Clinical trial results:
International, Multi-Center, Open-label, Treatment Extension Study of Iniparib as Monotherapy or in Combination Chemotherapeutic Regimens in Cancer Patients Who Have Derived Clinical Benefit From Iniparib Following Completion of a Phase 1, 2 or 3 Parental Study

Summary

EudraCT number	2011-006246-33
Trial protocol	BE ES IT
Global end of trial date	26 September 2016

Results information

Result version number	v1 (current)
This version publication date	13 September 2017
First version publication date	13 September 2017

Trial information

Trial identification

Sponsor protocol code	LTS12674

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01593228
WHO universal trial number (UTN)	U1111-1127-0888

Notes:

Sponsors

Sponsor organisation name	Sanofi aventis recherche & développement
Sponsor organisation address	1 avenue Pierre Brossolette, Chilly--Mazarin, France, 91380
Public contact	Trial Transparency Team, Sanofi aventis recherche & développement, Contact-US@sanofi.com
Scientific contact	Trial Transparency Team, Sanofi aventis recherche & développement, Contact-US@sanofi.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	24 October 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	26 September 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the safety and tolerability of iniparib administered as monotherapy or in combination regimens in subjects previously treated with iniparib in a clinical study and who had derived clinical benefit after completion of the parental study's objectives. Parental studies included EFC11553, EFC11614, TCD11484, TED11746 and TCD11418.

Protection of trial subjects:

Subjects were fully informed of all pertinent aspects of the clinical trial as well as the possibility to discontinue at any time in language and terms appropriate for the subject and considering the local culture. During the course of the trial, subjects were provided with individual subject cards indicating the nature of the trial the subject is participating, contact details and any information needed in the event of a medical emergency.
Collected personal data and human biological samples were processed in compliance with the Sanofi-Aventis Group Personal Data Protection Charter ensuring that the Group abides by the laws governing personal data protection in force in all countries in which it operates.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 May 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 32
Country: Number of subjects enrolled	Spain: 1
Country: Number of subjects enrolled	Belgium: 1
Country: Number of subjects enrolled	Italy: 1
Worldwide total number of subjects	35
EEA total number of subjects	3

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0

Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	28
From 65 to 84 years	7
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 32 study centers in 4 countries between 14 May 2012 and 26 September 2016. This is a safety roll over protocol for subjects who participated in Phase 1, 2 or 3 studies of iniparib given either as monotherapy or as part of a combination regimen. A total of 35 subjects were treated.

Pre-assignment

Screening details:

Iniparib was given either as monotherapy or as part of a combination regimen, to subjects who participated in Phase 1, 2 or 3 studies and completed assessments for primary objectives and who would benefit from continuation therapy of iniparib as per investigator's decision.

Period 1

Period 1 title	Overall Study (Overall period) (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Iniparib Monotherapy

Arm description:

Subjects received Iniparib as monotherapy according to the dose and schedule as in their parental study (Phase 1, 2 or 3 studies).

Arm type	Experimental
Investigational medicinal product name	Iniparib
Investigational medicinal product code	SAR240550
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Iniparib was administered as intravenous infusion at the same dose and schedule as in their parental study (Phase 1, 2 or 3 studies).

Arm title	Iniparib Combination Therapy

Arm description:

Subjects received Iniparib as combination regimen with other anti-cancer agents according to the dose and schedule as in their parental study (Phase 1, 2 or 3 studies).

Arm type	Experimental
Investigational medicinal product name	Iniparib
Investigational medicinal product code	SAR240550
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Iniparib was administered as monotherapy or in combination with other anti-cancer agents as intravenous injection at the same dose and schedule as in their parental study (Phase 1, 2 or 3 studies). Combination therapy included Iniparib + gemcitabine + carboplatin; Iniparib + topotecan; Iniparib + irinotecan; Iniparib + paclitaxel; Iniparib + liposomal doxorubicin + carboplatin.

Number of subjects in period 1	Iniparib Monotherapy	Iniparib Combination Therapy
Started	11	24
Completed	0	0
Not completed	11	24
Disease progression	6	10
Adverse events	-	3
Other than specified	5	10
Poor compliance to protocol	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Iniparib Monotherapy
Reporting group description:	
Subjects received Iniparib as monotherapy according to the dose and schedule as in their parental study (Phase 1, 2 or 3 studies).	
Reporting group title	Iniparib Combination Therapy
Reporting group description:	
Subjects received Iniparib as combination regimen with other anti-cancer agents according to the dose and schedule as in their parental study (Phase 1, 2 or 3 studies).	

Reporting group values	Iniparib Monotherapy	Iniparib Combination Therapy	Total
Number of subjects	11	24	35
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	51.9	53.8	
standard deviation	± 12.1	± 14.1	-
Gender categorical			
Units: Subjects			
Female	10	22	32
Male	1	2	3

End points

End points reporting groups

Reporting group title	Iniparib Monotherapy

Reporting group description:

Subjects received Iniparib as monotherapy according to the dose and schedule as in their parental study (Phase 1, 2 or 3 studies).

Reporting group title	Iniparib Combination Therapy

Reporting group description:

Subjects received Iniparib as combination regimen with other anti-cancer agents according to the dose and schedule as in their parental study (Phase 1, 2 or 3 studies).

Primary: Number of Subjects With Treatment-Emergent Adverse Events (TEAEs) and Serious Adverse Events

End point title	Number of Subjects With Treatment-Emergent Adverse Events (TEAEs) and Serious Adverse Events[1]

End point description:

Any untoward medical occurrence in a subject who received study drug was considered an AE without regard to possibility of causal relationship with treatment. TEAEs were AEs developed or worsened or became serious during on-treatment period (time from first dose of study drug up to 30 days after last dose of study drug). Serious adverse event (SAE) were any untoward medical occurrence that resulted in any of following outcomes: death,life-threatening,required initial or prolonged in-patient hospitalization,persistent or significant disability/incapacity,congenital anomaly/birth defect, or considered as medically important event. Any TEAE included subjects with both serious and non-serious AEs.All AEs were graded according to National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE) v.4.03 scale. Safety population included any subject who received at least one dose of study drug as single agent or as combination therapy.

End point type	Primary

End point timeframe:

Baseline up to 30 days after last dose of study drug (maximum exposure: 204 weeks)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

End point values	Iniparib Monotherapy	Iniparib Combination Therapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	24		
Units: subjects				
Any TEAEs	10	24		
SAEs	4	7		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All Adverse Events (AEs) were collected from signature of the informed consent form up to the final visit (maximum duration: 204 weeks) regardless of seriousness or relationship to investigational product.

Adverse event reporting additional description:

TEAEs are defined as AEs that developed/worsened during 'on treatment period' (time from first dose of study drug up to 30 days after last dose of study drug). Analysis was performed on safety population that included any subject who received at least one dose of study drug as single agent or as combination therapy.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.0

Reporting groups

Reporting group title	Iniparib Monotherapy

Reporting group description:

Subjects received Iniparib as monotherapy according to the dose and schedule as in their parental study (Phase 1, 2 or 3 studies).

Reporting group title	Iniparib Combination Therapy

Reporting group description:

Subjects received Iniparib as combination regimen with other anti-cancer agents according to the dose and schedule as in their parental study (Phase 1, 2 or 3 studies).

Serious adverse events	Iniparib Monotherapy	Iniparib Combination Therapy	
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 11 (36.36%)	7 / 24 (29.17%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases To Central Nervous System			
subjects affected / exposed	1 / 11 (9.09%)	3 / 24 (12.50%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Ankle Fracture			
subjects affected / exposed	1 / 11 (9.09%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			

Brain Oedema			
subjects affected / exposed	1 / 11 (9.09%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	0 / 11 (0.00%)	2 / 24 (8.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure Like Phenomena			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Febrile Neutropenia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Pancreatitis Acute			
subjects affected / exposed	1 / 11 (9.09%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Confusional State			
subjects affected / exposed	1 / 11 (9.09%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental Status Changes			

subjects affected / exposed	1 / 11 (9.09%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Iniparib Monotherapy	Iniparib Combination Therapy	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 11 (90.91%)	24 / 24 (100.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Seborrhoeic Keratosis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Hot Flush			

subjects affected / exposed	1 / 11 (9.09%)	2 / 24 (8.33%)	
occurrences (all)	1	3	
Hypertension			
subjects affected / exposed	1 / 11 (9.09%)	1 / 24 (4.17%)	
occurrences (all)	2	2	
Hypotension			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	2	
Lymphoedema			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	2	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Axillary Pain			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	2	
Catheter Site Pain			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Chills			
subjects affected / exposed	1 / 11 (9.09%)	1 / 24 (4.17%)	
occurrences (all)	1	1	
Fatigue			
subjects affected / exposed	2 / 11 (18.18%)	10 / 24 (41.67%)	
occurrences (all)	4	20	
Gait Disturbance			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Impaired Healing			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Influenza Like Illness			

subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	3	
Malaise			
subjects affected / exposed	1 / 11 (9.09%)	1 / 24 (4.17%)	
occurrences (all)	1	1	
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Oedema Peripheral			
subjects affected / exposed	2 / 11 (18.18%)	2 / 24 (8.33%)	
occurrences (all)	2	2	
Pain			
subjects affected / exposed	1 / 11 (9.09%)	4 / 24 (16.67%)	
occurrences (all)	1	4	
Pyrexia			
subjects affected / exposed	2 / 11 (18.18%)	1 / 24 (4.17%)	
occurrences (all)	2	1	
Immune system disorders			
Drug Hypersensitivity			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	2	
Seasonal Allergy			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Reproductive system and breast disorders			
Breast Pain			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Pruritus Genital			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Vulvovaginal Dryness			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	4 / 11 (36.36%)	7 / 24 (29.17%)	
occurrences (all)	9	9	
Dysphonia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Dyspnoea			
subjects affected / exposed	3 / 11 (27.27%)	6 / 24 (25.00%)	
occurrences (all)	6	7	
Dyspnoea Exertional			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Epistaxis			
subjects affected / exposed	1 / 11 (9.09%)	2 / 24 (8.33%)	
occurrences (all)	1	2	
Nasal Congestion			
subjects affected / exposed	0 / 11 (0.00%)	2 / 24 (8.33%)	
occurrences (all)	0	2	
Oropharyngeal Pain			
subjects affected / exposed	0 / 11 (0.00%)	4 / 24 (16.67%)	
occurrences (all)	0	4	
Pleural Effusion			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Rhinitis Allergic			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Rhinorrhoea			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Upper-Airway Cough Syndrome			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	2	
Wheezing			
subjects affected / exposed	1 / 11 (9.09%)	0 / 24 (0.00%)	
occurrences (all)	1	0	

Psychiatric disorders			
Affect Lability			
subjects affected / exposed	1 / 11 (9.09%)	0 / 24 (0.00%)	
occurrences (all)	1	0	
Insomnia			
subjects affected / exposed	3 / 11 (27.27%)	4 / 24 (16.67%)	
occurrences (all)	4	4	
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 11 (0.00%)	2 / 24 (8.33%)	
occurrences (all)	0	2	
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 11 (0.00%)	2 / 24 (8.33%)	
occurrences (all)	0	2	
Blood Creatinine Increased			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	2	
Blood Pressure Increased			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Haemoglobin Decreased			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	12	
Lipase Increased			
subjects affected / exposed	1 / 11 (9.09%)	0 / 24 (0.00%)	
occurrences (all)	1	0	
Neutrophil Count Decreased			
subjects affected / exposed	1 / 11 (9.09%)	2 / 24 (8.33%)	
occurrences (all)	8	11	
Platelet Count Decreased			
subjects affected / exposed	0 / 11 (0.00%)	3 / 24 (12.50%)	
occurrences (all)	0	18	
Weight Decreased			
subjects affected / exposed	1 / 11 (9.09%)	2 / 24 (8.33%)	
occurrences (all)	1	4	
Weight Increased			

subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	6	
White Blood Cell Count Decreased			
subjects affected / exposed	1 / 11 (9.09%)	1 / 24 (4.17%)	
occurrences (all)	5	2	
Injury, poisoning and procedural complications			
Animal Bite			
subjects affected / exposed	1 / 11 (9.09%)	0 / 24 (0.00%)	
occurrences (all)	1	0	
Foot Fracture			
subjects affected / exposed	1 / 11 (9.09%)	0 / 24 (0.00%)	
occurrences (all)	1	0	
Contusion			
subjects affected / exposed	1 / 11 (9.09%)	1 / 24 (4.17%)	
occurrences (all)	2	3	
Infusion Related Reaction			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	3	
Laceration			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Procedural Dizziness			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Procedural Site Reaction			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	2	
Tooth Fracture			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Wound Dehiscence			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	2	
Cardiac disorders			

Angina Pectoris			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Palpitations			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Sinus Tachycardia			
subjects affected / exposed	1 / 11 (9.09%)	2 / 24 (8.33%)	
occurrences (all)	1	2	
Tachycardia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Nervous system disorders			
Brain Oedema			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Cognitive Disorder			
subjects affected / exposed	1 / 11 (9.09%)	0 / 24 (0.00%)	
occurrences (all)	1	0	
Dizziness			
subjects affected / exposed	3 / 11 (27.27%)	4 / 24 (16.67%)	
occurrences (all)	7	5	
Dizziness Postural			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Dysgeusia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Facial Paralysis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Generalised Tonic-Clonic Seizure			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Headache			

subjects affected / exposed	1 / 11 (9.09%)	6 / 24 (25.00%)	
occurrences (all)	2	10	
Hemiparesis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Hypoaesthesia			
subjects affected / exposed	0 / 11 (0.00%)	2 / 24 (8.33%)	
occurrences (all)	0	2	
Migraine			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Myoclonus			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Neuropathy Peripheral			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Paraesthesia			
subjects affected / exposed	1 / 11 (9.09%)	1 / 24 (4.17%)	
occurrences (all)	1	1	
Peripheral Sensory Neuropathy			
subjects affected / exposed	1 / 11 (9.09%)	0 / 24 (0.00%)	
occurrences (all)	1	0	
Seizure			
subjects affected / exposed	0 / 11 (0.00%)	2 / 24 (8.33%)	
occurrences (all)	0	2	
Somnolence			
subjects affected / exposed	0 / 11 (0.00%)	2 / 24 (8.33%)	
occurrences (all)	0	2	
Syncope			
subjects affected / exposed	0 / 11 (0.00%)	2 / 24 (8.33%)	
occurrences (all)	0	2	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 11 (9.09%)	4 / 24 (16.67%)	
occurrences (all)	3	14	

Increased Tendency To Bruise			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Leukopenia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	11	
Neutropenia			
subjects affected / exposed	0 / 11 (0.00%)	8 / 24 (33.33%)	
occurrences (all)	0	29	
Thrombocytopenia			
subjects affected / exposed	1 / 11 (9.09%)	10 / 24 (41.67%)	
occurrences (all)	1	38	
Ear and labyrinth disorders			
Ear Discomfort			
subjects affected / exposed	1 / 11 (9.09%)	1 / 24 (4.17%)	
occurrences (all)	1	1	
Ear Pain			
subjects affected / exposed	0 / 11 (0.00%)	2 / 24 (8.33%)	
occurrences (all)	0	2	
Tinnitus			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Vertigo			
subjects affected / exposed	1 / 11 (9.09%)	1 / 24 (4.17%)	
occurrences (all)	1	1	
Eye disorders			
Lacrimation Increased			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	2	
Periorbital Oedema			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Vision Blurred			
subjects affected / exposed	2 / 11 (18.18%)	1 / 24 (4.17%)	
occurrences (all)	2	1	
Gastrointestinal disorders			

Abdominal Discomfort			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Abdominal Distension			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Abdominal Pain			
subjects affected / exposed	2 / 11 (18.18%)	0 / 24 (0.00%)	
occurrences (all)	2	0	
Abdominal Pain Lower			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Abdominal Pain Upper			
subjects affected / exposed	1 / 11 (9.09%)	2 / 24 (8.33%)	
occurrences (all)	2	2	
Constipation			
subjects affected / exposed	2 / 11 (18.18%)	2 / 24 (8.33%)	
occurrences (all)	2	2	
Diarrhoea			
subjects affected / exposed	2 / 11 (18.18%)	6 / 24 (25.00%)	
occurrences (all)	5	9	
Duodenal Ulcer			
subjects affected / exposed	1 / 11 (9.09%)	0 / 24 (0.00%)	
occurrences (all)	1	0	
Dysphagia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Gastritis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 24 (0.00%)	
occurrences (all)	1	0	
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 11 (0.00%)	2 / 24 (8.33%)	
occurrences (all)	0	2	
Glossodynia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	

Mouth Ulceration			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Nausea			
subjects affected / exposed	3 / 11 (27.27%)	8 / 24 (33.33%)	
occurrences (all)	5	16	
Oral Discomfort			
subjects affected / exposed	1 / 11 (9.09%)	0 / 24 (0.00%)	
occurrences (all)	1	0	
Oral Pain			
subjects affected / exposed	0 / 11 (0.00%)	2 / 24 (8.33%)	
occurrences (all)	0	2	
Paraesthesia Oral			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	2	
Stomatitis			
subjects affected / exposed	2 / 11 (18.18%)	2 / 24 (8.33%)	
occurrences (all)	8	3	
Tongue Ulceration			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Toothache			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	2	
Vomiting			
subjects affected / exposed	3 / 11 (27.27%)	6 / 24 (25.00%)	
occurrences (all)	4	11	
Hepatobiliary disorders			
Hepatic Function Abnormal			
subjects affected / exposed	1 / 11 (9.09%)	0 / 24 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Alopecia			

subjects affected / exposed	0 / 11 (0.00%)	2 / 24 (8.33%)	
occurrences (all)	0	2	
Dermatitis Contact			
subjects affected / exposed	1 / 11 (9.09%)	0 / 24 (0.00%)	
occurrences (all)	1	0	
Dry Skin			
subjects affected / exposed	1 / 11 (9.09%)	0 / 24 (0.00%)	
occurrences (all)	1	0	
Ecchymosis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Erythema			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Ingrowing Nail			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Macule			
subjects affected / exposed	1 / 11 (9.09%)	1 / 24 (4.17%)	
occurrences (all)	1	1	
Nail Discolouration			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Onycholysis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 24 (0.00%)	
occurrences (all)	1	0	
Onychomadesis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Pain Of Skin			
subjects affected / exposed	1 / 11 (9.09%)	0 / 24 (0.00%)	
occurrences (all)	2	0	
Palmar Erythema			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Pruritus Generalised			

subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	2	
Psoriasis			
subjects affected / exposed	1 / 11 (9.09%)	1 / 24 (4.17%)	
occurrences (all)	1	1	
Rash			
subjects affected / exposed	0 / 11 (0.00%)	2 / 24 (8.33%)	
occurrences (all)	0	2	
Rash Macular			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Rash Maculo-Papular			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Rash Vesicular			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Pollakiuria			
subjects affected / exposed	1 / 11 (9.09%)	0 / 24 (0.00%)	
occurrences (all)	1	0	
Urine Odour Abnormal			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Endocrine disorders			
Adrenal Insufficiency			
subjects affected / exposed	1 / 11 (9.09%)	0 / 24 (0.00%)	
occurrences (all)	1	0	
Hypothyroidism			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			

Arthralgia				
subjects affected / exposed	1 / 11 (9.09%)	4 / 24 (16.67%)		
occurrences (all)	1	5		
Back Pain				
subjects affected / exposed	1 / 11 (9.09%)	2 / 24 (8.33%)		
occurrences (all)	1	2		
Bone Pain				
subjects affected / exposed	1 / 11 (9.09%)	2 / 24 (8.33%)		
occurrences (all)	7	2		
Exostosis				
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)		
occurrences (all)	0	1		
Flank Pain				
subjects affected / exposed	1 / 11 (9.09%)	1 / 24 (4.17%)		
occurrences (all)	1	1		
Fracture Pain				
subjects affected / exposed	1 / 11 (9.09%)	0 / 24 (0.00%)		
occurrences (all)	1	0		
Muscular Weakness				
subjects affected / exposed	1 / 11 (9.09%)	3 / 24 (12.50%)		
occurrences (all)	1	3		
Musculoskeletal Chest Pain				
subjects affected / exposed	0 / 11 (0.00%)	2 / 24 (8.33%)		
occurrences (all)	0	3		
Musculoskeletal Pain				
subjects affected / exposed	1 / 11 (9.09%)	2 / 24 (8.33%)		
occurrences (all)	2	2		
Myalgia				
subjects affected / exposed	1 / 11 (9.09%)	2 / 24 (8.33%)		
occurrences (all)	1	2		
Neck Pain				
subjects affected / exposed	1 / 11 (9.09%)	0 / 24 (0.00%)		
occurrences (all)	1	0		
Osteonecrosis Of Jaw				
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)		
occurrences (all)	0	1		

Pain In Jaw			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Pain In Extremity			
subjects affected / exposed	1 / 11 (9.09%)	3 / 24 (12.50%)	
occurrences (all)	1	3	
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 24 (0.00%)	
occurrences (all)	1	0	
Cellulitis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Cystitis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Ear Infection			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	2	
Fungal Skin Infection			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	2	
Gastroenteritis Viral			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Gastrointestinal Infection			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Herpes Zoster			
subjects affected / exposed	1 / 11 (9.09%)	3 / 24 (12.50%)	
occurrences (all)	1	3	
Hordeolum			
subjects affected / exposed	1 / 11 (9.09%)	0 / 24 (0.00%)	
occurrences (all)	1	0	
Implant Site Infection			

subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Infected Bite			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Influenza			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Lung Infection			
subjects affected / exposed	1 / 11 (9.09%)	0 / 24 (0.00%)	
occurrences (all)	1	0	
Nasopharyngitis			
subjects affected / exposed	0 / 11 (0.00%)	2 / 24 (8.33%)	
occurrences (all)	0	2	
Oral Candidiasis			
subjects affected / exposed	1 / 11 (9.09%)	1 / 24 (4.17%)	
occurrences (all)	1	1	
Oral Herpes			
subjects affected / exposed	2 / 11 (18.18%)	2 / 24 (8.33%)	
occurrences (all)	2	2	
Sinusitis			
subjects affected / exposed	0 / 11 (0.00%)	4 / 24 (16.67%)	
occurrences (all)	0	8	
Pharyngitis Streptococcal			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Upper Respiratory Tract Infection			
subjects affected / exposed	2 / 11 (18.18%)	5 / 24 (20.83%)	
occurrences (all)	2	10	
Urinary Tract Infection			
subjects affected / exposed	0 / 11 (0.00%)	2 / 24 (8.33%)	
occurrences (all)	0	4	
Viral Infection			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Metabolism and nutrition disorders			

Decreased Appetite			
subjects affected / exposed	2 / 11 (18.18%)	3 / 24 (12.50%)	
occurrences (all)	3	3	
Hypercalcaemia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	2	
Hypercholesterolaemia			
subjects affected / exposed	1 / 11 (9.09%)	1 / 24 (4.17%)	
occurrences (all)	1	1	
Hypokalaemia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	
Hyponatraemia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The purpose of trial was to provide subjects with an opportunity to continue iniparib treatment after completing parental trials. As such, safety results in this study do not fully reflect safety profile of drug given in monotherapy or in combination

Notes: