Afatinib significantly increased median PFS vs gefitinib; 11.0 months vs 10.9 months (p=0.017). The increase in PFS became more pronounced over time, showing a greater long-term benefit with afatinib vs gefitinib.

Median OS was increased with afatinib compared with gefitinib (27.9 vs 24.5 months) but the difference did not reach statistical significance.

Afatinib significantly increased TTF vs gefitinib; 13.7 months vs 11.5 months (p=0.0073). Improvements in efficacy endpoints with afatinib vs gefitinib were reported consistently across prespecified subgroups including EGFR mutation type, age, gender, and race.

Risk of progression reduced by 27% with afatinib vs gefitinib (HR=0.73; 95% CI: 0.57–0.95)

Risk of treatment failure reduced by 27% with afatinib vs gefitinib (HR=0.73; 95% CI: 0.58–0.92)

Safety Profile
- AEs were consistent with the known safety profiles of both treatments
- Treatment with either monotherapy was generally tolerable, with an equally low rate of treatment-related discontinuation in both arms (6%)
**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 <15ml/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, rhinorrhea, diarrhoea, stomatitis, nausea, vomiting, cheilitis, dyspepsia, alanine aminotransferase increased, aspartate aminotransferase increased, rash, acneiform dermatitis, pruritus, dry skin, palmar-plantar erythrodysaesthesia 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.