How can head-to-head data help GEORGE?

Stage IV squamous NSCLC

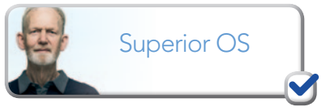
- **Age:** 64 years old
- **Tobacco status:** Down to ½ pack per day (45 pack-years)
- **Previous treatment:** Progressed after platinum-based chemotherapy
- **ECOG:** 1
- **Key symptoms:** Cough
- **Favourite activities:** Picking up his granddaughter from school, walking his dog in the park

not an actual patient

GIOTRIF® (afatinib) tablets

RAISING EXPECTATIONS

GIOTRIF® – Superior OS vs erlotinib in first head-to-head study of EGFR targeting agents in squamous NSCLC[1]



LUX-Lung 8: a large, multi-national, prospective, randomised phase III trial

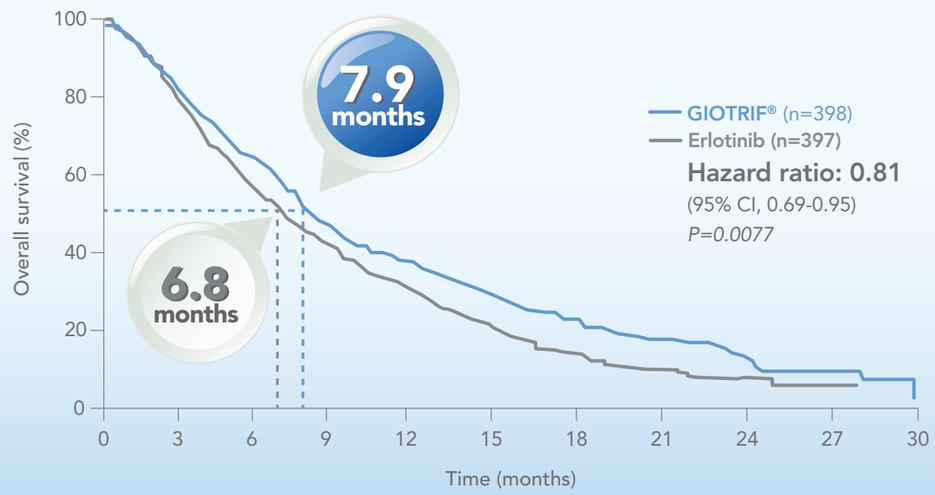
- Advanced NSCLC (Stage IIIB/IV)
- Squamous histology*
- ≥4 cycles of a first-line platinum doublet
- ECOG PS 0–1
- Adequate organ function

Randomisation 1:1 (N=795)

- **GIOTRIF® 40 mg oral once daily (n=398)**
- Erlotinib 150 mg oral once daily (n=397)

Median follow-up for:
- Primary PFS analysis: 6.7 months
- Primary OS and follow-up PFS analysis: 18.4 months

Overall survival (key secondary endpoint)

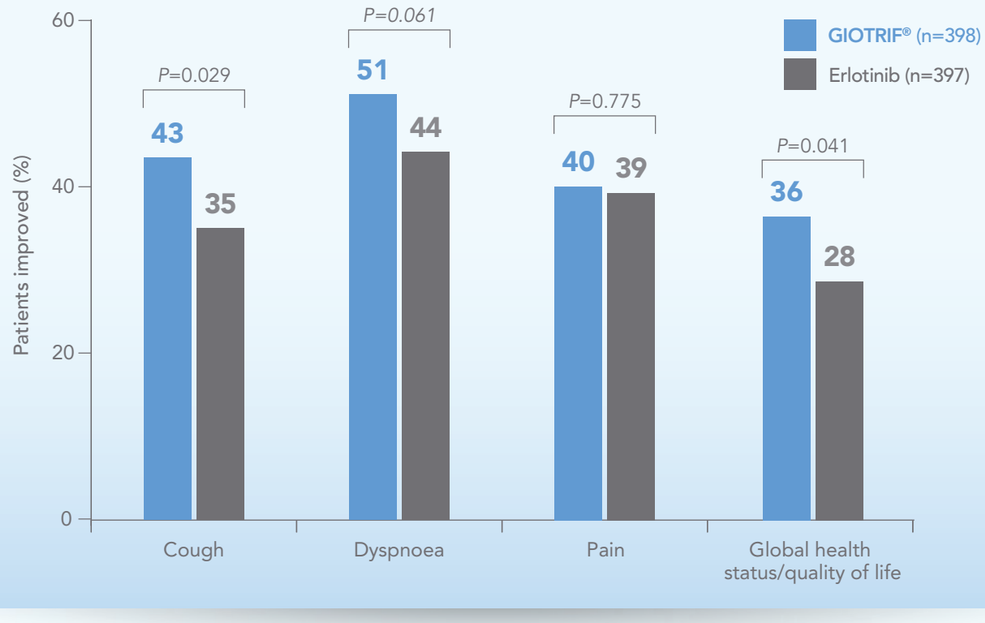


- Median PFS (primary endpoint) was 2.6 months and 1.9 months (HR 0.81; 95% CI, 0.69-0.96; P=0.0103)
- 19% relative reduction in the risk of death vs erlotinib (HR 0.81, 95% CI 0.691-0.946; P=0.0077)
- PFS and OS were consistent across clinically relevant subgroups

* Includes mixed histology.
ECOG=Eastern Cooperative Oncology Group.

GIOTRIF® – Significant improvements in cough and quality of life vs erlotinib[1]

Patients with improvement in symptoms (EORTC scores improved by ≥10 points)



- GIOTRIF® also significantly delayed deterioration of dyspnoea with favourable trends noted in delaying deterioration of cough and global health status/quality of life
- Patients on GIOTRIF® had significantly better mean EORTC scores for cough, dyspnoea and pain compared to erlotinib over time

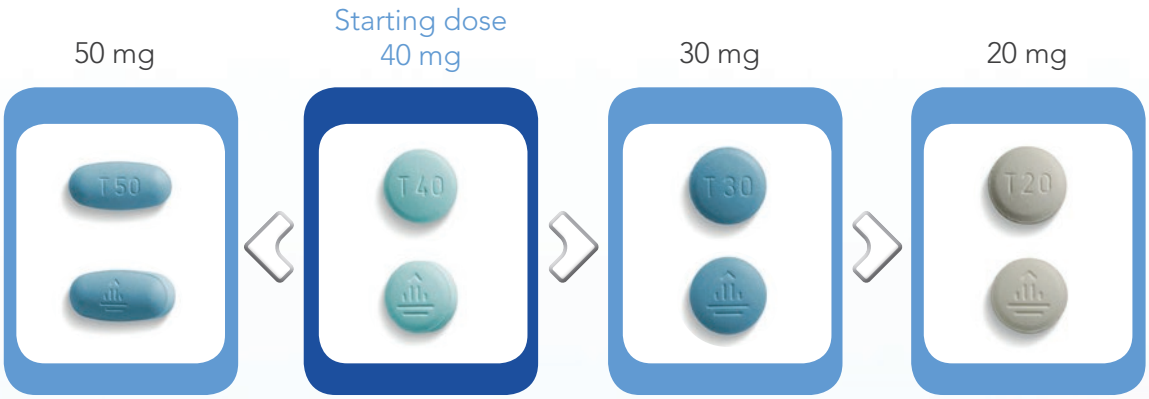
GIOTRIF® – AEs consistent with known profiles of both agents[1]

- The overall rate of drug related adverse events and ≥ grade 3 events was similar for both treatments (GIOTRIF® vs erlotinib: 99% vs 97%; 57% vs 57%, respectively)
- The most common AEs differed between treatment arms:
  - GIOTRIF®: diarrhoea, rash/acne, stomatitis and fatigue
  - Erlotinib: rash/acne, diarrhoea, fatigue and pruritus
- Treatment-related discontinuation due to any AE was similar in both arms (20% vs 17% for GIOTRIF® vs erlotinib)

EORTC=European Organisation for Research and Treatment of Cancer.
Symptom improvement=a linear transformation was applied to standardise the raw score to a range from 0 to 100. A 10-point change is accepted as the threshold for being clinically meaningful (Osoba D et al. J Clin Oncol. 1998;16(1):139-44.)

GIOTRIF® – Convenient oral once-daily dosing[2]

- Multiple tablet strengths for patients requiring dose adjustment



- GIOTRIF® dose may be escalated to 50 mg when tolerated*
- Adverse events may be managed through dose interruption and adjustment if needed
- Dose adjustment not required for smokers

Is GIOTRIF® right for George?[1,2]

- ✔ Superior OS vs erlotinib
- ✔ Familiar AE profile with flexible oral dosing
- ✔ Significant improvements in cough and QoL vs erlotinib
- ✔ Dosing independent of smoking status

*Patients who tolerate a 40 mg/day dose: i.e. absence of diarrhoea, skin rash, stomatitis, and other adverse reactions with CTCAE Grade > 1 in the first 3 weeks.

References: 1. Soria JC et al. Lancet Oncol. 2015;16(8):897-907. **2.** GIOTRIF® Summary of Product Characteristics 2013.

Procedure ID code: 4879 - March 2016

LET'S WORK
ONCOLOGY FROM BOEHRINGER INGELHEIM

Boehringer Ingelheim

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