Adverse Event Expedited Report

Protocol Number :NCT01198158 **CTC Version :**CTCAE v4.0 **Principal Investigator :**

Title :

Institution : Duke University Medical Center **Report Type :** Original **Ticket #:** **Amendment #:** 0

Created Date :02/15/2012

Reporter Information

Reporter Name : Don Johnson
Phone : 555-555-5555 **Fax :** 555-555-5555 **Email :** dj@email.com

Submitter Name : Don Johnson
Phone : 555-555-5555 **Fax :** 555-555-5555 **Email :** dj@email.com

Physician Name : Michael Scott
Phone : 555-555-5555 **Fax :** **Email :** ms@email.com

Patient Information

Patient ID :	1	**Birth Date :**	04/ 21/ 1965	**Gender :**	Female
Race :	Not Reported	**Ethnicity :**	Not Hispanic or Latino		
Height(Inch) :	65.0	**Weight(Pound) :**	180.0	**Body Surface Area :**	1.8915

Baseline performance status at initiation of protocol - ECOG/Zubrod scale : 1

Disease Name : Renal cell carcinoma, clear cell adenocarcinoma

Disease Name Not Listed :

Primary Site of Disease :

Date of Initial Diagnosis : 04/2011

Course Information

Treatment Assignment Code : Arm A

Description : - Everolimus 10 mg PO on Days 1-28 - Placebo 10 mg/kg IV on Days 1 and 15 - Give 28-day cycles until disease progression or unacceptable toxicity.

Start date of first course : 02/01/2012

Start date of course associated with Expedited Report : 02/01/2012

Start date of primary AE : 02/07/2012

End date of primary AE : 02/08/2012

Course Number on which event(s) occurred : 1

Total number of courses to date : 1

Was Investigational Agent(s) administered on this protocol?: Yes

Description of Event

Description and Treatment of Event : Vomiting caused sever dehydration.

Present Status : Recovered/Resolved without Sequelae **Date of Recovery or Death :** 02/13/2012

Retreated : Yes

Removed from Protocol Treatment (to date) : No **Date Removed from Protocol Treatment :**

Cause of Death :

Run Date : 02/16/2012 9:41:21 AM

(Site Reported)

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Death Date : **Autopsy Performed :**

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Prior Therapies

Therapy	Therapy Start Date	Therapy End Date	Comments	Chemotherapy Agents
Radiation Therapy				

Pre-Existing Conditions

Electrolyte depletion

Sites of Metastatic Disease

Liver

Protocol Agents

Treatment Assignment Code : Arm A

Agent	Total Dose Administered this Course	Last Administered Date	Comments	Agent Adjustment	Agent Delayed	Delay
Everolimus (RAD-001)	2mL	02/15/2012			No	

Concomitant Medications

Aspirin

Other Contributing Causes

Electrolyte depletion

Adverse Events (CTCAE)

CTCAE CATEGORY	Adverse Event	Grade	Hospitalization/ Prolongation of Hospitalization	Start Date of AE	End Date of AE	Is Primary AE?	Comments
Gastrointestinal disorders	Vomiting	4	Yes	02/07/2012	02/08/2012	Yes	vomiting

Attribution for Adverse Events

Attribute to	Gr.4 Vomiting: vomiting
Course	
Everolimus (RAD-001)	Probable
Concomitant medications	
Aspirin	Unlikely
Other causes	
Electrolyte depletion	Possible
Disease	

(Site Reported)

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Renal cell carcinoma, clear cell adenocarcinoma	Possible

Abnormal and Relevant Normal Lab Results

Lab	Baseline date	Value	Worst Date	Value	Recovery/Latest Date	Value	Microbiology Site	Date	Infectious Agent
Hemoglobin (Hb)	02/01/2012	14 gm/dl	02/08/2012	10 gm/dl	02/14/2012	12 gm/dl			