	0 (0.00%)	1 (16.67 %)	0 (0.00%)	1 (12.50 %)	0 (0.00%)	1 (33.33 %)	5 (10.64 %)
Hyperglycaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Hyperkalaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (40.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (4.26%)
Hypertriglyceridaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Hyperuricaemia	0 (0.00%)	1 (25.00 %)	0 (0.00%)	1 (20.00 %)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (6.38%)
Hypoalbuminaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00 %)	0 (0.00%)	0 (0.00%)	2 (22.22 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (6.38%)
Hypokalaemia	0 (0.00%)	1 (25.00 %)	0 (0.00%)	1 (20.00 %)	0 (0.00%)	0 (0.00%)	2 (22.22 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (8.51%)
Hyponatraemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00 %)	1 (25.00 %)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (6.38%)
Hypophosphataemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Malnutrition	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Musculoskeletal and connective tissue disorders											
Arthralgia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00 %)	2 (33.33 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (6.38%)
Back pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (50.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (4.26%)
Bursitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)

Flank pain	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Muscle spasms	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Musculoskeletal chest pain	0 (0.00%)	2 (50.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (4.26%)
Musculoskeletal pain	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Myalgia	1 (33.33 %)	1 (25.00 %)	1 (25.00 %)	1 (20.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33 %)	5 (10.64 %)
Neck pain	1 (33.33 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Pain in extremity	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Pain in jaw	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Scleroderma	0 (0.00%)	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)											
Oncologic complication	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Skin papilloma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Tumour pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Nervous system disorders											
Aphonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	1 (2.13%)

Dizziness	1 (33.33 %)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	1 (25.00 %)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (8.51%)
Dysgeusia	0 (0.00%)	1 (25.00 %)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	4 (8.51%)
Headache	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (4.26%)
Neuralgia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Paraesthesia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (33.33 %)	1 (11.11 %)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	4 (8.51%)
Psychiatric disorders											
Agitation	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Anxiety	0 (0.00%)	1 (25.00 %)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (4.26%)
Insomnia	1 (33.33 %)	0 (0.00%)	1 (25.00 %)	1 (20.00 %)	0 (0.00%)	2 (33.33 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	5 (10.64 %)
Renal and urinary disorders											
Dysuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Haematuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33 %)	2 (4.26%)
Proteinuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (4.26%)
Urinary incontinence	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Reproductive system and breast disorders											
Perineal pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)

Respiratory, thoracic and mediastinal disorders											
Cough	0 (0.00%)	1 (25.00 %)	0 (0.00%)	1 (20.00 %)	1 (25.00 %)	1 (16.67 %)	0 (0.00%)	2 (25.00 %)	0 (0.00%)	0 (0.00%)	6 (12.77 %)
Dysphonia	1 (33.33 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Dyspnoea	1 (33.33 %)	0 (0.00%)	0 (0.00%)	2 (40.00 %)	0 (0.00%)	1 (16.67 %)	2 (22.22 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	6 (12.77 %)
Dyspnoea exertional	1 (33.33 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Epistaxis	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	1 (33.33 %)	3 (6.38%)
Haemoptysis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (33.33 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33 %)	3 (6.38%)
Nasal dryness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Oropharyngeal pain	0 (0.00%)	2 (50.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (4.26%)
Pneumonia aspiration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33 %)	1 (2.13%)
Productive cough	0 (0.00%)	2 (50.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (6.38%)
Pulmonary embolism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Pulmonary haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Respiratory disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Respiratory distress	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)

Rhinorrhoea	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	2 (4.26%)
Wheezing	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Skin and subcutaneous tissue disorders											
Alopecia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Dermatitis acneiform	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	1 (11.11 %)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	4 (8.51%)
Dry skin	1 (33.33 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Eczema	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Erythema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Papule	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Pruritus	0 (0.00%)	0 (0.00%)	1 (25.00 %)	1 (20.00 %)	0 (0.00%)	1 (16.67 %)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (8.51%)
Rash	0 (0.00%)	1 (25.00 %)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (4.26%)
Rash erythematous	1 (33.33 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Rash generalised	0 (0.00%)	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Rash macular	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Rash maculo-papular	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Rosacea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	1 (2.13%)

Skin ulcer	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Vascular disorders											
Deep vein thrombosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Flushing	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.13%)
Hypertension	1 (33.33 %)	0 (0.00%)	0 (0.00%)	1 (20.00 %)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (66.67 %)	5 (10.64 %)

Other Relevant Findings

None.

Conclusion:

- PCA062 3.6 mg/kg q2w was determined to be the MTD.
- Dose proportionality of PCA062 was observed in the dose range of 0.4 to 5 mg/kg q2w, and treatment with PCA062 did not induce anti-drug antibodies.
- PCA062 had limited clinical activity with only one subject achieving a partial response.
- The study was terminated early as testing of higher doses was precluded by tolerability.

Date of Clinical Trial Report

13-Mar-2019