

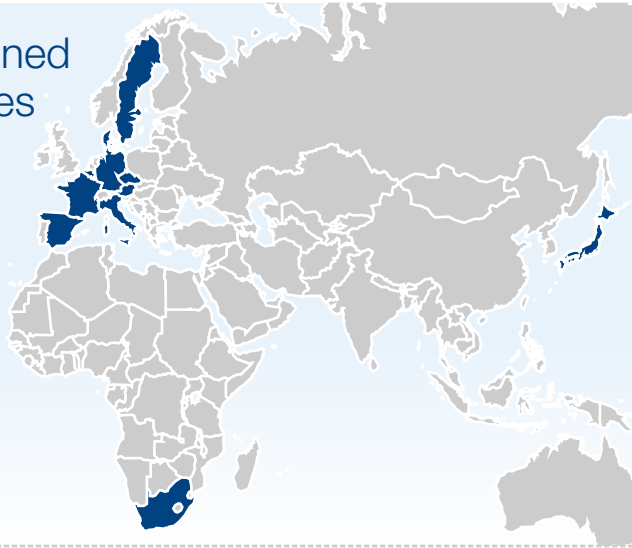
LUX-HEAD & NECK 1

A randomised, open-label, Phase III study to evaluate the efficacy of oral afatinib* versus intravenous methotrexate in patients with recurrent and/or metastatic (R/M) head and neck squamous cell carcinoma** (HNSCC) who have progressed after platinum-based chemotherapy.

Countries with planned or activated trial sites

Austria
Belgium
Czech Republic
Denmark
France
Germany
Italy
Japan
South Africa
Spain
Sweden

AS OF JANUARY 2012



Inclusion criteria

- Male and female patients aged 18 years or older
- **Patients with histologically or cytologically confirmed R/M HNSCC of the oral cavity, oropharynx, hypopharynx or larynx, not amenable for salvage surgery or radiotherapy**
- Documented progressive disease based on investigator assessment according to RECIST following receipt of at least two cycles of cisplatin or carboplatin administered for R/M disease
- Measurable disease according to RECIST
- ECOG performance status 0 or 1



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474 ESTIMATED NUMBER OF PATIENTS TO BE RANDOMISED INTO STUDY
FIRST PATIENT IN: JANUARY 2012

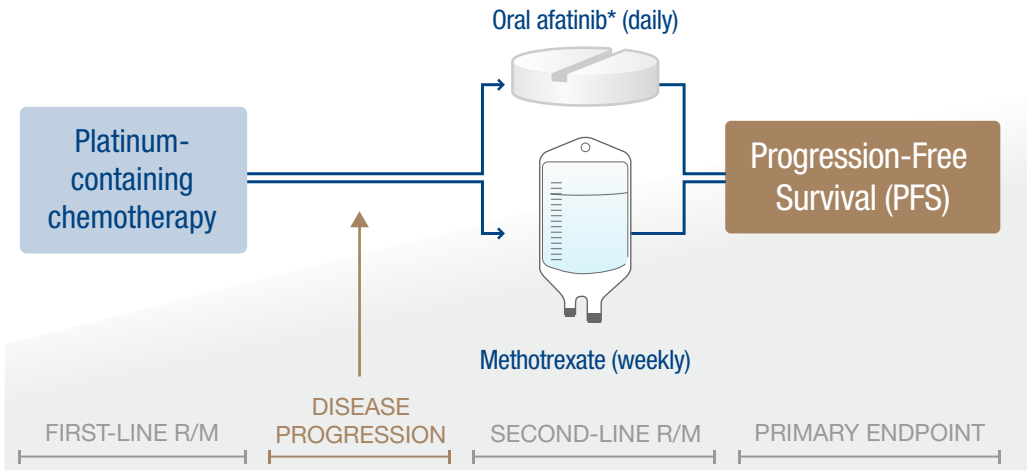
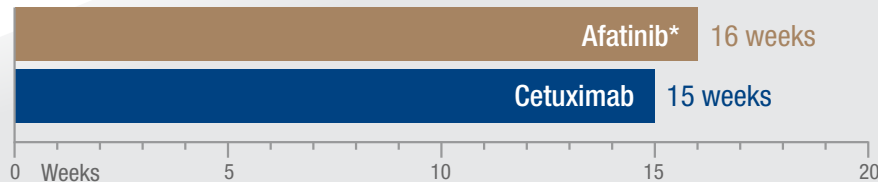
Study rationale

- Advanced/metastatic HNSCC patients have a poor prognosis, with a median survival of 6-10 months and high recurrence rates, reflecting the high medical need for new treatment options¹
- Results from the 1200.28 Phase II clinical trial suggest that afatinib* is the first oral, targeted therapy ErbB Family Blocker, which demonstrates comparable efficacy to cetuximab in second-line treatment, leading to the initiation of a Phase III trial²

Phase III trial design

Median Progression-Free Survival (PFS)²

as shown in the Phase II trial (as per investigator assessment)



*Afatinib is an investigational compound. Its safety and efficacy have not yet been fully established. **Head and neck cancers are identified by the area in which they begin. Most head and neck cancers begin in the squamous cells that line the mucosal surfaces in the head and neck. (ref: NCI - <http://www.cancer.gov/cancertopics/factsheet/Sites-Types/head-and-neck>). 1. Bozec A *et al.* 2008. Vertical VEGF targeting: A combination of ligand blockade with receptor tyrosine kinase inhibition. *European Journal of Cancer*, 13, pp.1922-1930. 2. Seiwert TY *et al.* A randomized, open-label, Phase II study of afatinib (BIBW 2992) versus cetuximab in recurrent or metastatic Squamous Cell Carcinoma of the Head and Neck. *Oral presentation presented at 3rd Trends in Head & Neck Oncology (THNO)*; 2011 Nov 3-5; Rome, Italy. Abstract 40. © 2011 Boehringer Ingelheim GmbH. All rights reserved | Last updated: January 2012

LET'S WORK

