

# LUX-Lung 8: A randomized, open-label Phase III trial of afatinib versus erlotinib in patients with advanced squamous cell carcinoma of the lung as second-line therapy following first-line platinum-based chemotherapy

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Respiratory and mediastinal neoplasms malignant and unspecified
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON38119

### Source

ToetsingOnline

### Brief title

LUX-Lung 8

### Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

### Synonym

lung cancer, Non-small cell lung cancer

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Boehringer Ingelheim

**Source(s) of monetary or material Support:** Boehringer Ingelheim BV.

## Intervention

**Keyword:** afatinib, erlotinib, NSCLC, squamous cel carcinoma

## Outcome measures

### Primary outcome

Progression free Survial (PFS)

### Secondary outcome

- Overall Survival (OS)
- Objective response
- Disease control
- Tumour shrinkage
- Health related quality of life (QoL)
- Safety

# Study description

## Background summary

Treatment options for patients with advanced squamous cell carcinoma of the lung are limited following first line chemotherapy with most patients recurring and eventually succumbing to their disease. For patients eligible to tolerate, chemotherapy has been an option and docetaxel is indicated in the second line setting for patients with advanced NSCLC with associated chemotherapy related morbidity. The EGFR pathway has been shown to play a significant role in propagation of human epithelial malignancies including NSCLC. Erlotinib inhibits the TK domain of the EGFR and is indicated in the treatment of NSCLC following failure of one prior chemotherapy regimen or in patients not progressing after receiving four cycles of platinum based chemotherapy. Patients with adenocarcinoma tend to derive higher response rates than other histologies of NSCLC in erlotinib trials. There remains thus a significant void for patients with squamous cell carcinoma of the lung whose therapeutic options are limited in the second line and maintenance setting.

Afatinib is an irreversible EGFR inhibitor with a favourable risk benefit ratio that is currently in Phase 3 clinical trials in lung cancer, breast cancer and squamous cancer of head and neck (SCCHN). The clinical experience of afatinib includes over 2000 patients. Afatinib is relatively well tolerated, with most common adverse events being diarrhea, rash and stomatitis as expected for this class of agents.

Afatinib has shown evidence of clinical activity in patients with Squamous cancer of the head and neck in a randomized clinical Phase 2 trial and early evidence of clinical activity in patients with squamous carcinoma of the lung in ongoing clinical trials.

## Study objective

This randomized, open label phase III trial will be performed in patients with squamous carcinoma of the lung. The objectives of the trial are to compare the efficacy of afatinib with erlotinib as maintenance and second-line treatment for this group of patients.

## Study design

A randomized phase III open-label trial

## Intervention

Patients will be randomized to receive a 2nd line cancer treatment of either afatinib or erlotinib.

## Study burden and risks

Patients will be screened for eligibility for the trial (Full physical exam, Limited physical exam, ECOG Performance Score, ECG, echo or MUGA scans, blood samples and CT/MRI voor tumor assessment. Treatment follows with an oral tablet intake for 28 days per cycle.

During the first treatment cycle the patients will visit the clinic twice (day 1 and day 8), thereafter only once every 28 days.

CT scans (or MRI) will be performed at week 8, 12, 16 , and every 8 weeks thereafter.

## Contacts

### Public

Boehringer Ingelheim

Comeniusstraat 6  
ALKMAAR 1817 MS  
NL

### Scientific

Boehringer Ingelheim

Comeniusstraat 6  
ALKMAAR 1817 MS  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

1. Diagnosis of advanced stage NSCLC squamous histology , including mixed histology.;2. Completion of at least 4 cycles of platinum-based doublet chemotherapy, with or without additional [non-EGFR] targeted agents, as 1st line treatment of Stage IIIB/IV NSCLC. Note the below scenarios are also considered to meet this requirement:;A) Patients relapsing within 6 months of receiving adjuvant-intent/neo-adjuvant/curative-intent chemoradiotherapy/chemoradiotherapy(Note: these patients are still to have had the equivalent of 4 cycles of platinum-based doublet chemotherapy except in setting below).;OR;B) Patients intending to receive four cycles of platinum-based doublet chemotherapy but due to toxicity, and not PD, discontinue just the platinum agent after at least two cycles of platinum doublet had been administered.;3. Eligible to receive 2nd line therapy in the opinion of the investigator.;4. Measurable disease according to RECIST 1.1 (R09-0262). ;5. Eastern Cooperative Oncology Group (ECOG) score of 0 or 1 (R01-0787). ;6. Availability of tumour tissue material for correlative studies. Archived tumour tissue is acceptable.;7. Adequate organ function.

## Exclusion criteria

1. Prior treatment with EGFR directed small molecules or antibodies.;2. Curative intent chemoradiotherapy as the only treatment for stage IIIB NSCLC unless relapse occurs within 6 months of completion of treatment, and in the opinion of the investigator the patient has received an equivalent of 4 cycles of platinum-based doublet therapy.;3. Radiotherapy within 4 weeks prior to randomization.;4. Active brain metastases (stable for <4 weeks, symptomatic, or leptomeningeal disease). Dexamethasone therapy will be allowed if administered as a stable dose for at least 4 weeks before randomization.;5. Patients without Progressive Disease

## Study design

### Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

## Recruitment

NL  
Recruitment status: Recruitment stopped  
Start date (anticipated): 30-07-2012  
Enrollment: 60  
Type: Actual

## Medical products/devices used

Product type: Medicine  
Brand name: Nog nietbekend  
Generic name: Afatinib  
Product type: Medicine  
Brand name: Tarceva  
Generic name: Erlotinib  
Registration: Yes - NL intended use

## Ethics review

Approved WMO  
Date: 16-04-2012  
Application type: First submission  
Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO  
Date: 15-05-2012  
Application type: First submission  
Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO  
Date: 12-07-2012  
Application type: Amendment  
Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO  
Date: 27-08-2012

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-09-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-10-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-12-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-12-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-01-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-03-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-04-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO	
Date:	11-07-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	18-07-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	21-11-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	22-11-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	28-11-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	29-11-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	29-01-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	13-03-2014
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	02-10-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	05-10-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
EudraCT	EUCTR2011-002380-24-NL
ClinicalTrials.gov	NCT01523587
CCMO	NL37158.060.11