About Afatinib

Afatinib is an investigational oral, once-daily irreversible ErbB Family Blocker that specifically inhibits epidermal growth factor receptor (EGFR or ErbB1), human epidermal receptor 2 (HER2 or ErbB2), and ErbB4.

Boehringer Ingelheim is investigating afatinib in various tumor types, including colorectal, head and neck, and non-small cell lung cancers. Afatinib is currently in Phase III clinical development in head and neck and advanced non-small cell lung cancers.

Afatinib Clinical Trial Program

The LUX-Lung clinical trial program is investigating the use of afatinib in various settings of advanced non-small cell lung cancer (NSCLC), including in patients harboring EGFR mutations and those with recurrent disease. These trials include:

- **LUX-Lung 1** ([Clinical Trial Identifier NCT00656136](https://clinicaltrials.gov/ct2/show/NCT00656136)), a Phase IIb/III trial investigating afatinib plus best supportive care (BSC) versus placebo plus BSC in NSCLC patients who were previously treated with first-line chemotherapy and the reversible EGFR tyrosine kinase inhibitors (TKIs) erlotinib or gefitinib.** (note: gefitinib is not available in the US)**
- **LUX-Lung 2** ([Clinical Trial Identifier NCT00525148](https://clinicaltrials.gov/ct2/show/NCT00525148)), a Phase II trial evaluating afatinib in NSCLC patients with EGFR mutations, either treatment-naïve or after one line of treatment with chemotherapy.***
- **LUX-Lung 3** ([Clinical Trial Identifier NCT00949650](https://clinicaltrials.gov/ct2/show/NCT00949650)), a Phase III trial investigating afatinib as a first-line treatment in patients with advanced NSCLC with EGFR mutations.*
- **LUX-Lung 4** ([Clinical Trial Identifier NCT00711594](https://clinicaltrials.gov/ct2/show/NCT00711594)), a Phase I/II trial investigating afatinib in NSCLC patients who have progressed after EGFR-TKI treatment.***
- **LUX-Lung 5** ([Clinical Trial Identifier NCT01085136](https://clinicaltrials.gov/ct2/show/NCT01085136)), a Phase III trial investigating afatinib plus paclitaxel versus investigator’s choice of chemotherapy after progressing on afatinib monotherapy in patients with advanced NSCLC previously treated with erlotinib or gefitinib.***
- **LUX-Lung 6** ([Clinical Trial Identifier NCT01121393](https://clinicaltrials.gov/ct2/show/NCT01121393)), a Phase III trial investigating the efficacy and safety of afatinib compared to standard chemotherapy for first-line treatment of NSCLC patients with EGFR mutations.***
- **LUX-Lung 7** ([Clinical Trial Identifier NCT01466660](https://clinicaltrials.gov/ct2/show/NCT01466660)), a Phase IIb trial evaluating afatinib head-to-head versus gefitinib as a first-line treatment in patients with advanced NSCLC with EGFR mutations.***
- **LUX-Lung 8** ([Clinical Trial Identifier NCT01523587](https://clinicaltrials.gov/ct2/show/NCT01523587)), a Phase III trial evaluating

*Afatinib is investigational. Its safety and efficacy have not been established.  
**Completed Trial  
***Ongoing Trial
afatinib head-to-head versus erlotinib in second-line treatment of squamous cell carcinoma of the lung.***

LUX-Head & Neck Clinical Trial Program
The LUX-Head & Neck clinical trial program is evaluating afatinib in patients with recurrent/metastatic head and neck cancer that progresses after platinum-based treatment. These trials include:
- LUX-Head & Neck 1 (Clinical Trial Identifier NCT01345682), a Phase III trial that investigates afatinib in patients with recurrent/metastatic head and neck cancer who progress after platinum-based chemotherapy.***
- LUX-Head & Neck 2 (Clinical Trial Identifier NCT01345669), a Phase III trial that evaluates afatinib in patients with locally advanced disease after chemoradiotherapy.***

For more information on these trials, please visit www.clinicaltrials.gov.

BI in Oncology
Building on scientific expertise and excellence in the fields of pulmonary and cardiovascular medicine, metabolic disease, neurology, virology and immunology, Boehringer Ingelheim has embarked on a major research program to discover and develop innovative cancer treatments. Working in close collaboration with the international scientific community and a number of the world’s leading cancer centers, Boehringer Ingelheim’s commitment to oncology is underpinned by using advances in science to develop a range of targeted therapies for various solid tumors and hematological cancers. The current focus of late-stage research includes compounds in three areas: signal transduction inhibition, angiogenesis inhibition and cell-cycle kinase inhibition. The company is also evaluating a robust and growing pipeline of early-stage oncology compounds in areas including growth/survival signaling, immunotherapy and epigenetics.

For information about participating in a Boehringer Ingelheim clinical trial, please visit www.bicancertrials.com or call 1.866.725.7110. Healthcare providers interested in learning more about Boehringer Ingelheim clinical trials in oncology can visit www.inoncologyus.com for additional information.

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**Completed Trial
***Ongoing Trial