Afatinib was associated with significant improvements in GHS and coughing compared with erlotinib. A higher proportion of patients in the afatinib arm reported improved dyspnoea compared with the erlotinib arm, but the difference was not significant.

The most common AEs reported with afatinib were diarrhoea, rash/acne, fatigue and stomatitis; the most common AEs reported with erlotinib were rash/acne, diarrhoea, fatigue and pruritus.

The proportion of patients who discontinued treatment because of AEs was 20% in the afatinib group and 17% in the erlotinib group.

Incidence of treatment-related Grade 3 diarrhoea was higher with afatinib than with erlotinib (10% vs 2%), while incidence of Grade 3 rash/acne was higher with erlotinib than with afatinib (10% vs 6%).
LUX-LUNG 8

Abbreviated EU SmPC:

EGFR M+ NSCLC and sqNSCLC

GIOTRIF®: Irreversible ErbB family blocker. **Active substance:** Afatinib. **Indications:** GIOTRIF is indicated as monotherapy for (1) patients with locally advanced or metastatic NSCLC with activating EGFR mutations not previously treated with EGFR TKIs, (2) patients with NSCLC of squamous histology progressing on or after platinum-based chemotherapy. **Posology:** The recommended dose is 40 mg once daily, orally. Not recommended in patients with an eGFR <15 ml/min and severe hepatic impairment. **Contraindications:** Hypersensitivity to afatinib or any of the excipients. **Interactions:** Potent P-gp inhibitors may lead to increased afatinib exposure, concomitant treatment with potent P-gp inducers may lead to a reduction in afatinib exposure. Afatinib is not an inhibitor or inducer of CYP enzymes. **Undesirable effects:** Paronychia, cystitis, decreased appetite, dehydration, hypokalaemia, dysgeusia, conjunctivitis, dry eye, epistaxis, rhinorrhoea, diarrhoea, stomatitis, nausea, vomiting, cheilitis, dyspepsia, alanine aminotransferase increased, aspartate aminotransferase increased, rash, acneiform dermatitis, pruritus, dry skin, palmar-plantar erythrodysesthesia syndrome, nail disorders, Stevens-Johnson syndrome, toxic epidermal necrolysis, muscle spasms, renal impairment/renal failure, pyrexia, weight decreased, interstitial lung disease, keratitis, pancreatitis. **Presentations:** 20 mg, 30 mg, 40 mg, and 50 mg film-coated tablets. For detailed information, please refer to the published Prescribing Information.

**Supply classification:** POM.

This medicine is subject to additional monitoring.

Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein, Germany

eGFR, estimated glomerular filtration rate; EGFR M+, epidermal growth factor receptor mutation positive; NSCLC, non-small cell lung cancer; POM, prescription only medicine; sqNSCLC, non-small cell lung cancer of squamous histology; TKI, tyrosine kinase inhibitor.

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