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Trial record **1 of 1** for: CR016909

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A Safety and Efficacy Study of Abiraterone Acetate in Participants With Prostate Cancer Who Have Failed Hormone Therapy

This study has been completed.

Sponsor:
Cougar Biotechnology, Inc.

Information provided by (Responsible Party):
Cougar Biotechnology, Inc.

ClinicalTrials.gov Identifier:
NCT00473512

First received: May 11, 2007
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History of Changes

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Results First Received: June 7, 2013

Study Type:	Interventional
Study Design:	Endpoint Classification: Safety/Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Prostatic Neoplasms
Interventions:	Drug: Abiraterone acetate Drug: Abiraterone acetate MTD Drug: Dexamethasone

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
250 mg/Day	Abiraterone acetate 250 milligram (mg) capsule administered orally daily for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study. Participants received MTD (1000 mg) of abiraterone acetate for 12 cycles (28 day each) in Phase 2 of the study. Dexamethasone 0.5 mg administered orally (if participants have disease progression) daily up to 12 cycles.
500 mg/Day	Abiraterone acetate 500 mg capsules (2 x 250 mg capsules) administered orally daily for 28-day treatment period to determine the MTD in Phase 1 of the study. Participants received MTD of abiraterone acetate for 12 cycles (28 day each) in Phase 2 of the study. Dexamethasone 0.5 mg administered orally (if participants have disease progression) daily up to 12 cycles.

750 mg/Day	Abiraterone acetate 750 mg capsules (3 x 250 mg capsules) administered orally daily for 28-day treatment period to determine the MTD in Phase 1 of the study. Participants received MTD of abiraterone acetate for 12 cycles (28 day each) in Phase 2 of the study. Dexamethasone 0.5 mg administered orally (if participants have disease progression) daily up to 12 cycles.
1000 mg/Day	Abiraterone acetate 1000 mg capsules (4 x 250 mg capsules) administered orally daily for 28-day treatment period to determine the MTD in Phase 1 of the study. Participants received MTD of abiraterone acetate for 12 cycles (28 day each) in Phase 2 of the study. Dexamethasone 0.5 mg administered orally (if participants have disease progression) daily up to 12 cycles.
2000 mg/Day	Abiraterone acetate 2000 mg capsules (8 x 250 mg capsules) administered orally daily for 28-day treatment period to determine the MTD in Phase 1 of the study. Participants received MTD of abiraterone acetate for 12 cycles (28 day each) in Phase 2 of the study. Dexamethasone 0.5 mg administered orally (if participants have disease progression) daily up to 12 cycles.

Participant Flow for 2 periods

Period 1: Period 1 (Phase 1)

	250 mg/Day	500 mg/Day	750 mg/Day	1000 mg/Day	2000 mg/Day
STARTED	3	3	3	42	3
COMPLETED	2	2	3	25	2
NOT COMPLETED	1	1	0	17	1
Adverse Event	0	0	0	5	0
Death	0	0	0	1	0
Disease Progression	1	1	0	10	1
Unspecified	0	0	0	1	0

Period 2: Period 2 (Phase 2)

	250 mg/Day	500 mg/Day	750 mg/Day	1000 mg/Day	2000 mg/Day
STARTED	1 [1]	2	2 [1]	23 [2]	2
COMPLETED	0	0	0	0	0
NOT COMPLETED	1	2	2	23	2
Adverse Event	0	0	0	1	0
Death	0	0	0	1	1
Disease Progression	0	2	2	17	1
Symptomatic Deterioration	0	0	0	1	0
Unspecified	1	0	0	3	0

[1] 1 participant did not continue to Phase 2 of the study.
[2] 2 participants did not continue to Phase 2 of the study.

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description

250 mg/Day	Abiraterone acetate 250 mg capsule administered orally daily for 28-day treatment period to determine the MTD in Phase 1 of the study. Participants received MTD of abiraterone acetate for 12 cycles (28 day each) in Phase 2 of the study. Dexamethasone 0.5 mg administered orally (if participants have disease progression) daily up to 12 cycles.
500 mg/Day	Abiraterone acetate 500 mg capsules (2 x 250 mg capsules) administered orally daily for 28-day treatment period to determine the MTD in Phase 1 of the study. Participants received MTD of abiraterone acetate for 12 cycles (28 day each) in Phase 2 of the study. Dexamethasone 0.5 mg administered orally (if participants have disease progression) daily up to 12 cycles.
750 mg/Day	Abiraterone acetate 750 mg capsules (3 x 250 mg capsules) administered orally daily for 28-day treatment period to determine the MTD in Phase 1 of the study. Participants received MTD of abiraterone acetate for 12 cycles (28 day each) in Phase 2 of the study. Dexamethasone 0.5 mg administered orally (if participants have disease progression) daily up to 12 cycles.
1000 mg/Day	Abiraterone acetate 1000 mg capsules (4 x 250 mg capsules) administered orally daily for 28-day treatment period to determine the MTD in Phase 1 of the study. Participants received MTD of abiraterone acetate for 12 cycles (28 day each) in Phase 2 of the study. Dexamethasone 0.5 mg administered orally (if participants have disease progression) daily up to 12 cycles.
2000 mg/Day	Abiraterone acetate 2000 mg capsules (8 x 250 mg capsules) administered orally daily for 28-day treatment period to determine the MTD in Phase 1 of the study. Participants received MTD of abiraterone acetate for 12 cycles (28 day each) in Phase 2 of the study. Dexamethasone 0.5 mg administered orally (if participants have disease progression) daily up to 12 cycles.
Total	Total of all reporting groups

Baseline Measures

	250 mg/Day	500 mg/Day	750 mg/Day	1000 mg/Day	2000 mg/Day	Total
Number of Participants [units: participants]	**3**	**3**	**3**	**42**	**3**	**54**
Age [units: years] Mean (Standard Deviation)	**61.3 (9.07)**	**68.7 (10.41)**	**76 (8.19)**	**70.4 (7.42)**	**68 (12.17)**	**69.9 (8.04)**
Gender [units: participants]						
Female	**0**	**0**	**0**	**0**	**0**	**0**
Male	**3**	**3**	**3**	**42**	**3**	**54**

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants With Confirmed Prostate Specific Antigen (PSA) Response at Week 12 [Time Frame: Baseline, Week 12]

Measure Type	Primary
Measure Title	Number of Participants With Confirmed Prostate Specific Antigen (PSA) Response at Week 12
Measure Description	The PSA response was measured according to PSA working group (PSAWG) criteria. All participants achieving a fall in PSA of greater than 50 percent from baseline, which has been confirmed by a second measurement at least 4 weeks after initial documentation, fulfill criteria for confirmed PSA response.
Time Frame	Baseline, Week 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who were enrolled in the study and received 1000 milligram abiraterone acetate therapy with or without dexamethasone (including participants who received 1000 mg AA monotherapy). Here 'N' (number of participants analyzed) signifies those participants

evaluable for this measure.

Reporting Groups

	Description
1000 mg AA Monotherapy	Participants received 1000 milligram (mg) abiraterone acetate (AA) without dexamethasone.
1000 mg AA Therapy	Participants received 1000 mg abiraterone acetate with or without dexamethasone.

Measured Values

	1000 mg AA Monotherapy	1000 mg AA Therapy
Number of Participants Analyzed [units: participants]	**11**	**29**
Number of Participants With Confirmed Prostate Specific Antigen (PSA) Response at Week 12 [units: Participants]	**10**	**25**

No statistical analysis provided for Number of Participants With Confirmed Prostate Specific Antigen (PSA) Response at Week 12

2. Secondary: Number of Participants With Objective Tumor Response [Time Frame: Baseline up to end of study (1160 days)]

Measure Type	Secondary
Measure Title	Number of Participants With Objective Tumor Response
Measure Description	Number of participants with objective response based on assessment of confirmed complete response (CR) or confirmed partial response (PR) according to Response Evaluation Criteria in Solid Tumors (RECIST). Confirmed CR defined as disappearance of all target lesions. Confirmed PR defined as greater than or equal to 30 percent decrease in sum of the longest dimensions (LD) of the target lesions taking as a reference the baseline sum LD according to RECIST. Confirmed responses are those that persist on repeat imaging study greater than or equal to 4 weeks after initial documentation of response.
Time Frame	Baseline up to end of study (1160 days)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who were enrolled in the study and received 1000 milligram abiraterone acetate therapy with or without dexamethasone (including participants who received 1000 mg AA monotherapy). Here 'N' (number of participants analyzed) signifies those participants evaluable for this measure.

Reporting Groups

	Description
1000 mg AA Therapy	Participants received 1000 mg abiraterone acetate with or without dexamethasone.

Measured Values

	1000 mg AA Therapy
Number of Participants Analyzed [units: participants]	**38**
Number of Participants With Objective Tumor Response [units: Participants]	
Complete response	**0**

Partial response	**8**

No statistical analysis provided for Number of Participants With Objective Tumor Response

3. Secondary: Duration of Prostate Specific Antigen (PSA) Response [Time Frame: Baseline up to end of study (1160 days)]

Measure Type	Secondary
Measure Title	Duration of Prostate Specific Antigen (PSA) Response
Measure Description	Duration of PSA response in participants on abiraterone acetate therapy was measured as the duration between PSA 50 percent decline date and PSA progression date as defined by the PSAWG criteria.
Time Frame	Baseline up to end of study (1160 days)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who were enrolled in the study and received 1000 milligram abiraterone acetate therapy with or without dexamethasone (including participants who received 1000 mg AA monotherapy). Here 'N' (number of participants analyzed) signifies those participants evaluable for this measure.

Reporting Groups

	Description
1000 mg AA Therapy	Participants received 1000 mg abiraterone acetate with or without dexamethasone.

Measured Values

	1000 mg AA Therapy
Number of Participants Analyzed [units: participants]	**27**
Duration of Prostate Specific Antigen (PSA) Response [units: Days] Median (Full Range)	**141 (85 to 235)**

No statistical analysis provided for Duration of Prostate Specific Antigen (PSA) Response

4. Secondary: Duration of Objective Tumor Response by Response Evaluation Criteria in Solid Tumors (RECIST) [Time Frame: Baseline up to end of study (1160 days)]

Measure Type	Secondary
Measure Title	Duration of Objective Tumor Response by Response Evaluation Criteria in Solid Tumors (RECIST)
Measure Description	Number of participants with objective response based on assessment of confirmed CR or confirmed PR according to RECIST. Confirmed CR defined as disappearance of all target lesions. Confirmed PR defined as greater than or equal to 30 percent decrease in sum of the LD of the target lesions taking as a reference the baseline sum LD according to RECIST. Confirmed responses are those that persist on repeat imaging study greater than or equal to 4 weeks after initial documentation of response.
Time Frame	Baseline up to end of study (1160 days)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Duration of response was not analyzed as majority of participants with objective tumor response were lost to follow-up.

Reporting Groups

	Description
1000 mg AA Therapy	Participants received 1000 mg abiraterone acetate with or without dexamethasone.

Measured Values

	1000 mg AA Therapy
Number of Participants Analyzed [units: participants]	**0**
Duration of Objective Tumor Response by Response Evaluation Criteria in Solid Tumors (RECIST)	

No statistical analysis provided for Duration of Objective Tumor Response by Response Evaluation Criteria in Solid Tumors (RECIST)

5. Secondary: Time to Disease Progression [Time Frame: Baseline up to end of study (1160 days)]

Measure Type	Secondary
Measure Title	Time to Disease Progression
Measure Description	Disease progression was defined as greater than 25 percent increase in sum of longest diameter of target lesions compared to baseline.
Time Frame	Baseline up to end of study (1160 days)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Data was not analyzed because at the time to progression, participants also received dexamethasone treatment, making it impractical to accurately define disease progression.

Reporting Groups

	Description
1000 mg AA Therapy	Participants received 1000 mg abiraterone acetate with or without dexamethasone.

Measured Values

	1000 mg AA Therapy
Number of Participants Analyzed [units: participants]	**0**
Time to Disease Progression	

No statistical analysis provided for Time to Disease Progression

6. Secondary: Overall Survival [Time Frame: Baseline up to end of study (1160 days)]

Measure Type	Secondary
Measure Title	Overall Survival

Measure Description	Overall survival was the duration from enrollment to death. For participants who are alive, overall survival was censored at the last contact.
Time Frame	Baseline up to end of study (1160 days)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Data was not analyzed due to high number of participants censored for survival.

Reporting Groups

	Description
1000 mg AA Therapy	Participants received 1000 mg abiraterone acetate with or without dexamethasone.

Measured Values

	1000 mg AA Therapy
Number of Participants Analyzed [units: participants]	**0**
Overall Survival	

No statistical analysis provided for Overall Survival

7. Other Pre-specified: Serum Blood Levels of Testosterone [Time Frame: Baseline, Cycle 2 (within 3 days prior to Day 29)]

Measure Type	Other Pre-specified
Measure Title	Serum Blood Levels of Testosterone
Measure Description	Concentration of testosterone in blood was measured in nanogram per deciliter (ng/dL).
Time Frame	Baseline, Cycle 2 (within 3 days prior to Day 29)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who were enrolled in the study and received 1000 mg abiraterone acetate therapy with or without dexamethasone (including participants who received 1000 mg AA monotherapy). Here 'N' (number of participants analyzed) signifies participants evaluable for this measure and 'n' signifies participants evaluable at specified time point.

Reporting Groups

	Description
1000 mg AA Therapy	Participants received 1000 mg abiraterone acetate with or without dexamethasone.

Measured Values

	1000 mg AA Therapy
Number of Participants Analyzed [units: participants]	**28**
Serum Blood Levels of Testosterone [units: ng/dL] Median (Full Range)	

Baseline (n = 23)	**3 (1 to 10)**
Cycle 2 (n = 28)	**1 (1 to 186)**

No statistical analysis provided for Serum Blood Levels of Testosterone

8. Other Pre-specified: Number of Participants With Treatment-Emergent Adverse Events (AEs) or Serious Adverse Events (SAEs) [Time Frame: Baseline up to 30 days after the last dose of study medication]

Measure Type	Other Pre-specified
Measure Title	Number of Participants With Treatment-Emergent Adverse Events (AEs) or Serious Adverse Events (SAEs)
Measure Description	An AE was any untoward medical occurrence in a participant who received study drug without regard to possibility of causal relationship. An SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. Treatment-emergent are events between first dose of study drug and up to 28 days after last dose that were absent before treatment or that worsened relative to pretreatment state.
Time Frame	Baseline up to 30 days after the last dose of study medication
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Included all participants who received any amount of the study medication.

Reporting Groups

	Description
250 mg/Day	Abiraterone acetate 250 mg capsule administered orally daily for 28-day treatment period to determine the MTD in Phase 1 of the study. Participants received MTD of abiraterone acetate for 12 cycles (28 day each) in Phase 2 of the study. Dexamethasone 0.5 mg administered orally (if participants have disease progression) daily up to 12 cycles.
500 mg/Day	Abiraterone acetate 500 mg capsules (2 x 250 mg capsules) administered orally daily for 28-day treatment period to determine the MTD in Phase 1 of the study. Participants received MTD of abiraterone acetate for 12 cycles (28 day each) in Phase 2 of the study. Dexamethasone 0.5 mg administered orally (if participants have disease progression) daily up to 12 cycles.
750 mg/Day	Abiraterone acetate 750 mg capsules (3 x 250 mg capsules) administered orally daily for 28-day treatment period to determine the MTD in Phase 1 of the study. Participants received MTD of abiraterone acetate for 12 cycles (28 day each) in Phase 2 of the study. Dexamethasone 0.5 mg administered orally (if participants have disease progression) daily up to 12 cycles.
1000 mg/Day	Abiraterone acetate 1000 mg capsules (4 x 250 mg capsules) administered orally daily for 28-day treatment period to determine the MTD in Phase 1 of the study. Participants received MTD of abiraterone acetate for 12 cycles (28 day each) in Phase 2 of the study. Dexamethasone 0.5 mg administered orally (if participants have disease progression) daily up to 12 cycles.
2000 mg/Day	Abiraterone acetate 2000 mg capsules (8 x 250 mg capsules) administered orally daily for 28-day treatment period to determine the MTD in Phase 1 of the study. Participants received MTD of abiraterone acetate for 12 cycles (28 day each) in Phase 2 of the study. Dexamethasone 0.5 mg administered orally (if participants have disease progression) daily up to 12 cycles.

Measured Values

	250 mg/Day	**500 mg/Day**	**750 mg/Day**	**1000 mg/Day**	**2000 mg/Day**
Number of Participants Analyzed	**3**	**3**	**3**	**42**	**3**

[units: participants]					
Number of Participants With Treatment-Emergent Adverse Events (AEs) or Serious Adverse Events (SAEs) [units: participants]					
AEs	**3**	**3**	**3**	**41**	**3**
SAEs	**2**	**2**	**0**	**20**	**2**

No statistical analysis provided for Number of Participants With Treatment-Emergent Adverse Events (AEs) or Serious Adverse Events (SAEs)

9. Other Pre-specified: Serum Blood Levels of Testosterone Precursors [Time Frame: Baseline, Cycle 2 (within 3 days prior to Day 29)]

Measure Type	Other Pre-specified
Measure Title	Serum Blood Levels of Testosterone Precursors
Measure Description	Concentration of Cortisol, Aldosterone, Corticosterone, 11-Deoxycortisol, Deoxycorticosterone and Dehydroepiandrostenedione Sulphate (DHEA-S) in blood was measured in nanogram per deciliter (ng/dL).
Time Frame	Baseline, Cycle 2 (within 3 days prior to Day 29)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who were enrolled in the study and received 1000 mg abiraterone acetate therapy with or without dexamethasone (including participants who received 1000 mg AA monotherapy). Here 'N' (number of participants analyzed) signifies participants evaluable for this measure and 'n' signifies participants evaluable at specified time point.

Reporting Groups

	Description
1000 mg AA Therapy	Participants received 1000 mg abiraterone acetate with or without dexamethasone.

Measured Values

	1000 mg AA Therapy
Number of Participants Analyzed [units: participants]	**33**
Serum Blood Levels of Testosterone Precursors [units: ng/dL] Median (Full Range)	
Cortisol; Baseline (n = 33)	**12000 (7000 to 23000)**
Cortisol; Cycle 2 (n = 29)	**4000 (1000 to 11000)**
Aldosterone; Baseline (n=33)	**8 (1 to 32)**
Aldosterone; Cycle 2 (n=29)	**8 (1 to 61)**
Corticosterone; Baseline (n=33)	**193 (4 to 1041)**
Corticosterone; Cycle 2 (n=27)	**6797 (12 to 17148)**
11-Deoxycortisol; Baseline (n=31)	**39**

	(20 to 233)
11-Deoxycortisol; Cycle 2 (n=25)	**73 (20 to 836)**
Deoxycorticosterone; Baseline (n=32)	**6 (2 to 31)**
Deoxycorticosterone; Cycle 2 (n=28)	**121 (33 to 1627)**
DHEA-S; Baseline (n=32)	**30000 (15000 to 176000)**
DHEA-S; Cycle 2 (n=28)	**15000 (15000 to 15000)**

No statistical analysis provided for Serum Blood Levels of Testosterone Precursors

10. Other Pre-specified: Time to Prostate Cancer Pain Progression [Time Frame: Baseline up to 12 cycles]

Measure Type	Other Pre-specified
Measure Title	Time to Prostate Cancer Pain Progression
Measure Description	The time from start of study treatment to the development/worsening of pain due to prostate cancer requiring one or more of the following treatments: 1- Opioid therapy (therapy with morphine like medicines for 10 out of 14 consecutive days); 2- Glucocorticoid therapy; 3- Initiation of >= 5 mg of prednisolone for 10 out of 14 consecutive days; 4- Radionuclide therapy; 5- Radiation therapy (x-ray or cobalt treatment); 6- Chemotherapy (treatment of disease by chemical agents). Participants who do not experience prostate cancer pain were censored on their last day on study. Time to prostate cancer pain progression was measured by Kaplan-Meier method.
Time Frame	Baseline up to 12 cycles
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Median time was not reached as data was not matured at the time of the analysis, hence no data could be reported.

Reporting Groups

	Description
1000 mg AA Therapy	Participants received 1000 mg abiraterone acetate with or without dexamethasone.

Measured Values

	1000 mg AA Therapy
Number of Participants Analyzed [units: participants]	**0**
Time to Prostate Cancer Pain Progression	

No statistical analysis provided for Time to Prostate Cancer Pain Progression

11. Other Pre-specified: Number of Participants With Change From Baseline in Biochemical Bone Markers [Time Frame: Baseline, Cycle 2, 4, 8, 12]

Measure Type	Other Pre-specified

Measure Title	Number of Participants With Change From Baseline in Biochemical Bone Markers
Measure Description	No text entered.
Time Frame	Baseline, Cycle 2, 4, 8, 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Data was reported in individual participant listings but not summarized due to statistical constraints.

Reporting Groups

	Description
1000 mg AA Therapy	Participants received 1000 mg abiraterone acetate with or without dexamethasone.

Measured Values

	1000 mg AA Therapy
Number of Participants Analyzed [units: participants]	**0**
Number of Participants With Change From Baseline in Biochemical Bone Markers	

No statistical analysis provided for Number of Participants With Change From Baseline in Biochemical Bone Markers

12. Other Pre-specified: Mean Plasma Concentration of Abiraterone [Time Frame: Pre-dose on Day 1, 8 and 15 of Cycle 1, Day 1 of Cycle 2, Day 1 of Cycle 3; 1, 2, 4, 6, 8, 24, 48 and 72 hours after first dose was given]

Measure Type	Other Pre-specified
Measure Title	Mean Plasma Concentration of Abiraterone
Measure Description	No text entered.
Time Frame	Pre-dose on Day 1, 8 and 15 of Cycle 1, Day 1 of Cycle 2, Day 1 of Cycle 3; 1, 2, 4, 6, 8, 24, 48 and 72 hours after first dose was given
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Data was not statistically summarized but reported in individual participant listing as per planned analysis.

Reporting Groups

	Description
Abiraterone Acetate 250 mg	Abiraterone acetate 250 mg capsule given orally daily for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.
Abiraterone Acetate 500 mg	Abiraterone acetate 500 mg capsules (2 x 250 mg capsules) given orally daily for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.
Abiraterone Acetate 750 mg	Abiraterone acetate 750 mg capsules (3 x 250 mg capsules) given orally daily for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.
Abiraterone Acetate 1000 mg	Abiraterone acetate 1000 mg capsules (4 x 250 mg capsules) orally daily given for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.

Abiraterone Acetate 2000 mg	Abiraterone acetate 2000 mg capsules (8 x 250 mg capsules) given orally daily for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.

Measured Values

	Abiraterone Acetate 250 mg	Abiraterone Acetate 500 mg	Abiraterone Acetate 750 mg	Abiraterone Acetate 1000 mg	Abiraterone Acetate 2000 mg
Number of Participants Analyzed [units: participants]	**0**	**0**	**0**	**0**	**0**
Mean Plasma Concentration of Abiraterone					

No statistical analysis provided for Mean Plasma Concentration of Abiraterone

13. Other Pre-specified: Maximum Observed Plasma Concentration (Cmax) of Abiraterone [Time Frame: Pre-dose on Day 1, 8 and 15 of Cycle 1, Day 1 of Cycle 2, Day 1 of Cycle 3; 1, 2, 4, 6, 8, 24, 48 and 72 hours after first dose was given]

Measure Type	Other Pre-specified
Measure Title	Maximum Observed Plasma Concentration (Cmax) of Abiraterone
Measure Description	The Cmax is defined as maximum observed analyte concentration.
Time Frame	Pre-dose on Day 1, 8 and 15 of Cycle 1, Day 1 of Cycle 2, Day 1 of Cycle 3; 1, 2, 4, 6, 8, 24, 48 and 72 hours after first dose was given
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Included all participants who enrolled into the study regardless of the amount of the trial medication received. Here 'N' (number of participants analyzed) signifies those participants evaluable for this measure.

Reporting Groups

	Description
Abiraterone Acetate 250 mg	Abiraterone acetate 250 mg capsule given orally daily for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.
Abiraterone Acetate 500 mg	Abiraterone acetate 500 mg capsules (2 x 250 mg capsules) given orally daily for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.
Abiraterone Acetate 750 mg	Abiraterone acetate 750 mg capsules (3 x 250 mg capsules) given orally daily for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.
Abiraterone Acetate 1000 mg	Abiraterone acetate 1000 mg capsules (4 x 250 mg capsules) orally daily given for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.
Abiraterone Acetate 2000 mg	Abiraterone acetate 2000 mg capsules (8 x 250 mg capsules) given orally daily for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.

Measured Values

	Abiraterone Acetate 250 mg	Abiraterone Acetate 500 mg	Abiraterone Acetate 750 mg	Abiraterone Acetate 1000 mg	Abiraterone Acetate 2000 mg
Number of Participants Analyzed [units: participants]	**3**	**3**	**2**	**9**	**3**
Maximum Observed Plasma Concentration (Cmax) of Abiraterone					

[units: nmol/L] Mean (Standard Deviation)	**219 (172.77)**	**284 (132.38)**	**1032 (344.01)**	**571 (443.18)**	**531 (219.02)**

No statistical analysis provided for Maximum Observed Plasma Concentration (Cmax) of Abiraterone

14. Other Pre-specified: Time to Reach Maximum Observed Plasma Concentration (Tmax) of Abiraterone [Time Frame: Pre-dose on Day 1, 8 and 15 of Cycle 1, Day 1 of Cycle 2, Day 1 of Cycle 3; 1, 2, 4, 6, 8, 24, 48 and 72 hours after first dose was given]

Measure Type	Other Pre-specified
Measure Title	Time to Reach Maximum Observed Plasma Concentration (Tmax) of Abiraterone
Measure Description	The Tmax is defined as actual sampling time to reach maximum observed plasma concentration. The analyte concentration associated with Tmax is referred to as Cmax.
Time Frame	Pre-dose on Day 1, 8 and 15 of Cycle 1, Day 1 of Cycle 2, Day 1 of Cycle 3; 1, 2, 4, 6, 8, 24, 48 and 72 hours after first dose was given
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Included all participants who enrolled into the study regardless of the amount of the trial medication received. Here 'N' (number of participants analyzed) signifies those participants evaluable for this measure.

Reporting Groups

	Description
Abiraterone Acetate 250 mg	Abiraterone acetate 250 mg capsule given orally daily for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.
Abiraterone Acetate 500 mg	Abiraterone acetate 500 mg capsules (2 x 250 mg capsules) given orally daily for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.
Abiraterone Acetate 750 mg	Abiraterone acetate 750 mg capsules (3 x 250 mg capsules) given orally daily for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.
Abiraterone Acetate 1000 mg	Abiraterone acetate 1000 mg capsules (4 x 250 mg capsules) orally daily given for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.
Abiraterone Acetate 2000 mg	Abiraterone acetate 2000 mg capsules (8 x 250 mg capsules) given orally daily for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.

Measured Values

	Abiraterone Acetate 250 mg	**Abiraterone Acetate 500 mg**	**Abiraterone Acetate 750 mg**	**Abiraterone Acetate 1000 mg**	**Abiraterone Acetate 2000 mg**
Number of Participants Analyzed [units: participants]	**3**	**3**	**2**	**9**	**3**
Time to Reach Maximum Observed Plasma Concentration (Tmax) of Abiraterone [units: hours] Mean (Standard Deviation)	**2.050 (0.02)**	**2.588 (1.02)**	**1.709 (0.41)**	**3.159 (1.79)**	**2.672 (1.14)**

No statistical analysis provided for Time to Reach Maximum Observed Plasma Concentration (Tmax) of Abiraterone

15. Other Pre-specified: Area Under the Curve From Time Zero to Last Quantifiable Concentration (AUClast) of Abiraterone [Time Frame:

Pre-dose on Day 1, 8 and 15 of Cycle 1, Day 1 of Cycle 2, Day 1 of Cycle 3; 1, 2, 4, 6, 8, 24, 48 and 72 hours after first dose was given]

Measure Type	Other Pre-specified
Measure Title	Area Under the Curve From Time Zero to Last Quantifiable Concentration (AUClast) of Abiraterone
Measure Description	Area under the plasma concentration time-curve from time zero to the last quantifiable concentration (AUClast).
Time Frame	Pre-dose on Day 1, 8 and 15 of Cycle 1, Day 1 of Cycle 2, Day 1 of Cycle 3; 1, 2, 4, 6, 8, 24, 48 and 72 hours after first dose was given
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Included all participants who enrolled into the study regardless of the amount of the trial medication received. Here 'N' (number of participants analyzed) signifies those participants evaluable for this measure.

Reporting Groups

	Description
Abiraterone Acetate 250 mg	Abiraterone acetate 250 mg capsule given orally daily for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.
Abiraterone Acetate 500 mg	Abiraterone acetate 500 mg capsules (2 x 250 mg capsules) given orally daily for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.
Abiraterone Acetate 750 mg	Abiraterone acetate 750 mg capsules (3 x 250 mg capsules) given orally daily for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.
Abiraterone Acetate 1000 mg	Abiraterone acetate 1000 mg capsules (4 x 250 mg capsules) orally daily given for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.
Abiraterone Acetate 2000 mg	Abiraterone acetate 2000 mg capsules (8 x 250 mg capsules) given orally daily for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.

Measured Values

	Abiraterone Acetate 250 mg	**Abiraterone Acetate 500 mg**	**Abiraterone Acetate 750 mg**	**Abiraterone Acetate 1000 mg**	**Abiraterone Acetate 2000 mg**
Number of Participants Analyzed [units: participants]	**3**	**3**	**2**	**9**	**3**
Area Under the Curve From Time Zero to Last Quantifiable Concentration (AUClast) of Abiraterone [units: hours*nmol/L] Mean (Standard Deviation)	**1253 (519.78)**	**1334 (731.47)**	**4294 (1295.20)**	**4371 (3427.54)**	**4754 (1659.13)**

No statistical analysis provided for Area Under the Curve From Time Zero to Last Quantifiable Concentration (AUClast) of Abiraterone

16. Other Pre-specified: Area Under the Curve From Time Zero to Extrapolated Infinite Time [AUC (0 - ∞)] of Abiraterone [Time Frame: Pre-dose on Day 1, 8 and 15 of Cycle 1, Day 1 of Cycle 2, Day 1 of Cycle 3; 1, 2, 4, 6, 8, 24, 48 and 72 hours after first dose was given]

Measure Type	Other Pre-specified
Measure Title	Area Under the Curve From Time Zero to Extrapolated Infinite Time [AUC (0 - ∞)] of Abiraterone
Measure Description	AUC (0 - ∞)= Area under the plasma concentration versus time curve (AUC) from time zero (pre-dose) to extrapolated infinite time (0 - ∞). It is obtained from AUC (0 - t) plus AUC (t - ∞).

Time Frame	Pre-dose on Day 1, 8 and 15 of Cycle 1, Day 1 of Cycle 2, Day 1 of Cycle 3; 1, 2, 4, 6, 8, 24, 48 and 72 hours after first dose was given
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Included all participants who enrolled into the study regardless of the amount of the trial medication received. Here 'N' (number of participants analyzed) signifies those participants evaluable for this measure.

Reporting Groups

	Description
Abiraterone Acetate 250 mg	Abiraterone acetate 250 mg capsule given orally daily for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.
Abiraterone Acetate 500 mg	Abiraterone acetate 500 mg capsules (2 x 250 mg capsules) given orally daily for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.
Abiraterone Acetate 750 mg	Abiraterone acetate 750 mg capsules (3 x 250 mg capsules) given orally daily for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.
Abiraterone Acetate 1000 mg	Abiraterone acetate 1000 mg capsules (4 x 250 mg capsules) orally daily given for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.
Abiraterone Acetate 2000 mg	Abiraterone acetate 2000 mg capsules (8 x 250 mg capsules) given orally daily for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.

Measured Values

	Abiraterone Acetate 250 mg	**Abiraterone Acetate 500 mg**	**Abiraterone Acetate 750 mg**	**Abiraterone Acetate 1000 mg**	**Abiraterone Acetate 2000 mg**
Number of Participants Analyzed [units: participants]	**3**	**3**	**2**	**9**	**3**
Area Under the Curve From Time Zero to Extrapolated Infinite Time [AUC (0 - ∞)] of Abiraterone [units: hours*nmol/L] Mean (Standard Deviation)	**1369 (505.39)**	**1448 (749.01)**	**4537 (1333.42)**	**4615 (3660.48)**	**4983 (1755.24)**

No statistical analysis provided for Area Under the Curve From Time Zero to Extrapolated Infinite Time [AUC (0 - ∞)] of Abiraterone

17. Other Pre-specified: Plasma Decay Half-Life (t1/2) of Abiraterone [Time Frame: Pre-dose on Day 1, 8 and 15 of Cycle 1, Day 1 of Cycle 2, Day 1 of Cycle 3; 1, 2, 4, 6, 8, 24, 48 and 72 hours after first dose was given]

Measure Type	Other Pre-specified
Measure Title	Plasma Decay Half-Life (t1/2) of Abiraterone
Measure Description	Plasma decay half-life is the time measured for the plasma concentration to decrease by one half.
Time Frame	Pre-dose on Day 1, 8 and 15 of Cycle 1, Day 1 of Cycle 2, Day 1 of Cycle 3; 1, 2, 4, 6, 8, 24, 48 and 72 hours after first dose was given
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

Included all participants who enrolled into the study regardless of the amount of the trial medication received. Here 'N' (number of participants analyzed) signifies those participants evaluable for this measure.

Reporting Groups

	Description
Abiraterone Acetate 250 mg	Abiraterone acetate 250 mg capsule given orally daily for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.
Abiraterone Acetate 500 mg	Abiraterone acetate 500 mg capsules (2 x 250 mg capsules) given orally daily for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.
Abiraterone Acetate 750 mg	Abiraterone acetate 750 mg capsules (3 x 250 mg capsules) given orally daily for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.
Abiraterone Acetate 1000 mg	Abiraterone acetate 1000 mg capsules (4 x 250 mg capsules) orally daily given for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.
Abiraterone Acetate 2000 mg	Abiraterone acetate 2000 mg capsules (8 x 250 mg capsules) given orally daily for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.

Measured Values

	Abiraterone Acetate 250 mg	Abiraterone Acetate 500 mg	Abiraterone Acetate 750 mg	Abiraterone Acetate 1000 mg	Abiraterone Acetate 2000 mg
Number of Participants Analyzed [units: participants]	**3**	**3**	**2**	**9**	**3**
Plasma Decay Half-Life (t1/2) of Abiraterone [units: hour] Mean (Standard Deviation)	**11.6 (10.14)**	**9.5 (7.02)**	**10.8 (5.91)**	**10.6 (4.69)**	**12.0 (2.29)**

No statistical analysis provided for Plasma Decay Half-Life (t1/2) of Abiraterone

18. Other Pre-specified: Time to Last Quantifiable Plasma Concentration (Tlast) of Abiraterone [Time Frame: Pre-dose on Day 1, 8 and 15 of Cycle 1, Day 1 of Cycle 2, Day 1 of Cycle 3; 1, 2, 4, 6, 8, 24, 48 and 72 hours after first dose was given]

Measure Type	Other Pre-specified
Measure Title	Time to Last Quantifiable Plasma Concentration (Tlast) of Abiraterone
Measure Description	The actual sampling time of last measurable (non-below the limit of quantification [BQL]) analyte concentration. The analyte concentration associated with Tlast is referred to as Clast.
Time Frame	Pre-dose on Day 1, 8 and 15 of Cycle 1, Day 1 of Cycle 2, Day 1 of Cycle 3; 1, 2, 4, 6, 8, 24, 48 and 72 hours after first dose was given
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Data was not statistically summarized but reported in individual participant listing as per planned analysis.

Reporting Groups

	Description
Abiraterone Acetate 250 mg	Abiraterone acetate 250 mg capsule given orally daily for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.
Abiraterone Acetate 500 mg	Abiraterone acetate 500 mg capsules (2 x 250 mg capsules) given orally daily for 28-day treatment period to

	determine the maximum tolerated dose (MTD) in Phase 1 of the study.
Abiraterone Acetate 750 mg	Abiraterone acetate 750 mg capsules (3 x 250 mg capsules) given orally daily for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.
Abiraterone Acetate 1000 mg	Abiraterone acetate 1000 mg capsules (4 x 250 mg capsules) orally daily given for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.
Abiraterone Acetate 2000 mg	Abiraterone acetate 2000 mg capsules (8 x 250 mg capsules) given orally daily for 28-day treatment period to determine the maximum tolerated dose (MTD) in Phase 1 of the study.

Measured Values

	Abiraterone Acetate 250 mg	Abiraterone Acetate 500 mg	Abiraterone Acetate 750 mg	Abiraterone Acetate 1000 mg	Abiraterone Acetate 2000 mg
Number of Participants Analyzed [units: participants]	**0**	**0**	**0**	**0**	**0**
Time to Last Quantifiable Plasma Concentration (Tlast) of Abiraterone					

No statistical analysis provided for Time to Last Quantifiable Plasma Concentration (Tlast) of Abiraterone

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
250 mg/Day	Abiraterone acetate 250 mg capsule administered orally daily for 28-day treatment period to determine the MTD in Phase 1 of the study. Participants received MTD of abiraterone acetate for 12 cycles (28 day each) in Phase 2 of the study. Dexamethasone 0.5 mg administered orally (if participants have disease progression) daily up to 12 cycles.
500 mg/Day	Abiraterone acetate 500 mg capsules (2 x 250 mg capsules) administered orally daily for 28-day treatment period to determine the MTD in Phase 1 of the study. Participants received MTD of abiraterone acetate for 12 cycles (28 day each) in Phase 2 of the study. Dexamethasone 0.5 mg administered orally (if participants have disease progression) daily up to 12 cycles.
750 mg/Day	Abiraterone acetate 750 mg capsules (3 x 250 mg capsules) administered orally daily for 28-day treatment period to determine the MTD in Phase 1 of the study. Participants received MTD of abiraterone acetate for 12 cycles (28 day each) in Phase 2 of the study. Dexamethasone 0.5 mg administered orally (if participants have disease progression) daily up to 12 cycles.
1000 mg/Day	Abiraterone acetate 1000 mg capsules (4 x 250 mg capsules) administered orally daily for 28-day treatment period to determine the MTD in Phase 1 of the study. Participants received MTD of abiraterone acetate for 12 cycles (28 day each) in Phase 2 of the study. Dexamethasone 0.5 mg administered orally (if participants have disease progression) daily up to 12 cycles.
2000 mg/Day	Abiraterone acetate 2000 mg capsules (8 x 250 mg capsules) administered orally daily for 28-day treatment period to determine the MTD in Phase 1 of the study. Participants received MTD of abiraterone acetate for 12 cycles (28 day each) in Phase 2 of the study. Dexamethasone 0.5 mg administered orally (if participants have disease progression) daily up to 12 cycles.

Serious Adverse Events

	250 mg/Day	500 mg/Day	750 mg/Day	1000 mg/Day	2000 mg/Day
Total, serious adverse events					
			0/3 (0.00%)		**2/3 (66.67%)**

# participants affected / at risk	2/3 (66.67%)	2/3 (66.67%)		20/42 (47.62%)	
Blood and lymphatic system disorders					
Eosinophilia * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	1/42 (2.38%)	0/3 (0.00%)
Cardiac disorders					
Myocardial infarction * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	1/42 (2.38%)	0/3 (0.00%)
Palpitations * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	1/42 (2.38%)	0/3 (0.00%)
Gastrointestinal disorders					
Vomiting * 1					
# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	0/3 (0.00%)	1/42 (2.38%)	0/3 (0.00%)
General disorders					
Oedema peripheral * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	0/42 (0.00%)	1/3 (33.33%)
Pain * 1					
# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
Pyrexia * 1					
# participants affected / at risk	0/3 (0.00%)	1/3 (33.33%)	0/3 (0.00%)	1/42 (2.38%)	0/3 (0.00%)
Infections and infestations					
Cellulitis * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	1/42 (2.38%)	0/3 (0.00%)
Infection * 1					
# participants affected / at risk	0/3 (0.00%)	1/3 (33.33%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
Infective exacerbation of chronic obstructive airways disease * 1					
# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
Lower respiratory tract infection * 1					
# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	0/3 (0.00%)	1/42 (2.38%)	0/3 (0.00%)
Lyme disease * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	1/42 (2.38%)	0/3 (0.00%)
Pneumonia * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	2/42 (4.76%)	0/3 (0.00%)
Postoperative wound infection * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	1/42 (2.38%)	0/3 (0.00%)
Sepsis * 1					
# participants affected / at risk	0/3 (0.00%)	1/3 (33.33%)	0/3 (0.00%)	2/42 (4.76%)	0/3 (0.00%)
Urinary tract infection * 1					
# participants affected / at risk	0/3 (0.00%)	1/3 (33.33%)	0/3 (0.00%)	1/42 (2.38%)	0/3 (0.00%)

Injury, poisoning and procedural complications					
Drug toxicity * 1					
# participants affected / at risk	**0/3 (0.00%)**	**0/3 (0.00%)**	**0/3 (0.00%)**	**1/42 (2.38%)**	**0/3 (0.00%)**
Fall * 1					
# participants affected / at risk	**0/3 (0.00%)**	**0/3 (0.00%)**	**0/3 (0.00%)**	**1/42 (2.38%)**	**0/3 (0.00%)**
Femur fracture * 1					
# participants affected / at risk	**0/3 (0.00%)**	**0/3 (0.00%)**	**0/3 (0.00%)**	**1/42 (2.38%)**	**0/3 (0.00%)**
Investigations					
Alanine aminotransferase increased * 1					
# participants affected / at risk	**0/3 (0.00%)**	**0/3 (0.00%)**	**0/3 (0.00%)**	**1/42 (2.38%)**	**0/3 (0.00%)**
Aspartate aminotransferase increased * 1					
# participants affected / at risk	**0/3 (0.00%)**	**0/3 (0.00%)**	**0/3 (0.00%)**	**1/42 (2.38%)**	**0/3 (0.00%)**
Metabolism and nutrition disorders					
Dehydration * 1					
# participants affected / at risk	**0/3 (0.00%)**	**1/3 (33.33%)**	**0/3 (0.00%)**	**1/42 (2.38%)**	**0/3 (0.00%)**
Fluid retention * 1					
# participants affected / at risk	**0/3 (0.00%)**	**0/3 (0.00%)**	**0/3 (0.00%)**	**1/42 (2.38%)**	**0/3 (0.00%)**
Hypokalaemia * 1					
# participants affected / at risk	**0/3 (0.00%)**	**0/3 (0.00%)**	**0/3 (0.00%)**	**3/42 (7.14%)**	**0/3 (0.00%)**
Musculoskeletal and connective tissue disorders					
Arthralgia * 1					
# participants affected / at risk	**0/3 (0.00%)**	**0/3 (0.00%)**	**0/3 (0.00%)**	**1/42 (2.38%)**	**0/3 (0.00%)**
Bone pain * 1					
# participants affected / at risk	**0/3 (0.00%)**	**0/3 (0.00%)**	**0/3 (0.00%)**	**1/42 (2.38%)**	**0/3 (0.00%)**
Mobility decreased * 1					
# participants affected / at risk	**0/3 (0.00%)**	**0/3 (0.00%)**	**0/3 (0.00%)**	**1/42 (2.38%)**	**0/3 (0.00%)**
Pathological fracture * 1					
# participants affected / at risk	**0/3 (0.00%)**	**0/3 (0.00%)**	**0/3 (0.00%)**	**1/42 (2.38%)**	**0/3 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
Colon cancer * 1					
# participants affected / at risk	**0/3 (0.00%)**	**0/3 (0.00%)**	**0/3 (0.00%)**	**0/42 (0.00%)**	**1/3 (33.33%)**
Metastases to liver * 1					
# participants affected / at risk	**0/3 (0.00%)**	**1/3 (33.33%)**	**0/3 (0.00%)**	**0/42 (0.00%)**	**0/3 (0.00%)**
Metastatic pain * 1					
# participants affected / at risk	**0/3 (0.00%)**	**0/3 (0.00%)**	**0/3 (0.00%)**	**1/42 (2.38%)**	**0/3 (0.00%)**
Nervous system disorders					
Headache * 1					
# participants affected / at risk	**0/3 (0.00%)**	**0/3 (0.00%)**	**0/3 (0.00%)**	**1/42 (2.38%)**	**0/3 (0.00%)**
Migraine * 1					
# participants affected / at risk	**0/3 (0.00%)**	**0/3 (0.00%)**	**0/3 (0.00%)**	**1/42 (2.38%)**	**0/3 (0.00%)**
Spinal cord compression * 1					

# participants affected / at risk	**0/3 (0.00%)**	**0/3 (0.00%)**	**0/3 (0.00%)**	**1/42 (2.38%)**	**0/3 (0.00%)**
Psychiatric disorders					
Confusional state * 1					
# participants affected / at risk	**1/3 (33.33%)**	**0/3 (0.00%)**	**0/3 (0.00%)**	**0/42 (0.00%)**	**0/3 (0.00%)**
Renal and urinary disorders					
Renal failure * 1					
# participants affected / at risk	**0/3 (0.00%)**	**0/3 (0.00%)**	**0/3 (0.00%)**	**2/42 (4.76%)**	**0/3 (0.00%)**
Respiratory, thoracic and mediastinal disorders					
Dyspnoea * 1					
# participants affected / at risk	**0/3 (0.00%)**	**0/3 (0.00%)**	**0/3 (0.00%)**	**2/42 (4.76%)**	**0/3 (0.00%)**
Pulmonary embolism * 1					
# participants affected / at risk	**0/3 (0.00%)**	**0/3 (0.00%)**	**0/3 (0.00%)**	**2/42 (4.76%)**	**0/3 (0.00%)**
Vascular disorders					
Hypotension * 1					
# participants affected / at risk	**0/3 (0.00%)**	**0/3 (0.00%)**	**0/3 (0.00%)**	**1/42 (2.38%)**	**0/3 (0.00%)**
Vasculitis * 1					
# participants affected / at risk	**0/3 (0.00%)**	**0/3 (0.00%)**	**0/3 (0.00%)**	**1/42 (2.38%)**	**0/3 (0.00%)**

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA Version 11.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
250 mg/Day	Abiraterone acetate 250 mg capsule administered orally daily for 28-day treatment period to determine the MTD in Phase 1 of the study. Participants received MTD of abiraterone acetate for 12 cycles (28 day each) in Phase 2 of the study. Dexamethasone 0.5 mg administered orally (if participants have disease progression) daily up to 12 cycles.
500 mg/Day	Abiraterone acetate 500 mg capsules (2 x 250 mg capsules) administered orally daily for 28-day treatment period to determine the MTD in Phase 1 of the study. Participants received MTD of abiraterone acetate for 12 cycles (28 day each) in Phase 2 of the study. Dexamethasone 0.5 mg administered orally (if participants have disease progression) daily up to 12 cycles.
750 mg/Day	Abiraterone acetate 750 mg capsules (3 x 250 mg capsules) administered orally daily for 28-day treatment period to determine the MTD in Phase 1 of the study. Participants received MTD of abiraterone acetate for 12 cycles (28 day each) in Phase 2 of the study. Dexamethasone 0.5 mg administered orally (if participants have disease progression) daily up to 12 cycles.
1000 mg/Day	Abiraterone acetate 1000 mg capsules (4 x 250 mg capsules) administered orally daily for 28-day treatment period to determine the MTD in Phase 1 of the study. Participants received MTD of abiraterone acetate for 12 cycles (28 day each) in Phase 2 of the study. Dexamethasone 0.5 mg administered orally (if participants have disease progression) daily up to 12 cycles.

2000 mg/Day	Abiraterone acetate 2000 mg capsules (8 x 250 mg capsules) administered orally daily for 28-day treatment period to determine the MTD in Phase 1 of the study. Participants received MTD of abiraterone acetate for 12 cycles (28 day each) in Phase 2 of the study. Dexamethasone 0.5 mg administered orally (if participants have disease progression) daily up to 12 cycles.

Other Adverse Events

	250 mg/Day	500 mg/Day	750 mg/Day	1000 mg/Day	2000 mg/Day
Total, other (not including serious) adverse events					
# participants affected / at risk	3/3 (100.00%)	3/3 (100.00%)	3/3 (100.00%)	41/42 (97.62%)	3/3 (100.00%)
Blood and lymphatic system disorders					
Anaemia * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	3/42 (7.14%)	0/3 (0.00%)
Neutropenia * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	2/42 (4.76%)	1/3 (33.33%)
Cardiac disorders					
Atrial fibrillation * 1					
# participants affected / at risk	0/3 (0.00%)	1/3 (33.33%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
Bundle branch block right * 1					
# participants affected / at risk	0/3 (0.00%)	1/3 (33.33%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
Ear and labyrinth disorders					
Tinnitus * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	1/42 (2.38%)	1/3 (33.33%)
Eye disorders					
Eye inflammation * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	0/42 (0.00%)	1/3 (33.33%)
Ocular hyperaemia * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	1/42 (2.38%)	1/3 (33.33%)
Gastrointestinal disorders					
Abdominal pain upper * 1					
# participants affected / at risk	0/3 (0.00%)	1/3 (33.33%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
Anal fissure * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	0/42 (0.00%)	1/3 (33.33%)
Constipation * 1					
# participants affected / at risk	2/3 (66.67%)	0/3 (0.00%)	1/3 (33.33%)	11/42 (26.19%)	0/3 (0.00%)
Diarrhoea * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	9/42 (21.43%)	0/3 (0.00%)
Dry mouth * 1					
# participants affected / at risk	1/3 (33.33%)	1/3 (33.33%)	0/3 (0.00%)	3/42 (7.14%)	0/3 (0.00%)
Dyspepsia * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	1/3 (33.33%)	4/42 (9.52%)	0/3 (0.00%)
Flatulence * 1					
# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	1/3 (33.33%)	2/42 (4.76%)	0/3 (0.00%)
Gastrooesophageal reflux disease * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	1/3 (33.33%)	0/42 (0.00%)	0/3 (0.00%)

Mouth ulceration * 1					
# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	0/3 (0.00%)	2/42 (4.76%)	0/3 (0.00%)
Nausea * 1					
# participants affected / at risk	3/3 (100.00%)	0/3 (0.00%)	2/3 (66.67%)	5/42 (11.90%)	1/3 (33.33%)
Proctalgia * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	0/42 (0.00%)	1/3 (33.33%)
Rectal haemorrhage * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	1/42 (2.38%)	1/3 (33.33%)
Vomiting * 1					
# participants affected / at risk	2/3 (66.67%)	0/3 (0.00%)	1/3 (33.33%)	8/42 (19.05%)	1/3 (33.33%)
General disorders					
Chest discomfort * 1					
# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	0/3 (0.00%)	1/42 (2.38%)	0/3 (0.00%)
Facial pain * 1					
# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
Fatigue * 1					
# participants affected / at risk	2/3 (66.67%)	1/3 (33.33%)	2/3 (66.67%)	21/42 (50.00%)	2/3 (66.67%)
Feeling cold * 1					
# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
Inflammation * 1					
# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
Influenza like illness * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	4/42 (9.52%)	0/3 (0.00%)
Injection site discolouration * 1					
# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
Oedema peripheral * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	1/3 (33.33%)	19/42 (45.24%)	3/3 (100.00%)
Pitting oedema * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	2/42 (4.76%)	2/3 (66.67%)
Pyrexia * 1					
# participants affected / at risk	1/3 (33.33%)	1/3 (33.33%)	1/3 (33.33%)	0/42 (0.00%)	0/3 (0.00%)
Hepatobiliary disorders					
Hepatomegaly * 1					
# participants affected / at risk	0/3 (0.00%)	1/3 (33.33%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
Infections and infestations					
Cellulitis * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	1/3 (33.33%)	0/42 (0.00%)	0/3 (0.00%)
Fungal infection * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	0/42 (0.00%)	1/3 (33.33%)
Gastroenteritis * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	1/3 (33.33%)	0/42 (0.00%)	1/3 (33.33%)
Gingival infection * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	1/3 (33.33%)	0/42 (0.00%)	0/3 (0.00%)
Groin abscess * 1					

# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
Herpes zoster * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	1/3 (33.33%)	1/42 (2.38%)	0/3 (0.00%)
Lower respiratory tract infection * 1					
# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	1/3 (33.33%)	5/42 (11.90%)	0/3 (0.00%)
Nasopharyngitis * 1					
# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	1/3 (33.33%)	3/42 (7.14%)	0/3 (0.00%)
Respiratory tract infection viral * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	1/3 (33.33%)	0/42 (0.00%)	0/3 (0.00%)
Rhinitis * 1					
# participants affected / at risk	0/3 (0.00%)	1/3 (33.33%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
Tooth infection * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	1/3 (33.33%)	2/42 (4.76%)	0/3 (0.00%)
Upper respiratory tract infection * 1					
# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	0/3 (0.00%)	8/42 (19.05%)	0/3 (0.00%)
Urinary tract infection * 1					
# participants affected / at risk	1/3 (33.33%)	1/3 (33.33%)	0/3 (0.00%)	5/42 (11.90%)	0/3 (0.00%)
Injury, poisoning and procedural complications					
Contusion * 1					
# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	0/3 (0.00%)	3/42 (7.14%)	1/3 (33.33%)
Fall * 1					
# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
Humerus fracture * 1					
# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
Limb injury * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	0/42 (0.00%)	1/3 (33.33%)
Radius fracture * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	0/42 (0.00%)	1/3 (33.33%)
Investigations					
Alanine aminotransferase increased * 1					
# participants affected / at risk	0/3 (0.00%)	1/3 (33.33%)	1/3 (33.33%)	4/42 (9.52%)	0/3 (0.00%)
Aspartate aminotransferase increased * 1					
# participants affected / at risk	0/3 (0.00%)	1/3 (33.33%)	1/3 (33.33%)	3/42 (7.14%)	0/3 (0.00%)
Blood acid phosphatase increased * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	1/3 (33.33%)	0/42 (0.00%)	0/3 (0.00%)
Blood albumin decreased * 1					
# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
Blood alkaline phosphatase decreased * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	1/3 (33.33%)	0/42 (0.00%)	0/3 (0.00%)
Blood alkaline phosphatase increased * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	1/3 (33.33%)	1/42 (2.38%)	0/3 (0.00%)
Blood creatine increased * 1					
# participants affected / at risk	0/3 (0.00%)	1/3 (33.33%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)

Blood creatinine increased [*1]					
# participants affected / at risk	0/3 (0.00%)	1/3 (33.33%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
Blood lactate dehydrogenase increased [*1]					
# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
C-reactive protein increased [*1]					
# participants affected / at risk	0/3 (0.00%)	1/3 (33.33%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
International normalised ratio increased [*1]					
# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
Protein total decreased [*1]					
# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
Weight decreased [*1]					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	1/3 (33.33%)	3/42 (7.14%)	0/3 (0.00%)
Weight increased [*1]					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	6/42 (14.29%)	1/3 (33.33%)
Metabolism and nutrition disorders					
Anorexia [*1]					
# participants affected / at risk	0/3 (0.00%)	2/3 (66.67%)	1/3 (33.33%)	3/42 (7.14%)	0/3 (0.00%)
Hyperglycaemia [*1]					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	3/42 (7.14%)	0/3 (0.00%)
Hypokalaemia [*1]					
# participants affected / at risk	1/3 (33.33%)	2/3 (66.67%)	3/3 (100.00%)	34/42 (80.95%)	1/3 (33.33%)
Musculoskeletal and connective tissue disorders					
Arthralgia [*1]					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	2/3 (66.67%)	12/42 (28.57%)	0/3 (0.00%)
Back pain [*1]					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	2/3 (66.67%)	8/42 (19.05%)	0/3 (0.00%)
Bone pain [*1]					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	6/42 (14.29%)	0/3 (0.00%)
Groin pain [*1]					
# participants affected / at risk	2/3 (66.67%)	0/3 (0.00%)	0/3 (0.00%)	3/42 (7.14%)	0/3 (0.00%)
Muscle spasms [*1]					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	4/42 (9.52%)	0/3 (0.00%)
Muscular weakness [*1]					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	3/42 (7.14%)	1/3 (33.33%)
Musculoskeletal chest pain [*1]					
# participants affected / at risk	0/3 (0.00%)	1/3 (33.33%)	1/3 (33.33%)	5/42 (11.90%)	0/3 (0.00%)
Musculoskeletal discomfort [*1]					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	1/3 (33.33%)	3/42 (7.14%)	0/3 (0.00%)
Musculoskeletal pain [*1]					
# participants affected / at risk	1/3 (33.33%)	1/3 (33.33%)	0/3 (0.00%)	9/42 (21.43%)	0/3 (0.00%)
Musculoskeletal stiffness [*1]					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	4/42 (9.52%)	0/3 (0.00%)
Neck pain [*1]					
# participants affected / at risk	0/3 (0.00%)	1/3 (33.33%)	0/3 (0.00%)	4/42 (9.52%)	0/3 (0.00%)

Pain in extremity * 1					
# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	0/3 (0.00%)	7/42 (16.67%)	2/3 (66.67%)
Nervous system disorders					
Balance disorder * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	1/42 (2.38%)	1/3 (33.33%)
Dizziness * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	6/42 (14.29%)	1/3 (33.33%)
Dysgeusia * 1					
# participants affected / at risk	1/3 (33.33%)	1/3 (33.33%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
Headache * 1					
# participants affected / at risk	1/3 (33.33%)	1/3 (33.33%)	2/3 (66.67%)	5/42 (11.90%)	0/3 (0.00%)
Hypoaesthesia * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	3/42 (7.14%)	0/3 (0.00%)
Lethargy * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	5/42 (11.90%)	0/3 (0.00%)
Paraesthesia * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	3/42 (7.14%)	0/3 (0.00%)
Parosmia * 1					
# participants affected / at risk	0/3 (0.00%)	1/3 (33.33%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
Peripheral sensory neuropathy * 1					
# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
Psychiatric disorders					
Anxiety * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	1/42 (2.38%)	1/3 (33.33%)
Depressed mood * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	1/3 (33.33%)	0/42 (0.00%)	0/3 (0.00%)
Insomnia * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	4/42 (9.52%)	0/3 (0.00%)
Renal and urinary disorders					
Bladder spasm * 1					
# participants affected / at risk	0/3 (0.00%)	1/3 (33.33%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
Haematuria * 1					
# participants affected / at risk	1/3 (33.33%)	1/3 (33.33%)	0/3 (0.00%)	1/42 (2.38%)	1/3 (33.33%)
Nocturia * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	1/3 (33.33%)	2/42 (4.76%)	0/3 (0.00%)
Pyuria * 1					
# participants affected / at risk	0/3 (0.00%)	1/3 (33.33%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
Urinary incontinence * 1					
# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
Urinary retention * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	0/42 (0.00%)	1/3 (33.33%)
Reproductive system and breast disorders					
Pelvic pain * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	1/3 (33.33%)	3/42 (7.14%)	0/3 (0.00%)

Testicular atrophy * 1					
# participants affected / at risk	0/3 (0.00%)	1/3 (33.33%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
Respiratory, thoracic and mediastinal disorders					
Cough * 1					
# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	1/3 (33.33%)	6/42 (14.29%)	1/3 (33.33%)
Dyspnoea * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	1/3 (33.33%)	8/42 (19.05%)	1/3 (33.33%)
Dyspnoea exertional * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	3/42 (7.14%)	0/3 (0.00%)
Epistaxis * 1					
# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	0/3 (0.00%)	1/42 (2.38%)	0/3 (0.00%)
Pharyngolaryngeal pain * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	5/42 (11.90%)	0/3 (0.00%)
Productive cough * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	3/42 (7.14%)	0/3 (0.00%)
Wheezing * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	3/42 (7.14%)	0/3 (0.00%)
Skin and subcutaneous tissue disorders					
Dry skin * 1					
# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	1/3 (33.33%)	3/42 (7.14%)	0/3 (0.00%)
Photosensitivity reaction * 1					
# participants affected / at risk	0/3 (0.00%)	1/3 (33.33%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
Psoriasis * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	1/42 (2.38%)	1/3 (33.33%)
Rash * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	0/3 (0.00%)	4/42 (9.52%)	1/3 (33.33%)
Rash maculo-papular * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	1/3 (33.33%)	1/42 (2.38%)	0/3 (0.00%)
Scab * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	1/3 (33.33%)	0/42 (0.00%)	0/3 (0.00%)
Skin atrophy * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	1/3 (33.33%)	1/42 (2.38%)	1/3 (33.33%)
Skin disorder * 1					
# participants affected / at risk	0/3 (0.00%)	1/3 (33.33%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
Skin lesion * 1					
# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	0/3 (0.00%)	0/42 (0.00%)	0/3 (0.00%)
Vascular disorders					
Flushing * 1					
# participants affected / at risk	0/3 (0.00%)	0/3 (0.00%)	1/3 (33.33%)	0/42 (0.00%)	0/3 (0.00%)
Hot flush * 1					
# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	1/3 (33.33%)	6/42 (14.29%)	0/3 (0.00%)
Hypertension * 1					
# participants affected / at risk	1/3 (33.33%)	0/3 (0.00%)	1/3 (33.33%)	15/42 (35.71%)	2/3 (66.67%)

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA Version 11.0

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☑ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

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No publications provided

Responsible Party:	Cougar Biotechnology, Inc.
ClinicalTrials.gov Identifier:	NCT00473512 History of Changes
Other Study ID Numbers:	**CR016909**, COU-AA-001
Study First Received:	May 11, 2007
Results First Received:	June 7, 2013
Last Updated:	February 27, 2014
Health Authority:	United States: Food and Drug Administration United Kingdom: Medicines and Healthcare Products Regulatory Agency

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