Trial record **1 of 1** for: COU-AA-004
Previous Study | Return to List | Next Study

An Efficacy and Safety Study of Abiraterone Acetate and Prednisone in Participants With Prostate Cancer Who Failed Androgen Deprivation and Docetaxel-Based Chemotherapy

This study has been completed.

Sponsor:
Cougar Biotechnology, Inc.

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

ClinicalTrials.gov Identifier:
NCT00485303

First received: June 8, 2007
Last updated: June 25, 2013
Last verified: June 2013
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: April 23, 2013

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

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
Abiraterone	Abiraterone acetate 1000 milligram (mg) (4 oral tablets of 250 mg each) was administered once daily along with 5 mg oral prednisolone or prednisone tablet administered twice daily for 28-days dosing cycle and was continued until disease progression or unacceptable toxicity.

Participant Flow: Overall Study

	Abiraterone
STARTED	**58**
COMPLETED	**2**
NOT COMPLETED	**56**
Adverse Event	**5**
Progressive Disease	**44**
Unspecified	**3**

Initiation of new anti-cancer treatment	**2**
Treatment ongoing at cutoff date	**2**

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
Abiraterone	Abiraterone acetate 1000 milligram (mg) (4 oral tablets of 250 mg each) was administered once daily along with 5 mg oral prednisolone or prednisone tablet administered twice daily for 28-days dosing cycle and was continued until disease progression or unacceptable toxicity.

Baseline Measures

	Abiraterone
Number of Participants [units: participants]	**58**
Age [units: Years] Mean (Standard Deviation)	**68.6 (9.78)**
Gender [units: Participants]	
Female	**0**

Male	**58**
Region of Enrollment [units: Participants]	
United Kingdom	**4**
United States	**54**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants With Prostate Specific Antigen (PSA) Response [Time Frame: Day 1 of each cycle (of 28 days each) up to Cycle 12]

Measure Type	Primary
Measure Title	Percentage of Participants With Prostate Specific Antigen (PSA) Response
Measure Description	The PSA response was evaluated according to Prostate-Specific Antigen Working Group (PSAWG) criterion, which is, greater than or equal to 50 percent decrease in PSA from Baseline during the study, which would be subsequently confirmed by a measurement that is at least 4 or more weeks after initial documentation of PSA response.
Time Frame	Day 1 of each cycle (of 28 days each) up to Cycle 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.
Per protocol population defined as participants who had received at least one dose of abiraterone acetate and must had PSA evaluation/tumor assessment at Baseline and at least 1 post-baseline, and had received a minimum of 3 cycles of study treatment.

Reporting Groups

	Description
Abiraterone	Abiraterone acetate 1000 milligram (mg) (4 oral tablets of 250 mg each) was administered once daily along with 5 mg oral prednisolone or prednisone tablet administered twice daily for 28-days dosing cycle and was continued until disease progression or unacceptable toxicity.

Measured Values

	Abiraterone
Number of Participants Analyzed [units: participants]	**58**
Percentage of Participants With Prostate Specific Antigen (PSA) Response [units: percentage of participants] Number (95% Confidence Interval)	**37.9 (25.5 to 51.6)**

No statistical analysis provided for Percentage of Participants With Prostate Specific Antigen (PSA) Response

2. Secondary: Prostate-Specific Antigen Based Progression-free Survival (PSA-PFS) [Time Frame: Baseline and Day 1 of each cycle until first documented disease progression or up to 60 months]

Measure Type	Secondary
Measure Title	Prostate-Specific Antigen Based Progression-free Survival (PSA-PFS)
Measure Description	The PSA-PFS is defined as time to first PSA failure (that is, two consecutive increases in PSA of 50 percent and greater than or equal to 5 nanogram per milliliter, as per Prostate-Specific Antigen Working Group [PSAWG] criterion) or death or the start of secondary anti-tumor therapy, whichever occurs first. If a PSA progression or death does not occur, subject will be censored at the last PSA evaluation.
Time Frame	Baseline and Day 1 of each cycle until first documented disease progression or up to 60 months
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.
Per protocol population defined as participants who had received at least one dose of abiraterone acetate and must had PSA evaluation/tumor assessment at Baseline and at least 1 post-baseline, and had received a minimum of 3 cycles of study treatment.

Reporting Groups

	Description
Abiraterone	Abiraterone acetate 1000 milligram (mg) (4 oral tablets of 250 mg each) was administered once daily along with 5 mg oral prednisolone or prednisone tablet administered twice daily for 28-days dosing cycle and was continued until disease progression or unacceptable toxicity.

Measured Values

	Abiraterone
Number of Participants Analyzed [units: participants]	**58**
Prostate-Specific Antigen Based Progression-free Survival (PSA-PFS) [units: days] Median (95% Confidence Interval)	**141 (110 to 200)**

No statistical analysis provided for Prostate-Specific Antigen Based Progression-free Survival (PSA-PFS)

3. Secondary: Radiographic Progression Free Survival (PFS) [Time Frame: Baseline, Day 1 of Cycle 4, 7 and 10, and thereafter every third cycle until first documented disease progression or up to 60 months]

Measure Type	Secondary
Measure Title	Radiographic Progression Free Survival (PFS)
Measure Description	The RAD-PFS is defined as the time from randomization to the earliest objective evidence of radiographic progression or death due to any cause. Progression is defined using Response Evaluation Criteria in Solid Tumors (RECIST) Version

	1.0, as at least a 20% increase in the sum of the longest diameter of target lesions, taking as reference the smallest sum longest diameter recorded since the treatment started or the appearance of one or more new lesions.
Time Frame	Baseline, Day 1 of Cycle 4, 7 and 10, and thereafter every third cycle until first documented disease progression or up to 60 months
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.
No text entered.

Reporting Groups

	Description
Abiraterone	Abiraterone acetate 1000 milligram (mg) (4 oral tablets of 250 mg each) was administered once daily along with 5 mg oral prednisolone or prednisone tablet administered twice daily for 28-days dosing cycle and was continued until disease progression or unacceptable toxicity.

Measured Values

	Abiraterone
Number of Participants Analyzed [units: participants]	**58**
Radiographic Progression Free Survival (PFS) [units: days] Median (95% Confidence Interval)	**126 (82 to 333)**

No statistical analysis provided for Radiographic Progression Free Survival (PFS)

4. Secondary: Overall Survival (OS) [Time Frame: Every 3 months until death or up to 60 months]

Measure Type	Secondary
Measure Title	Overall Survival (OS)
Measure Description	Overall survival is defined as the interval from the date of the first dose of abiraterone acetate to the date of death.
Time Frame	Every 3 months until death or up to 60 months
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.
Per protocol population defined as participants who had received at least one dose of abiraterone acetate and must had PSA evaluation/tumor assessment at Baseline and at least 1 post-baseline, and had received a minimum of 3 cycles of study treatment.

Reporting Groups

	Description
Abiraterone	Abiraterone acetate 1000 milligram (mg) (4 oral tablets of 250 mg each) was administered once daily along with 5 mg oral prednisolone or prednisone tablet administered twice daily for 28-days dosing cycle and was continued until disease progression or unacceptable toxicity.

Measured Values

	Abiraterone
Number of Participants Analyzed [units: participants]	**58**
Overall Survival (OS) [units: days] Median (95% Confidence Interval)	**492 (373 to 647)**

No statistical analysis provided for Overall Survival (OS)

5. Secondary: Percentage of Participants With Objective Radiographic Response [Time Frame: Baseline, Day 1 of Cycle 4, 7 and 10, and thereafter every third cycle until first documented disease progression or up to 60 months]

Measure Type	Secondary
Measure Title	Percentage of Participants With Objective Radiographic Response
Measure Description	Percentage of participants with radiographic objective response is defined as the percentage of participants with complete response (CR) or partial response (PR) as best overall response based on reconciled radiographic disease assessment according to RECIST Version 1.0. The CR is disappearance of all lesions. The PR is at least 30 percent decrease in sum of the longest diameter of target lesions or persistence of one or more non-target lesion(s) or/and maintenance of tumor marker level above the normal limits.
Time Frame	Baseline, Day 1 of Cycle 4, 7 and 10, and thereafter every third cycle until first documented disease progression or up to 60 months
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.
Per protocol population defined as participants who had received at least 1 dose of abiraterone acetate and must had PSA evaluation/tumor assessment at Baseline and at least 1 post-baseline, and had received a minimum of 3 cycles of study treatment. “N” (number of participants analyzed) =participants who were evaluable for this measure.

Reporting Groups

	Description
Abiraterone	Abiraterone acetate 1000 milligram (mg) (4 oral tablets of 250 mg each) was administered once daily along with 5 mg oral prednisolone or prednisone tablet administered twice daily for 28-days dosing cycle and was continued until disease progression or unacceptable toxicity.

Measured Values

	Abiraterone
Number of Participants Analyzed [units: participants]	**48**
Percentage of Participants With Objective Radiographic Response [units: percentage of participants]	
Complete response (CR)	**0**
Partial Response (PR)	**6.3**

No statistical analysis provided for Percentage of Participants With Objective Radiographic Response

6. Secondary: Time to PSA Progression [Time Frame: Day 8 of Cycle 1, thereafter Day 1 of each cycle up to end of study (60 months)]

Measure Type	Secondary
Measure Title	Time to PSA Progression
Measure Description	The time interval from first dose of abiraterone acetate to the date of PSA progression as defined by the Prostate-Specific Antigen Working Group (PSAWG) criteria. If a PSA progression does not occur, subject will be censored at the last PSA evaluation.
Time Frame	Day 8 of Cycle 1, thereafter Day 1 of each cycle up to end of study (60 months)
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.
Per protocol population defined as participants who had received at least one dose of abiraterone acetate and must had PSA evaluation/tumor assessment at Baseline and at least 1 post-baseline, and had received a minimum of 3 cycles of study treatment.

Reporting Groups

	Description
Abiraterone	Abiraterone acetate 1000 milligram (mg) (4 oral tablets of 250 mg each) was administered once daily along with 5 mg oral prednisolone or prednisone tablet administered twice daily for 28-days dosing cycle and was continued until disease progression or unacceptable toxicity.

Measured Values

	Abiraterone
Number of Participants Analyzed [units: participants]	**58**
Time to PSA Progression [units: days] Median (95% Confidence Interval)	**169 (99 to 225)**

No statistical analysis provided for Time to PSA Progression

7. Secondary: Time to Radiographic Progression [Time Frame: Baseline, Day 1 of Cycle 4, 7 and 10, and thereafter every third cycle until first documented disease progression or up to 60 months]

Measure Type	Secondary
Measure Title	Time to Radiographic Progression
Measure Description	Time to radiographic progression is defined as the time from first dose until the first radiographic progression date that was confirmed.
Time Frame	Baseline, Day 1 of Cycle 4, 7 and 10, and thereafter every third cycle until first documented disease progression or up to 60 months
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.
Per protocol population defined as participants who had received at least one dose of abiraterone acetate and must had PSA evaluation/tumor assessment at Baseline and at least 1 post-baseline, and had received a minimum of 3 cycles of study treatment.

Reporting Groups

	Description
Abiraterone	Abiraterone acetate 1000 milligram (mg) (4 oral tablets of 250 mg each) was administered once daily along with 5 mg oral prednisolone or prednisone tablet administered twice daily for 28-days dosing cycle and was continued until disease progression or unacceptable toxicity.

Measured Values

	Abiraterone
Number of Participants Analyzed [units: participants]	**58**
Time to Radiographic Progression [units: days] Median (95% Confidence Interval)	**88 (82 to 333)**

No statistical analysis provided for Time to Radiographic Progression

8. Secondary: Shift From Baseline in Number of Participants With Eastern Cooperative Oncology Group (ECOG) Performance Status Score [Time Frame: Baseline and Day 1 of each cycle until first documented disease progression or up to 60 months]

Measure Type	Secondary
	Shift From Baseline in Number of Participants With Eastern Cooperative Oncology Group (ECOG) Performance Status

Measure Title	Score
Measure Description	ECOG performance status score ranges from 0 to 5 where 0=fully active, perform all pre-disease activities without restriction. 1=restricted in physically strenuous activity but ambulatory, carry out work of a light or sedentary nature, 2=ambulatory, capable of self-care, unable to carry out any work activities, up and about more than (>) 50 percent of waking hours, 3=capable of limited self-care, confined to bed or chair >50 percent of waking hours, 4=completely disabled, not capable of any self-care, totally confined to bed or chair and 5=dead.
Time Frame	Baseline and Day 1 of each cycle until first documented disease progression or up to 60 months
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.
Per protocol population defined as participants who had received at least one dose of abiraterone acetate and must had PSA evaluation/tumor assessment at Baseline and at least 1 post-baseline, and had received a minimum of 3 cycles of study treatment. 'N' (number of participants analyzed) = participants who were evaluable for this measure.

Reporting Groups

	Description
Abiraterone	Abiraterone acetate 1000 milligram (mg) (4 oral tablets of 250 mg each) was administered once daily along with 5 mg oral prednisolone or prednisone tablet administered twice daily for 28-days dosing cycle and was continued until disease progression or unacceptable toxicity.

Measured Values

	Abiraterone
Number of Participants Analyzed [units: participants]	**57**
Shift From Baseline in Number of Participants With Eastern Cooperative Oncology Group (ECOG) Performance Status Score [units: participants]	

Baseline:0; Best Post-dose:0	**22**
Baseline:0; Best Post-dose:1	**2**
Baseline:0; Best Post-dose:2	**0**
Baseline:0; Best Post-dose:3	**0**
Baseline:0; Best Post-dose:4	**0**
Baseline:1; Best Post-dose:0	**14**
Baseline:1; Best Post-dose:1	**15**
Baseline:1; Best Post-dose:2	**2**
Baseline:1; Best Post-dose:3	**0**
Baseline:1; Best Post-dose:4	**0**
Baseline:2; Best Post-dose:0	**1**
Baseline:2; Best Post-dose:1	**1**
Baseline:2; Best Post-dose:2	**0**
Baseline:2; Best Post-dose:3	**0**
Baseline:2; Best Post-dose:4	**0**
Baseline:0; Worst Post-dose:0	**6**
Baseline:0; Worst Post-dose:1	**17**
Baseline:0; Worst Post-dose:2	**1**
Baseline:0; Worst Post-dose:3	**0**
Baseline:0; Worst Post-dose:4	**0**
Baseline:1; Worst Post-dose:0	**0**
Baseline:1; Worst Post-dose:1	**24**
Baseline:1; Worst Post-dose:2	**6**

Baseline:1; Worst Post-dose:3	**1**
Baseline:1; Worst Post-dose:4	**0**
Baseline:2; Worst Post-dose:0	**0**
Baseline:2; Worst Post-dose:1	**0**
Baseline:2; Worst Post-dose:2	**2**
Baseline:2; Worst Post-dose:3	**0**
Baseline:2; Worst Post-dose:4	**0**

No statistical analysis provided for Shift From Baseline in Number of Participants With Eastern Cooperative Oncology Group (ECOG) Performance Status Score

9. Secondary: Percentage of Participants With Clinical Benefit [Time Frame: Baseline, Day 1 of Cycle 4, 7 and 10, and thereafter every third cycle until first documented disease progression or up to 60 months]

Measure Type	Secondary
Measure Title	Percentage of Participants With Clinical Benefit
Measure Description	Clinical benefit was defined as an observation of at least 1 of the following: PSA response by PSAWG criteria; radiographic response by RECIST criteria; stable disease by RECIST criteria lasting 6 months; or improvement by at least 1 unit in ECOG performance status.
Time Frame	Baseline, Day 1 of Cycle 4, 7 and 10, and thereafter every third cycle until first documented disease progression or up to 60 months
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.

Per protocol population defined as participants who had received at least one dose of abiraterone acetate and must had PSA evaluation/tumor assessment at Baseline and at least 1 post-baseline, and had received a minimum of 3 cycles of study treatment.

Reporting Groups

	Description
Abiraterone	Abiraterone acetate 1000 milligram (mg) (4 oral tablets of 250 mg each) was administered once daily along with 5 mg oral prednisolone or prednisone tablet administered twice daily for 28-days dosing cycle and was continued until disease progression or unacceptable toxicity.

Measured Values

	Abiraterone
Number of Participants Analyzed [units: participants]	**58**
Percentage of Participants With Clinical Benefit [units: percentage of participants]	
Disease Stabilization	**12**
Change in participant ECOG score	**16**

No statistical analysis provided for Percentage of Participants With Clinical Benefit

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Day 8 of Cycle 1 up to End of Study
Additional Description	No text entered.

Reporting Groups

	Description
Abiraterone	Abiraterone acetate 1000 milligram (mg) (4 oral tablets of 250 mg each) was administered once daily along with 5 mg oral prednisolone or prednisone tablet administered twice daily for 28-days dosing cycle and was continued until disease progression or unacceptable toxicity.

Serious Adverse Events

	Abiraterone
Total, serious adverse events	
# participants affected / at risk	**23/58 (39.66%)**
Blood and lymphatic system disorders	
Anaemia [*1]	
# participants affected / at risk	**1/58 (1.72%)**
Cardiac disorders	
Angina pectoris [*1]	
# participants affected / at risk	**1/58 (1.72%)**
Atrial fibrillation [*1]	
# participants affected / at risk	**2/58 (3.45%)**
Supraventricular tachycardia [*1]	
# participants affected / at risk	**1/58 (1.72%)**
Ventricular tachycardia [*1]	
# participants affected / at risk	**1/58 (1.72%)**
Gastrointestinal disorders	
Constipation [*1]	
# participants affected / at risk	**1/58 (1.72%)**
Vomiting [*1]	

# participants affected / at risk	**1/58 (1.72%)**
General disorders	
Disease progression [*1]	
# participants affected / at risk	**1/58 (1.72%)**
Fatigue [*1]	
# participants affected / at risk	**2/58 (3.45%)**
Pyrexia [*1]	
# participants affected / at risk	**4/58 (6.90%)**
Infections and infestations	
Cellulitis [*1]	
# participants affected / at risk	**1/58 (1.72%)**
Pneumonia [*1]	
# participants affected / at risk	**2/58 (3.45%)**
Injury, poisoning and procedural complications	
Sternal fracture [*1]	
# participants affected / at risk	**1/58 (1.72%)**
Investigations	
Alanine aminotransferase increased [*1]	
# participants affected / at risk	**1/58 (1.72%)**
Aspartate aminotransferase increased [*1]	
# participants affected / at risk	**1/58 (1.72%)**
Blood amylase increased [*1]	
# participants affected / at risk	**1/58 (1.72%)**
Blood creatinine increased [*1]	
# participants affected / at risk	**1/58 (1.72%)**

Blood potassium increased [*1]	
# participants affected / at risk	**1/58 (1.72%)**
Haemoglobin decreased [*1]	
# participants affected / at risk	**2/58 (3.45%)**
White blood cell count decreased [*1]	
# participants affected / at risk	**1/58 (1.72%)**
Metabolism and nutrition disorders	
Dehydration [*1]	
# participants affected / at risk	**1/58 (1.72%)**
Hyperglycaemia [*1]	
# participants affected / at risk	**1/58 (1.72%)**
Musculoskeletal and connective tissue disorders	
Back pain [*1]	
# participants affected / at risk	**4/58 (6.90%)**
Muscular weakness [*1]	
# participants affected / at risk	**2/58 (3.45%)**
Musculoskeletal pain [*1]	
# participants affected / at risk	**1/58 (1.72%)**
Myalgia [*1]	
# participants affected / at risk	**1/58 (1.72%)**
Myositis [*1]	
# participants affected / at risk	**1/58 (1.72%)**
Pain in extremity [*1]	
# participants affected / at risk	**2/58 (3.45%)**
Nervous system disorders	

Dizziness [*1]	
# participants affected / at risk	**2/58 (3.45%)**
Spinal cord compression [*1]	
# participants affected / at risk	**2/58 (3.45%)**
Syncope [*1]	
# participants affected / at risk	**2/58 (3.45%)**
Renal and urinary disorders	
Haematuria [*1]	
# participants affected / at risk	**2/58 (3.45%)**
Haemorrhage urinary tract [*1]	
# participants affected / at risk	**1/58 (1.72%)**
Renal failure [*1]	
# participants affected / at risk	**2/58 (3.45%)**
Reproductive system and breast disorders	
Pelvic pain [*1]	
# participants affected / at risk	**1/58 (1.72%)**
Scrotal swelling [*1]	
# participants affected / at risk	**1/58 (1.72%)**
Respiratory, thoracic and mediastinal disorders	
Dyspnoea [*1]	
# participants affected / at risk	**1/58 (1.72%)**
Hypoxia [*1]	
# participants affected / at risk	**1/58 (1.72%)**
Lung infiltration [*1]	

# participants affected / at risk	**1/58 (1.72%)**
Pneumonitis * 1	
# participants affected / at risk	**1/58 (1.72%)**
Skin and subcutaneous tissue disorders	
Exfoliative rash * 1	
# participants affected / at risk	**1/58 (1.72%)**
Skin disorder * 1	
# participants affected / at risk	**1/58 (1.72%)**
Vascular disorders	
Aortic stenosis * 1	
# participants affected / at risk	**1/58 (1.72%)**
Hypotension * 1	
# participants affected / at risk	**1/58 (1.72%)**

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA Version 11.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	Day 8 of Cycle 1 up to End of Study
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5

Reporting Groups

	Description
Abiraterone	Abiraterone acetate 1000 milligram (mg) (4 oral tablets of 250 mg each) was administered once daily along with 5 mg oral prednisolone or prednisone tablet administered twice daily for 28-days dosing cycle and was continued until disease progression or unacceptable toxicity.

Other Adverse Events

	Abiraterone
Total, other (not including serious) adverse events	
# participants affected / at risk	**57/58 (98.28%)**
Blood and lymphatic system disorders	
Anaemia * 1	
# participants affected / at risk	**15/58 (25.86%)**
Lymphopenia * 1	
# participants affected / at risk	**6/58 (10.34%)**
Gastrointestinal disorders	
Abdominal pain * 1	
# participants affected / at risk	**4/58 (6.90%)**
Constipation * 1	
# participants affected / at risk	**15/58 (25.86%)**
Diarrhoea * 1	
# participants affected / at risk	**10/58 (17.24%)**
Nausea * 1	
# participants affected / at risk	**11/58 (18.97%)**
Vomiting * 1	

# participants affected / at risk	**9/58 (15.52%)**
General disorders	
Fatigue [*1]	
# participants affected / at risk	**23/58 (39.66%)**
Oedema peripheral [*1]	
# participants affected / at risk	**18/58 (31.03%)**
Pain [*1]	
# participants affected / at risk	**4/58 (6.90%)**
Pyrexia [*1]	
# participants affected / at risk	**9/58 (15.52%)**
Infections and infestations	
Upper respiratory tract infection [*1]	
# participants affected / at risk	**4/58 (6.90%)**
Urinary tract infection [*1]	
# participants affected / at risk	**6/58 (10.34%)**
Investigations	
Alanine aminotransferase increased [*1]	
# participants affected / at risk	**6/58 (10.34%)**
Aspartate aminotransferase increased [*1]	
# participants affected / at risk	**15/58 (25.86%)**
Blood albumin decreased [*1]	
# participants affected / at risk	**12/58 (20.69%)**
Blood alkaline phosphatase increased [*1]	
# participants affected / at risk	**4/58 (6.90%)**

Weight decreased [*1]	
# participants affected / at risk	**10/58 (17.24%)**
Metabolism and nutrition disorders	
Anorexia [*1]	
# participants affected / at risk	**8/58 (13.79%)**
Hyperglycaemia [*1]	
# participants affected / at risk	**12/58 (20.69%)**
Hyperkalaemia [*1]	
# participants affected / at risk	**7/58 (12.07%)**
Hypoglycaemia [*1]	
# participants affected / at risk	**5/58 (8.62%)**
Hypokalaemia [*1]	
# participants affected / at risk	**4/58 (6.90%)**
Musculoskeletal and connective tissue disorders	
Arthralgia [*1]	
# participants affected / at risk	**13/58 (22.41%)**
Back pain [*1]	
# participants affected / at risk	**15/58 (25.86%)**
Bone pain [*1]	
# participants affected / at risk	**7/58 (12.07%)**
Flank pain [*1]	
# participants affected / at risk	**3/58 (5.17%)**
Groin pain [*1]	
# participants affected / at risk	**5/58 (8.62%)**
Muscle spasms [*1]	

# participants affected / at risk	**6/58 (10.34%)**
Muscular weakness [*1]	
# participants affected / at risk	**6/58 (10.34%)**
Musculoskeletal pain [*1]	
# participants affected / at risk	**9/58 (15.52%)**
Pain in extremity [*1]	
# participants affected / at risk	**9/58 (15.52%)**
Nervous system disorders	
Headache [*1]	
# participants affected / at risk	**3/58 (5.17%)**
Hypoaesthesia [*1]	
# participants affected / at risk	**4/58 (6.90%)**
Peripheral sensory neuropathy [*1]	
# participants affected / at risk	**9/58 (15.52%)**
Psychiatric disorders	
Anxiety [*1]	
# participants affected / at risk	**4/58 (6.90%)**
Depressed mood [*1]	
# participants affected / at risk	**3/58 (5.17%)**
Insomnia [*1]	
# participants affected / at risk	**4/58 (6.90%)**
Renal and urinary disorders	
Dysuria [*1]	
# participants affected / at risk	**4/58 (6.90%)**

Haemorrhage urinary tract [*1]	
# participants affected / at risk	**5/58 (8.62%)**
Micturition urgency [*1]	
# participants affected / at risk	**3/58 (5.17%)**
Nocturia [*1]	
# participants affected / at risk	**4/58 (6.90%)**
Pollakiuria [*1]	
# participants affected / at risk	**4/58 (6.90%)**
Urinary incontinence [*1]	
# participants affected / at risk	**3/58 (5.17%)**
Respiratory, thoracic and mediastinal disorders	
Cough [*1]	
# participants affected / at risk	**5/58 (8.62%)**
Dyspnoea [*1]	
# participants affected / at risk	**10/58 (17.24%)**
Productive cough [*1]	
# participants affected / at risk	**3/58 (5.17%)**
Skin and subcutaneous tissue disorders	
Ecchymosis [*1]	
# participants affected / at risk	**4/58 (6.90%)**
Vascular disorders	
Hot flush [*1]	
# participants affected / at risk	**6/58 (10.34%)**
Hypertension [*1]	
# participants affected / at risk	**3/58 (5.17%)**

* 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.

Results Point of Contact:

Name/Title: Senior Director, Clinical Research
Organization: Janssen Research & Development, 10990 Wilshire Blvd, Suite 1200, Los Angeles, California 90024
phone: (310) 943-8040 ext 2917

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Danila DC, Anand A, Sung CC, Heller G, Leversha MA, Cao L, Lilja H, Molina A, Sawyers CL, Fleisher M, Scher HI. TMPRSS2-ERG status in circulating tumor cells as a predictive biomarker of sensitivity in castration-resistant prostate cancer patients treated with abiraterone acetate. Eur Urol. 2011 Nov;60(5):897-904. doi: 10.1016/j.eururo.2011.07.011. Epub 2011 Jul 14.

Responsible Party:	Cougar Biotechnology, Inc.
ClinicalTrials.gov Identifier:	NCT00485303 History of Changes
Other Study ID Numbers:	CR016921 **COU-AA-004** 2007-002725-74 (EudraCT Number)
Study First Received:	June 8, 2007
Results First Received:	April 23, 2013
Last Updated:	June 25, 2013
Health Authority:	United States: Food and Drug Administration United Kingdom: Medicines and Healthcare Products Regulatory Agency

Disclaimer

Information in this posting shall not be considered to be a claim for any marketed product. Some information in this posting may differ from, or not be included in, the approved labeling for the product. Please refer to the full prescribing information for indications and proper use of the product.