LUX-LUNG 8

A randomised, open-label, phase III trial of afatinib* versus erlotinib for the treatment of patients with advanced squamous cell carcinoma (SCC) of the lung previously treated with first-line platinum-based chemotherapy

LUX-Lung 8 Head-to-head Trial Design

LUX-Lung 8 directly compared the efficacy and safety of two EGFR-directed treatments, afatinib* and erlotinib in patients with advanced SCC of the lung.

**Inclusion Criteria**

1. Diagnosis of advanced stage SCC of the lung
2. Completion of at least 4 cycles of platinum-based chemotherapy as first-line treatment of Stage IIIb/IV NSCLC
3. Eligible to receive second-line therapy in the opinion of the investigator

**PRIMARY ENDPOINT:** Progression-Free Survival (PFS: length of time before the tumour starts to progress) after randomisation

**KEY SECONDARY ENDPOINT:** Overall Survival (OS: length of time a patient has survived) after randomisation

**OTHER ENDPOINTS:** Objective Response (ORR), Disease Control (DCR), Patient Reported Outcomes and Safety

**LUX-Lung 8 Results**

- **Median Progression-Free Survival**
  - Afatinib: 2.6 months
  - Erlotinib: 1.9 months
  - 19% reduction in the risk of disease progression with afatinib* versus erlotinib

- **Median Overall Survival**
  - Afatinib: 7.9 months
  - Erlotinib: 6.8 months
  - 19% reduction in the risk of death with afatinib* versus erlotinib

- **Overall Well-being / Quality of Life**
  - A higher proportion of patients treated with afatinib* reported an improvement in overall well-being/security of life

**Safety profile**

The rate of severe adverse events was similar between afatinib and erlotinib treatment arms (57.1 vs. 57.5%).

A higher incidence of severe diarrhoea and stomatitis (mouth sores) was observed with afatinib compared to erlotinib (grade 3/4 diarrhoea: 9.9/0.5 vs. 2.3/0.3%, grade 3 stomatitis: 4.1 vs. 0.0%), while a higher incidence of severe rash/acne was reported with erlotinib compared to afatinib (grade 3 rash/acne: 10.4 vs. 5.9%).

*Afatinib is approved in a number of markets, including the EU, Japan, Taiwan and Canada under the brand name GIOTRIF® and in the US under the brand name GILOTRIF® for use in patients with distinct types of EGFR mutation-positive NSCLC. Registration conditions differ internationally, please refer to locally approved prescribing information. Afatinib* is under regulatory review by health authorities in other countries worldwide. Afatinib* is not approved in SCC or other indications.

**SCC of the Lung**

- Develops in the cells lining the airway
- Represents approximately 30% of non-small cell lung cancer (NSCLC) cases
- Treatment options are limited
- SCC of the lung is associated with a poor prognosis, with less than 5% of patients with advanced SCC surviving for five years or longer

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1. LUX-Lung 8 on clinicaltrials.gov
2. Soria et al. Afatinib (A) vs erlotinib (E) as second-line therapy of patients (pts) with advanced squamous cell carcinoma (SCC) of the lung: Final results of a global phase III trial LUX-Lung 8 (LL8). Abstract #8002 at ASCO 2015 Annual Meeting.