

# EFFICACY AND SAFETY OF MONOTHERAPY WITH PEMBROLIZUMAB IN NON-MICROCYTIC METASTATIC LUNG CANCER IN CLINICAL PRACTICE.

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## Background and importance

Pembrolizumab is an anti-PD1 antibody used to treat metastatic non-small cell lung cancer (m-NSCLC).

## Aim and objectives

To analyze the efficacy and safety of first (1L) or successive lines ( $\geq 2L$ ) treatment of m-NSCLC with pembrolizumab monotherapy.

## Material and methods

Retrospective and observational study. It includes 82 patients with m-NSCLC treated with pembrolizumab monotherapy between January-2018 and April-2020.

1. Medical history review.
2. Statistic analysis  $\rightarrow$  SPSS<sup>®</sup>-v23.0
  - Measure of efficacy
    - ✓ Progression-free survival (PFS) } Kaplan
    - ✓ Overall survival (OS) } -Meier
    - ✓ Objective response rate (ORR)  $\rightarrow$  iRECIST criteria
  - Measure of safety
    - ✓ Adverse effects (AEs) and its severity  $\rightarrow$  NCI-CTCAE-v5.0.
3. Comparison with pivotal clinical trials.
  - KEYNOTE-024
  - KEYNOTE-010.

## Results

Variable	Pembrolizumab 200 mg / 3 weeks	Pembrolizumab 2 mg/kg / 3 weeks
Treatment line	1 L	$\geq 2 L$
Pivotal clinical trial	KEYNOTE-024	KEYNOTE-010
Number of patients (mens)	45 (34)	37 (30)
Age –median in years (range)-	66 (32-83)	67 (46-90)
Histology	35 Non-squamous / 6 squamous	18 Non-squamous / 14 Squamous
PD-L1 % expression-median (range)-	80 (55-100)	10 (1-90)
ALK, ROS or EGFR mutations	45 ALK - / ROS - / EGFR -	37 ALK - / ROS - // 2 EGFR + , 35 EGFR -
Number of previous treatments	-	34 patients = 1 / 3 patients $\geq 2$ *Always a platinum doublet regimen.
ECOG at the start of treatment.	35 ECOG = 0-1 / 10 ECOG $\geq 2$	30 ECOG = 0-1 / 7 ECOG $\geq 2$
Number of cycles -median (range)-	5 (1-37)	4 (1-24)
PFS -median in months (95%CI)-	5.1 (0,5-not reached)	3.4 (1,9-4,7)
OS -median months (95%CI)-	Not reached. *OS rate: 6 months = 66% / 12 months = 60%	9.1 (5,1-13,2)
ORR	40%	16%
Adverse effects	129 AEs. 6 patients (13%) grade 3-4 AEs	54 AEs. 3 patients (8%) grade 3-4 AEs

## Conclusion and relevance

Pembrolizumab in 1L of m-NSCLC in our patients presented lower PFS and OS than those recorded in KEYNOTE-024 and similar ORR. Could be partially explained by the greater deterioration of our patients at the beginning of treatment (22% ECOG $\geq 2$ ) compared to KEYNOTE-024. Pembrolizumab in  $\geq 2L$  obtained slightly lower PFS, SG and ORR than those recorded in KEYNOTE-010. AEs were mostly grade 1-2, and less frequent than in clinical trials.