Trial record **1 of 1** for: CNTO888PCR2001
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A Study of the Safety and Efficacy of Single-agent Carlumab (an Anti-Chemokine Ligand 2 [CCL2]) in Participants With Metastatic Castrate-Resistant Prostate Cancer

This study has been completed.

Sponsor:
Centocor Research & Development, Inc.

Information provided by (Responsible Party):
Centocor Research & Development, Inc.

ClinicalTrials.gov Identifier:
NCT00992186

First received: September 29, 2009
Last updated: June 18, 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: March 29, 2013

Study Type:	Interventional
Study Design:	Endpoint Classification: Safety/Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Prostate Cancer
Intervention:	Drug: Carlumab

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
16 out of 62 participants, who signed informed consent, were deemed ineligible for the study during screening because of screening failure, serious adverse events, unavailability of carlumab at the site and withdrawal of consent.

Reporting Groups

	Description
Carlumab	Carlumab diluted in 5 percent (%) dextrose administered at the dose of 15 milligram per kilogram (mg/kg) by intravenous (into a vein) infusion (a fluid or a medicine delivered into a vein by way of a needle) at a constant rate over a 90 minute period once every 2 weeks until disease progression.

Participant Flow: Overall Study

	Carlumab
STARTED	**46**
COMPLETED	**0**
NOT COMPLETED	**46**
Withdrawal by Subject	**2**
Protocol Violation	**1**
Physician Decision	**1**

Adverse Event	**9**
Progressive Disease	**30**
Refusal To Receive Study Agent	**3**

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
Carlumab	Carlumab diluted in 5 percent (%) dextrose administered at the dose of 15 milligram per kilogram (mg/kg) by intravenous (into a vein) infusion (a fluid or a medicine delivered into a vein by way of a needle) at a constant rate over a 90 minute period once every 2 weeks until disease progression.

Baseline Measures

	Carlumab
Number of Participants [units: participants]	**46**
Age [units: Years] Mean (Standard Deviation)	**67.5 (7.95)**
Gender [units: Participants]	

Female	**0**
Male	**46**
Region of Enrollment [units: participants]	
Belgium	**11**
Russian Federation	**10**
United Kingdom	**18**
United States	**7**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants With Composite Response [Time Frame: Up to 4 weeks before first dose, every 12 weeks after first dose, Week 12 after last dose of carlumab]

Measure Type	Primary
Measure Title	Percentage of Participants With Composite Response
Measure Description	The composite response is measured by change from Baseline in skeletal lesions, extra-skeletal lesions, and prostate specific antigen (PSA) values. A participant is considered to have composite response, if 1 of the following responses occurs after the first dose of carlumab: (1) Complete response (CR) or partial response (PR) according to Response Evaluation Criteria in Solid Tumors, Version 1.1 (RECIST), (2) PSA response at 12 weeks and absence of skeletal and extra-skeletal progression or (3) Stable disease at 24 weeks defined as the absence of PSA, skeletal, or extra-skeletal progression.
Time Frame	Up to 4 weeks before first dose, every 12 weeks after first dose, Week 12 after last dose of carlumab
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 population included all the participants who received at least 1 administration of carlumab and had at least 1 post-baseline disease evaluation. 'N' (number of participants analyzed) signifies those participants who were evaluable for this measure.

Reporting Groups

	Description
Carlumab	Carlumab diluted in 5 percent (%) dextrose administered at the dose of 15 milligram per kilogram (mg/kg) by intravenous (into a vein) infusion (a fluid or a medicine delivered into a vein by way of a needle) at a constant rate over a 90 minute period once every 2 weeks until disease progression.

Measured Values

	Carlumab
Number of Participants Analyzed [units: participants]	**41**
Percentage of Participants With Composite Response [units: Percentage of participants]	
CR or PR	**0.0**
PSA response	**0.0**
Stable disease	**2.4**

No statistical analysis provided for Percentage of Participants With Composite Response

2. Secondary: Percentage of Participants With Objective Tumor Response [Time Frame: Up to 4 weeks before first dose, every 12 weeks after first dose, Week 12 after last dose of carlumab]

Measure Type	Secondary

Measure Title	Percentage of Participants With Objective Tumor Response
Measure Description	Objective response based on assessment of confirmed CR or PR according to RECIST. CR defined as disappearance of all target lesions. Any pathological lymph nodes must have reduction in short axis to less than 10 millimeter (mm). PR defined as at least 30 percent (%) decrease in sum of the diameters of the target lesions taking as reference the Baseline sum diameters. Confirmed responses are those that persist on repeat imaging study for at least 4 weeks after initial documentation of response.
Time Frame	Up to 4 weeks before first dose, every 12 weeks after first dose, Week 12 after last dose of carlumab
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 population included all the participants who received at least 1 administration of carlumab and had a measurable, non-measurable or bone lesion at Baseline and had at least 1 post-treatment tumor evaluation. 'N' (number of participants analyzed) signifies those participants who were evaluable for this measure.

Reporting Groups

	Description
Carlumab	Carlumab diluted in 5% dextrose administered at the dose of 15 mg/kg by intravenous infusion at a constant rate over a 90 minute period once every 2 weeks until disease progression.

Measured Values

	Carlumab
Number of Participants Analyzed [units: participants]	**41**
Percentage of Participants With Objective Tumor Response [units: Percentage of participants]	
CR	**0.0**

PR	**0.0**

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

3. Secondary: Progression-Free Survival (PFS) [Time Frame: Up to 4 weeks before first dose, every 12 weeks after first dose, Week 12 after last dose of carlumab]

Measure Type	Secondary
Measure Title	Progression-Free Survival (PFS)
Measure Description	The PFS is defined as the time from the date of initiation of study treatment to the date of initial documented skeletal or extra-skeletal progressive disease, or date of death, whichever occurs first. A participant is considered to have extra-skeletal disease progression if the disease has progressed as per the Response Evaluation Criteria in Solid Tumors (RECIST v1.1) criteria. A participant is considered to have skeletal disease progression if they have 1 post-baseline bone scan demonstrating 2 or more new skeletal lesions compared to Baseline and confirmed by a second bone scan 6 to 12 weeks later or with evidence of clinical progression.
Time Frame	Up to 4 weeks before first dose, every 12 weeks after first dose, Week 12 after last dose of carlumab
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 population included all the participants who received at least 1 administration of carlumab.

Reporting Groups

	Description
Carlumab	Carlumab diluted in 5% dextrose administered at the dose of 15 mg/kg by intravenous infusion at a constant rate over a 90 minute period once every 2 weeks until disease progression.

Measured Values

	Carlumab
Number of Participants Analyzed [units: participants]	**46**
Progression-Free Survival (PFS) [units: Days] Median (95% Confidence Interval)	**81.0 (76.0 to 85.0)**

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

4. Secondary: Overall Survival (OS) [Time Frame: Week 8, 12, every 12 weeks up to 1 year after last dose of carlumab]

Measure Type	Secondary
Measure Title	Overall Survival (OS)
Measure Description	The OS is defined as the time from the date of initiation of study treatment to death due to any cause. Participants were followed for 1 year after the last administration of carlumab for survival or until the end of study, whichever occurs first. For participants with unknown survival status as of the data cutoff date, OS was censored at the last date that the participant was known to be alive.
Time Frame	Week 8, 12, every 12 weeks up to 1 year after last dose of carlumab
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 population included all the participants who received at least 1 administration of carlumab.

Reporting Groups

	Description
Carlumab	Carlumab diluted in 5% dextrose administered at the dose of 15 mg/kg by intravenous infusion at a constant rate over a 90 minute period once every 2 weeks until disease progression.

Measured Values

	Carlumab
Number of Participants Analyzed [units: participants]	**46**
Overall Survival (OS) [units: Days] Median (Full Range)	**309.0 (47 to 582)**

No statistical analysis provided for Overall Survival (OS)

5. Secondary: Percentage of Participants With Prostate Specific Antigen (PSA) Response [Time Frame: Up to 2 weeks before first dose, every 4 weeks after first dose, Week 4, 8, 12 after the last dose of carlumab]

Measure Type	Secondary
Measure Title	Percentage of Participants With Prostate Specific Antigen (PSA) Response
Measure Description	The PSA response for participants with elevated PSA levels at Baseline (more than or equal to 5 nanogram per milliliter (ng/mL) is defined as at least a 50% reduction in PSA from the Baseline value, confirmed by a second PSA value measurement 3 or more weeks later.
Time Frame	Up to 2 weeks before first dose, every 4 weeks after first dose, Week 4, 8, 12 after the last dose of carlumab
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 population included all the participants who received at least 1 administration of carlumab and had a Baseline PSA more than or equal to 5 ng/mL and at least 1 post-treatment PSA measurement. 'N' (number of participants analyzed) signifies those participants who were evaluable for this measure.

Reporting Groups

	Description
Carlumab	Carlumab diluted in 5% dextrose administered at the dose of 15 mg/kg by intravenous infusion at a constant rate over a 90 minute period once every 2 weeks until disease progression.

Measured Values

	Carlumab
Number of Participants Analyzed [units: participants]	**44**
Percentage of Participants With Prostate Specific Antigen (PSA) Response [units: Percentage of participants]	**0.0**

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

6. Secondary: Percentage of Participants With Urinary Crosslinked N-Telopeptide of Type I Collagen (NTx) Response [Time Frame: Up to 2 weeks before first dose, every 4 weeks after first dose, Week 4, 8, 12 after the last dose of carlumab]

Measure Type	Secondary
Measure Title	Percentage of Participants With Urinary Crosslinked N-Telopeptide of Type I Collagen (NTx) Response
Measure Description	Urinary NTx response for participants with elevated NTx level at Baseline (more than or equal to 50 nanomole per

	millimole (nmol/mmol)) is defined as a 30% reduction from Baseline NTx value, confirmed by a second NTx value 3 or more weeks later.
Time Frame	Up to 2 weeks before first dose, every 4 weeks after first dose, Week 4, 8, 12 after the last dose of carlumab
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 population included all the participants who received at least 1 administration of carlumab and had elevated urinary NTx level at Baseline (more than or equal to 50 nmol/mmol) and at least 1 post-treatment urinary NTx measurement. 'N' (number of participants analyzed) signifies those participants who were evaluable for this measure.

Reporting Groups

	Description
Carlumab	Carlumab diluted in 5% dextrose administered at the dose of 15 mg/kg by intravenous infusion at a constant rate over a 90 minute period once every 2 weeks until disease progression.

Measured Values

	Carlumab
Number of Participants Analyzed [units: participants]	**7**
Percentage of Participants With Urinary Crosslinked N-Telopeptide of Type I Collagen (NTx) Response [units: Percentage of participants]	**0.0**

No statistical analysis provided for Percentage of Participants With Urinary Crosslinked N-Telopeptide of Type I Collagen (NTx) Response

7. Secondary: Percentage of Participants With Pain Response [Time Frame: Up to 2 weeks before first dose, every 4 weeks after first dose, Week 4 after last dose of carlumab]

Measure Type	Secondary
Measure Title	Percentage of Participants With Pain Response
Measure Description	Pain response is defined as 2-point decrease from Baseline in 'worst pain' intensity score (item 3) on the Brief Pain Inventory (BPI) questionnaire. The BPI is a nine-item questionnaire with 0 to 10 numeric rating scales in response to each item, where 0=No pain and 10=Pain as bad as you can imagine. Measure can be scored by item, with lower scores being indicative of less pain or pain interference.
Time Frame	Up to 2 weeks before first dose, every 4 weeks after first dose, Week 4 after last dose of carlumab
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 population included all the participants who received at least 1 administration of carlumab, had Baseline BPI 'worst pain' intensity score (item 3) more than or equal to 2, and at least 1 post-treatment pain evaluation. Participants with disease progression were considered to be evaluable, regardless of the post-dose evaluation.

Reporting Groups

	Description
Carlumab	Carlumab diluted in 5% dextrose administered at the dose of 15 mg/kg by intravenous infusion at a constant rate over a 90 minute period once every 2 weeks until disease progression.

Measured Values

	Carlumab
Number of Participants Analyzed [units: participants]	**31**
Percentage of Participants With Pain Response [units: Percentage of participants]	

During stable use of analgesic medication	**32.3**
At any time	**38.7**

No statistical analysis provided for Percentage of Participants With Pain Response

8. Secondary: Time to Radiologic Response [Time Frame: Up to 4 weeks before first dose, every 12 weeks after first dose, Week 12 after last dose of carlumab]

Measure Type	Secondary
Measure Title	Time to Radiologic Response
Measure Description	Radiologic response based on assessment of confirmed CR or PR according to RECIST. CR defined as disappearance of all target lesions. Any pathological lymph nodes must have reduction in short axis to less than 10 millimeter (mm). PR defined as at least 30% decrease in sum of the diameters of the target lesions taking as reference the Baseline sum diameters. Confirmed responses are those that persist on repeat imaging study for at least 4 weeks after initial documentation of response.
Time Frame	Up to 4 weeks before first dose, every 12 weeks after first dose, Week 12 after last dose of carlumab
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 population included all the participants who received at least 1 administration of carlumab. No data was available for this endpoint as no participant achieved CR or PR.

Reporting Groups

	Description
Carlumab	Carlumab diluted in 5% dextrose administered at the dose of 15 mg/kg by intravenous infusion at a constant rate over a 90 minute period once every 2 weeks until disease progression.

Measured Values

	Carlumab
Number of Participants Analyzed [units: participants]	**0**
Time to Radiologic Response	

No statistical analysis provided for Time to Radiologic Response

9. Secondary: Duration of Radiologic Response [Time Frame: Up to 4 weeks before first dose, every 12 weeks after first dose, Week 12 after last dose of carlumab]

Measure Type	Secondary
Measure Title	Duration of Radiologic Response
Measure Description	Radiologic response based on assessment of confirmed CR or PR according to RECIST. CR defined as disappearance of all target lesions. Any pathological lymph nodes must have reduction in short axis to less than 10 millimeter (mm). PR defined as at least 30% decrease in sum of the diameters of the target lesions taking as reference the Baseline sum diameters. Confirmed responses are those that persist on repeat imaging study for at least 4 weeks after initial documentation of response.
Time Frame	Up to 4 weeks before first dose, every 12 weeks after first dose, Week 12 after last dose of carlumab
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 population included all the participants who received at least 1 administration of carlumab. No data was available for this endpoint as no participant achieved CR or PR.

Reporting Groups

	Description
Carlumab	Carlumab diluted in 5% dextrose administered at the dose of 15 mg/kg by intravenous infusion at a constant rate over a 90 minute period once every 2 weeks until disease progression.

Measured Values

	Carlumab
Number of Participants Analyzed [units: participants]	**0**
Duration of Radiologic Response	

No statistical analysis provided for Duration of Radiologic Response

10. Secondary: Minimum Observed Serum Concentration (Cmin) [Time Frame: Pre-dose and at the end of infusion for each Dose; 2, 4 hour (hr) and 1 week after Dose 1; 2 hr after Dose 4; Week 1, 4, 8 and 12 post-last dose]

Measure Type	Secondary
Measure Title	Minimum Observed Serum Concentration (Cmin)
Measure Description	No text entered.
Time Frame	Pre-dose and at the end of infusion for each Dose; 2, 4 hour (hr) and 1 week after Dose 1; 2 hr after Dose 4; Week 1, 4, 8 and 12 post-last dose
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 population included all the participants who received at least 1 administration of carlumab. 'N' (number of participants analyzed) signifies those participants who were evaluable for this measure.

Reporting Groups

	Description
Carlumab	Carlumab diluted in 5% dextrose administered at the dose of 15 mg/kg by intravenous infusion at a constant rate over a 90 minute period once every 2 weeks until disease progression.

Measured Values

	Carlumab
Number of Participants Analyzed [units: participants]	**35**
Minimum Observed Serum Concentration (Cmin) [units: microgram/milliliter (mcg/mL)] Mean (Standard Deviation)	**91.82 (87.240)**

No statistical analysis provided for Minimum Observed Serum Concentration (Cmin)

11. Secondary: Maximum Observed Serum Concentration (Cmax) [Time Frame: Pre-dose and at the end of infusion for each Dose; 2, 4 hour (hr) and 1 week after Dose 1; 2 hr after Dose 4; Week 1, 4, 8 and 12 post-last dose]

Measure Type	Secondary
Measure Title	Maximum Observed Serum Concentration (Cmax)
Measure Description	The maximum observed analyte concentration was measured.
Time Frame	Pre-dose and at the end of infusion for each Dose; 2, 4 hour (hr) and 1 week after Dose 1; 2 hr after Dose 4; Week 1, 4, 8 and 12 post-last dose
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 population included all the participants who received at least 1 administration of carlumab.

Reporting Groups

	Description
Carlumab	Carlumab diluted in 5% dextrose administered at the dose of 15 mg/kg by intravenous infusion at a constant rate over a 90 minute period once every 2 weeks until disease progression.

Measured Values

	Carlumab
Number of Participants Analyzed [units: participants]	**46**
Maximum Observed Serum Concentration (Cmax) [units: mcg/mL] Mean (Standard Deviation)	**320.27 (75.712)**

No statistical analysis provided for Maximum Observed Serum Concentration (Cmax)

12. Secondary: Area Under the Serum Concentration Versus Time Curve Between 0 And 14 Days (AUC 0-14d) [Time Frame: Pre-dose, at the end of infusion, 2, 4 hr and 1 week after end of infusion for the first dose]

Measure Type	Secondary
Measure Title	Area Under the Serum Concentration Versus Time Curve Between 0 And 14 Days (AUC 0-14d)
Measure Description	No text entered.

Time Frame	Pre-dose, at the end of infusion, 2, 4 hr and 1 week after end of infusion for the first dose
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 population included all the participants who received at least 1 administration of carlumab except those whose serum samples were missing at the end of infusion.

Reporting Groups

	Description
Carlumab	Carlumab diluted in 5% dextrose administered at the dose of 15 mg/kg by intravenous infusion at a constant rate over a 90 minute period once every 2 weeks until disease progression.

Measured Values

	Carlumab
Number of Participants Analyzed [units: participants]	**41**
Area Under the Serum Concentration Versus Time Curve Between 0 And 14 Days (AUC 0-14d) [units: mcg*day/mL] Mean (Standard Deviation)	**1635.67 (528.925)**

No statistical analysis provided for Area Under the Serum Concentration Versus Time Curve Between 0 And 14 Days (AUC 0-14d)

13. Secondary: Half-life (t1/2) [Time Frame: Pre-dose and at the end of infusion for each Dose; 2, 4 hour (hr) and 1 week after Dose 1; 2 hr after Dose 4; Week 1, 4, 8 and 12 post-last dose]

Measure Type	Secondary

Measure Title	Half-life (t1/2)
Measure Description	The time measured for the serum concentration to decrease by one half.
Time Frame	Pre-dose and at the end of infusion for each Dose; 2, 4 hour (hr) and 1 week after Dose 1; 2 hr after Dose 4; Week 1, 4, 8 and 12 post-last dose
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 population included all the participants who received at least 1 administration of carlumab except those whose serum samples were missing at the end of infusion.

Reporting Groups

	Description
Carlumab	Carlumab diluted in 5% dextrose administered at the dose of 15 mg/kg by intravenous infusion at a constant rate over a 90 minute period once every 2 weeks until disease progression.

Measured Values

	Carlumab
Number of Participants Analyzed [units: participants]	**7**
Half-life (t1/2) [units: Days] Median (Full Range)	**13.32 (8.7 to 20.0)**

No statistical analysis provided for Half-life (t1/2)

14. Other Pre-specified: Time to Worsening in Eastern Cooperative Oncology Group (ECOG) Status Score [Time Frame: Up to 2 weeks before first dose, pre-infusion, Week 4 after last dose of carlumab]

Measure Type	Other Pre-specified
Measure Title	Time to Worsening in Eastern Cooperative Oncology Group (ECOG) Status Score
Measure Description	A worsening in ECOG performance status score was defined as greater than or equal to 1-point increase from Baseline. Time to worsening is defined as the number of days from first dose to the first day of worsening in ECOG score, or death, whichever occurred first. ECOG is a 5-point scale 0=Fully active, 1=Ambulatory, carry out work of sedentary nature, 2=Ambulatory, capable of all selfcare, 3=Capable of limited selfcare, confined to bed or chair more than 50% of waking hours, 4=Completely disabled, no selfcare, totally confined to bed or chair, 5=Dead.
Time Frame	Up to 2 weeks before first dose, pre-infusion, Week 4 after last dose of carlumab
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Analysis population included all the participants who received at least 1 administration of carlumab.

Reporting Groups

	Description
Carlumab	Carlumab diluted in 5% dextrose administered at the dose of 15 mg/kg by intravenous infusion at a constant rate over a 90 minute period once every 2 weeks until disease progression.

Measured Values

	Carlumab
Number of Participants Analyzed [units: participants]	**46**
Time to Worsening in Eastern Cooperative Oncology Group (ECOG) Status Score	**86.0**

[units: Days] Median (95% Confidence Interval)	**(56.0 to 176.0)**

No statistical analysis provided for Time to Worsening in Eastern Cooperative Oncology Group (ECOG) Status Score

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Baseline up to 30 days after last dose of carlumab
Additional Description	No text entered.

Reporting Groups

	Description
Carlumab	Carlumab diluted in 5 percent (%) dextrose administered at the dose of 15 milligram per kilogram (mg/kg) by intravenous (into a vein) infusion (a fluid or a medicine delivered into a vein by way of a needle) at a constant rate over a 90 minute period once every 2 weeks until disease progression.

Serious Adverse Events

	Carlumab
Total, serious adverse events	
# participants affected / at risk	**20/46 (43.48%)**
Eye disorders	
Vitreous detachment * 1	
# participants affected / at risk	**1/46 (2.17%)**
Gastrointestinal disorders	

Abdominal pain [*1]	
# participants affected / at risk	**1/46 (2.17%)**
Constipation [*1]	
# participants affected / at risk	**1/46 (2.17%)**
Gastric perforation [*1]	
# participants affected / at risk	**1/46 (2.17%)**
Gastrointestinal perforation [*1]	
# participants affected / at risk	**1/46 (2.17%)**
General disorders	
General physical health deterioration [*1]	
# participants affected / at risk	**1/46 (2.17%)**
Multi-organ failure [*1]	
# participants affected / at risk	**1/46 (2.17%)**
Oedema peripheral [*1]	
# participants affected / at risk	**1/46 (2.17%)**
Pain [*1]	
# participants affected / at risk	**1/46 (2.17%)**
Pyrexia [*1]	
# participants affected / at risk	**1/46 (2.17%)**
Infections and infestations	
Pneumonia [*1]	
# participants affected / at risk	**3/46 (6.52%)**
Musculoskeletal and connective tissue disorders	
Back pain [*1]	
# participants affected / at risk	**3/46 (6.52%)**

Bone pain [*1]	
# participants affected / at risk	**1/46 (2.17%)**
Musculoskeletal pain [*1]	
# participants affected / at risk	**1/46 (2.17%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
Metastases to central nervous system [*1]	
# participants affected / at risk	**1/46 (2.17%)**
Metastases to stomach [*1]	
# participants affected / at risk	**1/46 (2.17%)**
Prostate cancer [*1]	
# participants affected / at risk	**1/46 (2.17%)**
Prostate cancer metastatic [*1]	
# participants affected / at risk	**1/46 (2.17%)**
Nervous system disorders	
Spinal cord compression [*1]	
# participants affected / at risk	**3/46 (6.52%)**
Nerve root compression [*1]	
# participants affected / at risk	**1/46 (2.17%)**
Psychiatric disorders	
Confusional state [*1]	
# participants affected / at risk	**1/46 (2.17%)**
Renal and urinary disorders	
Haematuria [*1]	
# participants affected / at risk	**1/46 (2.17%)**

Urinary tract obstruction * 1	
# participants affected / at risk	**1/46 (2.17%)**
Respiratory, thoracic and mediastinal disorders	
Epistaxis * 1	
# participants affected / at risk	**1/46 (2.17%)**
Pleural effusion * 1	
# participants affected / at risk	**1/46 (2.17%)**
Pneumothorax * 1	
# participants affected / at risk	**1/46 (2.17%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA Version 13.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	Baseline up to 30 days after last dose of carlumab
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5

Reporting Groups

	Description
Carlumab	Carlumab diluted in 5 percent (%) dextrose administered at the dose of 15 milligram per kilogram (mg/kg) by intravenous (into a vein) infusion (a fluid or a medicine delivered into a vein by way of a needle) at a constant rate over a 90 minute period once every 2 weeks until disease progression.

Other Adverse Events

	Carlumab
Total, other (not including serious) adverse events	
# participants affected / at risk	40/46 (86.96%)
Blood and lymphatic system disorders	
Anaemia * 1	
# participants affected / at risk	12/46 (26.09%)
Thrombocytopenia * 1	
# participants affected / at risk	4/46 (8.70%)
Gastrointestinal disorders	
Diarrhoea * 1	
# participants affected / at risk	8/46 (17.39%)
Nausea * 1	
# participants affected / at risk	8/46 (17.39%)
Constipation * 1	
# participants affected / at risk	7/46 (15.22%)
Vomiting * 1	
# participants affected / at risk	5/46 (10.87%)
Abdominal pain upper * 1	
# participants affected / at risk	3/46 (6.52%)
General disorders	
Fatigue * 1	
# participants affected / at risk	24/46 (52.17%)

Oedema peripheral [*1]	
# participants affected / at risk	**6/46 (13.04%)**
Asthenia [*1]	
# participants affected / at risk	**4/46 (8.70%)**
Infections and infestations	
Gastroenteritis [*1]	
# participants affected / at risk	**3/46 (6.52%)**
Investigations	
Weight decreased [*1]	
# participants affected / at risk	**3/46 (6.52%)**
Metabolism and nutrition disorders	
Decreased appetite [*1]	
# participants affected / at risk	**11/46 (23.91%)**
Dehydration [*1]	
# participants affected / at risk	**3/46 (6.52%)**
Musculoskeletal and connective tissue disorders	
Back pain [*1]	
# participants affected / at risk	**15/46 (32.61%)**
Bone pain [*1]	
# participants affected / at risk	**9/46 (19.57%)**
Arthralgia [*1]	
# participants affected / at risk	**6/46 (13.04%)**
Musculoskeletal pain [*1]	
# participants affected / at risk	**6/46 (13.04%)**

Groin pain [*1]	
# participants affected / at risk	**5/46 (10.87%)**
Pain in extremity [*1]	
# participants affected / at risk	**5/46 (10.87%)**
Muscular weakness [*1]	
# participants affected / at risk	**4/46 (8.70%)**
Musculoskeletal chest pain [*1]	
# participants affected / at risk	**4/46 (8.70%)**
Nervous system disorders	
Dizziness [*1]	
# participants affected / at risk	**4/46 (8.70%)**
Headache [*1]	
# participants affected / at risk	**4/46 (8.70%)**
Psychiatric disorders	
Confusional state [*1]	
# participants affected / at risk	**5/46 (10.87%)**
Insomnia [*1]	
# participants affected / at risk	**4/46 (8.70%)**
Respiratory, thoracic and mediastinal disorders	
Cough [*1]	
# participants affected / at risk	**6/46 (13.04%)**
Dyspnoea [*1]	
# participants affected / at risk	**3/46 (6.52%)**
Skin and subcutaneous tissue disorders	

Pruritus * 1	
# participants affected / at risk	**4/46 (8.70%)**
Vascular disorders	
Hypertension * 1	
# participants affected / at risk	**3/46 (6.52%)**

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA Version 13.1

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:** If Investigator wishes to publish information from study, a copy of manuscript must be provided to Sponsor for review at least 60 days before publication. Expedited reviews will be arranged for abstracts, poster presentations. If requested by Sponsor in writing, Investigator will withhold such publication for up to additional 60 days to allow for patent filing. If the issues arise regarding scientific integrity or regulatory compliance, Sponsor will review them with Investigator.

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Responsible Party:	Centocor Research & Development, Inc.
ClinicalTrials.gov Identifier:	NCT00992186 History of Changes
Other Study ID Numbers:	CR015907 2009-011251-48 **CNTO888PCR2001**
Study First Received:	September 29, 2009
Results First Received:	March 29, 2013
Last Updated:	June 18, 2013
Health Authority:	United States: Food and Drug Administration

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