ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
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A Study of MetMAb Administered to Patients With Advanced Non-Small Cell Lung Cancer, in Combination With Tarceva (Erlotinib)

This study has been completed.

Sponsor:	Genentech, Inc.
Collaborators:	
Information provided by (Responsible Party):	Genentech, Inc.
ClinicalTrials.gov Identifier:	NCT00854308

Purpose

This is a Phase II, double-blind, randomized, multicenter trial designed to preliminarily evaluate the activity and safety of treatment with MetMAb + erlotinib versus erlotinib + placebo in second- and third-line Non-Small Cell Lung Cancer (NSCLC). Up to 180 patients will be randomized in a 1:1 ratio to one of the two treatment arms.

Condition	Intervention	Phase
Non-Small Cell Lung Cancer	Drug: Erlotinib HCl Drug: MetMAb Drug: placebo (0.9 % saline)	Phase 2

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Double Blind (Subject, Investigator), Randomized
Official Title: A Randomized, Phase II, Multicenter, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Activity of MetMAb, a Monovalent Antagonist Antibody to the Receptor Met, Administered to Patients With Advanced Non-Small Cell Lung Cancer, in Combination With Tarceva (Erlotinib)

Further study details as provided by Genentech, Inc.:

Primary Outcome Measure:

- Progression-free Survival [Time Frame: Time from randomization to the first occurrence of progression/relapse or death on study. (Up to 20 months)] [Designated as safety issue: No]
  Progression-free survival was defined as the time from randomization to the first occurrence of progression or relapse (as per Response Evaluation Criteria in Solid Tumors (RECIST 1.0) and assessed by the site radiologist or investigator) or death on study from any cause (within 30 days of last treatment).
- Progression-free Survival in Patients With Met Diagnostic-Positive Tumors [Time Frame: Time from randomization to the first occurrence of progression/ relapse or death on study. (Up to 20 months)] [Designated as safety issue: No]
  Progression-free survival (PFS) in participants with Met Diagnostic-Positive tumors as determined by immunohistochemistry. PFS was defined as the time from randomization to the first occurrence of progression or relapse (as per Response Evaluation Criteria in Solid Tumors (RECIST 1.0) and assessed by the site radiologist or investigator) or death on study from any cause (within 30 days of last treatment).

Secondary Outcome Measures:

- Percentage of Participants With Objective Response [Time Frame: Start of treatment until disease progression/recurrence or death on study. (Up to 20 months)] [Designated as safety issue: No]
  Objective response (partial and complete response as determined using RECIST 1.0). Partial response was defined as at least a 30% decrease in the sum of the longest diameter of target lesions taking as reference the baseline sum longest diameter. Complete response was defined as disappearance of all target lesions.
- Percentage of Participants With Objective Response in Patients With Met Diagnostic-Positive Tumors [Time Frame: Start of treatment until disease progression/recurrence or death on study. (Up to 20 months)] [Designated as safety issue: No]
  Objective response (OR); partial and complete response as determined using RECIST 1.0 in patients with Met Diagnostic-Positive Tumors as determined by immunohistochemistry. Partial response was defined as at least a 30% decrease in the sum of the longest diameter of target lesions taking as reference the baseline sum longest diameter. Complete response was defined as disappearance of all target lesions.
- Duration of Overall Response [Time Frame: Date of initial response until date of progression or death on study. (Up to 20 months)] [Designated as safety issue: No]

Enrollment: 137
Study Start Date: April 2009
Primary Completion Date: November 2010
Study Completion Date: January 2012

Arms	Assigned Interventions
Experimental: MetMAb + Erlotinib MetMab 15 mg/kg intravenous (IV) infusion every 3 weeks + Erlotinib 150 mg orally once daily until progression of disease or unacceptable toxicity.	Drug: Erlotinib HCl Erlotinib 150 mg oral dose once daily. Other Names: Tarceva Drug: MetMAb MetMab (a monovalent antagonist antibody to the receptor MET) 15 mg/kg in 250 CC 0.9% saline intravenous infusion every 3 weeks.
Placebo Comparator: Placebo + Erlotinib	Drug: Erlotinib HCl Erlotinib 150 mg oral dose once daily.

Arms	Assigned Interventions
Placebo IV infusion every 3 weeks + Erlotinib 150 mg orally daily until progression of disease or unacceptable toxicity.	Other Names: Tarceva Drug: placebo (0.9 % saline) Placebo Intravenous infusion every 3 weeks.

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

Patients must meet the following criteria for study entry:

- Histologically confirmed NSCLC
- Availability of a tumor specimen
- Recurrent or progressive disease following at least one chemo containing regimen for Stage IIIB/IV disease
- Measurable disease in accordance with Response Evaluation Criteria in Solid Tumors (RECIST)
- At least one measurable lesion on a pre-treatment 18-fluorodeoxyglcose−positron emission tomography (FDG-PET) scan that is also a target lesion on computed tomography (CT) according to RECIST

Exclusion Criteria:

- More than two prior treatments for Stage IIIB/IV
- More than 30 days of exposure to an investigational or marketed agent that can act by EGFR inhibition, or a known epidermal growth factor receptor (EGFR)-related toxicity resulting in dose modifications
- Chemotherapy, biologic therapy, radiotherapy or investigational drug within 28 days prior to randomization
- Untreated and/or active (progressing or requiring anticonvulsants or corticosteroids for symptomatic control) central nervous system (CNS) metastasis
- History of serious systemic disease within the past 6 months prior to randomization
- Uncontrolled diabetes
- Major surgical procedure or significant traumatic injury within 28 days prior to randomization
- Anticipation of need for a major surgical procedure during the course of the study
- Local palliative radiotherapy within 7 days prior to randomization or persistent adverse effects from radiotherapy that have not been resolved to Grade II or less prior to randomization
- Symptomatic hypercalcemia requiring continued use of bisphosphonate therapy

Contacts and Locations

Investigators

Study Director:	Premal Patel, M.D., Ph.D.	Genentech, Inc.

More Information

Responsible Party: Genentech, Inc.
Study ID Numbers: OAM4558g
Health Authority: United States: Food and Drug Administration

Study Results

Participant Flow

Pre-Assignment Details	Twenty-seven patients in the placebo + erlotinib arm with disease progression in the blinded treatment stage elected to receive MetMAb + erlotinib in the optional open-label phase of the study.

Reporting Groups

	Description
MetMAb + Erlotinib	MetMab (a monovalent antagonist antibody to the receptor MET) 15 mg/kg intravenous (IV) infusion every 3 weeks + Erlotinib 150 mg orally once daily until progression of disease or unacceptable toxicity.
Placebo + Erlotinib	Placebo IV infusion every 3 weeks + Erlotinib 150 mg orally daily until progression of disease or unacceptable toxicity.

Overall Study

	MetMAb + Erlotinib	Placebo + Erlotinib
Started	69	68
Received Study Drug	69	67
Completed	7 [1]	1
Not Completed	62	67
Disease progression	42	50
Adverse Event	8	3
Death	2	5
Physician Decision	6	6
Withdrawal by Subject	4	2
Sponsor's decision to terminate study	0	1

[1] Completed participants in both arms were still receiving study drug when analyses were performed.

Baseline Characteristics

Reporting Groups

	Description
MetMAb + Erlotinib	MetMab 15 mg/kg intravenous (IV) infusion every 3 weeks + Erlotinib 150 mg orally once daily until progression of disease or unacceptable toxicity.
Placebo + Erlotinib	Placebo IV infusion every 3 weeks + Erlotinib 150 mg orally daily until progression of disease or unacceptable toxicity.

Baseline Measures

	MetMAb + Erlotinib	Placebo + Erlotinib	Total
Number of Participants	69	68	137
Age, Continuous [units: years] Mean (Standard Deviation)	63.6 (9.4)	62.7 (10.6)	63.1 (10.0)
Gender, Male/Female [units: participants]			
Female	29	26	55
Male	40	42	82

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Progression-free Survival
Measure Description	Progression-free survival was defined as the time from randomization to the first occurrence of progression or relapse (as per Response Evaluation Criteria in Solid Tumors (RECIST 1.0) and assessed by the site radiologist or investigator) or death on study from any cause (within 30 days of last treatment).
Time Frame	Time from randomization to the first occurrence of progression/relapse or death on study. (Up to 20 months)
Safety Issue?	No

Analysis Population Description

All randomized intent-to-treat patients.

Reporting Groups

	Description
MetMAb + Erlotinib	MetMab 15 mg/kg intravenous (IV) infusion every 3 weeks + Erlotinib 150 mg orally once daily until progression of disease or unacceptable toxicity.
Placebo + Erlotinib	Placebo IV infusion every 3 weeks + Erlotinib 150 mg orally daily until progression of disease or unacceptable toxicity.

Measured Values

	MetMAb + Erlotinib	Placebo + Erlotinib
Number of Participants Analyzed	69	68
Progression-free Survival [units: months] Number (95% Confidence Interval)	2.2 (1.38 to 2.86)	2.6 (1.45 to 2.76)

Statistical Analysis 1 for Progression-free Survival

Statistical Analysis Overview	Comparison Groups	MetMAb + Erlotinib, Placebo + Erlotinib
	Comments	The null hypothesis is that there is no difference in PFS between MetMab + Erlotinib and Placebo + Erlotinib. The alternate hypothesis is that MetMab + Erlotinib would have prolonged PFS compared with Placebo + Erlotinib.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.6873
	Comments	[Not specified]
	Method	Log Rank
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Hazard Ratio (HR)
	Estimated Value	1.086
	Confidence Interval	(2-Sided) 95% 0.727 to 1.622

	Estimation Comments	The hazard ratio was estimated using Cox Regression and was stratified for smoking status, Eastern Cooperative Oncology Group (ECOG) performance status and histology. The hazard ratio is relative to Placebo + Erlotinib.

2. Primary Outcome Measure:

Measure Title	Progression-free Survival in Patients With Met Diagnostic-Positive Tumors
Measure Description	Progression-free survival (PFS) in participants with Met Diagnostic-Positive tumors as determined by immunohistochemistry. PFS was defined as the time from randomization to the first occurrence of progression or relapse (as per Response Evaluation Criteria in Solid Tumors (RECIST 1.0) and assessed by the site radiologist or investigator) or death on study from any cause (within 30 days of last treatment).
Time Frame	Time from randomization to the first occurrence of progression/relapse or death on study. (Up to 20 months)
Safety Issue?	No

Analysis Population Description

All randomized intent-to-treat patients with Met Diagnostic-Positive tumors.

Reporting Groups

	Description
MetMAb + Erlotinib	MetMab 15 mg/kg intravenous (IV) infusion every 3 weeks + Erlotinib 150 mg orally once daily until progression of disease or unacceptable toxicity.
Placebo + Erlotinib	Placebo IV infusion every 3 weeks + Erlotinib 150 mg orally daily until progression of disease or unacceptable toxicity.

Measured Values

	MetMAb + Erlotinib	Placebo + Erlotinib
Number of Participants Analyzed	35	31
Progression-free Survival in Patients With Met Diagnostic-Positive Tumors [units: months] Median (95% Confidence Interval)	2.9 (1.38 to 6.21)	1.5 (1.35 to 2.63)

Statistical Analysis 1 for Progression-free Survival in Patients With Met Diagnostic-Positive Tumors

Statistical Analysis Overview	Comparison Groups	MetMAb + Erlotinib, Placebo + Erlotinib

	Comments	The null hypothesis is that there is no difference in PFS between MetMab + Erlotinib and Placebo + Erlotinib. The alternate hypothesis is that MetMab + Erlotinib would have prolonged PFS compared with Placebo + Erlotinib.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0418
	Comments	[Not specified]
	Method	Log Rank
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Hazard Ratio (HR)
	Estimated Value	0.529
	Confidence Interval	(2-Sided) 95% 0.284 to 0.986
	Estimation Comments	The hazard ratio was estimated using Cox Regression and was stratified for smoking status, ECOG performance status and histology. The hazard ratio is relative to Placebo + Erlotinib.

3. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Objective Response
Measure Description	Objective response (partial and complete response as determined using RECIST 1.0). Partial response was defined as at least a 30% decrease in the sum of the longest diameter of target lesions taking as reference the baseline sum longest diameter. Complete response was defined as disappearance of all target lesions.
Time Frame	Start of treatment until disease progression/recurrence or death on study. (Up to 20 months)
Safety Issue?	No

Analysis Population Description

All randomized intent-to-treat patients.

Reporting Groups

	Description
MetMAb + Erlotinib	MetMab 15 mg/kg intravenous (IV) infusion every 3 weeks + Erlotinib 150 mg orally once daily until progression of disease or unacceptable toxicity.
Placebo + Erlotinib	Placebo IV infusion every 3 weeks + Erlotinib 150 mg orally daily until progression of disease or unacceptable toxicity.

Measured Values

	MetMAb + Erlotinib	Placebo + Erlotinib
Number of Participants Analyzed	69	68
Percentage of Participants With Objective Response [units: Percentage of participants] Number (95% Confidence Interval)	5.8 (2.0 to 13.9)	4.4 (1.2 to 11.7)

Statistical Analysis 1 for Percentage of Participants With Objective Response

Statistical Analysis Overview	Comparison Groups	MetMAb + Erlotinib, Placebo + Erlotinib
	Comments	The null hypothesis is that there is no difference in Objective Response between MetMab + Erlotinib and Placebo + Erlotinib. The alternate hypothesis is that MetMab + Erlotinib would have better Objective Response compared with Placebo + Erlotinib.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.7101
	Comments	P-value was stratified for smoking status, ECOG performance status and histology.
	Method	Cochran-Mantel-Haenszel
	Comments	[Not specified]

4. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Objective Response in Patients With Met Diagnostic-Positive Tumors

Measure Description	Objective response (OR); partial and complete response as determined using RECIST 1.0 in patients with Met Diagnostic-Positive Tumors as determined by immunohistochemistry. Partial response was defined as at least a 30% decrease in the sum of the longest diameter of target lesions taking as reference the baseline sum longest diameter. Complete response was defined as disappearance of all target lesions.
Time Frame	Start of treatment until disease progression/recurrence or death on study. (Up to 20 months)
Safety Issue?	No

Analysis Population Description

All randomized intent-to-treat patients with Met Diagnostic-positive tumors.

Reporting Groups

	Description
MetMAb + Erlotinib	MetMab 15 mg/kg intravenous (IV) infusion every 3 weeks + Erlotinib 150 mg orally once daily until progression of disease or unacceptable toxicity.
Placebo + Erlotinib	Placebo IV infusion every 3 weeks + Erlotinib 150 mg orally daily until progression of disease or unacceptable toxicity.

Measured Values

	MetMAb + Erlotinib	Placebo + Erlotinib
Number of Participants Analyzed	35	31
Percentage of Participants With Objective Response in Patients With Met Diagnostic-Positive Tumors [units: Percentage of participants] Number (95% Confidence Interval)	8.6 (2.4 to 21.5)	3.2 (0.2 to 16.1)

Statistical Analysis 1 for Percentage of Participants With Objective Response in Patients With Met Diagnostic-Positive Tumors

Statistical Analysis Overview	Comparison Groups	MetMAb + Erlotinib, Placebo + Erlotinib
	Comments	The null hypothesis is that there is no difference in Objective Response between MetMab + Erlotinib and Placebo + Erlotinib. The alternate hypothesis is that MetMab + Erlotinib would have better Objective Response compared with Placebo + Erlotinib
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3671
	Comments	P-value was stratified for smoking status, ECOG performance status and histology.
	Method	Cochran-Mantel-Haenszel
	Comments	[Not specified]

5. Secondary Outcome Measure:

Measure Title	Duration of Overall Response
Measure Description	
Time Frame	Date of initial response until date of progression or death on study. (Up to 20 months)
Safety Issue?	No

Analysis Population Description

All randomized intent-to-treat patients. Analyses of duration of response were not performed because of the small number of patients with objective responses.

Reporting Groups

	Description
MetMAb + Erlotinib	MetMab 15 mg/kg intravenous (IV) infusion every 3 weeks + Erlotinib 150 mg orally once daily until progression of disease or unacceptable toxicity.
Placebo + Erlotinib	Placebo IV infusion every 3 weeks + Erlotinib 150 mg orally daily until progression of disease or unacceptable toxicity.

Measured Values

	MetMAb + Erlotinib	Placebo + Erlotinib
Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

Reported Adverse Events

Time Frame	Up to 20 months
Additional Description	[Not specified]

Reporting Groups

	Description
MetMAb + Erlotinib	MetMab 15 mg/kg intravenous (IV) infusion every 3 weeks + Erlotinib 150 mg orally once daily until progression of disease or unacceptable toxicity.
Placebo + Erlotinib	Placebo IV infusion every 3 weeks + Erlotinib 150 mg orally daily until progression of disease or unacceptable toxicity.

Serious Adverse Events

	MetMAb + Erlotinib	Placebo + Erlotinib
	Affected/At Risk (%)	Affected/At Risk (%)
Total	29/69 (42.03%)	22/67 (32.84%)
Blood and lymphatic system disorders		
ANAEMIA [A] †	1/69 (1.45%)	2/67 (2.99%)
Cardiac disorders		
ATRIAL FIBRILLATION [A] †	0/69 (0%)	1/67 (1.49%)
CARDIAC ARREST [A] †	1/69 (1.45%)	0/67 (0%)
TACHYCARDIA [A] †	1/69 (1.45%)	0/67 (0%)
Endocrine disorders		
ADRENAL INSUFFICIENCY [A] †	0/69 (0%)	1/67 (1.49%)
Gastrointestinal disorders		
CONSTIPATION [A] †	0/69 (0%)	1/67 (1.49%)
General disorders		
ASTHENIA [A] †	1/69 (1.45%)	0/67 (0%)
DEATH [A] †	0/69 (0%)	1/67 (1.49%)
HERNIA OBSTRUCTIVE [A] †	1/69 (1.45%)	0/67 (0%)
PAIN [A] †	1/69 (1.45%)	0/67 (0%)
PYREXIA [A] †	1/69 (1.45%)	0/67 (0%)
Immune system disorders		

	MetMAb + Erlotinib	Placebo + Erlotinib
	Affected/At Risk (%)	Affected/At Risk (%)
HYPERSENSITIVITY [A] †	0/69 (0%)	1/67 (1.49%)
Infections and infestations		
CELLULITIS [A] †	1/69 (1.45%)	0/67 (0%)
LUNG INFECTION [A] †	1/69 (1.45%)	1/67 (1.49%)
PNEUMONIA [A] †	4/69 (5.8%)	1/67 (1.49%)
STAPHYLOCOCCAL INFECTION [A] †	1/69 (1.45%)	0/67 (0%)
Metabolism and nutrition disorders		
DEHYDRATION [A] †	1/69 (1.45%)	1/67 (1.49%)
HYPOGLYCAEMIA [A] †	0/69 (0%)	1/67 (1.49%)
HYPOVOLAEMIA [A] †	0/69 (0%)	1/67 (1.49%)
Nervous system disorders		
CEREBRAL INFARCTION [A] †	1/69 (1.45%)	0/67 (0%)
CEREBROVASCULAR ACCIDENT [A] †	1/69 (1.45%)	0/67 (0%)
SPINAL CORD COMPRESSION [A] †	1/69 (1.45%)	0/67 (0%)
SYNCOPE [A] †	1/69 (1.45%)	0/67 (0%)
Psychiatric disorders		
DELIRIUM [A] †	0/69 (0%)	1/67 (1.49%)
Renal and urinary disorders		
RENAL FAILURE [A] †	0/69 (0%)	1/67 (1.49%)
Respiratory, thoracic and mediastinal disorders		
CHRONIC OBSTRUCTIVE PULMONARY DISEASE [A] †	1/69 (1.45%)	1/67 (1.49%)
COUGH [A] †	1/69 (1.45%)	0/67 (0%)

	MetMAb + Erlotinib	Placebo + Erlotinib
	Affected/At Risk (%)	Affected/At Risk (%)
DYSPNOEA [A] †	3/69 (4.35%)	0/67 (0%)
HAEMOPTYSIS [A] †	2/69 (2.9%)	0/67 (0%)
HYPOXIA [A] †	1/69 (1.45%)	0/67 (0%)
INTERSTITIAL LUNG DISEASE [A] †	0/69 (0%)	2/67 (2.99%)
OBSTRUCTIVE AIRWAYS DISORDER [A] †	0/69 (0%)	1/67 (1.49%)
PLEURAL EFFUSION [A] †	1/69 (1.45%)	1/67 (1.49%)
PNEUMONIA ASPIRATION [A] †	1/69 (1.45%)	0/67 (0%)
PULMONARY ARTERY THROMBOSIS [A] †	0/69 (0%)	1/67 (1.49%)
PULMONARY EMBOLISM [A] †	4/69 (5.8%)	1/67 (1.49%)
RESPIRATORY DISTRESS [A] †	0/69 (0%)	2/67 (2.99%)
RESPIRATORY FAILURE [A] †	1/69 (1.45%)	0/67 (0%)
Skin and subcutaneous tissue disorders		
RASH [A] †	2/69 (2.9%)	1/67 (1.49%)
Vascular disorders		
DEEP VEIN THROMBOSIS [A] †	0/69 (0%)	1/67 (1.49%)
EMBOLISM VENOUS [A] †	0/69 (0%)	1/67 (1.49%)
ORTHOSTATIC HYPOTENSION [A] †	0/69 (0%)	1/67 (1.49%)
SUPERIOR VENA CAVAL OCCLUSION [A] †	1/69 (1.45%)	0/67 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	MetMAb + Erlotinib	Placebo + Erlotinib
	Affected/At Risk (%)	Affected/At Risk (%)
Total	68/69 (98.55%)	67/67 (100%)
Blood and lymphatic system disorders		
ANAEMIA [A] †	10/69 (14.49%)	10/67 (14.93%)
Gastrointestinal disorders		
ABDOMINAL PAIN [A] †	5/69 (7.25%)	2/67 (2.99%)
CONSTIPATION [A] †	4/69 (5.8%)	5/67 (7.46%)
DIARRHOEA [A] †	28/69 (40.58%)	35/67 (52.24%)
DYSPEPSIA [A] †	5/69 (7.25%)	6/67 (8.96%)
NAUSEA [A] †	22/69 (31.88%)	21/67 (31.34%)
STOMATITIS [A] †	4/69 (5.8%)	3/67 (4.48%)
VOMITING [A] †	4/69 (5.8%)	13/67 (19.4%)
General disorders		
ASTHENIA [A] †	9/69 (13.04%)	6/67 (8.96%)
CHEST PAIN [A] †	2/69 (2.9%)	7/67 (10.45%)
FATIGUE [A] †	22/69 (31.88%)	24/67 (35.82%)
OEDEMA [A] †	6/69 (8.7%)	2/67 (2.99%)
OEDEMA PERIPHERAL [A] †	16/69 (23.19%)	5/67 (7.46%)
PAIN [A] †	4/69 (5.8%)	8/67 (11.94%)
PYREXIA [A] †	10/69 (14.49%)	6/67 (8.96%)
Infections and infestations		
PNEUMONIA [A] †	5/69 (7.25%)	3/67 (4.48%)
URINARY TRACT INFECTION [A] †	4/69 (5.8%)	6/67 (8.96%)

	MetMAb + Erlotinib	Placebo + Erlotinib
	Affected/At Risk (%)	Affected/At Risk (%)
Metabolism and nutrition disorders		
DECREASED APPETITE [A] †	14/69 (20.29%)	16/67 (23.88%)
HYPOKALAEMIA [A] †	4/69 (5.8%)	5/67 (7.46%)
Musculoskeletal and connective tissue disorders		
ARTHRALGIA [A] †	5/69 (7.25%)	3/67 (4.48%)
BACK PAIN [A] †	7/69 (10.14%)	7/67 (10.45%)
MUSCLE SPASMS [A] †	4/69 (5.8%)	3/67 (4.48%)
MUSCULOSKELETAL CHEST PAIN [A] †	4/69 (5.8%)	3/67 (4.48%)
MUSCULOSKELETAL PAIN [A] †	2/69 (2.9%)	4/67 (5.97%)
NECK PAIN [A] †	1/69 (1.45%)	4/67 (5.97%)
PAIN IN EXTREMITY [A] †	2/69 (2.9%)	4/67 (5.97%)
Nervous system disorders		
DIZZINESS [A] †	5/69 (7.25%)	6/67 (8.96%)
DYSGEUSIA [A] †	3/69 (4.35%)	4/67 (5.97%)
HEADACHE [A] †	2/69 (2.9%)	4/67 (5.97%)
Psychiatric disorders		
ANXIETY [A] †	6/69 (8.7%)	7/67 (10.45%)
INSOMNIA [A] †	8/69 (11.59%)	5/67 (7.46%)
Respiratory, thoracic and mediastinal disorders		
COUGH [A] †	13/69 (18.84%)	13/67 (19.4%)
DYSPNOEA [A] †	13/69 (18.84%)	16/67 (23.88%)
HAEMOPTYSIS [A] †	6/69 (8.7%)	5/67 (7.46%)
PLEURAL EFFUSION [A] †	4/69 (5.8%)	2/67 (2.99%)

	MetMAb + Erlotinib	Placebo + Erlotinib
	Affected/At Risk (%)	Affected/At Risk (%)
PULMONARY EMBOLISM [A] †	4/69 (5.8%)	1/67 (1.49%)
Skin and subcutaneous tissue disorders		
DERMATITIS ACNEIFORM [A] †	10/69 (14.49%)	10/67 (14.93%)
DRY SKIN [A] †	8/69 (11.59%)	10/67 (14.93%)
PRURITUS [A] †	4/69 (5.8%)	8/67 (11.94%)
RASH [A] †	42/69 (60.87%)	41/67 (61.19%)
Vascular disorders		
HYPOTENSION [A] †	6/69 (8.7%)	3/67 (4.48%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The Study being conducted under this Agreement is part of the Overall Study. Investigator is free to publish in reputable journals or to present at professional conferences the results of the Study, but only after the first publication or presentation that involves the Overall Study. The Sponsor may request that Confidential Information be deleted and/or the publication be postponed in order to protect the Sponsor's intellectual property rights.

Results Point of Contact:

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