ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 09/14/2015

ClinicalTrials.gov ID: NCT00461708

Study Identification

Unique Protocol ID:	ML20296
Brief Title:	A Study of Tarceva (Erlotinib) in Combination With Gemcitabine in Unresectable and/or Metastatic Cancer of the Pancreas: Relationship Between Skin Toxicity and Survival
Official Title:	An Open Label Study of Tarceva in Combination With Gemcitabine in Unresectable and/or Metastatic Cancer of the Pancreas : Relationship Between Skin Rash and Survival
Secondary IDs:	

Study Status

Record Verification:	September 2015
Overall Status:	Completed
Study Start:	May 2007
Primary Completion:	November 2010 [Actual]
Study Completion:	November 2010 [Actual]

Sponsor/Collaborators

Sponsor:	Hoffmann-La Roche
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	No

IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: unknown Board Name: Comite Etico de Investigacion Clinica del Hospital Clinico San Carlos Board Affiliation: Unknown Phone: +34913303819 Email: ceic.hcsc@salud.madrid.org
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	Spain: Agencia Espanola del Medicamento (AEM)

Study Description

Brief Summary:	This single arm study will evaluate the relationship between the skin toxicity of Tarceva in combination with gemcitabine, and survival, in patients with advanced and/or metastatic pancreatic cancer. All patients will receive gemcitabine 100mg/m2 i.v. weekly; Tarceva will be administered 100mg po per day. The anticipated time on study treatment is until disease progression, and the target sample size is 100-500 individuals.
Detailed Description:	

Conditions

Conditions:	Pancreatic Cancer
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Intervention Model:	Single Group Assignment
Number of Arms:	2
Masking:	Open Label
Allocation:	Non-Randomized
Endpoint Classification:	Safety/Efficacy Study

Enrollment: 153 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Rash, Grade <2 Participants with a rash graded less than (<) 2 according to the National Cancer Institute Common Toxicity Criteria (NCI-CTC) version (v.) 3.0 received erlotinib, 100 milligrams (mg), orally (PO), once per day until disease progression, unacceptable toxicity or refusal of patient to continue with the treatment. Participants also received gemcitabine, 1000 mg per (/) square meter (m^2), intravenously (IV), over 30 minutes on Days 1, 8 and 15 in 4-week cycles until disease progression, unacceptable toxicity or refusal of patient to continue with the treatment.	Drug: Erlotinib 100 mg, PO, once per day Other Names: • Tarceva Drug: Gemcitabine 1000 mg/m2, IV, on Days 1, 8 and 15 in 4-week cycles
Experimental: Rash, Grade ≥2 Participants with a rash graded greater than or equal to (≥) 2 according to the NCI-CTC v. 3.0 received erlotinib, 100 mg, PO, once per day until disease progression, unacceptable toxicity or refusal of patient to continue with the treatment. Participants also received gemcitabine, 1000 mg/m^2, IV, over 30 minutes on Days 1, 8 and 15 in 4-week cycles until disease progression, unacceptable toxicity or refusal of patient to continue with the treatment.	Drug: Erlotinib 100 mg, PO, once per day Other Names: • Tarceva Drug: Gemcitabine 1000 mg/m2, IV, on Days 1, 8 and 15 in 4-week cycles

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- adult patients, >=18 years of age;
- locally advanced and/or metastatic pancreatic cancer (stage III or IV);
- Karnofsky performance Status of >=60%.

Exclusion Criteria:

- local(stage IA to IIB) pancreatic cancer;

- <=6 months since last adjuvant chemotherapy;
- previous systemic therapy for metastatic pancreatic cancer;
- other primary tumor within last 5 years (except for adequately treated cancer in situ of cervix, or basal cell skin cancer);
- clinically significant cardiovascular disease.

Contacts/Locations

Study Officials: Clinical Trials
Study Director
Hoffmann-La Roche

Locations: Spain

Barcelona, Barcelona, Spain, 08227

Barcelona, Barcelona, Spain, 08906

Pontevedra, Pontevedra, Spain, 36002

Palma de Mallorca, Islas Baleares, Spain, 07198

Lugo, Lugo, Spain, 27004

Valencia, Valencia, Spain, 41014

Navarra, Navarra, Spain, 31008

Cordoba, Cordoba, Spain, 14004

Sabadell, Barcelona, Barcelona, Spain, 08208

Guadalajara, Guadalajara, Spain, 19002

Barcelona, Barcelona, Spain, 08916

Granada, Granada, Spain, 18014

Sagunto, Valencia, Spain, 46520

La Coruna, La Coruña, Spain, 15006

Lerida, Lerida, Spain, 25198

Girona, Girona, Spain, 17007

Alcorcon, Madrid, Spain, 28922

Alcoy, Alicante, Spain, 03804

Murcia, Murcia, Spain, 30120

Jaen, Jaen, Spain, 23007

Manresa, Barcelona, Spain, 08243

Zaragoza, Zaragoza, Spain, 50009

Sevilla, Sevilla, Spain, 41013

Barcelona, Barcelona, Spain, 08907

Murcia, Murcia, Spain, 30008

Santander, Cantabria, Spain, 39008

Madrid, Madrid, Spain, 28041

Elche, Alicante, Spain, 03203

Madrid, Madrid, Spain, 28040

References

Citations:

Links:

Study Data/Documents:

Participant Flow

Reporting Groups

	Description
Erlotinib, Gemcitabine: Rash Grade Less Than (<) 2	Participants with a rash Grade < 2 according to the National Cancer Institute Common Toxicity Criteria (NCI-CTC) version (V) 3.0 received erlotinib, 100 milligrams (mg), orally (PO), once per day of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant. Participants also received gemcitabine, 1000 milligrams per square meter (mg/m^2), intravenously (IV), over 30 minutes on Days 1, 8 and 15 of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant.
Erlotinib, Gemcitabine: Rash Grade Greater Than/Equal to (≥) 2	Participants with a rash Grade ≥ 2 according to the NCI-CTC V 3.0 received erlotinib, 100 mg, PO, once per day of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant. Participants also received gemcitabine, 1000 mg/m^2, IV, over 30 minutes on Days 1, 8 and 15 of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant.

Overall Study

	Erlotinib, Gemcitabine: Rash Grade Less Than (<) 2	Erlotinib, Gemcitabine: Rash Grade Greater Than/Equal to (≥) 2
Started	115	38
Completed	0	0
Not Completed	115	38
Adverse Event	17	7
Lack of Efficacy	68	20
Physician Decision	10	4
Withdrawal by Subject	8	2
Not specified	4	4
Death	8	1

Baseline Characteristics

Analysis Population Description

Intent-to-treat (ITT) population: all participants included in the study.

Reporting Groups

	Description
Erlotinib, Gemcitabine: Rash Grade < 2	Participants with a rash Grade < 2 according to the National NCI-CTC V 3.0 received erlotinib, 100 mg, PO, once per day of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant. Participants also received gemcitabine, 1000 mg/m^2, IV, over 30 minutes on Days 1, 8 and 15 of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant.
Erlotinib, Gemcitabine: Rash Grade ≥ 2	Participants with a rash Grade ≥ 2 according to the NCI-CTC V 3.0 received erlotinib, 100 mg, PO, once per day of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant. Participants also received gemcitabine, 1000 mg/m^2, IV, over 30 minutes on Days 1, 8 and 15 of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant.

Baseline Measures

	Erlotinib, Gemcitabine: Rash Grade < 2	Erlotinib, Gemcitabine: Rash Grade ≥ 2	Total
Number of Participants	115	38	153
Age, Continuous [units: years] Mean (Standard Deviation)	63.6 (9.9)	62.0 (10.6)	63.2 (10.1)
Gender, Male/Female [units: participants]			
Female	61	10	71
Male	54	28	82

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Number of Participants Who Died During the Study
Measure Description	
Time Frame	Enrollment through Cycle 24 (4-week cycles), up to 24 months.
Safety Issue?	No

Analysis Population Description

ITT population

Reporting Groups

	Description
Erlotinib, Gemcitabine: Rash Grade < 2	Participants with a rash Grade < 2 according to the National NCI-CTC V 3.0 received erlotinib, 100 mg, PO, once per day of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant. Participants also received gemcitabine, 1000 mg/m^2, IV, over 30 minutes on Days 1, 8 and 15 of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant.
Erlotinib, Gemcitabine: Rash Grade ≥ 2	Participants with a rash Grade ≥ 2 according to the NCI-CTC V 3.0 received erlotinib, 100 mg, PO, once per day of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant. Participants also received gemcitabine, 1000 mg/m^2, IV, over 30 minutes on Days 1, 8 and 15 of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant.

Measured Values

	Erlotinib, Gemcitabine: Rash Grade < 2	Erlotinib, Gemcitabine: Rash Grade ≥ 2
Number of Participants Analyzed	115	38
Number of Participants Who Died During the Study [units: participants]	102	27

2. Primary Outcome Measure:

Measure Title	Overall Survival (OS) During the Study
Measure Description	OS was defined as the time, in months, from the date of enrollment to the date of death due to any cause. Participants whose last recorded status was not death were censored. OS was estimated using Kaplan-Meier methodology.
Time Frame	Enrollment through Cycle 24 (4-week cycles), up to 24 months.
Safety Issue?	No

Analysis Population Description

ITT population; only participants who died were included in the analysis.

Reporting Groups

	Description
Erlotinib, Gemcitabine: Rash Grade < 2	Participants with a rash Grade < 2 according to the National NCI-CTC V 3.0 received erlotinib, 100 mg, PO, once per day of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant. Participants also received gemcitabine, 1000 mg/m^2, IV, over 30 minutes on Days 1, 8 and 15 of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant.

	Description
Erlotinib, Gemcitabine: Rash Grade ≥ 2	Participants with a rash Grade ≥ 2 according to the NCI-CTC V 3.0 received erlotinib, 100 mg, PO, once per day of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant. Participants also received gemcitabine, 1000 mg/m^2, IV, over 30 minutes on Days 1, 8 and 15 of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant.

Measured Values

	Erlotinib, Gemcitabine: Rash Grade < 2	Erlotinib, Gemcitabine: Rash Grade ≥ 2
Number of Participants Analyzed	102	27
Overall Survival (OS) During the Study [units: months] Median (95% Confidence Interval)	4.468 (3.618 to 5.318)	10.546 (9.679 to 11.414)

3. Secondary Outcome Measure:

Measure Title	Number of Participants Who Died at 6 Months
Measure Description	
Time Frame	Enrollment through Cycle 6 (4-week cycles), up to 6 months.
Safety Issue?	No

Analysis Population Description

ITT population

Reporting Groups

	Description
Erlotinib, Gemcitabine: Rash Grade < 2	Participants with a rash Grade < 2 according to the National NCI-CTC V 3.0 received erlotinib, 100 mg, PO, once per day of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant. Participants also received gemcitabine, 1000 mg/m^2, IV, over 30 minutes on Days 1, 8 and 15 of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant.
Erlotinib, Gemcitabine: Rash Grade ≥ 2	Participants with a rash Grade ≥ 2 according to the NCI-CTC V 3.0 received erlotinib, 100 mg, PO, once per day of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant. Participants also received gemcitabine, 1000 mg/m^2, IV, over 30 minutes on Days 1, 8 and 15 of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant.

Measured Values

	Erlotinib, Gemcitabine: Rash Grade < 2	Erlotinib, Gemcitabine: Rash Grade ≥ 2
Number of Participants Analyzed	115	38
Number of Participants Who Died at 6 Months [units: participants]	69	8

4. Secondary Outcome Measure:

Measure Title	OS At 6 Months
Measure Description	OS was defined as the time, in months, from the date of enrollment to the date of death due to any cause. Participants whose last recorded status was not death were censored. OS was estimated using Kaplan-Meier methodology.
Time Frame	Enrollment through Cycle 6 (4-week cycles), up to 6 months.
Safety Issue?	No

Analysis Population Description

ITT population; only participants who died were included in the analysis.

Reporting Groups

	Description
Erlotinib, Gemcitabine: Rash Grade < 2	Participants with a rash Grade < 2 according to the National NCI-CTC V 3.0 received erlotinib, 100 mg, PO, once per day of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant. Participants also received gemcitabine, 1000 mg/m^2, IV, over 30 minutes on Days 1, 8 and 15 of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant.
Erlotinib, Gemcitabine: Rash Grade ≥ 2	Participants with a rash Grade ≥ 2 according to the NCI-CTC V 3.0 received erlotinib, 100 mg, PO, once per day of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant. Participants also received gemcitabine, 1000 mg/m^2, IV, over 30 minutes on Days 1, 8 and 15 of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant.

Measured Values

	Erlotinib, Gemcitabine: Rash Grade < 2	Erlotinib, Gemcitabine: Rash Grade ≥ 2
Number of Participants Analyzed	69	8
OS At 6 Months [units: months] Median (95% Confidence Interval)	4.468 (3.618 to 5.318)	NA (NA to NA) [1]

[1] The median and 95% confidence interval could not be calculated because of the large number of censored events.

5. Secondary Outcome Measure:

Measure Title	Number of Participants Who Died During the Study By Rash Grade
Measure Description	
Time Frame	Enrollment through Cycle 24 (4-week cycles), up to 24 months.
Safety Issue?	No

Analysis Population Description

ITT population

Reporting Groups

	Description
Erlotinib, Gemcitabine: Rash Grade 0	Participants with a rash Grade 0 according to the National NCI-CTC V 3.0 received erlotinib, 100 mg, PO, once per day of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant. Participants also received gemcitabine, 1000 mg/m^2, IV, over 30 minutes on Days 1, 8 and 15 of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant.
Erlotinib, Gemcitabine: Rash Grade 1	Participants with a rash Grade 1 according to the National NCI-CTC V 3.0 received erlotinib, 100 mg, PO, once per day of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant. Participants also received gemcitabine, 1000 mg/m^2, IV, over 30 minutes on Days 1, 8 and 15 of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant.
Erlotinib, Gemcitabine: Rash Grade ≥ 2	Participants with a rash Grade ≥ 2 according to the NCI-CTC V 3.0 received erlotinib, 100 mg, PO, once per day of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant. Participants also received gemcitabine, 1000 mg/m^2, IV, over 30 minutes on Days 1, 8 and 15 of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant.

Measured Values

	Erlotinib, Gemcitabine: Rash Grade 0	Erlotinib, Gemcitabine: Rash Grade 1	Erlotinib, Gemcitabine: Rash Grade ≥ 2
Number of Participants Analyzed	71	44	38
Number of Participants Who Died During the Study By Rash Grade [units: participants]	65	37	27

6. Secondary Outcome Measure:

Measure Title	OS By Rash Grade
Measure Description	OS was defined as the time, in months, from the date of enrollment to the date of death due to any cause. Participants whose last recorded status was not death were censored. OS was estimated using Kaplan-Meier methodology.
Time Frame	Enrollment through Cycle 24 (4-week cycles), up to 24 months.
Safety Issue?	No

Analysis Population Description

ITT population; only participants who died were included in the analysis.

Reporting Groups

	Description
Erlotinib, Gemcitabine: Rash Grade 0	Participants with a rash Grade 0 according to the National NCI-CTC V 3.0 received erlotinib, 100 mg, PO, once per day of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant. Participants also received gemcitabine, 1000 mg/m^2, IV, over 30 minutes on Days 1, 8 and 15 of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant.
Erlotinib, Gemcitabine: Rash Grade 1	Participants with a rash Grade 1 according to the National NCI-CTC V 3.0 received erlotinib, 100 mg, PO, once per day of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant. Participants also received gemcitabine, 1000 mg/m^2, IV, over 30 minutes on Days 1, 8 and 15 of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant.
Erlotinib, Gemcitabine: Rash Grade ≥ 2	Participants with a rash Grade ≥ 2 according to the NCI-CTC V 3.0 received erlotinib, 100 mg, PO, once per day of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant. Participants also received gemcitabine, 1000 mg/m^2, IV, over 30 minutes on Days 1, 8 and 15 of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant.

Measured Values

	Erlotinib, Gemcitabine: Rash Grade 0	Erlotinib, Gemcitabine: Rash Grade 1	Erlotinib, Gemcitabine: Rash Grade ≥ 2
Number of Participants Analyzed	65	37	27
OS By Rash Grade [units: months] Median (95% Confidence Interval)	3.318 (2.446 to 4.191)	6.571 (5.139 to 8.003)	10.546 (9.679 to 11.414)

7. Secondary Outcome Measure:

Measure Title	Number of Participants With Disease Progression or Death
Measure Description	Progression-free survival (PFS) was defined as the time from the date of enrollment to the date of document disease progression or death due to any cause. As per Response Evaluation Criteria in Solid Tumors (RECIST) V 1.0, progressive disease (PD) was defined for target lesions (TLs) as at least a 20 percent (%) increase in the sum of the longest diameter (SLD), taking as reference the smallest SLD recorded since the start of treatment, and for non-target lesions (NTLs) as unequivocal progression of NTLs. Participants whose last recorded status was not PD or death were censored.
Time Frame	Enrollment, every 2 treatment cycles (4-week cycles) until disease progression, death, or end of study, for up to 24 months.
Safety Issue?	No

Analysis Population Description

ITT population

Reporting Groups

	Description
Erlotinib, Gemcitabine: Rash Grade < 2	Participants with a rash Grade < 2 according to the National NCI-CTC V 3.0 received erlotinib, 100 mg, PO, once per day of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant. Participants also received gemcitabine, 1000 mg/m^2, IV, over 30 minutes on Days 1, 8 and 15 of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant.
Erlotinib, Gemcitabine: Rash Grade ≥ 2	Participants with a rash Grade ≥ 2 according to the NCI-CTC V 3.0 received erlotinib, 100 mg, PO, once per day of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant. Participants also received gemcitabine, 1000 mg/m^2, IV, over 30 minutes on Days 1, 8 and 15 of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant.

Measured Values

	Erlotinib, Gemcitabine: Rash Grade < 2	Erlotinib, Gemcitabine: Rash Grade ≥ 2
Number of Participants Analyzed	115	38
Number of Participants With Disease Progression or Death [units: participants]	110	33

8. Secondary Outcome Measure:

Measure Title	PFS
Measure Description	The time, in months, from enrollment to PFS event. Participants whose last recorded status was not progression or death were censored. PFS was estimated using Kaplan-Meier methodology.
Time Frame	Enrollment, every 2 treatment cycles (4-week cycles) until disease progression, death, or end of study, for up to 24 months
Safety Issue?	No

Analysis Population Description

ITT population; only participants with an event (death or disease progression) were included in the analysis.

Reporting Groups

	Description
Erlotinib, Gemcitabine: Rash Grade < 2	Participants with a rash Grade < 2 according to the National NCI-CTC V 3.0 received erlotinib, 100 mg, PO, once per day of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant. Participants also received gemcitabine, 1000 mg/m^2, IV, over 30 minutes on Days 1, 8 and 15 of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant.
Erlotinib, Gemcitabine: Rash Grade ≥ 2	Participants with a rash Grade ≥ 2 according to the NCI-CTC V 3.0 received erlotinib, 100 mg, PO, once per day of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant. Participants also received gemcitabine, 1000 mg/m^2, IV, over 30 minutes on Days 1, 8 and 15 of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant.

Measured Values

	Erlotinib, Gemcitabine: Rash Grade < 2	Erlotinib, Gemcitabine: Rash Grade ≥ 2
Number of Participants Analyzed	110	33
PFS [units: months] Median (95% Confidence Interval)	2.497 (2.130 to 2.864)	6.439 (4.919 to 7.960)

9. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Best Overall Response (BOR) of Complete Response (CR) or Partial Response (PR) According to RECIST

Measure Description	As per RECIST V 1.0: for TLs, a CR was defined as the disappearance of all TLs; and a PR was defined as at least a 30% decrease in the SLD of the TLs, taking as a reference the baseline (BL) SLD. For NTLs, a CR was defined as the disappearance of all NTLs and normalization of tumor marker levels. Participants for whom no assessment of response was available and who had finalized the study due to disease progression or tumor-related death, disease progression was considered the BOR.
Time Frame	Enrollment, every 2 treatment cycles (4-week cycles) until disease progression, death, or end of study, for up to 24 months.
Safety Issue?	No

Analysis Population Description
ITT population

Reporting Groups

	Description
Erlotinib, Gemcitabine: Rash Grade < 2	Participants with a rash Grade < 2 according to the National NCI-CTC V 3.0 received erlotinib, 100 mg, PO, once per day of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant. Participants also received gemcitabine, 1000 mg/m^2, IV, over 30 minutes on Days 1, 8 and 15 of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant.
Erlotinib, Gemcitabine: Rash Grade ≥ 2	Participants with a rash Grade ≥ 2 according to the NCI-CTC V 3.0 received erlotinib, 100 mg, PO, once per day of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant. Participants also received gemcitabine, 1000 mg/m^2, IV, over 30 minutes on Days 1, 8 and 15 of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant.

Measured Values

	Erlotinib, Gemcitabine: Rash Grade < 2	Erlotinib, Gemcitabine: Rash Grade ≥ 2
Number of Participants Analyzed	115	38
Percentage of Participants With Best Overall Response (BOR) of Complete Response (CR) or Partial Response (PR) According to RECIST [units: percentage of participants]	7.0	21.1

Statistical Analysis 1 for Percentage of Participants With Best Overall Response (BOR) of Complete Response (CR) or Partial Response (PR) According to RECIST

Statistical Analysis Overview	Comparison Groups	Erlotinib, Gemcitabine: Rash Grade < 2, Erlotinib, Gemcitabine: Rash Grade ≥ 2
	Comments	[Not specified]

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.05
	Comments	[Not specified]
	Method	Chi-squared
	Comments	[Not specified]

10. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Disease Control According to RECIST
Measure Description	Disease control was defined as BOR of CR, PR, or stable disease (SD). As per RECIST V 1.0: for TLs, a CR was defined as the disappearance of all TLs; and a PR was defined as at least a 30% decrease in the SLD of the TLs, taking as a reference the BL SLD; SD was defined as neither sufficient decrease in SLD to qualify for PR nor sufficient increase in SLD to qualify for PD. For NTLs, a CR was defined as the disappearance of all NTLs and normalization of tumor marker levels; SD was defined as the persistence of one or more NTLs and/or maintenance of tumor marker level above the normal limits. Participants for whom no assessment of response was available and who had finalized the study due to disease progression or tumor-related death, disease progression was considered the BOR.
Time Frame	Enrollment, every 2 treatment cycles (4-week cycles) until disease progression, death, or end of study, for up to 24 months.
Safety Issue?	No

Analysis Population Description

ITT population

Reporting Groups

	Description
Erlotinib, Gemcitabine: Rash Grade < 2	Participants with a rash Grade < 2 according to the National NCI-CTC V 3.0 received erlotinib, 100 mg, PO, once per day of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant. Participants also received gemcitabine, 1000 mg/m^2, IV, over 30 minutes on Days 1, 8 and 15 of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant.
Erlotinib, Gemcitabine: Rash Grade ≥ 2	Participants with a rash Grade ≥ 2 according to the NCI-CTC V 3.0 received erlotinib, 100 mg, PO, once per day of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant. Participants also received gemcitabine, 1000 mg/m^2, IV, over 30 minutes on Days 1, 8 and 15 of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant.

Measured Values

	Erlotinib, Gemcitabine: Rash Grade < 2	Erlotinib, Gemcitabine: Rash Grade ≥ 2
Number of Participants Analyzed	115	38
Percentage of Participants With Disease Control According to RECIST [units: percentage of participants]	42.6	84.2

Statistical Analysis 1 for Percentage of Participants With Disease Control According to RECIST

Statistical Analysis Overview	Comparison Groups	Erlotinib, Gemcitabine: Rash Grade < 2, Erlotinib, Gemcitabine: Rash Grade ≥ 2
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.05
	Comments	[Not specified]
	Method	Chi-squared
	Comments	[Not specified]

Reported Adverse Events

Time Frame	Adverse events (AEs) were recorded at every study visit for up to a maximum of 24 treatment cycles.
Additional Description	All participants who received at least 1 dose of study treatment were included in the safety analysis.

Reporting Groups

	Description
Erlotinib, Gemcitabine: Rash Grade < 2	Participants with a rash Grade < 2 according to the National NCI-CTC V 3.0 received erlotinib, 100 mg, PO, once per day of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant. Participants also received gemcitabine, 1000 mg/m^2, IV, over 30 minutes on Days 1, 8 and 15 of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant.

	Description
Erlotinib, Gemcitabine: Rash Grade ≥ 2	Participants with a rash Grade ≥ 2 according to the NCI-CTC V 3.0 received erlotinib, 100 mg, PO, once per day of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant. Participants also received gemcitabine, 1000 mg/m^2, IV, over 30 minutes on Days 1, 8 and 15 of Cycles 1 up through a maximum of Cycle 24 (4-week cycles) until disease progression, unacceptable toxicity, or treatment refusal by participant.

Serious Adverse Events

	Erlotinib, Gemcitabine: Rash Grade < 2	Erlotinib, Gemcitabine: Rash Grade ≥ 2
	Affected/At Risk (%)	Affected/At Risk (%)
Total	58/115 (50.43%)	14/38 (36.84%)
Blood and lymphatic system disorders		
Anaemia [A] *	1/115 (0.87%)	0/38 (0%)
Myelosuppression [A] *	1/115 (0.87%)	0/38 (0%)
Thrombocytopenia [A] *	1/115 (0.87%)	0/38 (0%)
Cardiac disorders		
Cardiac failure congestive [A] *	1/115 (0.87%)	0/38 (0%)
Left ventricular dysfunction [A] *	0/115 (0%)	1/38 (2.63%)
Pericardial effusion [A] *	1/115 (0.87%)	0/38 (0%)
Valvular heart disease [A] *	0/115 (0%)	1/38 (2.63%)
Gastrointestinal disorders		
Abdomen nos [A] *	5/115 (4.35%)	0/38 (0%)
Diarrhea [A] *	1/115 (0.87%)	0/38 (0%)
Gastrointestinal syndrome [A] *	1/115 (0.87%)	0/38 (0%)
Gastrointestinal toxicity [A] *	1/115 (0.87%)	0/38 (0%)
Haemorrhage, GI [A] *	3/115 (2.61%)	1/38 (2.63%)
Haemorrhage, rectal [A] *	1/115 (0.87%)	0/38 (0%)
Obstruction, GI [A] *	11/115 (9.57%)	2/38 (5.26%)

	Erlotinib, Gemcitabine: Rash Grade < 2	Erlotinib, Gemcitabine: Rash Grade ≥ 2
	Affected/At Risk (%)	Affected/At Risk (%)
Pancreatitis [A] *	1/115 (0.87%)	1/38 (2.63%)
Perforation, GI [A] *	1/115 (0.87%)	0/38 (0%)
Visceral arterial ischemia [A] *	1/115 (0.87%)	0/38 (0%)
Vomiting [A] *	2/115 (1.74%)	0/38 (0%)
General disorders		
Fatigue [A] *	4/115 (3.48%)	1/38 (2.63%)
Fever [A] *	4/115 (3.48%)	2/38 (5.26%)
Pain [A] *	0/115 (0%)	1/38 (2.63%)
Sudden death [A] *	1/115 (0.87%)	0/38 (0%)
Hepatobiliary disorders		
Bilirubin (Hyperbilirubinemia) [A] *	1/115 (0.87%)	0/38 (0%)
Liver dysfunction [A] *	1/115 (0.87%)	0/38 (0%)
Liver dysfunction/failure [A] *	1/115 (0.87%)	0/38 (0%)
Infections and infestations		
Anal/perianal [A] *	1/115 (0.87%)	0/38 (0%)
Blood [A] *	4/115 (3.48%)	2/38 (5.26%)
Cellulitis [A] *	1/115 (0.87%)	0/38 (0%)
Lung (pneumonia) [A] *	3/115 (2.61%)	3/38 (7.89%)
Peritoneal cavity [A] *	1/115 (0.87%)	1/38 (2.63%)
Upper airway nos [A] *	1/115 (0.87%)	0/38 (0%)
Urinary tract nos [A] *	1/115 (0.87%)	0/38 (0%)
Investigations		
Weight loss [A] *	0/115 (0%)	1/38 (2.63%)

	Erlotinib, Gemcitabine: Rash Grade < 2	Erlotinib, Gemcitabine: Rash Grade ≥ 2
	Affected/At Risk (%)	Affected/At Risk (%)
Metabolism and nutrition disorders		
Calcium, serum-low (hypocalcemia) [A] *	1/115 (0.87%)	0/38 (0%)
Diabetes [A] *	3/115 (2.61%)	0/38 (0%)
Glucose, serum-high (hyperglycemia) [A] *	1/115 (0.87%)	0/38 (0%)
Musculoskeletal and connective tissue disorders		
Back pain [A] *	1/115 (0.87%)	0/38 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Benign prostatic hyperplasia [A] *	1/115 (0.87%)	0/38 (0%)
Tumor pain [A] *	1/115 (0.87%)	0/38 (0%)
Nervous system disorders		
CNS Cerebrovascular ischemia [A] *	1/115 (0.87%)	2/38 (5.26%)
Haemorrhage, CNS [A] *	1/115 (0.87%)	0/38 (0%)
Speech impairment [A] *	0/115 (0%)	1/38 (2.63%)
Psychiatric disorders		
Confusion [A] *	1/115 (0.87%)	0/38 (0%)
Renal and urinary disorders		
Obstruction, GU [A] *	1/115 (0.87%)	0/38 (0%)
Renal failure [A] *	1/115 (0.87%)	0/38 (0%)
Respiratory, thoracic and mediastinal disorders		
Dyspnea [A] *	3/115 (2.61%)	0/38 (0%)
Respiratory failure [A] *	1/115 (0.87%)	1/38 (2.63%)
Surgical and medical procedures		
Liver [A] *	1/115 (0.87%)	0/38 (0%)

	Erlotinib, Gemcitabine: Rash Grade < 2	Erlotinib, Gemcitabine: Rash Grade ≥ 2
	Affected/At Risk (%)	Affected/At Risk (%)
Vascular disorders		
Hypertension [A] *	1/115 (0.87%)	0/38 (0%)
Thrombosis/Embolism [A] *	3/115 (2.61%)	1/38 (2.63%)
Thrombosis/Thrombus [A] *	3/115 (2.61%)	0/38 (0%)
Visceral arterial ischemia [A] *	1/115 (0.87%)	0/38 (0%)

* Indicates events were collected by non-systematic methods.
A Term from vocabulary, NCI-CTC V 3.0

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 0%

	Erlotinib, Gemcitabine: Rash Grade < 2	Erlotinib, Gemcitabine: Rash Grade ≥ 2
	Affected/At Risk (%)	Affected/At Risk (%)
Total	115/115 (100%)	38/38 (100%)
Blood and lymphatic system disorders		
Anaemia [A] *	32/115 (27.83%)	11/38 (28.95%)
Edema [A] *	11/115 (9.57%)	3/38 (7.89%)
Edema: limb [A] *	22/115 (19.13%)	2/38 (5.26%)
Granulocytopenia [A] *	1/115 (0.87%)	0/38 (0%)
Hemoglobin [A] *	3/115 (2.61%)	1/38 (2.63%)
Hemorrhage [A] *	1/115 (0.87%)	0/38 (0%)
Leukocytes [A] *	0/115 (0%)	1/38 (2.63%)
Leukocytosis [A] *	3/115 (2.61%)	0/38 (0%)
Leukopenia [A] *	8/115 (6.96%)	3/38 (7.89%)
Lymphatics- other [A] *	1/115 (0.87%)	0/38 (0%)
Lymphopenia [A] *	2/115 (1.74%)	0/38 (0%)

	Erlotinib, Gemcitabine: Rash Grade < 2	Erlotinib, Gemcitabine: Rash Grade ≥ 2
	Affected/At Risk (%)	Affected/At Risk (%)
Monocytopenia [A] *	1/115 (0.87%)	0/38 (0%)
Neutropenia [A] *	20/115 (17.39%)	16/38 (42.11%)
Thrombocytosis [A] *	1/115 (0.87%)	0/38 (0%)
Thrombopenia [A] *	21/115 (18.26%)	10/38 (26.32%)
Cardiac disorders		
Atrial fibrillation [A] *	1/115 (0.87%)	0/38 (0%)
Left ventricular dysfunction [A] *	0/115 (0%)	2/38 (5.26%)
Ear and labyrinth disorders		
Hearing loss [A] *	1/115 (0.87%)	0/38 (0%)
Endocrine disorders		
Endocrine- other [A] *	1/115 (0.87%)	0/38 (0%)
Eye disorders		
Cataract [A] *	0/115 (0%)	1/38 (2.63%)
Eyelid dysfunction [A] *	1/115 (0.87%)	0/38 (0%)
Ocular surface disease [A] *	1/115 (0.87%)	0/38 (0%)
Ocular/visual- other [A] *	2/115 (1.74%)	0/38 (0%)
Vision - Blurred vision [A] *	1/115 (0.87%)	0/38 (0%)
Gastrointestinal disorders		
Anal haemorrhage [A] *	1/115 (0.87%)	0/38 (0%)
Ascites [A] *	7/115 (6.09%)	2/38 (5.26%)
Constipation [A] *	38/115 (33.04%)	12/38 (31.58%)
Diarrhea [A] *	55/115 (47.83%)	15/38 (39.47%)
Distension/bloating [A] *	3/115 (2.61%)	3/38 (7.89%)

	Erlotinib, Gemcitabine: Rash Grade < 2	Erlotinib, Gemcitabine: Rash Grade ≥ 2
	Affected/At Risk (%)	Affected/At Risk (%)
Dysphagia [A] *	2/115 (1.74%)	0/38 (0%)
Flatulence [A] *	3/115 (2.61%)	2/38 (5.26%)
Gastritis [A] *	2/115 (1.74%)	0/38 (0%)
Gastrointestinal toxicity [A] *	1/115 (0.87%)	0/38 (0%)
Gastrointestinal - other [A] *	21/115 (18.26%)	5/38 (13.16%)
Heartburn/dyspepsia [A] *	13/115 (11.3%)	3/38 (7.89%)
Hemorrhage rectal [A] *	1/115 (0.87%)	0/38 (0%)
Hemorrhoids [A] *	3/115 (2.61%)	1/38 (2.63%)
Mucositis/stomatitis [A] *	19/115 (16.52%)	9/38 (23.68%)
Nausea [A] *	43/115 (37.39%)	12/38 (31.58%)
Obstruction, GI [A] *	2/115 (1.74%)	1/38 (2.63%)
Oral cavity [A] *	0/115 (0%)	1/38 (2.63%)
Pancreas, exocrine [A] *	3/115 (2.61%)	0/38 (0%)
Perforation, GI [A] *	1/115 (0.87%)	0/38 (0%)
Periodontal disease [A] *	1/115 (0.87%)	0/38 (0%)
Vomiting [A] *	34/115 (29.57%)	8/38 (21.05%)
Xerostomia [A] *	6/115 (5.22%)	2/38 (5.26%)
General disorders		
Chest/thorax nos [A] *	2/115 (1.74%)	0/38 (0%)
Chills [A] *	1/115 (0.87%)	0/38 (0%)
Constitutional symptoms- other [A] *	11/115 (9.57%)	6/38 (15.79%)
Fatigue [A] *	89/115 (77.39%)	31/38 (81.58%)

	Erlotinib, Gemcitabine: Rash Grade < 2	Erlotinib, Gemcitabine: Rash Grade ≥ 2
	Affected/At Risk (%)	Affected/At Risk (%)
Fever [A] *	18/115 (15.65%)	11/38 (28.95%)
Nasal/ paranasal [A] *	1/115 (0.87%)	1/38 (2.63%)
Other [A] *	1/115 (0.87%)	0/38 (0%)
Pain [A] *	18/115 (15.65%)	8/38 (21.05%)
Peritoneum [A] *	1/115 (0.87%)	0/38 (0%)
Skin [A] *	0/115 (0%)	1/38 (2.63%)
Hepatobiliary disorders		
Bilirubin [A] *	4/115 (3.48%)	4/38 (10.53%)
Liver dysfunction [A] *	8/115 (6.96%)	3/38 (7.89%)
Immune system disorders		
Allergic reaction [A] *	1/115 (0.87%)	0/38 (0%)
Allergy /immunology- other [A] *	2/115 (1.74%)	0/38 (0%)
Infections and infestations		
Abdomen nos [A] *	0/115 (0%)	1/38 (2.63%)
Anal/perianal [A] *	1/115 (0.87%)	0/38 (0%)
Blood [A] *	1/115 (0.87%)	1/38 (2.63%)
Conjunctiva [A] *	5/115 (4.35%)	0/38 (0%)
Cystitis [A] *	6/115 (5.22%)	2/38 (5.26%)
Esophagitis [A] *	1/115 (0.87%)	1/38 (2.63%)
Infection [A] *	1/115 (0.87%)	0/38 (0%)
Lung (Pneumonia) [A] *	1/115 (0.87%)	1/38 (2.63%)
Middle ear [A] *	0/115 (0%)	1/38 (2.63%)

	Erlotinib, Gemcitabine: Rash Grade < 2	Erlotinib, Gemcitabine: Rash Grade ≥ 2
	Affected/At Risk (%)	Affected/At Risk (%)
Myelitis [A] *	0/115 (0%)	1/38 (2.63%)
Oral cavity-gums [A] *	2/115 (1.74%)	0/38 (0%)
Proctitis [A] *	1/115 (0.87%)	0/38 (0%)
Rhinitis [A] *	1/115 (0.87%)	1/38 (2.63%)
Skin [A] *	3/115 (2.61%)	0/38 (0%)
Soft tissue nos [A] *	1/115 (0.87%)	0/38 (0%)
Upper airway nos [A] *	6/115 (5.22%)	3/38 (7.89%)
Urinary tract nos [A] *	3/115 (2.61%)	1/38 (2.63%)
Injury, poisoning and procedural complications		
Fracture [A] *	1/115 (0.87%)	0/38 (0%)
Investigations		
ALT, SGPT [A] *	1/115 (0.87%)	1/38 (2.63%)
ALT, SGPT [A] *	4/115 (3.48%)	2/38 (5.26%)
Alkaline phosphatase [A] *	3/115 (2.61%)	0/38 (0%)
GGT (Gamma-glutamyl) [A] *	5/115 (4.35%)	1/38 (2.63%)
Weight loss [A] *	27/115 (23.48%)	5/38 (13.16%)
Metabolism and nutrition disorders		
Albumin, serum-low [A] *	1/115 (0.87%)	0/38 (0%)
Anorexia [A] *	62/115 (53.91%)	11/38 (28.95%)
Calcium, serum high [A] *	4/115 (3.48%)	1/38 (2.63%)
Diabetes [A] *	2/115 (1.74%)	1/38 (2.63%)
Glucose, serum high [A] *	6/115 (5.22%)	1/38 (2.63%)

	Erlotinib, Gemcitabine: Rash Grade < 2	Erlotinib, Gemcitabine: Rash Grade ≥ 2
	Affected/At Risk (%)	Affected/At Risk (%)
Glucose, serum low [A] *	5/115 (4.35%)	1/38 (2.63%)
Hypercreatinaemia [A] *	0/115 (0%)	1/38 (2.63%)
Magnesium, serum low [A] *	3/115 (2.61%)	1/38 (2.63%)
Metabolic/laboratory [A] *	3/115 (2.61%)	1/38 (2.63%)
Obesity [A] *	2/115 (1.74%)	0/38 (0%)
Potassium, serum high [A] *	1/115 (0.87%)	1/38 (2.63%)
Potassium, serum low [A] *	3/115 (2.61%)	0/38 (0%)
Sweating [A] *	1/115 (0.87%)	0/38 (0%)
Musculoskeletal and connective tissue disorders		
Abdomen nos [A] *	78/115 (67.83%)	19/38 (50%)
Arthritis [A] *	1/115 (0.87%)	0/38 (0%)
Back [A] *	9/115 (7.83%)	7/38 (18.42%)
Bone [A] *	4/115 (3.48%)	0/38 (0%)
Joint [A] *	2/115 (1.74%)	0/38 (0%)
Muscle [A] *	5/115 (4.35%)	6/38 (15.79%)
Muscle weakness [A] *	2/115 (1.74%)	1/38 (2.63%)
Neck [A] *	1/115 (0.87%)	0/38 (0%)
Neck/back [A] *	0/115 (0%)	1/38 (2.63%)
Rhabdomyolysis [A] *	1/115 (0.87%)	0/38 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Tumor pain [A] *	4/115 (3.48%)	2/38 (5.26%)
Nervous system disorders		

	Erlotinib, Gemcitabine: Rash Grade < 2	Erlotinib, Gemcitabine: Rash Grade ≥ 2
	Affected/At Risk (%)	Affected/At Risk (%)
Dizziness [A] *	3/115 (2.61%)	2/38 (5.26%)
Dysgeusia [A] *	4/115 (3.48%)	5/38 (13.16%)
Extrapyramidal [A] *	0/115 (0%)	1/38 (2.63%)
Headache [A] *	6/115 (5.22%)	1/38 (2.63%)
Neuropathy [A] *	6/115 (5.22%)	1/38 (2.63%)
Somnolence [A] *	4/115 (3.48%)	0/38 (0%)
Tremor [A] *	2/115 (1.74%)	0/38 (0%)
Psychiatric disorders		
Confusion [A] *	0/115 (0%)	1/38 (2.63%)
Insomnia [A] *	4/115 (3.48%)	2/38 (5.26%)
Personality/behavioral [A] *	19/115 (16.52%)	2/38 (5.26%)
Renal and urinary disorders		
Genitourinary [A] *	0/115 (0%)	1/38 (2.63%)
Incontinence, urinary [A] *	0/115 (0%)	1/38 (2.63%)
Kidney [A] *	1/115 (0.87%)	0/38 (0%)
Renal failure [A] *	4/115 (3.48%)	1/38 (2.63%)
Renal/genitourinary [A] *	1/115 (0.87%)	0/38 (0%)
Urinary retention [A] *	2/115 (1.74%)	0/38 (0%)
Urine color change [A] *	6/115 (5.22%)	0/38 (0%)
Reproductive system and breast disorders		
Testicular oedema [A] *	1/115 (0.87%)	0/38 (0%)
Respiratory, thoracic and mediastinal disorders		
Cough [A] *	12/115 (10.43%)	4/38 (10.53%)

	Erlotinib, Gemcitabine: Rash Grade < 2	Erlotinib, Gemcitabine: Rash Grade ≥ 2
	Affected/At Risk (%)	Affected/At Risk (%)
Dyspnea [A] *	11/115 (9.57%)	5/38 (13.16%)
Hemorrhage nasal [A] *	2/115 (1.74%)	1/38 (2.63%)
Hiccoughs [A] *	1/115 (0.87%)	0/38 (0%)
Nasal/paranasal reactions [A] *	6/115 (5.22%)	4/38 (10.53%)
Pulmonay/upper respiratoy- other [A] *	1/115 (0.87%)	0/38 (0%)
Voice changes [A] *	1/115 (0.87%)	1/38 (2.63%)
Skin and subcutaneous tissue disorders		
Alopecia [A] *	0/115 (0%)	1/38 (2.63%)
Cheilitis [A] *	1/115 (0.87%)	0/38 (0%)
Dermatology/skin- other [A] *	2/115 (1.74%)	1/38 (2.63%)
Dry skin [A] *	0/115 (0%)	1/38 (2.63%)
Hypopigmentation [A] *	1/115 (0.87%)	0/38 (0%)
Nail changes [A] *	2/115 (1.74%)	0/38 (0%)
Pruritus/itching [A] *	3/115 (2.61%)	0/38 (0%)
Rash/desquamation [A] *	1/115 (0.87%)	1/38 (2.63%)
Surgical and medical procedures		
Upper airway nos [A] *	1/115 (0.87%)	0/38 (0%)
Vein nos [A] *	1/115 (0.87%)	0/38 (0%)
Vascular disorders		
Haematoma [A] *	1/115 (0.87%)	0/38 (0%)
Hypertension [A] *	2/115 (1.74%)	1/38 (2.63%)
Hypotension [A] *	1/115 (0.87%)	0/38 (0%)

	Erlotinib, Gemcitabine: Rash Grade < 2	Erlotinib, Gemcitabine: Rash Grade ≥ 2
	Affected/At Risk (%)	Affected/At Risk (%)
Phlebitis [A] *	5/115 (4.35%)	4/38 (10.53%)
Pulmonary hypertension [A] *	0/115 (0%)	1/38 (2.63%)
Thrombosis/embolism [A] *	7/115 (6.09%)	5/38 (13.16%)
Thrombosis/thrombus [A] *	4/115 (3.48%)	0/38 (0%)
Vein injury [A] *	0/115 (0%)	1/38 (2.63%)

* Indicates events were collected by non-systematic methods.
A Term from vocabulary, NCI-CTC V 3.0

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:

Name/Official Title: Medical Communications
Organization: Hoffman-LaRoche
Phone: 800-821-8590
Email: genentech@druginfo.com