ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 05/24/2016

ClinicalTrials.gov ID: NCT00701558

Study Identification

Unique Protocol ID: ML20951

Brief Title: A Study of First Line Treatment With Tarceva (Erlotinib) in Combination With Gemcitabine in Patients With Unresectable Advanced and/or Metastatic Non-Small Cell Lung Cancer

Official Title: An Open Label Study to Evaluate the Effect of First Line Treatment With Tarceva in Combination With Gemcitabine on Disease Progression in Patients With Unresectable Advanced and/or Metastatic Non-small Cell Lung Cancer

Secondary IDs: 2007-002135-83

Study Status

Record Verification: May 2016

Overall Status: Completed

Study Start: August 2008

Primary Completion: October 2010 [Actual]

Study Completion: December 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: 4340/26 OCT.2007 Board Name: National Ethics Committee Board Affiliation: Unknown Phone: 004021 317 11 02 Email:
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	Romania: National Medicines Agency

Study Description

Brief Summary:	This single arm study will assess the efficacy and safety of erlotinib + gemcitabine in chemotherapy-naive participants with unresectable, advanced and/or metastatic non-small cell lung cancer. Participants will receive erlotinib 150 mg orally (po) daily, in combination with gemcitabine 1000 mg/m^2 intravenously (iv) weekly for 3 weeks of each 4 week cycle. The anticipated time on study treatment is until disease progression, and the target sample size is <100 individuals.
Detailed Description:	

Conditions

Conditions:	Non-small Cell Lung Cancer Metastatic
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Intervention Model:	Single Group Assignment
Number of Arms:	1
Masking:	Open Label
Allocation:	N/A
Endpoint Classification:	Safety/Efficacy Study

Enrollment: 20 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Erlotinib + Gemcitabine Participants received erlotinib 150 mg/day, orally (po) on a continuous schedule in combination with gemcitabine at 1000 mg/m^2 administered intravenously (iv) on days 1, 8, 15 of each 4 week cycle for 6 cycles as per standard medical care, or until disease progression or participant's withdrawal due to any reason or death.	Drug: Erlotinib 150 mg po daily Other Names: • Tarceva Drug: Gemcitabine 1000 mg/m^2 iv on days 1, 8, 15 of each 4 week cycle for 6 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;
- advanced and/or metastatic (stage IIIB/IV) unresectable non-small cell lung cancer;
- no previous systemic chemotherapy, radiation therapy or immunotherapy;
- Eastern Cooperative Oncology Group (ECOG) >=2.

Exclusion Criteria:

- prior systemic anti-tumor therapy with human epidermal growth factor receptor 1 (HER1/EGFR) inhibitors;
- active, non-controlled systemic disease;
- any other malignancies within 5 years (except for adequately treated cancer in situ of cervix, or basal or squamous cell skin cancer).

Contacts/Locations

Study Officials: Clinical Trials
Study Director

Hoffmann-La Roche

Locations: Romania
Bucuresti, Romania, 022328

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
Erlotinib + Gemcitabine	Participants received erlotinib 150 mg/day, orally (po) on a continuous schedule in combination with gemcitabine at 1000 mg/m^2 administered intravenously (iv) on days 1, 8, 15 of each 4 week cycle for 6 cycles as per standard medical care, or until disease progression or participant's withdrawal due to any reason or death.

Overall Study

	Erlotinib + Gemcitabine
Started	19
Completed	4
Not Completed	15
Death	7
Lost to Follow-up	8

Baseline Characteristics

Reporting Groups

	Description
Erlotinib + Gemcitabine	Participants received erlotinib 150 mg/day, orally (po) on a continuous schedule in combination with gemcitabine at 1000 mg/m^2 administered intravenously (iv) on days 1, 8, 15 of each 4 week cycle for 6 cycles as per standard medical care, or until disease progression or participant's withdrawal due to any reason or death.

Baseline Measures

	Erlotinib + Gemcitabine
Number of Participants	19
Age, Continuous [units: years] Mean (Standard Deviation)	62.47 (9.67)
Gender, Male/Female [units: participants]	
Female	3
Male	16

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Time to Disease Progression
Measure Description	Time to disease progression or progression free survival (PFS) was defined as the interval between the day of randomization and the date of the first documentation of disease progression or date of death (from any cause), whichever occurs first.
Time Frame	From the time of randomization until disease progression or death (up to 193 weeks)]
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) population included all participants who were randomized to treatment group.

Reporting Groups

	Description
Erlotinib + Gemcitabine	Participants received erlotinib 150 mg/day, orally (po) on a continuous schedule in combination with gemcitabine at 1000 mg/m^2 administered intravenously (iv) on days 1, 8, 15 of each 4 week cycle for 6 cycles as per standard medical care, or until disease progression or participant's withdrawal due to any reason or death.

Measured Values

	Erlotinib + Gemcitabine
Number of Participants Analyzed	18
Time to Disease Progression [units: weeks] Median (95% Confidence Interval)	15 (7 to 36)

2. Primary Outcome Measure:

Measure Title	Overall Response Rate (ORR)
Measure Description	Overall response rate was defined as the percentage of participants who had any evidence of confirmed objective complete response (CR) or partial response (PR), per the Response Evaluation Criteria In Solid Tumors Criteria (RECIST v1.0) and assessed by computed tomography imaging (CT): Complete Response (CR), Disappearance of all target lesions; Partial Response (PR), >=30% decrease in the sum of the longest diameter of target lesions; Overall Response (OR) = CR + PR.
Time Frame	From the time of randomization until disease progression or death (up to 193 weeks)
Safety Issue?	No

Analysis Population Description

ITT population included all participants who were randomized to treatment group.

Reporting Groups

	Description
Erlotinib + Gemcitabine	Participants received erlotinib 150 mg/day, orally (po) on a continuous schedule in combination with gemcitabine at 1000 mg/m^2 administered intravenously (iv) on days 1, 8, 15 of each 4 week cycle for 6 cycles as per standard medical care, or until disease progression or participant's withdrawal due to any reason or death.

Measured Values

	Erlotinib + Gemcitabine
Number of Participants Analyzed	19
Overall Response Rate (ORR) [units: percentage of participants]	15.8

3. Secondary Outcome Measure:

Measure Title	Overall Survival
Measure Description	Overall survival was defined as the interval between the day of randomization and the date of death from any cause.
Time Frame	From the time of randomization until death (up to 193 weeks)
Safety Issue?	No

Analysis Population Description

ITT population included all participants who were randomized to treatment group.

Reporting Groups

	Description
Erlotinib + Gemcitabine	Participants received erlotinib 150 mg/day, orally (po) on a continuous schedule in combination with gemcitabine at 1000 mg/m^2 administered intravenously (iv) on days 1, 8, 15 of each 4 week cycle for 6 cycles as per standard medical care, or until disease progression or participant's withdrawal due to any reason or death.

Measured Values

	Erlotinib + Gemcitabine
Number of Participants Analyzed	19
Overall Survival [units: weeks] Median (95% Confidence Interval)	39 (27 to 51)

Reported Adverse Events

Time Frame	Up to 28 days after last study drug administration in the study treatment phase (up to 197 Weeks)
Additional Description	[Not specified]

Reporting Groups

	Description
Erlotinib + Gemcitabine	Participants received erlotinib 150 mg/day, orally (po) on a continuous schedule in combination with gemcitabine at 1000 mg/m^2 administered intravenously (iv) on days 1, 8, 15 of each 4 week cycle for 6 cycles as per standard medical care, or until disease progression or participant's withdrawal due to any reason or death.

Serious Adverse Events

	Erlotinib + Gemcitabine
	Affected/At Risk (%)
Total	2/19 (10.53%)
Gastrointestinal disorders	
Diarrhoea [A] †	1/19 (5.26%)
Respiratory, thoracic and mediastinal disorders	
Respiratory tract infection [A] †	1/19 (5.26%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (18.1)

Other Adverse Events

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

	Erlotinib + Gemcitabine
	Affected/At Risk (%)
Total	15/19 (78.95%)
Blood and lymphatic system disorders	
Anaemia of malignant disease [A] †	7/19 (36.84%)
Leukopenia [A] †	1/19 (5.26%)
Neutropenia [A] †	2/19 (10.53%)

	Erlotinib + Gemcitabine
	Affected/At Risk (%)
Thrombocytopenia [A] †	6/19 (31.58%)
Gastrointestinal disorders	
Diarrhoea [A] †	2/19 (10.53%)
General disorders	
Fatigue [A] †	1/19 (5.26%)
Investigations	
Blood bilirubin increased [A] †	2/19 (10.53%)
Metabolism and nutrition disorders	
Appetite lost [A] †	1/19 (5.26%)
Skin and subcutaneous tissue disorders	
Rash [A] †	3/19 (15.79%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (18.1)

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

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