



## Clinical trial results:

### Phase II study with pazopanib and weekly paclitaxel in metastatic or locally advanced squamous penile carcinoma patients previously treated with cisplatin based chemotherapy

#### Summary

EudraCT number	2014-003127-22
Trial protocol	ES
Global end of trial date	30 September 2016

#### Results information

Result version number	v1 (current)
This version publication date	15 October 2021
First version publication date	15 October 2021

#### Trial information

##### Trial identification

Sponsor protocol code	SOG-CPE-2014-03
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02279576
WHO universal trial number (UTN)	-

Notes:

#### Sponsors

Sponsor organisation name	SOGUG (Spanish Oncology Genitourinary Group)
Sponsor organisation address	Calle Velázquez, 7, planta 3, Madrid, Spain, 28001
Public contact	Clinical Operations Department, APICES SOLUCIONES, S.L., +34 91 816 68 04 Ext 103, juanluis.sanz@apices.es
Scientific contact	Clinical Operations Department, APICES SOLUCIONES, S.L., +34 91 816 68 04 Ext 103, juanluis.sanz@apices.es

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:

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**Results analysis stage**

Analysis stage	Final
Date of interim/final analysis	30 September 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 September 2016
Global end of trial reached?	Yes
Global end of trial date	30 September 2016
Was the trial ended prematurely?	Yes

Notes:

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**General information about the trial**

Main objective of the trial:

Evaluate response rate in terms of complete and partial response (RECIST criteria version 1.1)

Protection of trial subjects:

Not applicable.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 January 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

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**Population of trial subjects**

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**Subjects enrolled per country**

Country: Number of subjects enrolled	Spain: 4
Worldwide total number of subjects	4
EEA total number of subjects	4

Notes:

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**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)	1
From 65 to 84 years	3
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

Patients were recruited in the study from 13th March 2015 until 09th November.

### Pre-assignment

Screening details:

Patients included in the study had confirmed histological diagnosis of penile squamous cell carcinoma, disease progression of carbo/cis-based CT, ECOG PS of 0-1 and adequate organ function.

### Pre-assignment period milestones

Number of subjects started	4
Number of subjects completed	4

### Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

Not applicable

### Arms

Arm title	Experimental
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Arm description:

Patients who participated in the study received pazopanib 800mg/day orally and paclitaxel 65 mg/m<sup>2</sup> IV every week administered 3 consecutive weeks in 28-day cycles until disease progression, investigator criteria or withdrawn consent.

Arm type	Experimental
Investigational medicinal product name	Pazopanib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Pazopanib 800 mg/day

Investigational medicinal product name	Paclitaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Paclitaxel 65 mg/m<sup>2</sup>, days 1, 8 and 15 in 28 days-cycle.

<b>Number of subjects in period 1</b>	Experimental
Started	4
Completed	0
Not completed	4
Disease progression	2
Adverse event/Disease not related	1
Exitus	1

## Baseline characteristics

### Reporting groups

Reporting group title	Overall trial
Reporting group description: -	

Reporting group values	Overall trial	Total	
Number of subjects	4	4	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	1	1	
From 65-84 years	3	3	
85 years and over	0	0	
Adults	0	0	
Age continuous			
Units: years			
median	67.8		
full range (min-max)	60.4 to 73.8	-	
Gender categorical			
Units: Subjects			
Female	0	0	
Male	4	4	
ECOG-PS			
Units: Subjects			
0)	2	2	
1)	2	2	
Histological diagnosis			
Units: Subjects			
Epidermoid carcinoma	3	3	
Moderately differentiated squamous cell carcinoma	1	1	
Histological grade			
Units: Subjects			
G1	1	1	
G2	1	1	
G4	1	1	
Unknown	1	1	
TNM at diagnosis: T			
Units: Subjects			
T2	3	3	
Not available	1	1	
TNM at diagnosis: N			

Units: Subjects			
N0	2	2	
N1	2	2	
TNM at diagnosis: M			
Units: Subjects			
M0	4	4	
Current TNM: T			
Units: Subjects			
T1	0	0	
T2	4	4	
T3	0	0	
T4	0	0	
Current TNM: N			
Units: Subjects			
N0	0	0	
N1	4	4	
Current TNM: M			
Units: Subjects			
M0	0	0	
M1	4	4	
Previous treatments: Surgery			
Units: Subjects			
Glandectomy	1	1	
Lymphadenectomy	1	1	
Bilateral inguinal lymphadenectomy and partial pen	1	1	
Partial penectomy	1	1	
Previous treatments: Radiotherapy			
Units: Subjects			
Yes	1	1	
No	3	3	
Previous treatments: Chemotherapy			
Units: Subjects			
5-FU + Cisplatin	3	3	
Cisplatin + Gemcitabine	1	1	
Tumor location: Lungs			
Units: Subjects			
Yes	4	4	
No	0	0	
Tumor location: Lymphatic system			
Units: Subjects			
Yes	3	3	
No	1	1	
Tumor location: Skin and soft tissues			
Units: Subjects			
Yes	2	2	
No	2	2	
Tumor location: Bone			
Units: Subjects			
Yes	2	2	
No	2	2	

Tumor location: Liver Units: Subjects			
Yes	1	1	
No	3	3	
Number of locations per patient Units: Subjects			
2)	1	1	
3)	2	2	
4)	1	1	
Number of lesions per patient Units: Subjects			
3)	1	1	
4)	1	1	
6)	1	1	
10)	1	1	
Number of cycles administered Units: Subjects			
2)	2	2	
3)	1	1	
11)	1	1	
Height Units: cm			
median	166.5		
full range (min-max)	160.0 to 172.0	-	
Weight Units: Kg			
median	88.8		
full range (min-max)	72.0 to 115.0	-	
Time since initial diagnosis Units: Months			
median	38.4		
full range (min-max)	6.3 to 119.4	-	
Relative dose intensity of pazopanib Units: Percentage			
median	96		
full range (min-max)	58 to 100	-	
Relative dose intensity of paclitaxel Units: Percentage			
median	66		
full range (min-max)	57 to 97	-	

## End points

### End points reporting groups

Reporting group title	Experimental
Reporting group description: Patients who participated in the study received pazopanib 800mg/day orally and paclitaxel 65 mg/m2 IV every week administered 3 consecutive weeks in 28-day cycles until disease progression, investigator criteria or withdrawn consent.	

### Primary: Objective Response Rate

End point title	Objective Response Rate <sup>[1]</sup>
End point description: Objective response has been calculated taking into account patients which has been response to treatment. 1 patient had a partial response to treatment.	
End point type	Primary
End point timeframe: Every 8 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: Phase II non-comparative study

End point values	Experimental			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: % of subjects				
number (confidence interval 95%)				
Partial response	25 (0.0 to 67.4)			

### Statistical analyses

No statistical analyses for this end point

### Secondary: Clinical benefit rate

End point title	Clinical benefit rate
End point description: Clinical benefit has been calculated taking into account patient which has been response to treatment and stable disease. 1 patient had partial response, 2 disease progression and 1 was not evaluable. Thus, objective response rate and clinical benefit match.	
End point type	Secondary
End point timeframe: Every 8 weeks	



<b>End point values</b>	Experimental			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: % of subjects				
number (confidence interval 95%)				
Yes (partial response + stable disease)	25 (0.0 to 67.4)			

### Statistical analyses

No statistical analyses for this end point

### Secondary: Response duration

End point title	Response duration
End point description: Response duration has been calculated according the only patient that has been partial response to treatment.	
End point type	Secondary
End point timeframe: Every 8 weeweeks	

<b>End point values</b>	Experimental			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Months	8			

### Statistical analyses

No statistical analyses for this end point

### Secondary: Progression free survival

End point title	Progression free survival
End point description:	
End point type	Secondary
End point timeframe: Every 8 weeks	

<b>End point values</b>	Experimental			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: Months				
median (confidence interval 95%)	1.7 (0.0 to 8.5)			

### Statistical analyses

No statistical analyses for this end point

### Secondary: Overall survival

End point title	Overall survival
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End point description:

End point type	Secondary
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End point timeframe:

Every 8 weeks

<b>End point values</b>	Experimental			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: Months				
median (confidence interval 95%)	2.6 (1.6 to 3.5)			

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Every 4 weeks

Adverse event reporting additional description:

NCI-CTC-AE 4.03 criteria

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	17
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### Reporting groups

Reporting group title	Pazopanib + Paclitaxel
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Reporting group description:

All patients

Serious adverse events	Pazopanib + Paclitaxel		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 4 (75.00%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		
Investigations			
Alanine aminotransferase increased	Additional description: Alanine aminotransferase increased related with pazopanib and paclitaxel		
subjects affected / exposed	1 / 4 (25.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Spinal cord compression			
subjects affected / exposed	1 / 4 (25.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 4 (25.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			

General physical health deterioration subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 4 (25.00%) 0 / 1 0 / 0		
Renal and urinary disorders Renal failure subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 4 (25.00%) 0 / 1 0 / 0		
Infections and infestations Wound infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 4 (25.00%) 0 / 1 0 / 0		
Pneumonia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 4 (25.00%) 0 / 1 0 / 1		
Metabolism and nutrition disorders Hypercalcaemia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 4 (25.00%) 0 / 1 0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

<b>Non-serious adverse events</b>	Pazopanib + Paclitaxel		
Total subjects affected by non-serious adverse events subjects affected / exposed	4 / 4 (100.00%)		
Vascular disorders Hypertension subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1		
Blood and lymphatic system disorders			

Neutropenia subjects affected / exposed occurrences (all)	Additional description: 2 Neutropenia Grade 2		
	2 / 4 (50.00%) 2		
General disorders and administration site conditions Asthenia subjects affected / exposed occurrences (all)	Additional description: 1 Asthenia grade 1, 1 grade 2 and 1 grade 3		
	3 / 4 (75.00%) 3		
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)  Nausea subjects affected / exposed occurrences (all)	Additional description: 2 Diarrhoea Grade 1		
	2 / 4 (50.00%) 2		
	Additional description: 1 Nausea Grade 1 and 1 Grade 2.		
	2 / 4 (50.00%) 2		
Skin and subcutaneous tissue disorders Alopecia subjects affected / exposed occurrences (all)	Additional description: Alopecia Grade 1		
	1 / 4 (25.00%) 1		
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)  Hypertriglyceridaemia subjects affected / exposed occurrences (all)	Additional description: 1 Decreased appetite grade 1 and 1 Grade 2		
	2 / 4 (50.00%) 2		
	Additional description: Hypertriglyceridaemia Grade 3		
	1 / 4 (25.00%) 1		

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### 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.

Only 4 patients were included. Recruitment was not completed as expected.
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Notes: