GIOTAG: A REAL-WORLD STUDY OF AFATINIB* FOLLOWED BY OSIMERTINIB IN EGFR MUTATION-POSITIVE ADVANCED NSCLC[1,2]

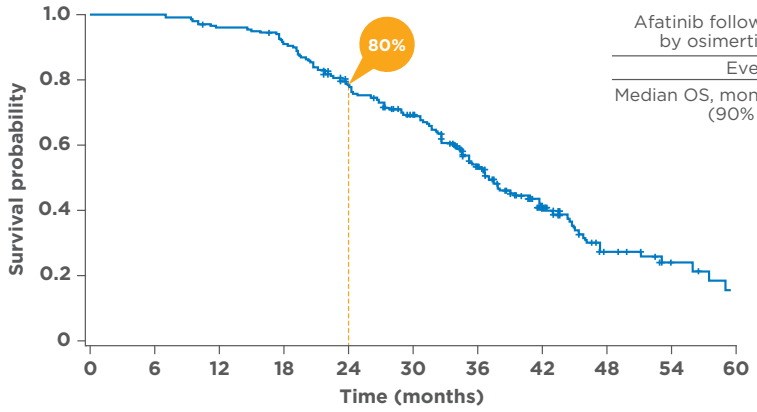
A global, retrospective, non-blinded, observational study based on existing medical records of 204 patients with *EGFR* mutation-positive advanced NSCLC

Patients with *EGFR* mutation-positive advanced NSCLC (Del19, L858R) → First-line treatment with afatinib → Acquisition of T790M → Second-line treatment with osimertinib

Data were collected from existing medical records from Q4 2017 to Q4 2019[2]

Reflecting the situation in clinical practice, the **patient population** included patients with an ECOG PS ≥2 (15% of patients) and those with brain metastases at baseline (10% of patients)[2]

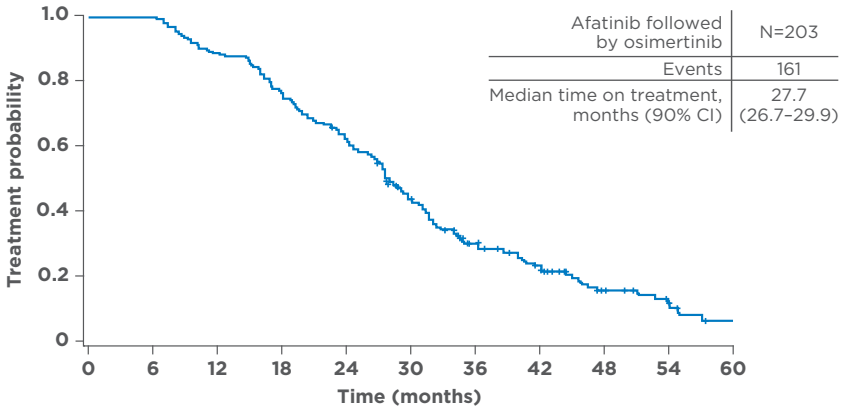
In the final analysis,** sequential afatinib and osimertinib conferred median OS of over 3 years[2]



Afatinib followed by osimertinib	N=203
Events	120
Median OS, months (90% CI)	37.6 (35.5–41.3)

Patients at risk: 203 203 194 186 157 127 86 48 19 11 6

Median time on treatment with sequential afatinib and osimertinib was 27.7 months[2]



Afatinib followed by osimertinib	N=203
Events	161
Median time on treatment, months (90% CI)	27.7 (26.7–29.9)

Patients at risk: 203 203 180 157 127 82 52 32 15 7 3

Median OS was longer in **Asian patients (44.8 months)** and patients with **Del19 mutations (41.6 months)[2]**

Afatinib was **effective in controlling CNS progression** and **maintaining ECOG PS[1]**

- Of patients with no brain metastases at baseline in the initial analysis, 6.6% developed brain metastases during afatinib treatment. Of 21 patients with brain metastases when starting afatinib, 38% had no brain metastases when they began osimertinib
- 75% of patients in the initial analysis maintained or improved ECOG PS during afatinib treatment

The median time on targeted therapies was longer in **Asian patients (37.1 months)** and patients with **Del19 mutations (30.0 months)[2]**

Clinical benefit with this treatment sequence was observed across patient subgroups, including those with ECOG PS ≥2 or stable brain metastases[2]

Limitations of this study include its retrospective nature, the lack of a comparator arm, and the potential for selection bias by excluding patients who died after first-line afatinib treatment or under-representing patients who derived long-term benefit from first-line afatinib treatment.

*Afatinib is approved in more than 80 markets, including the EU, Japan, Taiwan and Canada under the brand name GIOTRIF®, in the US under the brand name GILOTRIF® and in India under the brand name Xovoltib®. Registration conditions differ internationally; please refer to locally approved prescribing information; **At the time of the final analysis (December 2019); median follow-up was 33.9 months.

CI, confidence interval; CNS, central nervous system; ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, epidermal growth factor receptor; NSCLC, non-small cell lung cancer; OS, overall survival.

1. Hochmair MJ, et al. Future Oncol 2018;14(27):2861–7; 2. Hochmair MJ, et al. Future Oncol 2020. Aug 28. doi: 10.2217/fon-2020-0740 [Epub ahead of print].

ClinicalTrials.gov NCT number: NCT03370770.

European Union Summary of Product Characteristics (https://www.inoncology.com/sites/default/files/emea-combined-afatinib_SmPC_EU_Approval.pdf).

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