ID: APR-407 p53 Suppressor Activation in Recurrent High Grade Serous Ovarian Cancer, a Phase Ib/II Study of Systemic Carboplatin Combination Chemotherapy With or Without APR-246 NCT02098343

View Results Section

Record Summary

Participant Flow

Recruitment Details	
Pre-assignment Details	

Arm/Group Title	Phase Ib. APR-246 + Carboplatin/PLD.	Phase II: Arm A. APR-246 + Carboplatin/PLD.	Phase II: Arm B. Carboplatin/PLD.	Total (Not public)
Arm/Group Description	Dose escalation of APR-246. APR-246: Intravenous infusion. Carboplatin and Pegylated Liposomal Doxorubicin Hydrochloride (PLD): Intravenous infusion.	Experimental APR-246: Intravenous infusion. Carboplatin and Pegylated Liposomal Doxorubicin Hydrochloride (PLD): Intravenous infusion.	Active Comparator Carboplatin and Pegylated Liposomal Doxorubicin Hydrochloride (PLD): Intravenous infusion.	
Period Title: **Overall Study**				
Started	36	105	106	247
Completed	35 [1]	105	106	246
Not Completed	1	0	0	1

[1] 36 patients were enrolled in the Phase Ib study. One patient from the 67.5 mg/kg dose cohort was withdrawn from the study prior to initiating APR-246 treatment due to Investigator's decision

Baseline Characteristics

NOTE : A Study Specific Baseline Measure for an Outcome Measure has not been entered.

Arm/Group Title	Phase Ib. APR-246 +	Phase II: Arm A. APR-246 +	Phase II: Arm B. Carboplatin/PLD.	Total

		Carboplatin/PLD.	Carboplatin/PLD.		
▼ Arm/Group Description		Dose escalation of APR-246. APR-246: Intravenous infusion. Carboplatin and Pegylated Liposomal Doxorubicin Hydrochloride (PLD): Intravenous infusion.	Experimental APR-246: Intravenous infusion. Carboplatin and Pegylated Liposomal Doxorubicin Hydrochloride (PLD): Intravenous infusion.	Active Comparator Carboplatin and Pegylated Liposomal Doxorubicin Hydrochloride (PLD): Intravenous infusion.	
Overall Number of Baseline Participants		36	105	106	**247**
▼ Baseline Analysis Population Description		A total of 36 pts in Ph1b, and 211 patients in Ph2 were enrolled. Eprenetapopt in combination with carboplatin and PLD was generally well tolerated and adverse events were generally transient and reversible. Although a higher CR rate was observed in Arm A (9.5%) vs. Arm B (2.8%), a statistically significant difference in the PFS, OS, ORR, and DOR was not observed across the two arms in the limited number of patients enrolled to the study.			
Age, Categorical [1] Measure Type: Count of Participants Unit of measure: participants					
	Number Analyzed	35 participants	105 participants	106 participants	246 participants
	<=18 years	0 0%	0 0%	0 0%	0 0%
	Between 18 and 65 years	19 54.29%	69 65.71%	57 53.77%	145 58.94%
	>=65 years	16 45.71%	36 34.29%	49 46.23%	101 41.06%
		[1] Measure Analysis Population Description: 36 patients were enrolled in the Phase Ib study. One patient from the 67.5 mg/kg dose cohort was withdrawn from the study prior to initiating APR-246 treatment due to Investigator's decision.			
Age, Continuous Median (Full Range) Unit of measure: years	Number Analyzed	36 participants	105 participants	106 participants	247 participants
		64 (47 to 78)	61 (31 to 80)	64 (37 to 88)	62 (31 to 88)
Sex: Female,	Number	36 participants	105 participants	106 participants	247

Male Measure Type: Count of Participants Unit of measure: participants	Analyzed				participants
	Female	36 100%	105 100%	106 100%	247 100%
	Male	0 0%	0 0%	0 0%	0 0%
Race (NIH/OMB) Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	36 participants	105 participants	106 participants	247 participants
	American Indian or Alaska Native	0 0%	0 0%	0 0%	0 0%
	Asian	3 8.33%	3 2.86%	2 1.89%	8 3.24%
	Native Hawaiian or Other Pacific Islander	0 0%	0 0%	0 0%	0 0%
	Black or African American	0 0%	1 0.95%	1 0.94%	2 0.81%
	White	32 88.89%	88 83.81%	81 76.42%	201 81.38%
	More than one race	0 0%	0 0%	0 0%	0 0%
	Unknown or Not Reported	1 2.78%	13 12.38%	22 20.75%	36 14.57%
Region of Enrollment Measure Type: Number Unit of measure: participants	Number Analyzed	36 participants	105 participants	106 participants	247 participants
Netherlands		0	12	2	14
Sweden		0	1	3	4
Belgium		7	10	10	27
United States		0	17	20	37
United Kingdom		29	33	19	81
France		0	12	20	32
Germany		0	1	10	11
Spain		0	19	22	41

Outcome Measures

1. Primary Outcome

Title:	Phase Ib: Dose-limiting Toxicities (DLT) (See Description) of Combined APR-246 and Carboplatin/PLD Regimen
▼ Description:	DLT: Hematological and non-hematological toxicities according to grade/days stated in the protocol. NOTE : Outcome Measure Description is shorter than the Outcome Measure Title.
Time Frame:	Until the end of the first treatment cycle, i.e., Day 28

▼ Outcome Measure Data

▼ Analysis Population Description

One DLT of Grade 3 large intestine perforation was reported in a patient in the 50mg/kg dose cohort. No DLTs were reported in 35 mg/kg and 67.5 mg/kg dose cohorts.

Arm/Group Title	Phase Ib. APR-246 + Carboplatin/PLD.
▼ Arm/Group Description:	Dose escalation of APR-246. APR-246: Intravenous infusion. Carboplatin and Pegylated Liposomal Doxorubicin Hydrochloride (PLD): Intravenous infusion.
Overall Number of Participants Analyzed	35
Measure Type: Number Unit of Measure: participants	1

2. Primary Outcome

Title:	Phase Ib and II: Progression Free Survival (PFS)
▼ Description:	Phase Ib: Progression-free Survival is calculated from date of enrollment to the date of disease progression or death due to any cause, whichever occurs first. Symptomatic deterioration is not considered PD. For a patient without evidence of disease progression or death, Progression-free survival will be censored at the date of last evaluable tumor assessment. Patients with no evaluable tumor assessments will be censored at the date of first study drug administration. Phase II: Progression-free survival (PFS) based on Blinded Independent Central Review (BICR) is the primary endpoint and is defined as the number of days from the date of randomization to the date of objective disease progression or relapse (according to RECIST v1.1 only) or death due to any cause, whichever occurs first. If neither event occurs, PFS is censored at the date of the last evaluable tumor assessment. Symptomatic deterioration is not considered objective disease progression.
Time Frame:	Up to 24 months

▼ Outcome Measure Data

▼ Analysis Population Description

Ph Ib = Efficacy Evaluable
Ph II = ITT

Arm/Group Title	Phase Ib. APR-246 + Carboplatin/PLD.	Phase II: Arm A. APR-246 + Carboplatin/PLD.	Phase II: Arm B. Carboplatin/PLD.
▼ Arm/Group Description:	Dose escalation of APR-246. APR-246: Intravenous infusion. Carboplatin and Pegylated Liposomal Doxorubicin Hydrochloride (PLD): Intravenous infusion.	Experimental APR-246: Intravenous infusion. Carboplatin and Pegylated Liposomal Doxorubicin Hydrochloride (PLD): Intravenous infusion.	Active Comparator Carboplatin and Pegylated Liposomal Doxorubicin Hydrochloride (PLD): Intravenous infusion.
Overall Number of Participants Analyzed	30	105	106
Median (95% Confidence Interval) Unit of Measure: days	330 (287 to 375)	283 (240 to 314)	295 (259 to 335)

3. Secondary Outcome

Title:	Phase Ib and Phase II: Overall Response Rate (RR)
▼ Description:	Overall Response based on patients with either a Complete Response (CR) or Partial Response (PR).
Time Frame:	Up to 24 months

▼ Outcome Measure Data

▼ Analysis Population Description
Phase Ib = Efficacy Evaluable population
Phase II = ITT population

Arm/Group Title	Phase Ib. APR-246 + Carboplatin/PLD.	Phase II: Arm A. APR-246 + Carboplatin/PLD.	Phase II: Arm B. Carboplatin/PLD.

▼ Arm/Group Description:		Dose escalation of APR-246. APR-246: Intravenous infusion. Carboplatin and Pegylated Liposomal Doxorubicin Hydrochloride (PLD): Intravenous infusion.	Experimental APR-246: Intravenous infusion. Carboplatin and Pegylated Liposomal Doxorubicin Hydrochloride (PLD): Intravenous infusion.	Active Comparator Carboplatin and Pegylated Liposomal Doxorubicin Hydrochloride (PLD): Intravenous infusion.
Overall Number of Participants Analyzed		30	105	106
Measure Type: Count of Participants Unit of Measure: participants				
	Category Title			
	Complete Response (CR)	3 10%	10 9.52%	3 2.83%
	Partial response (PR)	15 50%	42 40%	50 47.17%
	Stable Disease (SD)	9 30%	27 25.71%	37 34.91%
	Progressive Disease (PD)	0 0%	15 14.29%	5 4.72%
	Not Evaluable (NE)	3 10%	11 10.48%	11 10.38%

Adverse Events

Time Frame	TEAEs were defined as events occurring on or after Day 1 Cycle 1 up to and including 30 days after last dose.		
Adverse Event Reporting Description			
Source Vocabulary Name for Table Default	MedDRA (17.1)		
Collection Approach for Table Default	Systematic Assessment		
Arm/Group Title	Phase Ib. APR-246 + Carboplatin/PLD.	Phase II: Arm A. APR-246 + Carboplatin/PLD.	Phase II: Arm B. Carboplatin/PLD.
▼ Arm/Group Description	Dose escalation of APR-246.	Experimental APR-246: Intravenous	Active Comparator Carboplatin and Pegylated

	APR-246: Intravenous infusion. Carboplatin and Pegylated Liposomal Doxorubicin Hydrochloride (PLD): Intravenous infusion.	infusion. Carboplatin and Pegylated Liposomal Doxorubicin Hydrochloride (PLD): Intravenous infusion.	Liposomal Doxorubicin Hydrochloride (PLD): Intravenous infusion.

All-Cause Mortality

	Phase Ib. APR-246 + Carboplatin/PLD.	Phase II: Arm A. APR-246 + Carboplatin/PLD.	Phase II: Arm B. Carboplatin/PLD.
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	17/35 (48.57%)	0/105 (0%)	2/106 (1.89%)

▼ **Serious Adverse Events**

	Phase Ib. APR-246 + Carboplatin/PLD.	Phase II: Arm A. APR-246 + Carboplatin/PLD.	Phase II: Arm B. Carboplatin/PLD.
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	19/35 (54.29%)	31/99 (31.31%)	17/101 (16.83%)
Blood and lymphatic system disorders			
Anaemia † A	0/35 (0%)	2/99 (2.02%)	1/101 (0.99%)
Febrile neutropenia † A	2/35 (5.71%)	0/99 (0%)	1/101 (0.99%)
Leukopenia † A	0/35 (0%)	1/99 (1.01%)	0/101 (0%)
Neutropenia † A	0/35 (0%)	0/99 (0%)	1/101 (0.99%)
Thrombocytopenia † A	2/35 (5.71%)	4/99 (4.04%)	1/101 (0.99%)
Cardiac disorders			
Cardiomyopathy † A	0/35 (0%)	0/99 (0%)	1/101 (0.99%)
Gastrointestinal disorders			
Abdominal pain † A	0/35 (0%)	1/99 (1.01%)	2/101 (1.98%)
Constipation † A	0/35 (0%)	2/99 (2.02%)	0/101 (0%)
Diarrhoea † A	1/35 (2.86%)	1/99 (1.01%)	0/101 (0%)
Faecaloma † A	0/35 (0%)	1/99 (1.01%)	0/101 (0%)
Ileus † A	0/35 (0%)	1/99 (1.01%)	0/101 (0%)
Intestinal obstruction † A	2/35 (5.71%)	1/99 (1.01%)	0/101 (0%)
Large intestinal obstruction † A	0/35 (0%)	1/99 (1.01%)	1/101 (0.99%)
Large intestine	1/35 (2.86%)	0/99 (0%)	2/101 (1.98%)

perforation † A			
Nausea † A	0/35 (0%)	2/99 (2.02%)	2/101 (1.98%)
Small intestinal obstruction † A	2/35 (5.71%)	4/99 (4.04%)	4/101 (3.96%)
Small intestinal perforation † A	0/35 (0%)	1/99 (1.01%)	0/101 (0%)
Stomatitis † A	0/35 (0%)	1/99 (1.01%)	0/101 (0%)
Vomitting † A	6/35 (17.14%)	2/99 (2.02%)	2/101 (1.98%)
General disorders			
Asthenia † A	0/35 (0%)	1/99 (1.01%)	0/101 (0%)
Injection site haemorrhage † A	0/35 (0%)	1/99 (1.01%)	0/101 (0%)
Malaise † A	0/35 (0%)	1/99 (1.01%)	0/101 (0%)
Pyrexia † A	1/35 (2.86%)	1/99 (1.01%)	0/101 (0%)
Hepatobiliary disorders			
Drug-induced liver injury † A	0/35 (0%)	1/99 (1.01%)	0/101 (0%)
Infections and infestations			
Abdominal abscess † A	0/35 (0%)	1/99 (1.01%)	0/101 (0%)
Abdominal infection † A	1/35 (2.86%)	0/99 (0%)	0/101 (0%)
Bronchitis † A	0/35 (0%)	1/99 (1.01%)	0/101 (0%)
Campylobacter infection † A	1/35 (2.86%)	0/99 (0%)	0/101 (0%)
Device related infection † A	6/35 (17.14%)	0/99 (0%)	1/101 (0.99%)
Device related sepsis † A	1/35 (2.86%)	1/99 (1.01%)	0/101 (0%)
Enterocolitis infectious † A	1/35 (2.86%)	0/99 (0%)	0/101 (0%)
Escherichia infection † A	1/35 (2.86%)	0/99 (0%)	0/101 (0%)
Infection † A	2/35 (5.71%)	0/99 (0%)	0/101 (0%)
Infectious pleural effusion † A	0/35 (0%)	1/99 (1.01%)	1/101 (0.99%)
Influenza † A	1/35 (2.86%)	0/99 (0%)	0/101 (0%)
Klebsiella infection † A	0/35 (0%)	1/99 (1.01%)	0/101 (0%)
Lower respiratory tract infection † A	0/35 (0%)	0/99 (0%)	1/101 (0.99%)
Phlebitis infective † A	1/35 (2.86%)	0/99 (0%)	0/101 (0%)
Pneumonia † A	0/35 (0%)	0/99 (0%)	1/101 (0.99%)
Upper respiratory tract infection † A	0/35 (0%)	1/99 (1.01%)	0/101 (0%)

Urinary tract infection † A	0/35 (0%)	1/99 (1.01%)	1/101 (0.99%)
Viral upper respiratory tract infection † A	0/35 (0%)	1/99 (1.01%)	0/101 (0%)
Injury, poisoning and procedural complications			
Lumbar vertebral fracture † A	0/35 (0%)	0/99 (0%)	1/101 (0.99%)
Thoracic vertebral fracture † A	0/35 (0%)	0/99 (0%)	1/101 (0.99%)
Investigations			
Alanine aminotransferase increased † A	0/35 (0%)	1/99 (1.01%)	0/101 (0%)
Aspartate aminotransferase increased † A	0/35 (0%)	1/99 (1.01%)	0/101 (0%)
Metabolism and nutrition disorders			
Decreased appetite † A	0/35 (0%)	0/99 (0%)	1/101 (0.99%)
Dehydration † A	0/35 (0%)	1/99 (1.01%)	1/101 (0.99%)
Hypocalcaemia † A	1/35 (2.86%)	0/99 (0%)	0/101 (0%)
Hypokalaemia † A	1/35 (2.86%)	0/99 (0%)	0/101 (0%)
Hypomagnesaemia † A	0/35 (0%)	1/99 (1.01%)	0/101 (0%)
Nervous system disorders			
Ataxia † A	0/35 (0%)	1/99 (1.01%)	0/101 (0%)
Balance disorder † A	0/35 (0%)	1/99 (1.01%)	0/101 (0%)
Cerebral infarction † A	0/35 (0%)	1/99 (1.01%)	0/101 (0%)
Dizziness † A	1/35 (2.86%)	2/99 (2.02%)	0/101 (0%)
Dysarthria † A	0/35 (0%)	1/99 (1.01%)	0/101 (0%)
Syncope † A	0/35 (0%)	0/99 (0%)	1/101 (0.99%)
Transient ischaemic attack † A	0/35 (0%)	0/99 (0%)	1/101 (0.99%)
Renal and urinary disorders			
Renal impairment † A	0/35 (0%)	3/99 (3.03%)	1/101 (0.99%)
Reproductive system and breast disorders			
Vaginal hemorrhage † A	1/35 (2.86%)	0/99 (0%)	0/101 (0%)
Respiratory, thoracic			

and mediastinal disorders			
Dyspnoea † A	0/35 (0%)	4/99 (4.04%)	0/101 (0%)
Pleural effusion † A	0/35 (0%)	1/99 (1.01%)	0/101 (0%)
Pulmonary embolism † A	0/35 (0%)	1/99 (1.01%)	0/101 (0%)
Vascular disorders			
Peripheral artery stenosis † A	0/35 (0%)	1/99 (1.01%)	0/101 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (17.1)

▼ Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	5%		
	Phase Ib. APR-246 + Carboplatin/PLD.	**Phase II: Arm A. APR-246 + Carboplatin/PLD.**	**Phase II: Arm B. Carboplatin/PLD.**
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	35/35 (100%)	99/99 (100%)	101/101 (100%)
Blood and lymphatic system disorders			
Anemia † A	12/35 (34.29%)	31/99 (31.31%)	30/101 (29.7%)
Febrile neutropenia † A	3/35 (8.57%)	1/99 (1.01%)	1/101 (0.99%)
Leukopenia † A	4/35 (11.43%)	6/99 (6.06%)	5/101 (4.95%)
Neutropenia † A	28/35 (80%)	56/99 (56.57%)	39/101 (38.61%)
Thrombocytopenia † A	11/35 (31.43%)	23/99 (23.23%)	14/101 (13.86%)
Ear and labyrinth disorders			
Vertigo † A	1/35 (2.86%)	8/99 (8.08%)	2/101 (1.98%)
Eye disorders			
Photophobia † A	2/35 (5.71%)	0/99 (0%)	0/101 (0%)
Gastrointestinal disorders			
Abdominal distension † A	1/35 (2.86%)	4/99 (4.04%)	5/101 (4.95%)
Abdominal pain † A	10/35 (28.57%)	16/99 (16.16%)	16/101 (15.84%)
Abdominal pain lower † A	4/35 (11.43%)	3/99 (3.03%)	3/101 (2.97%)
Abdominal pain upper † A	3/35 (8.57%)	5/99 (5.05%)	6/101 (5.94%)
Cheilitis † A	2/35 (5.71%)	0/99 (0%)	0/101 (0%)

Constipation †A	16/35 (45.71%)	36/99 (36.36%)	33/101 (32.67%)
Diarrhea †A	17/35 (48.57%)	12/99 (12.12%)	16/101 (15.84%)
Dyspepsia †A	4/35 (11.43%)	8/99 (8.08%)	6/101 (5.94%)
Gastrooesophageal reflux disease †A	0/35 (0%)	7/99 (7.07%)	1/101 (0.99%)
Mouth ulceration †A	1/35 (2.86%)	5/99 (5.05%)	5/101 (4.95%)
Nausea †A	27/35 (77.14%)	67/99 (67.68%)	57/101 (56.44%)
Small intestinal obstruction †A	2/35 (5.71%)	4/99 (4.04%)	4/101 (3.96%)
Stomatitis †A	4/35 (11.43%)	12/99 (12.12%)	11/101 (10.89%)
Vomitting †A	22/35 (62.86%)	42/99 (42.42%)	23/101 (22.77%)
General disorders			
Asthenia †A	0/35 (0%)	19/99 (19.19%)	22/101 (21.78%)
Chills †A	3/35 (8.57%)	3/99 (3.03%)	2/101 (1.98%)
Device occlusion †A	6/35 (17.14%)	1/99 (1.01%)	0/101 (0%)
Fatigue †A	29/35 (82.86%)	47/99 (47.47%)	38/101 (37.62%)
Infusion site erythema †A	2/35 (5.71%)	2/99 (2.02%)	1/101 (0.99%)
Malaise †A	1/35 (2.86%)	5/99 (5.05%)	2/101 (1.98%)
Mucosal inflammation †A	10/35 (28.57%)	20/99 (20.2%)	22/101 (21.78%)
Oedema peripheral †A	2/35 (5.71%)	7/99 (7.07%)	3/101 (2.97%)
Pyrexia †A	7/35 (20%)	13/99 (13.13%)	10/101 (9.9%)
Infections and infestations			
Device related infection †A	6/35 (17.14%)	0/99 (0%)	3/101 (2.97%)
Infection †A	2/35 (5.71%)	0/99 (0%)	1/101 (0.99%)
Infusion site infection †A	2/35 (5.71%)	0/99 (0%)	0/101 (0%)
Lip infection †A	3/35 (8.57%)	0/99 (0%)	0/101 (0%)
Mucosal infection †A	2/35 (5.71%)	0/99 (0%)	0/101 (0%)
Nasopharyngitis †A	0/35 (0%)	6/99 (6.06%)	4/101 (3.96%)
Oral candidiasis †A	2/35 (5.71%)	2/99 (2.02%)	2/101 (1.98%)
Oral herpes †A	3/35 (8.57%)	2/99 (2.02%)	1/101 (0.99%)
Upper respiratory tract infection †A	2/35 (5.71%)	5/99 (5.05%)	3/101 (2.97%)
Urinary tract infection †A	5/35 (14.29%)	10/99 (10.1%)	18/101 (17.82%)
Injury, poisoning and procedural complications			

Infusion related reaction † A	2/35 (5.71%)	2/99 (2.02%)	4/101 (3.96%)
Procedural pain † A	3/35 (8.57%)	0/99 (0%)	0/101 (0%)
Investigations			
Neutrophil count decreased † A	1/35 (2.86%)	12/99 (12.12%)	11/101 (10.89%)
Platelet count decreased † A	0/35 (0%)	11/99 (11.11%)	5/101 (4.95%)
Weight decreased † A	3/35 (8.57%)	2/99 (2.02%)	3/101 (2.97%)
White blood cell count decreased † A	1/35 (2.86%)	7/99 (7.07%)	5/101 (4.95%)
Metabolism and nutrition disorders			
Decreased appetite † A	14/35 (40%)	19/99 (19.19%)	18/101 (17.82%)
Hypoalbuminaemia † A	2/35 (5.71%)	2/99 (2.02%)	3/101 (2.97%)
Hypokalaemia † A	2/35 (5.71%)	5/99 (5.05%)	7/101 (6.93%)
Hypomagnesaemia † A	5/35 (14.29%)	12/99 (12.12%)	11/101 (10.89%)
Musculoskeletal and connective tissue disorders			
Arthralgia † A	7/35 (20%)	10/99 (10.1%)	5/101 (4.95%)
Back pain † A	9/35 (25.71%)	13/99 (13.13%)	7/101 (6.93%)
Muscle spasms † A	5/35 (14.29%)	2/99 (2.02%)	2/101 (1.98%)
Muscular weakness † A	7/35 (20%)	1/99 (1.01%)	1/101 (0.99%)
Musculoskeletal chest pain † A	3/35 (8.57%)	0/99 (0%)	0/101 (0%)
Myalgia † A	1/35 (2.86%)	9/99 (9.09%)	2/101 (1.98%)
Pain in extremity † A	1/35 (2.86%)	7/99 (7.07%)	1/101 (0.99%)
Nervous system disorders			
Ataxia † A	0/35 (0%)	5/99 (5.05%)	0/101 (0%)
Balance disorder † A	0/35 (0%)	8/99 (8.08%)	0/101 (0%)
Dizziness † A	24/35 (68.57%)	42/99 (42.42%)	5/101 (4.95%)
Dysarthria † A	0/35 (0%)	5/99 (5.05%)	0/101 (0%)
Dysgeusia † A	12/35 (34.29%)	3/99 (3.03%)	6/101 (5.94%)
Dyskinesia † A	3/35 (8.57%)	3/99 (3.03%)	0/101 (0%)
Headache † A	16/35 (45.71%)	16/99 (16.16%)	11/101 (10.89%)
Hyperaesthesia † A	2/35 (5.71%)	1/99 (1.01%)	0/101 (0%)
Neuropathy	4/35 (11.43%)	11/99 (11.11%)	6/101 (5.94%)

peripheral †A			
Paraesthesia †A	0/35 (0%)	8/99 (8.08%)	2/101 (1.98%)
Peripheral sensory neuropathy †A	1/35 (2.86%)	6/99 (6.06%)	3/101 (2.97%)
Somnolence †A	2/35 (5.71%)	3/99 (3.03%)	0/101 (0%)
Tremor †A	5/35 (14.29%)	8/99 (8.08%)	0/101 (0%)
Psychiatric disorders			
Anxiety †A	2/35 (5.71%)	4/99 (4.04%)	1/101 (0.99%)
Depressed mood †A	2/35 (5.71%)	3/99 (3.03%)	3/101 (2.97%)
Insomnia †A	3/35 (8.57%)	2/99 (2.02%)	10/101 (9.9%)
Renal and urinary disorders			
Pollakiuria †A	2/35 (5.71%)	2/99 (2.02%)	3/101 (2.97%)
Reproductive system and breast disorders			
Vaginal haemorrhage †A	2/35 (5.71%)	1/99 (1.01%)	0/101 (0%)
Respiratory, thoracic and mediastinal disorders			
Cough †A	5/35 (14.29%)	15/99 (15.15%)	6/101 (5.94%)
Dyspnoea †A	3/35 (8.57%)	16/99 (16.16%)	4/101 (3.96%)
Epistaxis †A	0/35 (0%)	5/99 (5.05%)	3/101 (2.97%)
Oropharyngeal pain †A	4/35 (11.43%)	2/99 (2.02%)	0/101 (0%)
Pulmonary embolism †A	3/35 (8.57%)	2/99 (2.02%)	4/101 (3.96%)
Rhinorrhoea †A	3/35 (8.57%)	0/99 (0%)	0/101 (0%)
Skin and subcutaneous tissue disorders			
Alopecia †A	5/35 (14.29%)	6/99 (6.06%)	6/101 (5.94%)
Dry skin †A	1/35 (2.86%)	3/99 (3.03%)	7/101 (6.93%)
Erythema †A	3/35 (8.57%)	1/99 (1.01%)	0/101 (0%)
Palmar-plantar erythrodysaesthesia syndrome †A	5/35 (14.29%)	11/99 (11.11%)	18/101 (17.82%)
Pruritus †A	2/35 (5.71%)	0/99 (0%)	3/101 (2.97%)
Rash †A	6/35 (17.14%)	10/99 (10.1%)	12/101 (11.88%)
Rash maculo-papular †A	3/35 (8.57%)	2/99 (2.02%)	1/101 (0.99%)
Vascular disorders			
Flushing †A	2/35 (5.71%)	5/99 (5.05%)	2/101 (1.98%)
Palpitations †A	3/35 (8.57%)	4/99 (4.04%)	0/101 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (17.1)

Limitations and Caveats

[Not Specified]

More Information

Certain Agreements

Principal Investigators are NOT employed by the organization sponsoring the study.

There is NOT an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact

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Record Summary