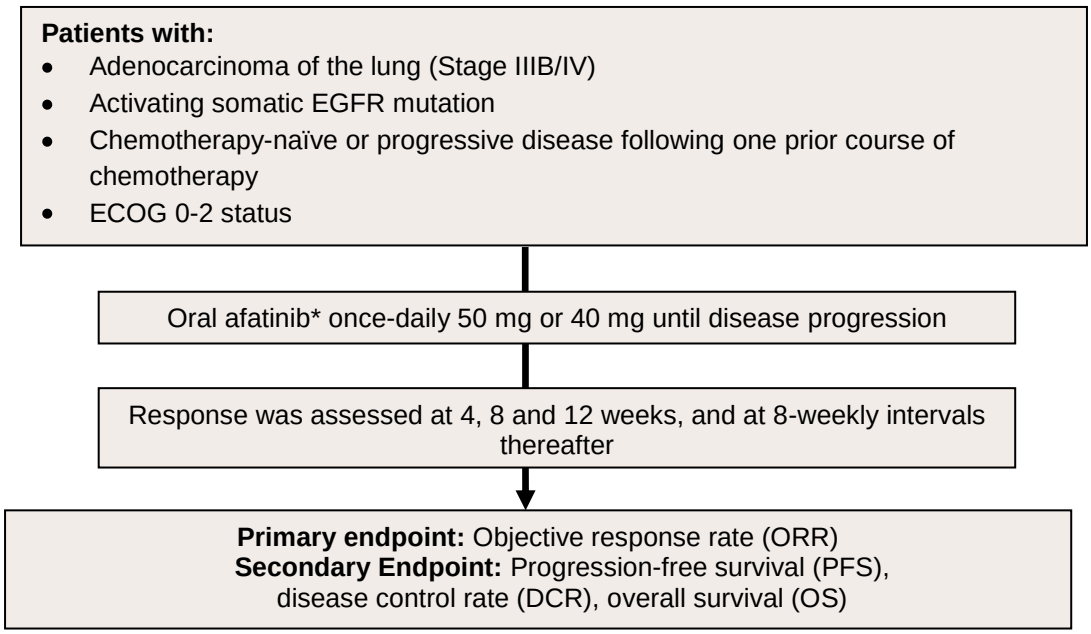
The LUX-Lung 2 clinical trial

FACTSHEET

1. What is the LUX-Lung 2 trial?

LUX-Lung 2 is a multicentre Phase II, randomised, open-label, single arm trial of afatinib* in patients with advanced lung cancer that were untreated or progressed after one course of chemotherapy. Patients were tested for activating EGFR mutations prior to their inclusion in the trial.

2. What is the LUX-Lung 2 trial design?



3. How many patients were involved in the LUX-Lung 2 trial?

129 male and female patients took part in the LUX-Lung 2 trial.

4. Where was the LUX-Lung 2 trial conducted?

The LUX-Lung 2 trial was carried out in the USA and Taiwan.

*Afatinib is an investigational compound. Its efficacy and safety have not been fully established.

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5. What were the clinical endpoints of the trial?

The primary endpoint was objective response rate (ORR).

The secondary endpoints were:

- Progression-free survival (PFS)
- Disease control rate (DCR)
- Overall survival (OS).

6. What are the LUX-Lung 2 trial results?

Patients with the activating EGFR mutations (del 19 and L858R) showed high response rates and remarkable progression-free survival rates when treated with afatinib*:

Objective response rate (ORR) is the proportion of patients with distinct tumour shrinkage; it is the sum of partial responses (tumour shrinkage of at least 30%) plus complete responses (tumour no longer detectable).

Disease control rate (DCR) is share of patients with stabilised tumours or tumour shrinkage.

Progression-free survival (PFS) is a measure of the clinical benefit from therapy. It is defined as the time between treatment initiation and objective tumour progression or death from any cause.

Overall survival (OS) is the time between the start of treatment and the end of the patient's life by any cause.

	All patients N=129	EGFR mutation DEL 19/L858R
Overall response rate (ORR)	61%	65%
Disease control rate (DCR)	86%	88%
Median progression-free survival (PFS)	14 months	15%
Median overall survival (OS)	24 months	-

7. Is afatinib* being investigated in other tumour types?

The LUX-Lung 2 trial is part of the LUX-Lung clinical trial programme investigating afatinib* in a number of different lung cancer patient populations. Due to the encouraging results of the LUX-Lung 2 study, a Phase III trial has been initiated. This trial is called LUX-Lung 3.

The LUX-Lung 3 trial will compare the efficacy and safety of single-agent afatinib* to that of standard chemotherapy (cisplatin/pemetrexed) as a potential first-line treatment for NSCLC patients with EGFR mutations. Furthermore, an additional Phase III trial, LUX-Lung 6, which has same study criteria as LUX-Lung 3, but uses cisplatin/gemcitabine in the comparator arm, is also underway.

Afatinib* is also being investigated for use in a number of other solid tumours, including breast cancer, head and neck cancer, colorectal cancer, and glioblastoma.

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References:

1. Yang et al. A Phase II study of BIBW 2992 in patients with adenocarcinoma of the lung and activating EGFR/HER1 mutations (LUX-Lung 2). Poster presentation at the 35th European Society of Medical Oncology (ESMO) annual meeting, Milan, October 2010. Abstract ID: 367PD

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