Trial record **1 of 1** for: COU-AA-301
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Abiraterone Acetate in Castration-Resistant Prostate Cancer Previously Treated With Docetaxel-Based Chemotherapy

This study has been completed.

Sponsor:
Cougar Biotechnology, Inc.

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

ClinicalTrials.gov Identifier:
NCT00638690

First received: March 13, 2008
Last updated: April 10, 2014
Last verified: April 2014
History of Changes

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Results First Received: August 23, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Prostatic Neoplasms
Interventions:	Drug: Placebo Drug: Abiraterone acetate Drug: Prednisone/prednisolone

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 Acetate	Abiraterone acetate plus prednisone/prednisolone administered as four 250 mg tablets of abiraterone acetate once daily plus 5 mg prednisone/5 mg prednisolone twice daily until disease progression.
Placebo	Placebo plus prednisone/prednisolone administered as four placebo tablets once daily plus 5 mg prednisone/5 mg prednisolone tablet twice daily until disease progression.

Participant Flow: Overall Study

	Abiraterone Acetate	Placebo
STARTED	797	398
COMPLETED	116	56
NOT COMPLETED	681	342
Death	655	335
Withdrawal by Subject	22	5
Lost to Follow-up	4	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 Acetate	Abiraterone acetate plus prednisone/prednisolone administered as four 250 mg tablets of abiraterone acetate once daily plus 5 mg prednisone/5 mg prednisolone twice daily until disease progression.
Placebo	Placebo plus prednisone/prednisolone
Total	Total of all reporting groups

Baseline Measures

	Abiraterone Acetate	Placebo	Total
Number of Participants [units: participants]	797	398	1195
Age [units: years] Mean (Standard Deviation)	69.1 (8.4)	68.9 (8.61)	69 (8.46)
Gender [units: participants]			
Female	0	0	0
Male	797	398	1195
Region of Enrollment [units: participants]			
Australia	69	35	104
Austria	11	1	12
Belgium	32	11	43
Canada	97	57	154
France	57	33	90
Germany	26	12	38
Hungary	5	2	7
Italy	21	12	33
Netherlands	4	2	6

Republic of Ireland	**7**	**7**	**14**
Spain	**13**	**3**	**16**
United Kingdom	**119**	**61**	**180**
United States	**336**	**162**	**498**

Outcome Measures

Hide All Outcome Measures

1. Primary: Overall Survival [Time Frame: Up to 60 months]

Measure Type	Primary
Measure Title	Overall Survival
Measure Description	Overall survival is defined as the time interval from the date of randomization to the date of death from any cause.
Time Frame	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.
Analysis was performed on the Intent-to-Treat (ITT) population. The ITT population is composed of all patients randomized into the study and who will be classified according to their assigned teatment group, regardless of the actual treatment received.

Reporting Groups

	Description
Abiraterone Acetate	Abiraterone acetate plus prednisone/prednisolone administered as four 250 mg tablets of abiraterone acetate once daily plus 5 mg prednisone/5 mg prednisolone twice daily until disease progression.
Placebo	Placebo plus prednisone/prednisolone administered as four placebo tablets once daily plus 5 mg prednisone/5 mg prednisolone tablet twice daily until disease progression.

Measured Values

	Abiraterone Acetate	**Placebo**
Number of Participants Analyzed [units: participants]	**797**	**398**
Overall Survival [units: Days] Median (95% Confidence Interval)	**450.0 (430.0 to 470.0)**	**332.0 (310.0 to 366.0)**

Statistical Analysis 1 for Overall Survival

Groups [1]	All groups
Method [2]	Log Rank
P Value [3]	<0.0001
Hazard Ratio (HR) [4]	0.646
95% Confidence Interval	0.543 to 0.768

[1]	Additional details about the analysis, such as null hypothesis and power calculation:

	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	This was a stratified analysis.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Nominal P-value is 0.0142 at interim analysis based on group sequential design.
[4]	Other relevant estimation information:
	No text entered.

2. Secondary: Time to Prostate-Specific Antigen Progression According to Prostate Specific Antigen Working Group Criteria [Time Frame: Up to 12 months]

Measure Type	Secondary
Measure Title	Time to Prostate-Specific Antigen Progression According to Prostate Specific Antigen Working Group Criteria
Measure Description	The time interval from the date of randomization to the date of the prostate-specific antigen (PSA) progression as defined in the protocol-specific Prostate Specific Antigen Working Group (PSAWG) criteria, namely, a PSA level of at least 5 ng/ml that has risen on at least 2 successive occasions, at least 2 weeks apart.
Time Frame	Up to 12 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.
Analysis was performed on the Intent-to-Treat (ITT) population. The ITT population is composed of all patients randomized into the study and who will be classified according to their assigned teatment group, regardless of the actual treatment received.

Reporting Groups

	Description
Abiraterone Acetate	Abiraterone acetate plus prednisone/prednisolone administered as four 250 mg tablets of abiraterone acetate once daily plus 5 mg prednisone/5 mg prednisolone twice daily until disease progression.
Placebo	Placebo plus prednisone/prednisolone administered as four placebo tablets once daily plus 5 mg prednisone/5 mg prednisolone tablet twice daily until disease progression.

Measured Values

	Abiraterone Acetate	**Placebo**
Number of Participants Analyzed [units: participants]	**797**	**398**
Time to Prostate-Specific Antigen Progression According to Prostate Specific Antigen Working Group Criteria [units: Days] Median (95% Confidence Interval)	**309.0 (255.0 to 421.0)**	**200.0 (170.0 to 254.0)**

Statistical Analysis 1 for Time to Prostate-Specific Antigen Progression According to Prostate Specific Antigen Working Group Criteria

Groups [1]	All groups
Method [2]	Log Rank

P Value [3]	<0.0001
Hazard Ratio (HR) [4]	0.580
95% Confidence Interval	0.462 to 0.728

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	This was a stratified analysis.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Nominal P-value = 0.05.
[4]	Other relevant estimation information:
	No text entered.

3. Secondary: Number of Patients Achieving a Prostate-Specific Antigen Decline >=50% [Time Frame: Up to 12 months]

Measure Type	Secondary
Measure Title	Number of Patients Achieving a Prostate-Specific Antigen Decline >=50%
Measure Description	A prostate-specific antigen (PSA) response was defined as a >=50% decline from baseline.
Time Frame	Up to 12 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.
Analysis was performed on the Intent-to-Treat (ITT) population. The ITT population is composed of all patients randomized into the study and who will be classified according to their assigned teatment group, regardless of the actual treatment received.

Reporting Groups

	Description
Abiraterone Acetate	Abiraterone acetate plus prednisone/prednisolone administered as four 250 mg tablets of abiraterone acetate once daily plus 5 mg prednisone/5 mg prednisolone twice daily until disease progression.
Placebo	Placebo plus prednisone/prednisolone administered as four placebo tablets once daily plus 5 mg prednisone/5 mg prednisolone tablet twice daily until disease progression.

Measured Values

	Abiraterone Acetate	**Placebo**
Number of Participants Analyzed [units: participants]	**797**	**398**
Number of Patients Achieving a Prostate-Specific Antigen Decline >=50% [units: Participants]	**232**	**22**

Statistical Analysis 1 for Number of Patients Achieving a Prostate-Specific Antigen Decline >=50%

Groups [1]	All groups

Method [2]	Chi-squared
P Value [3]	<0.001
Risk Ratio (RR) [4]	5.266
95% Confidence Interval	3.459 to 8.018

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Nominal P-value = 0.05.
[4]	Other relevant estimation information:
	No text entered.

4. Secondary: Radiographic Progression-free Survival [Time Frame: Up to 11 months]

Measure Type	Secondary
Measure Title	Radiographic Progression-free Survival
Measure Description	Radiographic progression-free survival is based on imaging studies according to modified Response Evaluation Criteria in Solid Tumors (RECIST): baseline lymph node size must be >=2.0 cm to be considered a target lesion; progression on bone scans with >=2 new lesions not consistent with tumor flare, confirmed on a second scan >=6 weeks later that shows >=1 additional new lesion.
Time Frame	Up to 11 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.
Analysis was performed on the Intent-to-Treat (ITT) population. The ITT population is composed of all patients randomized into the study and who will be classified according to their assigned teatment group, regardless of the actual treatment received.

Reporting Groups

	Description
Abiraterone Acetate	Abiraterone acetate plus prednisone/prednisolone administered as four 250 mg tablets of abiraterone acetate once daily plus 5 mg prednisone/5 mg prednisolone twice daily until disease progression.
Placebo	Placebo plus prednisone/prednisolone administered as four placebo tablets once daily plus 5 mg prednisone/5 mg prednisolone tablet twice daily until disease progression.

Measured Values

	Abiraterone Acetate	**Placebo**
Number of Participants Analyzed [units: participants]	**797**	**398**
Radiographic Progression-free Survival [units: Days] Median (95% Confidence Interval)	**171.0 (169.0 to 192.0)**	**110.0 (88.0 to 168.0)**

Statistical Analysis 1 for Radiographic Progression-free Survival

Groups [1]	All groups
Method [2]	Log Rank
P Value [3]	<0.0001
Hazard Ratio (HR) [4]	0.673
95% Confidence Interval	0.585 to 0.776

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	This was a stratified analysis.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The nominal P-value = 0.05.
[4]	Other relevant estimation information:
	No text entered.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	5 years
Additional Description	Following interim analysis of the study by the Independent Data Monitoring Committee in August 2010, the protocol was amended to provide for the unblinding of all study participants and the option for placebo participants to receive abiraterone acetate treatment; 67 placebo participants crossed over.

Reporting Groups

	Description
Abiraterone Acetate	Abiraterone acetate plus prednisone/prednisolone administered as four 250 mg tablets of abiraterone acetate once daily plus 5 mg prednisone/5 mg prednisolone twice daily until disease progression.
Placebo	Placebo plus prednisone/prednisolone
Placebo to Abiraterone Acetate	Placebo plus prednisone/prednisolone crossed over to abiraterone acetate plus prednisone/prednisolone

Serious Adverse Events

	Abiraterone Acetate	Placebo	Placebo to Abiraterone Acetate
Total, serious adverse events			
# participants affected / at risk	**365/791 (46.14%)**	**175/394 (44.42%)**	**29/67 (43.28%)**
Blood and lymphatic system disorders			
Anaemia † [1]			
# participants affected / at risk	**26/791 (3.29%)**	**15/394 (3.81%)**	**1/67 (1.49%)**
Coagulopathy † [1]			

# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Pancytopenia † 1			
# participants affected / at risk	1/791 (0.13%)	1/394 (0.25%)	0/67 (0.00%)
Thrombocytopenia † 1			
# participants affected / at risk	6/791 (0.76%)	1/394 (0.25%)	0/67 (0.00%)
Febrile bone marrow aplasia † 1			
# participants affected / at risk	0/791 (0.00%)	1/394 (0.25%)	0/67 (0.00%)
Febrile neutropenia † 1			
# participants affected / at risk	3/791 (0.38%)	0/394 (0.00%)	0/67 (0.00%)
Neutropenia † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Cardiac disorders			
Bradycardia † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Acute coronary syndrome † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Angina pectoris † 1			
# participants affected / at risk	3/791 (0.38%)	0/394 (0.00%)	0/67 (0.00%)
Atrial fibrillation † 1			
# participants affected / at risk	6/791 (0.76%)	3/394 (0.76%)	1/67 (1.49%)
Atrioventricular block complete † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Cardiac failure † 1			
# participants affected / at risk	2/791 (0.25%)	0/394 (0.00%)	0/67 (0.00%)
Cardiac failure congestive † 1			
# participants affected / at risk	4/791 (0.51%)	1/394 (0.25%)	0/67 (0.00%)
Cardio-respiratory arrest † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Cardiogenic shock † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Chest pain † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Left ventricular dysfunction † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Myocardial infarction † 1			
# participants affected / at risk	7/791 (0.88%)	1/394 (0.25%)	0/67 (0.00%)
Pericardial effusion † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Supraventricular extrasystoles † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Supraventricular tachycardia † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Tachycardia † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)

Ear and labyrinth disorders			
Hypoacusis † 1			
# participants affected / at risk	**0/791 (0.00%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Tinnitus † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Vertigo † 1			
# participants affected / at risk	**0/791 (0.00%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Endocrine disorders			
Hyperglycaemia † 1			
# participants affected / at risk	**0/791 (0.00%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Adrenal insufficiency † 1			
# participants affected / at risk	**3/791 (0.38%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Adrenal suppression † 1			
# participants affected / at risk	**0/791 (0.00%)**	**0/394 (0.00%)**	**1/67 (1.49%)**
Hyperthyroidism † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Eye disorders			
Blindness † 1			
# participants affected / at risk	**0/791 (0.00%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Cataract † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Diplopia † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Keratitis † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Blindness unilateral † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Eye pain † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Pupils unequal † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Retinal vein occlusion † 1			
# participants affected / at risk	**0/791 (0.00%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Vitreous haemorrhage † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Gastrointestinal disorders			
Constipation † 1			
# participants affected / at risk	**5/791 (0.63%)**	**3/394 (0.76%)**	**0/67 (0.00%)**
Diarrhoea † 1			
# participants affected / at risk	**3/791 (0.38%)**	**2/394 (0.51%)**	**0/67 (0.00%)**
Dysphagia † 1			
# participants affected / at risk	**1/791 (0.13%)**	**2/394 (0.51%)**	**0/67 (0.00%)**
Enteritis † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**

Faecaloma † 1			
# participants affected / at risk	**0/791 (0.00%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Gastritis † 1			
# participants affected / at risk	**0/791 (0.00%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Haematemesis † 1			
# participants affected / at risk	**0/791 (0.00%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Ileus † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Melaena † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Nausea † 1			
# participants affected / at risk	**8/791 (1.01%)**	**3/394 (0.76%)**	**0/67 (0.00%)**
Oesophagitis † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Subileus † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Vomiting † 1			
# participants affected / at risk	**17/791 (2.15%)**	**9/394 (2.28%)**	**1/67 (1.49%)**
Abdominal pain † 1			
# participants affected / at risk	**6/791 (0.76%)**	**3/394 (0.76%)**	**0/67 (0.00%)**
Anal fistula † 1			
# participants affected / at risk	**0/791 (0.00%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Colitis ischaemic † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Colonic obstruction † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Diverticular perforation † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**1/67 (1.49%)**
Gastrointestinal haemorrhage † 1			
# participants affected / at risk	**4/791 (0.51%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Gastrointestinal obstruction † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Gastrooesophageal reflux disease † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Haemorrhoids † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Inguinal hernia † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Intestinal obstruction † 1			
# participants affected / at risk	**1/791 (0.13%)**	**2/394 (0.51%)**	**1/67 (1.49%)**
Intestinal perforation † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Pancreatitis † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**

Pancreatitis acute † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Rectal haemorrhage † 1			
# participants affected / at risk	**3/791 (0.38%)**	**3/394 (0.76%)**	**0/67 (0.00%)**
Small intestinal perforation † 1			
# participants affected / at risk	**0/791 (0.00%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Upper gastrointestinal haemorrhage † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
General disorders			
Malaise † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Pain † 1			
# participants affected / at risk	**1/791 (0.13%)**	**6/394 (1.52%)**	**0/67 (0.00%)**
Pyrexia † 1			
# participants affected / at risk	**6/791 (0.76%)**	**9/394 (2.28%)**	**3/67 (4.48%)**
Asthenia † 1			
# participants affected / at risk	**9/791 (1.14%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Catheter related complication † 1			
# participants affected / at risk	**0/791 (0.00%)**	**0/394 (0.00%)**	**1/67 (1.49%)**
Chest pain † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Disease progression † 1			
# participants affected / at risk	**12/791 (1.52%)**	**2/394 (0.51%)**	**2/67 (2.99%)**
Fatigue † 1			
# participants affected / at risk	**9/791 (1.14%)**	**6/394 (1.52%)**	**1/67 (1.49%)**
General physical health deterioration † 1			
# participants affected / at risk	**5/791 (0.63%)**	**2/394 (0.51%)**	**0/67 (0.00%)**
Generalised oedema † 1			
# participants affected / at risk	**2/791 (0.25%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Hernia obstructive † 1			
# participants affected / at risk	**0/791 (0.00%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Injection site haemorrhage † 1			
# participants affected / at risk	**0/791 (0.00%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Localised oedema † 1			
# participants affected / at risk	**0/791 (0.00%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Non-cardiac chest pain † 1			
# participants affected / at risk	**1/791 (0.13%)**	**2/394 (0.51%)**	**0/67 (0.00%)**
Oedema peripheral † 1			
# participants affected / at risk	**3/791 (0.38%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Performance status decreased † 1			
# participants affected / at risk	**1/791 (0.13%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Hepatobiliary disorders			
Cholecystitis † 1			
# participants affected / at risk	**1/791 (0.13%)**	**1/394 (0.25%)**	**0/67 (0.00%)**

Hepatitis † 1			
# participants affected / at risk	**0/791 (0.00%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Hepatotoxicity † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Hyperbilirubinaemia † 1			
# participants affected / at risk	**1/791 (0.13%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Bile duct obstruction † 1			
# participants affected / at risk	**2/791 (0.25%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Cholecystitis acute † 1			
# participants affected / at risk	**0/791 (0.00%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Cholecystitis chronic † 1			
# participants affected / at risk	**0/791 (0.00%)**	**0/394 (0.00%)**	**1/67 (1.49%)**
Infections and infestations			
Bronchitis † 1			
# participants affected / at risk	**0/791 (0.00%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Cellulitis † 1			
# participants affected / at risk	**1/791 (0.13%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Cystitis † 1			
# participants affected / at risk	**1/791 (0.13%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Diverticulitis † 1			
# participants affected / at risk	**2/791 (0.25%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Gastroenteritis † 1			
# participants affected / at risk	**5/791 (0.63%)**	**0/394 (0.00%)**	**1/67 (1.49%)**
Infection † 1			
# participants affected / at risk	**0/791 (0.00%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Meningitis † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Parotitis † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Pneumonia † 1			
# participants affected / at risk	**21/791 (2.65%)**	**5/394 (1.27%)**	**3/67 (4.48%)**
Pyelonephritis † 1			
# participants affected / at risk	**2/791 (0.25%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Sepsis † 1			
# participants affected / at risk	**14/791 (1.77%)**	**2/394 (0.51%)**	**1/67 (1.49%)**
Sinusitis † 1			
# participants affected / at risk	**0/791 (0.00%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Urosepsis † 1			
# participants affected / at risk	**4/791 (0.51%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Abscess jaw † 1			
# participants affected / at risk	**0/791 (0.00%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Arthritis infective † 1			
# participants affected / at risk	**0/791 (0.00%)**	**0/394 (0.00%)**	**1/67 (1.49%)**
Bacterial sepsis † 1			

# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Bronchopneumonia † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Candida sepsis † 1			
# participants affected / at risk	0/791 (0.00%)	1/394 (0.25%)	0/67 (0.00%)
Catheter sepsis † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Central line infection † 1			
# participants affected / at risk	2/791 (0.25%)	0/394 (0.00%)	0/67 (0.00%)
Enterocolitis infectious † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Escherichia infection † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Escherichia sepsis † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	1/67 (1.49%)
Escherichia urinary tract infection † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Genitourinary tract infection † 1			
# participants affected / at risk	0/791 (0.00%)	1/394 (0.25%)	0/67 (0.00%)
Groin infection † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Herpes zoster † 1			
# participants affected / at risk	1/791 (0.13%)	1/394 (0.25%)	0/67 (0.00%)
Influenza † 1			
# participants affected / at risk	0/791 (0.00%)	1/394 (0.25%)	0/67 (0.00%)
Kidney infection † 1			
# participants affected / at risk	2/791 (0.25%)	0/394 (0.00%)	0/67 (0.00%)
Lobar pneumonia † 1			
# participants affected / at risk	0/791 (0.00%)	3/394 (0.76%)	0/67 (0.00%)
Localised infection † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Lower respiratory tract infection † 1			
# participants affected / at risk	3/791 (0.38%)	0/394 (0.00%)	0/67 (0.00%)
Lung infection † 1			
# participants affected / at risk	3/791 (0.38%)	0/394 (0.00%)	0/67 (0.00%)
Osteomyelitis † 1			
# participants affected / at risk	0/791 (0.00%)	0/394 (0.00%)	1/67 (1.49%)
Pelvic abscess † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Pneumonia escherichia † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Post procedural infection † 1			
# participants affected / at risk	0/791 (0.00%)	1/394 (0.25%)	0/67 (0.00%)
Pyelonephritis acute † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)

Respiratory tract infection † 1			
# participants affected / at risk	**1/791 (0.13%)**	**2/394 (0.51%)**	**0/67 (0.00%)**
Staphylococcal infection † 1			
# participants affected / at risk	**3/791 (0.38%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Tooth infection † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Urinary tract infection † 1			
# participants affected / at risk	**19/791 (2.40%)**	**3/394 (0.76%)**	**3/67 (4.48%)**
Wound infection † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Injury, poisoning and procedural complications			
Fall † 1			
# participants affected / at risk	**3/791 (0.38%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Accidental overdose † 1			
# participants affected / at risk	**0/791 (0.00%)**	**0/394 (0.00%)**	**1/67 (1.49%)**
Ankle fracture † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Cervical vertebral fracture † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Concussion † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Cystitis radiation † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Dislocation of joint prosthesis † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Drug toxicity † 1			
# participants affected / at risk	**0/791 (0.00%)**	**2/394 (0.51%)**	**0/67 (0.00%)**
Femur fracture † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Foot fracture † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Gastroenteritis radiation † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Head injury † 1			
# participants affected / at risk	**0/791 (0.00%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Hip fracture † 1			
# participants affected / at risk	**5/791 (0.63%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Humerus fracture † 1			
# participants affected / at risk	**1/791 (0.13%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Incisional hernia † 1			
# participants affected / at risk	**0/791 (0.00%)**	**0/394 (0.00%)**	**1/67 (1.49%)**
Joint dislocation † 1			
# participants affected / at risk	**2/791 (0.25%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Lumbar vertebral fracture † 1			

# participants affected / at risk	2/791 (0.25%)	0/394 (0.00%)	0/67 (0.00%)
Medical device complication † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Pathological fracture † 1			
# participants affected / at risk	3/791 (0.38%)	0/394 (0.00%)	0/67 (0.00%)
Radiation associated pain † 1			
# participants affected / at risk	0/791 (0.00%)	1/394 (0.25%)	0/67 (0.00%)
Radius fracture † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Rib fracture † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Spinal compression fracture † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Spinal cord injury † 1			
# participants affected / at risk	0/791 (0.00%)	1/394 (0.25%)	0/67 (0.00%)
Spinal fracture † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Stent occlusion † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Subdural haematoma † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Tibia fracture † 1			
# participants affected / at risk	1/791 (0.13%)	1/394 (0.25%)	0/67 (0.00%)
Traumatic haematoma † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Upper limb fracture † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Urostomy complication † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Investigations			
Alanine aminotransferase increased † 1			
# participants affected / at risk	3/791 (0.38%)	1/394 (0.25%)	0/67 (0.00%)
Aspartate aminotransferase increased † 1			
# participants affected / at risk	1/791 (0.13%)	1/394 (0.25%)	0/67 (0.00%)
Blood alkaline phosphatase increased † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Blood creatinine increased † 1			
# participants affected / at risk	4/791 (0.51%)	2/394 (0.51%)	0/67 (0.00%)
Blood phosphorus decreased † 1			
# participants affected / at risk	0/791 (0.00%)	1/394 (0.25%)	0/67 (0.00%)
Electrocardiogram QT prolonged † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Heart rate increased † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)

International normalised ratio increased † 1			
# participants affected / at risk	**3/791 (0.38%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Liver function test abnormal † 1			
# participants affected / at risk	**0/791 (0.00%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Platelet count decreased † 1			
# participants affected / at risk	**0/791 (0.00%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Metabolism and nutrition disorders			
Alkalosis † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Anorexia † 1			
# participants affected / at risk	**4/791 (0.51%)**	**2/394 (0.51%)**	**0/67 (0.00%)**
Dehydration † 1			
# participants affected / at risk	**14/791 (1.77%)**	**4/394 (1.02%)**	**1/67 (1.49%)**
Gout † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Hyperglycaemia † 1			
# participants affected / at risk	**0/791 (0.00%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Hyperuricaemia † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Hypocalcaemia † 1			
# participants affected / at risk	**0/791 (0.00%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Hypoglycaemia † 1			
# participants affected / at risk	**1/791 (0.13%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Hypokalaemia † 1			
# participants affected / at risk	**7/791 (0.88%)**	**0/394 (0.00%)**	**1/67 (1.49%)**
Hyponatraemia † 1			
# participants affected / at risk	**4/791 (0.51%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Hypophosphataemia † 1			
# participants affected / at risk	**2/791 (0.25%)**	**2/394 (0.51%)**	**0/67 (0.00%)**
Diabetes mellitus † 1			
# participants affected / at risk	**0/791 (0.00%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Failure to thrive † 1			
# participants affected / at risk	**2/791 (0.25%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Hyperkalaemia † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**1/67 (1.49%)**
Hypomagnesaemia † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Musculoskeletal and connective tissue disorders			
Arthralgia † 1			
# participants affected / at risk	**3/791 (0.38%)**	**4/394 (1.02%)**	**0/67 (0.00%)**
Bursitis † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Coccydynia † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**

Myopathy † 1			
# participants affected / at risk	**2/791 (0.25%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Osteoarthritis † 1			
# participants affected / at risk	**2/791 (0.25%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Osteonecrosis † 1			
# participants affected / at risk	**2/791 (0.25%)**	**0/394 (0.00%)**	**2/67 (2.99%)**
Back pain † 1			
# participants affected / at risk	**12/791 (1.52%)**	**11/394 (2.79%)**	**4/67 (5.97%)**
Bone lesion † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Bone pain † 1			
# participants affected / at risk	**16/791 (2.02%)**	**13/394 (3.30%)**	**1/67 (1.49%)**
Flank pain † 1			
# participants affected / at risk	**3/791 (0.38%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Groin pain † 1			
# participants affected / at risk	**0/791 (0.00%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Intervertebral disc protrusion † 1			
# participants affected / at risk	**1/791 (0.13%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Mobility decreased † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Muscular weakness † 1			
# participants affected / at risk	**4/791 (0.51%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Musculoskeletal chest pain † 1			
# participants affected / at risk	**1/791 (0.13%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Musculoskeletal pain † 1			
# participants affected / at risk	**3/791 (0.38%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Neck pain † 1			
# participants affected / at risk	**3/791 (0.38%)**	**1/394 (0.25%)**	**1/67 (1.49%)**
Osteoporotic fracture † 1			
# participants affected / at risk	**0/791 (0.00%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Pain in extremity † 1			
# participants affected / at risk	**4/791 (0.51%)**	**7/394 (1.78%)**	**2/67 (2.99%)**
Pathological fracture † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Spinal column stenosis † 1			
# participants affected / at risk	**0/791 (0.00%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Spinal disorder † 1			
# participants affected / at risk	**0/791 (0.00%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Synovial cyst † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**

Cancer pain † 1			
# participants affected / at risk	**3/791 (0.38%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Chronic lymphocytic leukaemia † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Colon cancer † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Gastric cancer † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Malignant melanoma † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Malignant pleural effusion † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**1/67 (1.49%)**
Metastases to bone † 1			
# participants affected / at risk	**3/791 (0.38%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Metastases to central nervous system † 1			
# participants affected / at risk	**4/791 (0.51%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Metastases to liver † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Metastases to lung † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Metastases to meninges † 1			
# participants affected / at risk	**2/791 (0.25%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Metastases to soft tissue † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Metastases to spine † 1			
# participants affected / at risk	**0/791 (0.00%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Metastatic pain † 1			
# participants affected / at risk	**1/791 (0.13%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Myelodysplastic syndrome † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Tumour pain † 1			
# participants affected / at risk	**1/791 (0.13%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Nervous system disorders			
Convulsion † 1			
# participants affected / at risk	**2/791 (0.25%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Dizziness † 1			
# participants affected / at risk	**3/791 (0.38%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Encephalopathy † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Epiduritis † 1			
# participants affected / at risk	**0/791 (0.00%)**	**2/394 (0.51%)**	**0/67 (0.00%)**
Headache † 1			
# participants affected / at risk	**3/791 (0.38%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Hemiparesis † 1			

# participants affected / at risk	2/791 (0.25%)	0/394 (0.00%)	0/67 (0.00%)
Neuralgia † 1			
# participants affected / at risk	1/791 (0.13%)	1/394 (0.25%)	0/67 (0.00%)
Paraplegia † 1			
# participants affected / at risk	0/791 (0.00%)	1/394 (0.25%)	0/67 (0.00%)
Syncope † 1			
# participants affected / at risk	3/791 (0.38%)	2/394 (0.51%)	0/67 (0.00%)
Brachial plexopathy † 1			
# participants affected / at risk	0/791 (0.00%)	1/394 (0.25%)	0/67 (0.00%)
Brain compression † 1			
# participants affected / at risk	0/791 (0.00%)	2/394 (0.51%)	0/67 (0.00%)
Brain oedema † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Bulbar palsy † 1			
# participants affected / at risk	0/791 (0.00%)	1/394 (0.25%)	0/67 (0.00%)
Cauda equina syndrome † 1			
# participants affected / at risk	1/791 (0.13%)	1/394 (0.25%)	0/67 (0.00%)
Cerebral haemorrhage † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Cerebral ischaemia † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Cerebrovascular accident † 1			
# participants affected / at risk	4/791 (0.51%)	0/394 (0.00%)	0/67 (0.00%)
Cervical cord compression † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Cranial neuropathy † 1			
# participants affected / at risk	0/791 (0.00%)	1/394 (0.25%)	0/67 (0.00%)
Facial paresis † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Hydrocephalus † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Loss of consciousness † 1			
# participants affected / at risk	2/791 (0.25%)	0/394 (0.00%)	0/67 (0.00%)
Lumbar radiculopathy † 1			
# participants affected / at risk	0/791 (0.00%)	1/394 (0.25%)	0/67 (0.00%)
Nerve root compression † 1			
# participants affected / at risk	1/791 (0.13%)	1/394 (0.25%)	0/67 (0.00%)
Nerve root lesion † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Neurological symptom † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Neuropathy peripheral † 1			
# participants affected / at risk	1/791 (0.13%)	2/394 (0.51%)	0/67 (0.00%)
Peroneal nerve palsy † 1			

# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Polyneuropathy † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Radiculopathy † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Spinal cord compression † 1			
# participants affected / at risk	23/791 (2.91%)	18/394 (4.57%)	3/67 (4.48%)
Subdural hygroma † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Syncope vasovagal † 1			
# participants affected / at risk	0/791 (0.00%)	1/394 (0.25%)	0/67 (0.00%)
Transient ischaemic attack † 1			
# participants affected / at risk	4/791 (0.51%)	2/394 (0.51%)	0/67 (0.00%)
VIth nerve paralysis † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Psychiatric disorders			
Delirium † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	1/67 (1.49%)
Depression † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Confusional state † 1			
# participants affected / at risk	4/791 (0.51%)	3/394 (0.76%)	0/67 (0.00%)
Mental status changes † 1			
# participants affected / at risk	2/791 (0.25%)	0/394 (0.00%)	0/67 (0.00%)
Renal and urinary disorders			
Anuria † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Dysuria † 1			
# participants affected / at risk	2/791 (0.25%)	0/394 (0.00%)	0/67 (0.00%)
Haematuria † 1			
# participants affected / at risk	12/791 (1.52%)	11/394 (2.79%)	0/67 (0.00%)
Hydronephrosis † 1			
# participants affected / at risk	12/791 (1.52%)	3/394 (0.76%)	2/67 (2.99%)
Polyuria † 1			
# participants affected / at risk	0/791 (0.00%)	1/394 (0.25%)	0/67 (0.00%)
Bladder stenosis † 1			
# participants affected / at risk	0/791 (0.00%)	1/394 (0.25%)	0/67 (0.00%)
Bladder tamponade † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Calculus ureteric † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Haemorrhage urinary tract † 1			
# participants affected / at risk	3/791 (0.38%)	1/394 (0.25%)	0/67 (0.00%)
Nephrolithiasis † 1			

# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Obstructive uropathy † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Pollakiuria † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Renal failure † 1			
# participants affected / at risk	4/791 (0.51%)	2/394 (0.51%)	0/67 (0.00%)
Renal failure acute † 1			
# participants affected / at risk	7/791 (0.88%)	5/394 (1.27%)	2/67 (2.99%)
Renal impairment † 1			
# participants affected / at risk	3/791 (0.38%)	0/394 (0.00%)	0/67 (0.00%)
Stress urinary incontinence † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Ureteric obstruction † 1			
# participants affected / at risk	3/791 (0.38%)	1/394 (0.25%)	1/67 (1.49%)
Urinary hesitation † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Urinary incontinence † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Urinary retention † 1			
# participants affected / at risk	9/791 (1.14%)	6/394 (1.52%)	0/67 (0.00%)
Urinary tract obstruction † 1			
# participants affected / at risk	0/791 (0.00%)	2/394 (0.51%)	0/67 (0.00%)
Reproductive system and breast disorders			
Benign prostatic hyperplasia † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Oedema genital † 1			
# participants affected / at risk	0/791 (0.00%)	1/394 (0.25%)	0/67 (0.00%)
Pelvic haematoma † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Pelvic pain † 1			
# participants affected / at risk	2/791 (0.25%)	2/394 (0.51%)	0/67 (0.00%)
Respiratory, thoracic and mediastinal disorders			
Asthma † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Dyspnoea † 1			
# participants affected / at risk	11/791 (1.39%)	4/394 (1.02%)	1/67 (1.49%)
Pneumothorax † 1			
# participants affected / at risk	2/791 (0.25%)	0/394 (0.00%)	0/67 (0.00%)
Acute respiratory distress syndrome † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Acute respiratory failure † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Bronchial obstruction † 1			

# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Chronic obstructive pulmonary disease † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	1/67 (1.49%)
Epistaxis † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Hypoxia † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Pleural effusion † 1			
# participants affected / at risk	2/791 (0.25%)	0/394 (0.00%)	2/67 (2.99%)
Pleuritic pain † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Pneumonia aspiration † 1			
# participants affected / at risk	0/791 (0.00%)	2/394 (0.51%)	0/67 (0.00%)
Pulmonary embolism † 1			
# participants affected / at risk	7/791 (0.88%)	10/394 (2.54%)	2/67 (2.99%)
Pulmonary oedema † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Respiratory distress † 1			
# participants affected / at risk	0/791 (0.00%)	1/394 (0.25%)	0/67 (0.00%)
Respiratory failure † 1			
# participants affected / at risk	0/791 (0.00%)	1/394 (0.25%)	0/67 (0.00%)
Skin and subcutaneous tissue disorders			
Purpura † 1			
# participants affected / at risk	0/791 (0.00%)	1/394 (0.25%)	0/67 (0.00%)
Erythema † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Leukocytoclastic vasculitis † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Skin ulcer † 1			
# participants affected / at risk	2/791 (0.25%)	0/394 (0.00%)	0/67 (0.00%)
Surgical and medical procedures			
Eye muscle recession † 1			
# participants affected / at risk	0/791 (0.00%)	1/394 (0.25%)	0/67 (0.00%)
Malignant tumour excision † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Pain management † 1			
# participants affected / at risk	1/791 (0.13%)	0/394 (0.00%)	0/67 (0.00%)
Ureteral stent insertion † 1			
# participants affected / at risk	0/791 (0.00%)	1/394 (0.25%)	0/67 (0.00%)
Vascular disorders			
Hypertension † 1			
# participants affected / at risk	3/791 (0.38%)	0/394 (0.00%)	0/67 (0.00%)
Hypotension † 1			
# participants affected / at risk	4/791 (0.51%)	1/394 (0.25%)	1/67 (1.49%)

Cardiovascular insufficiency † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Deep vein thrombosis † 1			
# participants affected / at risk	**5/791 (0.63%)**	**1/394 (0.25%)**	**0/67 (0.00%)**
Embolism † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Hot flush † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Peripheral ischaemia † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Phlebitis † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**
Superior vena caval occlusion † 1			
# participants affected / at risk	**1/791 (0.13%)**	**0/394 (0.00%)**	**0/67 (0.00%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA Version 11.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	5 years
Additional Description	Following interim analysis of the study by the Independent Data Monitoring Committee in August 2010, the protocol was amended to provide for the unblinding of all study participants and the option for placebo participants to receive abiraterone acetate treatment; 67 placebo participants crossed over.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Abiraterone Acetate	Abiraterone acetate plus prednisone/prednisolone administered as four 250 mg tablets of abiraterone acetate once daily plus 5 mg prednisone/5 mg prednisolone twice daily until disease progression.
Placebo	Placebo plus prednisone/prednisolone
Placebo to Abiraterone Acetate	Placebo plus prednisone/prednisolone crossed over to abiraterone acetate plus prednisone/prednisolone

Other Adverse Events

	Abiraterone Acetate	**Placebo**	**Placebo to Abiraterone Acetate**
Total, other (not including serious) adverse events			
# participants affected / at risk	**766/791 (96.84%)**	**381/394 (96.70%)**	**57/67 (85.07%)**
Blood and lymphatic system disorders			
Anaemia † 1			
# participants affected / at risk	**202/791 (25.54%)**	**105/394 (26.65%)**	**11/67 (16.42%)**
Gastrointestinal disorders			
Constipation † 1			
# participants affected / at risk	**236/791 (29.84%)**	**124/394 (31.47%)**	**14/67 (20.90%)**

Diarrhoea † 1			
# participants affected / at risk	**166/791 (20.99%)**	**57/394 (14.47%)**	**13/67 (19.40%)**
Dyspepsia † 1			
# participants affected / at risk	**54/791 (6.83%)**	**15/394 (3.81%)**	**4/67 (5.97%)**
Nausea † 1			
# participants affected / at risk	**272/791 (34.39%)**	**132/394 (33.50%)**	**19/67 (28.36%)**
Vomiting † 1			
# participants affected / at risk	**204/791 (25.79%)**	**97/394 (24.62%)**	**14/67 (20.90%)**
Abdominal pain † 1			
# participants affected / at risk	**111/791 (14.03%)**	**45/394 (11.42%)**	**4/67 (5.97%)**
Dry mouth † 1			
# participants affected / at risk	**61/791 (7.71%)**	**20/394 (5.08%)**	**4/67 (5.97%)**
General disorders			
Pyrexia † 1			
# participants affected / at risk	**87/791 (11.00%)**	**28/394 (7.11%)**	**7/67 (10.45%)**
Asthenia † 1			
# participants affected / at risk	**131/791 (16.56%)**	**54/394 (13.71%)**	**5/67 (7.46%)**
Fatigue † 1			
# participants affected / at risk	**384/791 (48.55%)**	**172/394 (43.65%)**	**19/67 (28.36%)**
Oedema peripheral † 1			
# participants affected / at risk	**228/791 (28.82%)**	**75/394 (19.04%)**	**11/67 (16.42%)**
Pain † 1			
# participants affected / at risk	**40/791 (5.06%)**	**15/394 (3.81%)**	**2/67 (2.99%)**
Infections and infestations			
Nasopharyngitis † 1			
# participants affected / at risk	**58/791 (7.33%)**	**25/394 (6.35%)**	**6/67 (8.96%)**
Upper respiratory tract infection † 1			
# participants affected / at risk	**57/791 (7.21%)**	**11/394 (2.79%)**	**2/67 (2.99%)**
Urinary tract infection † 1			
# participants affected / at risk	**100/791 (12.64%)**	**27/394 (6.85%)**	**6/67 (8.96%)**
Injury, poisoning and procedural complications			
Contusion † 1			
# participants affected / at risk	**70/791 (8.85%)**	**22/394 (5.58%)**	**3/67 (4.48%)**
Investigations			
Weight decreased † 1			
# participants affected / at risk	**110/791 (13.91%)**	**57/394 (14.47%)**	**4/67 (5.97%)**
Metabolism and nutrition disorders			
Anorexia † 1			
# participants affected / at risk	**155/791 (19.60%)**	**74/394 (18.78%)**	**4/67 (5.97%)**
Hyperglycaemia † 1			
# participants affected / at risk	**61/791 (7.71%)**	**20/394 (5.08%)**	**2/67 (2.99%)**
Hypokalaemia † 1			
# participants affected / at risk	**149/791 (18.84%)**	**36/394 (9.14%)**	**10/67 (14.93%)**
Decreased appetite † 1			

# participants affected / at risk	89/791 (11.25%)	36/394 (9.14%)	4/67 (5.97%)
Dehydration † 1			
# participants affected / at risk	43/791 (5.44%)	18/394 (4.57%)	2/67 (2.99%)
Hypomagnesaemia † 1			
# participants affected / at risk	9/791 (1.14%)	3/394 (0.76%)	4/67 (5.97%)
Musculoskeletal and connective tissue disorders			
Arthralgia † 1			
# participants affected / at risk	246/791 (31.10%)	93/394 (23.60%)	20/67 (29.85%)
Back pain † 1			
# participants affected / at risk	282/791 (35.65%)	138/394 (35.03%)	23/67 (34.33%)
Bone pain † 1			
# participants affected / at risk	219/791 (27.69%)	112/394 (28.43%)	12/67 (17.91%)
Groin pain † 1			
# participants affected / at risk	51/791 (6.45%)	22/394 (5.58%)	5/67 (7.46%)
Muscle spasms † 1			
# participants affected / at risk	79/791 (9.99%)	37/394 (9.39%)	4/67 (5.97%)
Muscular weakness † 1			
# participants affected / at risk	94/791 (11.88%)	38/394 (9.64%)	8/67 (11.94%)
Musculoskeletal pain † 1			
# participants affected / at risk	140/791 (17.70%)	56/394 (14.21%)	12/67 (17.91%)
Myalgia † 1			
# participants affected / at risk	50/791 (6.32%)	17/394 (4.31%)	6/67 (8.96%)
Neck pain † 1			
# participants affected / at risk	35/791 (4.42%)	20/394 (5.08%)	4/67 (5.97%)
Pain in extremity † 1			
# participants affected / at risk	170/791 (21.49%)	81/394 (20.56%)	13/67 (19.40%)
Nervous system disorders			
Dizziness † 1			
# participants affected / at risk	99/791 (12.52%)	40/394 (10.15%)	2/67 (2.99%)
Headache † 1			
# participants affected / at risk	111/791 (14.03%)	42/394 (10.66%)	6/67 (8.96%)
Hypoaesthesia † 1			
# participants affected / at risk	41/791 (5.18%)	15/394 (3.81%)	2/67 (2.99%)
Paraesthesia † 1			
# participants affected / at risk	41/791 (5.18%)	15/394 (3.81%)	3/67 (4.48%)
Psychiatric disorders			
Anxiety † 1			
# participants affected / at risk	55/791 (6.95%)	21/394 (5.33%)	2/67 (2.99%)
Depression † 1			
# participants affected / at risk	47/791 (5.94%)	21/394 (5.33%)	2/67 (2.99%)
Insomnia † 1			
# participants affected / at risk	98/791 (12.39%)	52/394 (13.20%)	5/67 (7.46%)
Renal and urinary disorders			
Haematuria † 1			

# participants affected / at risk	**76/791 (9.61%)**	**27/394 (6.85%)**	**2/67 (2.99%)**
Nocturia † 1			
# participants affected / at risk	**54/791 (6.83%)**	**17/394 (4.31%)**	**4/67 (5.97%)**
Pollakiuria † 1			
# participants affected / at risk	**61/791 (7.71%)**	**21/394 (5.33%)**	**4/67 (5.97%)**
Urinary incontinence † 1			
# participants affected / at risk	**42/791 (5.31%)**	**15/394 (3.81%)**	**4/67 (5.97%)**
Reproductive system and breast disorders			
Pelvic pain † 1			
# participants affected / at risk	**20/791 (2.53%)**	**20/394 (5.08%)**	**2/67 (2.99%)**
Respiratory, thoracic and mediastinal disorders			
Cough † 1			
# participants affected / at risk	**116/791 (14.66%)**	**33/394 (8.38%)**	**7/67 (10.45%)**
Dyspnoea † 1			
# participants affected / at risk	**117/791 (14.79%)**	**49/394 (12.44%)**	**10/67 (14.93%)**
Skin and subcutaneous tissue disorders			
Ecchymosis † 1			
# participants affected / at risk	**17/791 (2.15%)**	**12/394 (3.05%)**	**4/67 (5.97%)**
Hyperhidrosis † 1			
# participants affected / at risk	**44/791 (5.56%)**	**16/394 (4.06%)**	**1/67 (1.49%)**
Vascular disorders			
Hypertension † 1			
# participants affected / at risk	**79/791 (9.99%)**	**27/394 (6.85%)**	**5/67 (7.46%)**
Hot flush † 1			
# participants affected / at risk	**157/791 (19.85%)**	**68/394 (17.26%)**	**2/67 (2.99%)**
Hypotension † 1			
# participants affected / at risk	**35/791 (4.42%)**	**18/394 (4.57%)**	**4/67 (5.97%)**

† Events were collected by 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.

☑ **Restriction Description:** The sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is at least 60 days from the time submitted to the sponsor for review. After 1) publication of multi-center results, 2) notification by sponsor that a multi-center submission is no longer planned, or 3) the 18 month anniversary of the termination of the study at all sites, the institution and investigator may publish or publicly present study data.

Results Point of Contact:

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Organization: Johnson & Johnson Pharmaceutical Research & Development
phone: 310-914-2915

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

Antoun S, Bayar A, Ileana E, Laplanche A, Fizazi K, di Palma M, Escudier B, Albiges L, Massard C, Loriot Y. High subcutaneous adipose tissue predicts the prognosis in metastatic castration-resistant prostate cancer patients in post chemotherapy setting. Eur J Cancer. 2015 Nov;51(17):2570-7. doi: 10.1016/j.ejca.2015.07.042. Epub 2015 Aug 13.

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Responsible Party: Cougar Biotechnology, Inc.

ClinicalTrials.gov Identifier:	NCT00638690 History of Changes
Other Study ID Numbers:	CR016924 **COU-AA-301** (Other Identifier: Cougar Biotechnology, Inc)
Study First Received:	March 13, 2008
Results First Received:	August 23, 2011
Last Updated:	April 10, 2014
Health Authority:	United States: Food and Drug Administration European Union: European Medicines Agency Australia: National Health and Medical Research Council Canada: Health Canada

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