Dose Escalation Study Design Example (With Results)

Disclaimer: The following information is fictional and is only intended for the purpose of illustrating key concepts for results data entry in the Protocol Registration and Results System (PRS).

ClinicalTrials.gov Identifier: NCT00055581

Recruitment Status: Completed
First Posted: January 2, 2018
Results First Posted: July 31, 2019
Last Update Posted: July 31, 2019

Sponsor:

PRS Results Training

Information provided by (Responsible Party):

PRS Results Training

Study Description

Brief Summary:

The primary aim of the study is to establish the maximum-tolerated dose (MTD) of Ender-G in participants with cancer. The secondary aims are to describe the pharmacokinetics of Ender-G and the toxic effects of Ender-G in participants with cancer.

Condition or disease	Intervention/treatment	Phase
Cancer	Drug: Ender-G	Phase 1

Detailed Description:

This study will enroll patients with various cancer types from a single academic medical center in the United States. All participants will be informed about the study and potential risks and required to provide written informed consent prior to undergoing study-related procedures.

A traditional 3 + 3 dose escalation design will be implemented. Successive cohorts of patients (3 participants/cohort) will each be started on a fixed dose of Ender-G. The protocol specifies

100 mg/m^2, via intravenous catheter (IV), twice a day for 4 weeks for the first cohort. Successive cohorts will be given doses of 125 and 150 mg/m^2 twice a day.

Dose escalation will continue until the maximum-tolerated dose (MTD), defined as one dose level below the dose in which dose-limiting toxicities (DLTs) are observed in >33% of the participants (e.g., in at least 2 participants in a cohort of 3 or in at least 3 participants in a cohort of 6). If no DLTs are observed for 4 weeks after administration of the last dose of Ender-G, a new cohort will be enrolled at the next planned dose level. If DLTs are observed in 2 of the three participants, the MTD will be determined to be the dose administered to the previous cohort. If DLTs are observed in one participant in the cohort, another three participants will be treated with the same dose level. In that case, 3 of the 6 participants would have to experience DLTs to determine the MTD.

Toxicities will be graded using the Common Terminology Criteria for Adverse Events Version 3.0 (CTCAE 3.0). If the CTCAE 3.0 does not apply to an adverse event, it will be graded as mild, moderate, or severe. DLT is defined as any Ender-G-related CTCAE 3.0 grade 3 or 4 adverse event.

Health status assessments, including physical exams, complete blood chemistry, and urinalysis will be conducted at weeks 1, 2, 4, and 8.

The protocol and informed consent documents have been reviewed and approved by the hospital human subjects review board and the study will be performed in accordance with the Declaration of Helsinki.

Study Design

Study Type:	Interventional
Actual Enrollment:	15 participants
Allocation:	Non-Randomized
Intervention Model:	Sequential Assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	A Phase 1 Clinical Trial of Ender-G in Adults With Cancer
Actual Study Start Date:	January 2, 2018
Actual Primary Completion Date:	August 29, 2018
Actual Study Completion Date:	August 29, 2018

Arms and Interventions

Arm	Intervention/treatment
Experimental: Ender-G 100 mg/m^2 Cohort 1: Participants were administered 100 mg/m^2 of Ender-G twice a day, via intravenous catheter (IV), for 4 weeks, with 4 weeks of follow-up after the last dose was administered.	Drug: Ender-G 100 mg/m^2 intravenous solution
Experimental: Ender-G 125 mg/m^2 Cohort 2: Participants were administered 125 mg/m^2 of Ender-G twice a day, via intravenous catheter (IV), for 4 weeks, with 4 weeks of follow-up after the last dose was administered.	Drug: Ender-G 125 mg/m^2 intravenous solution
Experimental: Ender-G 150 mg/m^2 Cohort 3: Participants were administered 150 mg/m^2 of Ender-G twice a day, via intravenous catheter (IV), for 4 weeks, with 4 weeks of follow-up after the last dose was administered.	Drug: Ender-G 150 mg/m^2 intravenous solution

Outcome Measures

Primary Outcome Measures:

1. Maximum Tolerated Dose (MTD) of Ender-G [Time Frame: Up to 8 weeks for each dosing cohort]

   MTD was determined by testing increasing doses up to 150 mg/m^2 twice a day via IV on dose escalation cohorts 1 to 3 with 3 to 6 participants each. MTD reflects the highest dose of drug that did not cause a Dose-Limiting Toxicity (DLT) in > 33% of participants. DLTs were defined as any Ender-G-related Common Terminology Criteria for Adverse Events Version 3.0 (CTCAE 3.0) Grade 3 or 4 adverse events (reported in the subsequent Primary Outcome Measure).

2. Number of Participants Who Experienced Dose-Limiting Toxicities (DLTs) [Time Frame: Up to 8 weeks for each dosing cohort]

   A DLT was any Grade 3 or 4 adverse event (AE) using the Common Terminology Criteria for Adverse Events Version 3.0 (CTCAE 3.0) that was possibly Ender-G-related. CTCAE 3.0 Grade 3 is a severe AE and Grade 4 is a life-threatening or disabling AE. (e.g., skin toxicity, diarrhea or antidiarrheal therapy, vomiting at same grade for >4 days despite aggressive antiemetic therapy, central nervous system, lung or renal toxicity or elevation of liver transaminases or bilirubin lasting more than 1 week)

DLTs were collected to determine the Maximum-Tolerated Dose (MTD), which is defined as the dose level below the dose at which > 33% of participants experienced a DLT.

Secondary Outcome Measures:

1. Maximum Observed Plasma Concentration of Ender-G (Cmax) [Time Frame: prior to the initial dose on day 1 and 0.25, 0.5, 0.75, 1, 2, 3, 4, 5, 6, 7, 8, 16, 24, 36, 48 and 72 hours post-dose]

   Blood samples were obtained and plasma concentrations were determined using a validated high-pressure liquid chromatography method.

2. Time to Maximum Observed Plasma Concentration of Ender-G (Tmax) [Time Frame: prior to the initial dose on day 1 and 0.25, 0.5, 0.75, 1, 2, 3, 4, 5, 6, 7, 8, 16, 24, 36, 48 and 72 hours post-dose]

   Blood samples were obtained and plasma concentrations were determined using a validated high-pressure liquid chromatography method.

3. Area Under the Concentration-Time Curve (AUC 0-72h) [Time Frame: prior to the initial dose on day 1 and 0.25, 0.5, 0.75, 1, 2, 3, 4, 5, 6, 7, 8, 16, 24, 36, 48 and 72 hours post-dose]

   Blood samples were obtained and plasma concentrations were determined using a validated high-pressure liquid chromatography method.

4. The Number of Participants Who Experienced Serious or Non-Serious Adverse Events [Time Frame: Up to 8 weeks for each dosing cohort]

   A non-serious adverse event is any untoward medical occurrence. A serious adverse event is any adverse event that meets one or more of the following: results in death; is life-threatening; requires inpatient hospitalization or prolongation of existing hospitalization; results in persistent or significant disability/incapacity; is a congenital anomaly/birth defect; requires intervention to prevent permanent impairment or damage. Specific Adverse Event terms are provided in the Adverse Event module.

Eligibility Criteria

Ages Eligible for Study: 21 Years and older (Adult, Older Adult)
Sexes Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Clinically confirmed cancer

- A World Health Organization (WHO) performance status < 3

Exclusion Criteria:

- Receiving enzyme-inducing anticonvulsants, steroids, or other experimental drugs
- History of migraines
- Clinically significant electrocardiogram (ECG) abnormalities
- White blood cell (WBC) count ≤ 2,000/mm^3

Contacts and Locations

Locations

United States, Maryland

NIH

Bethesda, Maryland, United States, 20892

Study Documents (Full-Text)

Documents provided by PRS Results Training

Study Protocol and Statistical Analysis Plan [PDF] August 30, 2017

More Information

Responsible Party:	PRS Results Training
ClinicalTrials.gov Identifier:	NCT00055581
Other Study ID Numbers:	TTTDoseEscalationR
First Posted:	January 2, 2018
Results First Posted:	July 31, 2019
Last Update Posted:	July 31, 2019
Last Verified:	July 2019

Human Subjects Protection Review Board Status:	Approved
Studies a U.S. FDA-regulated Drug Product:	Yes
Studies a U.S. FDA-regulated Device Product:	No

Study Results

Study Type	Interventional
Study Design	Allocation: Non-Randomized; Intervention Model: Sequential Assignment; Masking: None (Open Label); Primary Purpose: Treatment
Condition	Cancer
Interventions	Drug: Ender-G
Enrollment	15

Participant Flow

Recruitment Details	
Pre-assignment Details	

Arm/Group Title	Ender-G 100 mg/m^2	Ender-G 125 mg/m^2	Ender-G 150 mg/m^2
Arm/Group Description	Cohort 1: Participants were administered 100 mg/m^2 of Ender-G twice a day, via intravenous catheter (IV), for 4 weeks, with 4 weeks of follow-up after the last dose was administered.	Cohort 2: Participants were administered 125 mg/m^2 of Ender-G twice a day, via intravenous catheter (IV), for 4 weeks, with 4 weeks of follow-up after the last dose was administered.	Cohort 3: Participants were administered 150 mg/m^2 of Ender-G twice a day, via intravenous catheter (IV), for 4 weeks, with 4 weeks of follow-up after the last dose was administered.
Period Title: **Cohort 1: Dose Level 1 (Weeks 1-8)**			
Started	3	0	0
Completed	3	0	0
Not Completed	0	0	0

Period Title: **Cohort 2: Dose Level 2 (Weeks 9-24)**			
Started	0	6	0
Completed	0	6	0
Not Completed	0	0	0
Period Title: **Cohort 3: Dose Level 3 (Weeks 25-40)**			
Started	0	0	6
Completed	0	0	5
Not Completed	0	0	1
Reason Not Completed			
Withdrawal by Subject	0	0	1

Baseline Characteristics

Arm/Group Title		Ender-G 100 mg/m^2	Ender-G 125 mg/m^2	Ender-G 150 mg/m^2	Total
Arm/Group Description		Cohort 1: Participants were administered 100 mg/m^2 of Ender-G twice a day, via intravenous catheter (IV), for 4 weeks, with 4 weeks of follow-up after the last dose was administered.	Cohort 2: Participants were administered 125 mg/m^2 of Ender-G twice a day, via intravenous catheter (IV), for 4 weeks, with 4 weeks of follow-up after the last dose was administered.	Cohort 3: Participants were administered 150 mg/m^2 of Ender-G twice a day, via intravenous catheter (IV), for 4 weeks, with 4 weeks of follow-up after the last dose was administered.	Total of all reporting groups
Overall Number of Baseline Participants		3	6	6	15
Baseline Analysis Population Description		[Not Specified]			
Age, Continuous Median (Full Range) Unit of Measure: years					
	Number Analyzed	3 participants	6 participants	6 participants	15 participants
		67 (43 to 72)	63 (36 to 74)	62.5 (42 to 82)	67 (36 to 82)

Sex: Female, Male Measure Type: Count of Participants Unit of measure: participants					
	Number Analyzed	3 participants	6 participants	6 participants	15 participants
	Female	2 66.67%	3 50%	2 33.33%	7 46.67%
	Male	1 33.33%	3 50%	4 66.67%	8 53.33%
Race (NIH/OMB) Measure Type: Count of Participants Unit of measure: participants					
	Number Analyzed	3 participants	6 participants	6 participants	15 participants
	American Indian or Alaska Native	0 0%	0 0%	0 0%	0 0%
	Asian	0 0%	0 0%	0 0%	0 0%
	Native Hawaiian or Other Pacific Islander	0 0%	0 0%	0 0%	0 0%
	Black or African American	1 33.33%	2 33.33%	1 16.67%	4 26.67%

	White	2 66.67%	4 66.67%	5 83.33%	11 73.33%
	More than one race	0 0%	0 0%	0 0%	0 0%
	Unknown or Not Reported	0 0%	0 0%	0 0%	0 0%
Region of Enrollment Measure Type: Count of Participants Unit of measure: participants					
United States	Number Analyzed	3 participants	6 participants	6 participants	15 participants
		3 100%	6 100%	6 100%	15 100%
WHO Performance Status [1] Measure Type: Count of Participants Unit of measure: participants					
	Number Analyzed	3 participants	6 participants	6 participants	15 participants
	0 (Asymptomatic)	1 33.33%	2 33.33%	2 33.33%	5 33.33%
	1 (Symptomatic, but ambulatory)	1 33.33%	3 50%	3 50%	7 46.67%

	2 (Symptomatic, <50% in bed)	1 33.33%	1 16.67%	1 16.67%	3 20%
		[1] Measure Description: World Health Organization (WHO) performance status: • 0 = Asymptomatic (Fully active, able to carry out predisease activities without restriction) • 1 = Symptomatic, but ambulatory (only physically strenuous activity restricted) • 2 = Symptomatic, <50% in bed (Ambulatory, capable of all self care, unable to carry out any work activities. Up and about >50% of waking hours) • 3 = Symptomatic, >50% in bed, but not bedbound (only limited self-care, confined to bed or chair >50% of waking hours) • 4 = Bedbound (Completely disabled, no self-care, Totally confined to bed or chair) • 5 = Death			
Tumor Type Measure Type: Count of Participants Unit of measure: participants					
	Number Analyzed	3 participants	6 participants	6 participants	15 participants
	Non-small-cell lung carcinoma (NSCLC)	1 33.33%	2 33.33%	2 33.33%	5 33.33%
	Prostate	1 33.33%	2 33.33%	2 33.33%	5 33.33%
	Ovarian	1 33.33%	2 33.33%	2 33.33%	5 33.33%

Number of Prior Chemotherapy Regimens Measure Type: Count of Participants Unit of measure: participants					
	Number Analyzed	3 participants	6 participants	6 participants	15 participants
	1	1 33.33%	1 16.67%	2 33.33%	4 26.67%
	2	0 0%	1 16.67%	1 16.67%	2 13.33%
	3	1 33.33%	1 16.67%	0 0%	2 13.33%
	≥ 4	1 33.33%	3 50%	3 50%	7 46.67%

Outcome Measures

1. Primary Outcome

Title	Maximum Tolerated Dose (MTD) of Ender-G
Description	MTD was determined by testing increasing doses up to 150 mg/m^2 twice a day via IV on dose escalation cohorts 1 to 3 with 3 to 6 participants each. MTD reflects the highest dose of drug that did not cause a Dose-Limiting Toxicity (DLT) in > 33% of participants. DLTs were defined as any Ender-G-related Common Terminology Criteria for Adverse Events Version 3.0 (CTCAE 3.0) Grade 3 or 4 adverse events (reported in the subsequent Primary Outcome Measure).
Time Frame	Up to 8 weeks for each dosing cohort

Outcome Measure Data

Analysis Population Description
[Not Specified]

Arm/Group Title	All Participants
Arm/Group Description:	All participants who received at least 1 dose of Ender-G, either at 100 mg/m^2, 125 mg/m^2 or 150 mg/m^2 via IV.
Overall Number of Participants Analyzed	15
Measure Type: Number Unit of Measure: mg/m^2	125

2. Primary Outcome

Title	Number of Participants Who Experienced Dose-Limiting Toxicities (DLTs)
Description	A DLT was any Grade 3 or 4 adverse event (AE) using the Common Terminology Criteria for Adverse Events Version 3.0 (CTCAE 3.0) that was possibly Ender-G-related. CTCAE 3.0 Grade 3 is a severe AE and Grade 4 is a life-threatening or disabling AE. (e.g., skin toxicity, diarrhea or antidiarrheal therapy, vomiting at same grade for >4 days despite aggressive antiemetic therapy, central nervous system, lung or renal toxicity or elevation of liver transaminases or bilirubin lasting more than 1 week) DLTs were collected to determine the Maximum-Tolerated Dose (MTD), which is defined as the dose level below the dose at which > 33% of participants experienced a DLT.
Time Frame	Up to 8 weeks for each dosing cohort

Outcome Measure Data

Analysis Population Description
All participants who received at least one dose of Ender-G.

Arm/Group Title	Ender-G 100 mg/m^2	Ender-G 125 mg/m^2	Ender-G 150 mg/m^2
Arm/Group Description:	Cohort 1: Participants were administered 100 mg/m^2 of Ender-G via IV twice a day for 4 weeks, with 4 weeks of follow-up after the last dose was administered.	Cohort 2: Participants were administered 125 mg/m^2 of Ender-G via IV twice a day for 4 weeks, with 4 weeks of follow-up after the last dose was administered.	Cohort 3: Participants were administered 150 mg/m^2 of Ender-G via IV twice a day for 4 weeks, with 4 weeks of follow-up after the last dose was administered.
Overall Number of Participants Analyzed	3	6	6
Measure Type: Count of Participants Unit of Measure: participants	0 0%	1 16.67%	3 50%

3. Secondary Outcome

Title	Maximum Observed Plasma Concentration of Ender-G (Cmax)
Description	Blood samples were obtained and plasma concentrations were determined using a validated high-pressure liquid chromatography method.
Time Frame	prior to the initial dose on day 1 and 0.25, 0.5, 0.75, 1, 2, 3, 4, 5, 6, 7, 8, 16, 24, 36, 48 and 72 hours post-dose

Outcome Measure Data

Analysis Population Description
[Not Specified]

Arm/Group Title	Ender-G 100 mg/m^2	Ender-G 125 mg/m^2	Ender-G 150 mg/m^2
Arm/Group Description:	Cohort 1: Participants were administered 100 mg/m^2 of Ender-G via IV twice a day for 4 weeks, with 4 weeks of follow-up after the last dose was administered.	Cohort 2: Participants were administered 125 mg/m^2 of Ender-G via IV twice a day for 4 weeks, with 4 weeks of follow-up after the last dose was administered.	Cohort 3: Participants were administered 150 mg/m^2 of Ender-G via IV twice a day for 4 weeks, with 4 weeks of follow-up after the last dose was administered.
Overall Number of Participants Analyzed	3	6	6
Geometric Mean (Geometric Coefficient of Variation) Unit of Measure: mcg/mL	0.535 (119%)	1.10 (75%)	1.58 (102%)

4. Secondary Outcome

Title	Time to Maximum Observed Plasma Concentration of Ender-G (Tmax)
Description	Blood samples were obtained and plasma concentrations were determined using a validated high-pressure liquid chromatography method.
Time Frame	prior to the initial dose on day 1 and 0.25, 0.5, 0.75, 1, 2, 3, 4, 5, 6, 7, 8, 16, 24, 36, 48 and 72 hours post-dose

Outcome Measure Data

Analysis Population Description
[Not Specified]

Arm/Group Title	Ender-G 100 mg/m^2	Ender-G 125 mg/m^2	Ender-G 150 mg/m^2
Arm/Group Description:	Cohort 1: Participants were administered 100 mg/m^2 of Ender-G via IV twice a day for 4 weeks, with 4 weeks of follow-up after the last dose was administered.	Cohort 2: Participants were administered 125 mg/m^2 of Ender-G via IV twice a day for 4 weeks, with 4 weeks of follow-up after the last dose was administered.	Cohort 3: Participants were administered 150 mg/m^2 of Ender-G via IV twice a day for 4 weeks, with 4 weeks of follow-up after the last dose was administered.
Overall Number of Participants Analyzed	3	6	6
Median (Full Range) Unit of Measure: hours	5 (4 to 5)	5 (5 to 6)	5 (2 to 5)

5. Secondary Outcome

Title	Area Under the Concentration-Time Curve (AUC 0-72h)
Description	Blood samples were obtained and plasma concentrations were determined using a validated high-pressure liquid chromatography method.
Time Frame	prior to the initial dose on day 1 and 0.25, 0.5, 0.75, 1, 2, 3, 4, 5, 6, 7, 8, 16, 24, 36, 48 and 72 hours post-dose

Outcome Measure Data

Analysis Population Description
[Not Specified]

Arm/Group Title	Ender-G 100 mg/m^2	Ender-G 125 mg/m^2	Ender-G 150 mg/m^2
Arm/Group Description:	Cohort 1: Participants were administered 100 mg/m^2 of Ender-G via IV twice a day for 4 weeks, with 4 weeks of follow-up after the last dose was administered.	Cohort 2: Participants were administered 125 mg/m^2 of Ender-G via IV twice a day for 4 weeks, with 4 weeks of follow-up after the last dose was administered.	Cohort 3: Participants were administered 150 mg/m^2 of Ender-G via IV twice a day for 4 weeks, with 4 weeks of follow-up after the last dose was administered.
Overall Number of Participants Analyzed	3	6	6
Mean (Standard Deviation Unit of Measure: (mcg/mL)*h	7.41 (7.8)	18.1 (12.7)	18.8 (14.3)

6. Secondary Outcome

Title	The Number of Participants Who Experienced Serious or Non-Serious Adverse Events
Description	A non-serious adverse event is any untoward medical occurrence. A serious adverse event is any adverse event that meets one or more of the following: results in death; is life-threatening; requires inpatient hospitalization or prolongation of existing hospitalization; results in persistent or significant disability/incapacity; is a congenital anomaly/birth defect; requires intervention to prevent permanent impairment or damage. Specific Adverse Event terms are provided in the Adverse Event module.
Time Frame	Up to 8 weeks for each dosing cohort

Outcome Measure Data

Analysis Population Description
[Not Specified]

Arm/Group Title	Ender-G 100 mg/m^2	Ender-G 125 mg/m^2	Ender-G 150 mg/m^2
Arm/Group Description:	Cohort 1: Participants were administered 100 mg/m^2 of Ender-G via IV twice a day for 4 weeks, with 4 weeks of follow-up after the last dose was administered.	Cohort 2: Participants were administered 125 mg/m^2 of Ender-G via IV twice a day for 4 weeks, with 4 weeks of follow-up after the last dose was administered.	Cohort 3: Participants were administered 150 mg/m^2 of Ender-G via IV twice a day for 4 weeks, with 4 weeks of follow-up after the last dose was administered.
Overall Number of Participants Analyzed	3	6	6
Measure Type: Count of Participants Unit of Measure: participants	3 100%	6 100%	6 100%

Adverse Events

Time Frame	Up to 8 weeks for each dosing cohort
Adverse Event Reporting Description	Safety population = all participants who received at least one dose of Ender-G
Source Vocabulary Name for Table Default	CTCAE (3.0)
Collection Approach for Table Default	Systematic Assessment

Arm/Group Title	Ender-G 100 mg/m^2	Ender-G 125 mg/m^2	Ender-G 150 mg/m^2
Arm/Group Description	Cohort 1: Participants were administered 100 mg/m^2 of Ender-G via IV twice a day for 4 weeks, with 4 weeks of follow-up after the last dose was administered.	Cohort 2: Participants were administered 125 mg/m^2 of Ender-G via IV twice a day for 4 weeks, with 4 weeks of follow-up after the last dose was administered.	Cohort 3: Participants were administered 150 mg/m^2 of Ender-G via IV twice a day for 4 weeks, with 4 weeks of follow-up after the last dose was administered.

All-Cause Mortality

	Ender-G 100 mg/m^2	Ender-G 125 mg/m^2	Ender-G 150 mg/m^2
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	0/3 (0%)	0/6 (0%)	0/6 (0%)

Serious Adverse Events

	Ender-G 100 mg/m^2	Ender-G 125 mg/m^2	Ender-G 150 mg/m^2
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	0/3 (0%)	1/6 (16.67%)	3/6 (50%)
Gastrointestinal disorders			
Diarrhea † 1 [1]	0/3 (0%)	0/6 (0%)	1/6 (16.67%)
Vomitting † 1 [1]	0/3 (0%)	1/6 (16.67%)	1/6 (16.67%)
Renal and urinary disorders			
Renal toxicity † 1 [2]	0/3 (0%)	0/6 (0%)	1/6 (16.67%)

1 Term from vocabulary, CTCAE (3.0)

† Indicates events were collected by systematic assessment

[1] Grade 4

[2] Grade 3

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	0%

	Ender-G 100 mg/m^2	Ender-G 125 mg/m^2	Ender-G 150 mg/m^2
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	3/3 (100%)	6/6 (100%)	6/6 (100%)
Endocrine disorders			
Chills † 1	2/3 (66.67%)	1/6 (16.67%)	3/6 (50%)
Gastrointestinal disorders			
Diarrhea † 1	1/3 (33.33%)	3/6 (50%)	2/6 (33.33%)
Nausea † 1	3/3 (100%)	3/6 (50%)	3/6 (50%)
Vomiting † 1	1/3 (33.33%)	3/6 (50%)	5/6 (83.33%)
General disorders			
Fatigue † 1	1/3 (33.33%)	2/6 (33.33%)	6/6 (100%)

Immune system disorders			
Pyrexia †1	2/3 (66.67%)	1/6 (16.67%)	3/6 (50%)
Musculoskeletal and connective tissue disorders			
Pain in extremity †1	2/3 (66.67%)	2/6 (33.33%)	4/6 (66.67%)
Nervous system disorders			
Headache †1	2/3 (66.67%)	1/6 (16.67%)	3/6 (50%)
Psychiatric disorder			
Anorexia †1	3/3 (100%)	1/6 (16.67%)	4/6 (66.67%)
Respiratory, thoracic and mediastinal disorders			
Cough †1	2/3 (66.67%)	2/6 (33.33%)	4/6 (66.67%)
Skin and subcutaneous tissue disorders			
Dry skin †1	2/3 (66.67%)	1/6 (16.67%)	3/6 (50%)
Pruritus †1	2/3 (66.67%)	1/6 (16.67%)	3/6 (50%)
Rash †1	1/3 (33.33%)	3/6 (50%)	5/6 (83.33%)

1 Term from vocabulary, CTCAE (3.0)

† Indicates events were collected by systematic assessment

Limitations and Caveats

[Not Specified]

More Information

Certain Agreements

All Principal Investigators ARE employed by the organization sponsoring the study.

Results Point of Contact

Name/Title: PRS Training Lead
Organization: PRS Results Training
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Responsible Party: PRS Results Training
ClinicalTrials.gov Identifier: NCT00055581
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First Submitted: December 28, 2017
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