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Afatinib as second-line treatment in patients with recurrent/metastatic squamous cell carcinoma of the head and neck: Subgroup analyses of treatment adherence, safety and mode of afatinib administration in the LUX-Head and Neck 1 trial

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Abstract

Objectives: Patients with head and neck squamous cell carcinoma (HNSCC) can experience severe symptom burden and/or difficulty swallowing, leading to problems with treatment adherence/administration. In LUX-Head and Neck 1 (LH&N1; NCT01345682), second-line afatinib improved progression-free survival (PFS) versus methotrexate in patients with recurrent/metastatic HNSCC. We report adherence and safety across pre-specified and additional subgroups potentially linked to afatinib PFS benefit in LH&N1 (p16 status, smoking history), and afatinib adherence, safety and efficacy by administration (oral versus feeding tube; post-hoc analysis).

Methods: Patients were randomized (2:1) to afatinib (40 mg/day) or intravenous methotrexate (40 mg/m^2/week).

Results: Among 320 afatinib-treated and 160 methotrexate-treated patients, 83-92% and 76-92% (of patients with data available) across all subgroups took ≥80% of treatment. Across p16 status and smoking history subgroups, the most common treatment-related adverse events (AEs) were diarrhea (70-91%), rash/acne (72-84%), stomatitis (34-73%) with afatinib; and included stomatitis (39-100%), fatigue (22-50%), nausea (19-36%) with methotrexate. Dose reduction decreased AE incidence/severity. Baseline characteristics were generally similar between oral/feeding tube (n = 276/n = 46) groups. 89%/89% (of patients with data available) took ≥80% of assigned afatinib. Median PFS was 2.6 versus 2.7 months (hazard ratio: 0.997; 95% confidence interval: 0.72-1.38). The most common afatinib-related AEs were: rash/acne (74% versus 74%), diarrhea (73% versus 65%), stomatitis (40% versus 30%).

Conclusion: Subgroup analyses of LH&N1 demonstrate that afatinib has predictable and manageable safety across patient subgroups, with high treatment adherence, and is effective via oral and feeding tube administration.

Keywords: Adherence; Afatinib; Feeding tube; HNSCC; Methotrexate; Recurrent/metastatic; Safety.