

SAFETY AND TOLERANCE PROFILE OF OSIMERTINIB FOR TREATMENT OF NON-SMALL CELL LUNG CANCER

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Background and importance

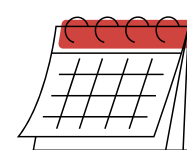
Osimertinib is an irreversible tyrosine kinase inhibitor approved for the treatment of **metastatic non-small cell lung cancer (mNSCLC)** with EGFR mutations and EGFR T790M mutation.

Aim and Objectives

To evaluate the effectiveness and safety of osimertinib in mNSCLC in clinical practice.

Materials and Methods

- **Retrospective observational study**



February 2018– June 2024

- **Variables collected** → age/ sex / smokers / quality of life (Eastern Cooperative Oncology Group (ECOG) score / brain metastases / type of mutation / n° lines received / n° cycles administered

- **Effectiveness** → progression-free survival (**PFS**)
→ overall survival (**OS**)

- **Safety** → adverse events (**AEs**) and classifying the degree of toxicity according to the Common Terminology Criteria for Adverse Events v.5.0.

Results

53 patients

Age	Sex	Non-smokers	ECOG
64 (48-89)	75,5 % women 24,5 % men	62,3%	0-1: 88,9%
Brain metastases	Type of mutation	n° lines (L)	n° cycles
64,2 %	54,7 %: exon 19 deletion 35,8 %: L858R mutation	79,25 %: 1L 20,75%: 2L	Median 9

Median PFS

- **1L → 22 months**
95% CI (10,74-33,25)
- **2L → 17 months**
95% CI (3,42-30,57)

Median OS

- **1L → 31 months**
95% CI (9,76-52,23)
- **2L → 17 months**
95% CI (10,91-47,08)

→ **EAs** → 57,4% patients (**grade 1: 48,4%, grade 2-3: 9%**)

Most frequent AEs → diarrhoea (18,5%), rash (16,5%), asthenia (16,5%).

Grade 3 AEs → retinal necrosis, skin lesions, elevated GGT and cardiac failure.

Conclusion and Relevance

The effectiveness results achieved in **SLP** were superior in both **treatment lines compared to their pivotal trials FLAURA (1L) and AURA 3 (2L)**. However, the **OS** achieved was lower in 1L and higher in 2L.

In terms of safety, **there was a lower incidence of AEs** and generally mild AEs.

