

# LUX-HEAD & NECK 2

A randomised, double-blind, placebo-controlled, Phase III study to evaluate the efficacy and safety of afatinib\* as adjuvant therapy after chemoradiotherapy in primary unresected patients with stage III, IVa, or IVb loco-regionally advanced head and neck squamous cell carcinoma\*\* (HNSCC).



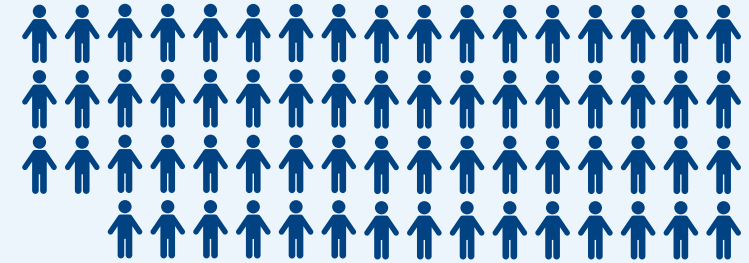
Countries with planned or activated trial sites

- |           |             |
|-----------|-------------|
| Australia | Japan       |
| Austria   | Netherlands |
| Belgium   | Russia      |
| Canada    | Spain       |
| Finland   | UK          |
| France    |             |
| Germany   |             |
| Greece    |             |
| Italy     |             |

AS OF JANUARY 2012

## Inclusion criteria

- Male and female patients aged 18 years or older
- **Patients with histologically or cytologically confirmed loco-regionally advanced HNSCC, stage III to IVb**
- Unresected tumour prior to chemoradiotherapy (CRT)
- Concomitant CRT completed prior to randomisation
- After concomitant platinum-based CRT, no evidence of disease (NED) on clinical and radiographic examinations
- ECOG performance status 0 or 1



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**669**

ESTIMATED NUMBER OF PATIENTS TO BE RANDOMISED INTO STUDY



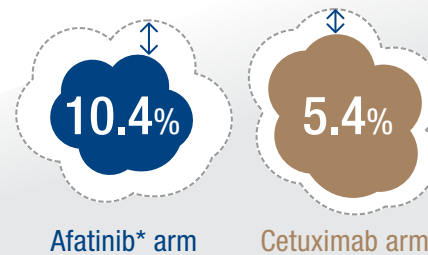
FIRST PATIENT IN: NOVEMBER 2011

## Study rationale

- After treatment with chemoradiotherapy (CRT), patients are currently 'just observed', and between 35-65% of these patients will experience a recurrence, depending on tumour location, stage and resectability<sup>1,2</sup>
- 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 of R/M head and neck cancer leading to initiation of a Phase III trial<sup>3</sup>

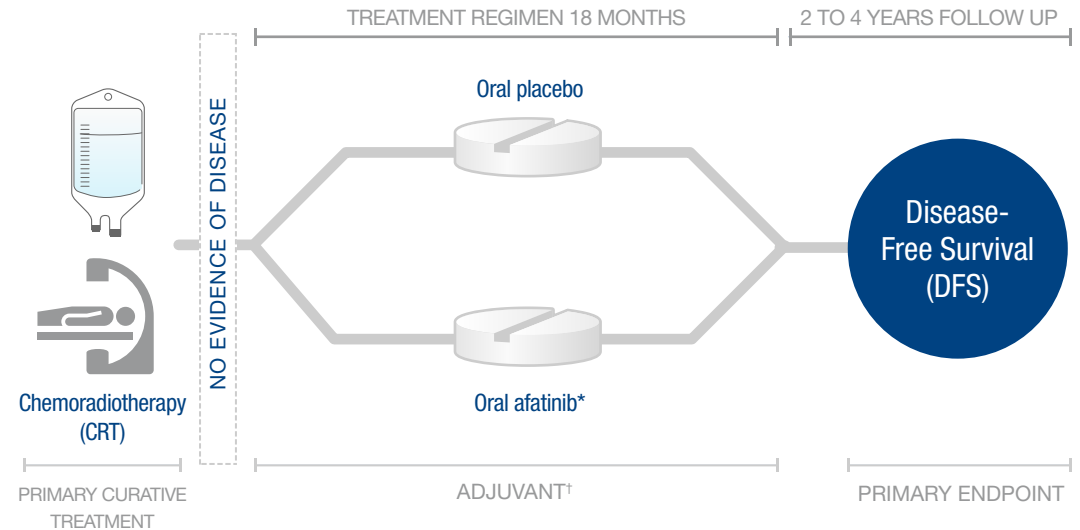
## Phase II trial results

### Mean tumour shrinkage<sup>3</sup>



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

## Phase III trial design



\*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>). \*Additional cancer treatment given after the primary treatment (where all detectable disease has been removed) to reduce the risk of the cancer returning. 1. Bernier J *et al.* (2004) Postoperative irradiation with or without concomitant chemotherapy for locally advanced head and neck cancer. *N Engl J Med* 350:1945-1952. 2. Cooper JS *et al.* (2004) Postoperative concurrent radiotherapy and chemotherapy for high-risk squamous-cell carcinoma of the head and neck. *N Engl J Med* 350: 1937-1944. 3. 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 3<sup>rd</sup> 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

