Introduction

- The oral, irreversible Erbb family blockers afatinib is approved in the US and for the first time for treatment of EGFR-mutated metastatic NSCLC (LUX-Lung 3) in the European Union (EU) by the European Medicines Agency (EMA).
- Afatinib is a pan-ErbB inhibitor that interferes with both Erbb1 (EGFR) and Erbb2 (HER2) kinase activity.
- This study assessed the safety and efficacy of afatinib in patients with NSCLC harboring common mutations (Del19 and/or L858R), which are found in ~50% of NSCLC patients.
- Patients received afatinib 40 mg/day.
- The study was open-label, single-arm, and conducted across 35 centers in 13 countries (Afatinib Multicenter Study Group).
- Methods

Methods (Cont’d)

- Eligible patients received afatinib 40 mg/day.
- In the EU, afatinib is also approved as a second-line treatment option for NSCLC harboring common mutations (Del19 and/or L858R), which are found in ~50% of NSCLC patients.
- Patients were treated with afatinib until disease progression or discontinuation for other reasons.
- Results

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- 60 patients received at least one dose of afatinib 40 mg/day.
- 50% of patients achieved a confirmed OR, with a median duration of 11.9 months.
- The most commonly occurring drug-related AEs of any grade/grade 3 were diarrhea (72%/10%), rash (28%/2%), paronychia (23%/0%), nausea (29%/3%), and vomiting (28%/1%).
- Efficacy and safety were evaluated in a descriptive manner, and there were no formal statistical hypotheses.
- The primary study endpoint of OR by investigator assessment was achieved by 30 (50%) patients.
- The most frequent sites of distant metastases were the ipsilateral lung (49%), liver (46%), lymph nodes (43%), adrenal glands (41%), and brain (31%).
- The Kaplan–Meier curve of PFS is shown in the figure.
- The median duration of confirmed disease control was 11.9 months.
- The median duration of OR was 13.8 months (95% CI 10.6, 18.8).

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- Efficacy (Cont’d)

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Efficacy

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