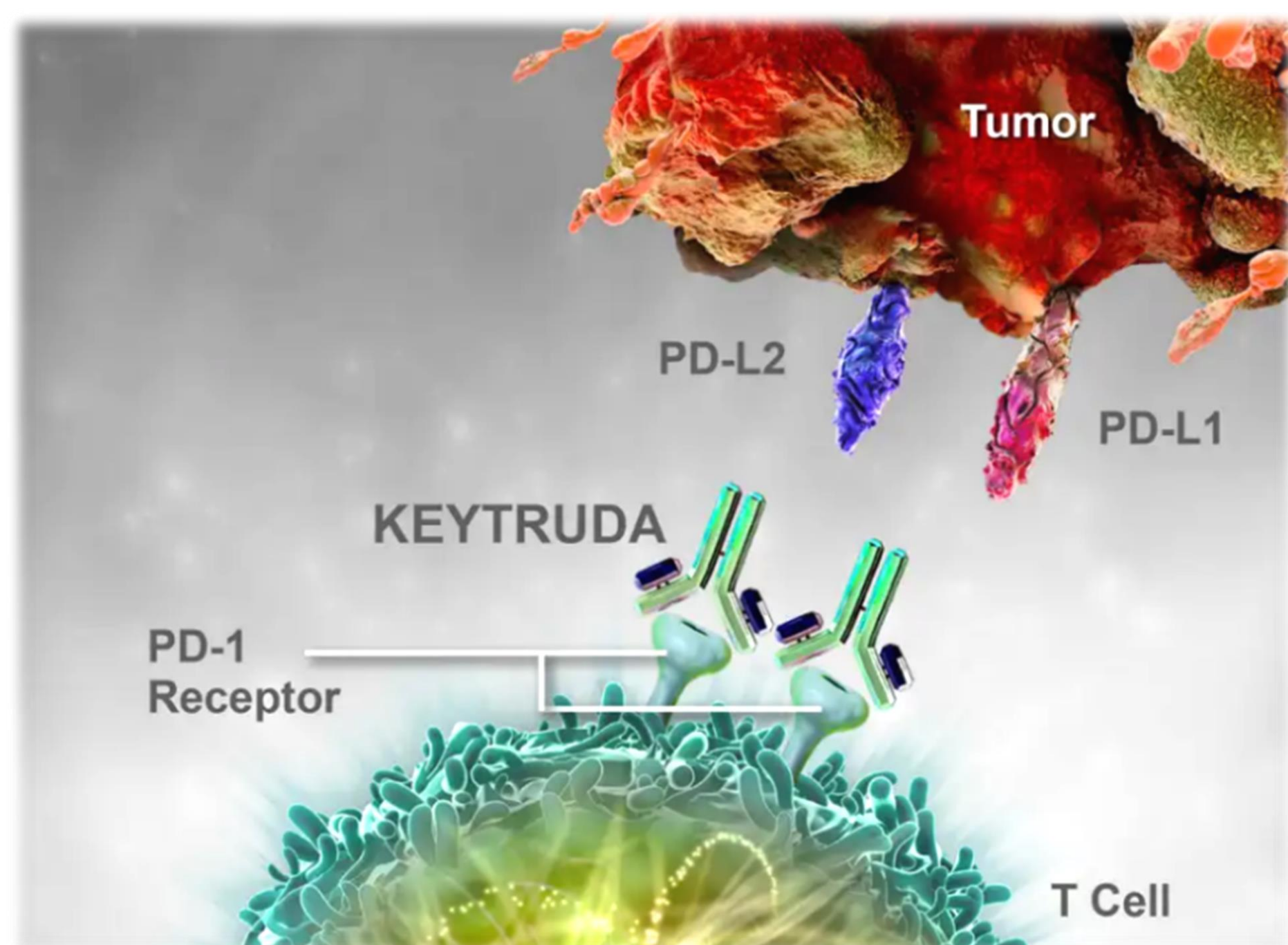




EFFICACY OF PEMBROLIZUMAB FOR NON-SMALL CELL LUNG CANCER (NSCLC): PRELIMINARY REAL-WORLD ANALYSIS AND COMPARISON WITH THE PIVOTAL STUDY (PS)

A. CAR, A. COIS, M. BONI, S. AINA, G. BORRA, A. GENNARI, A. PISTERNA



BACKGROUND AND IMPORTANCE

Pembrolizumab (P) is a monoclonal antibody used in immunotherapy, indicated for NSCLC.

AIM AND OBJECTIVES

Evaluate the effectiveness of P, in terms of progression free survival (PFS) in patients affected by NSCLC in an Italian Hospital (IH), and comparing it with the PS. The Italian regulatory agency (AIFA) authorized P at 2 mg per kg dose, subsequently at a flat dose of 200 mg (1). Therefore, a secondary aim is to verify whether there was a difference in terms of PFS between flat dose and per kg dose.

MATERIALS AND METHODS

The death and progression data were taken from the AIFA monitoring registers (RA) and compared with the company management system. PFS is the time from the first prescription to the date of end of treatment due to death or progression. The period considered is 2017-2023. The PS is Keynote024 (2). Patients were divided into two homogeneous groups: the first at <3mg/kg (group1) and the second \geq 3mg/kg (group2). We calculated OS and PFS for each group.

RESULTS

Patients evaluated were 165, 71.6% male, median age 71 years. All administrations were recorded in the RAs. Median PFS IH 218 days (0.95CI 114;230) vs PS 288 (0.95CI 187.6; nr). At 182 days, 57% of patients progressed (IH) vs 62.1% (PS). 52% of patients took a dose < 3 mg/kg, 48% \geq 3 mg/kg. Median PFS is 258 days for the group1 (0.95CI 186;456) and 218 for the group2 (0.95CI 158;393). At 182 days: 30 patients had an event (group1) vs 29 patients (group2).

Pembrolizumab PFS

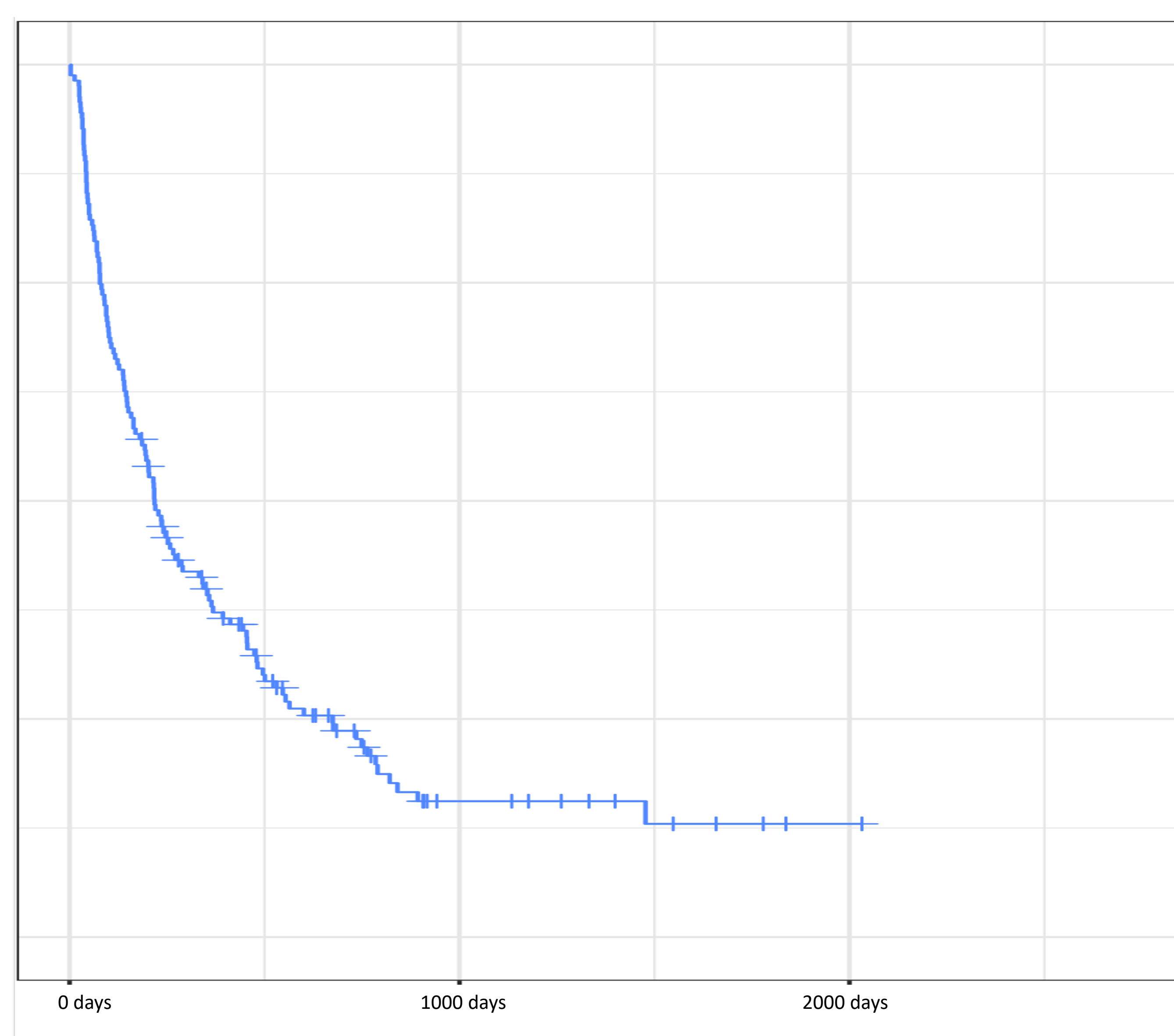


Figure 1. Pembrolizumab PFS-data real world IH expressed as a median days

drug	n° patients	n° events	median (days)	0,95LCL	0,95UCL
pembrolizumab	165	128	218	114	230

Table 1. PFS expressed as a median days

time	drug	n° events	progression	std.err	0,95 CI
182 gg upper 95% CI 0,6518	pembrolizumab	70	0,5706	0,0388	0,4994

Table 2. PFS expressed as a % of patients who progressed 6 months (182 days) after treatment.

DISCUSSION AND CONCLUSIONS

PFS data resembles PS data. There is no significant difference in using a dose > 3 mg/kg compared to a lower one, this means that a dose per kg would lead to a reduction in drug consumption and in costs. The future goal is to reach more significant numbers and to investigate adverse reactions from immunotherapy, related to different doses.

Pembrolizumab PFS. Doses <3 mg/kg VS \geq 3 mg/kg.

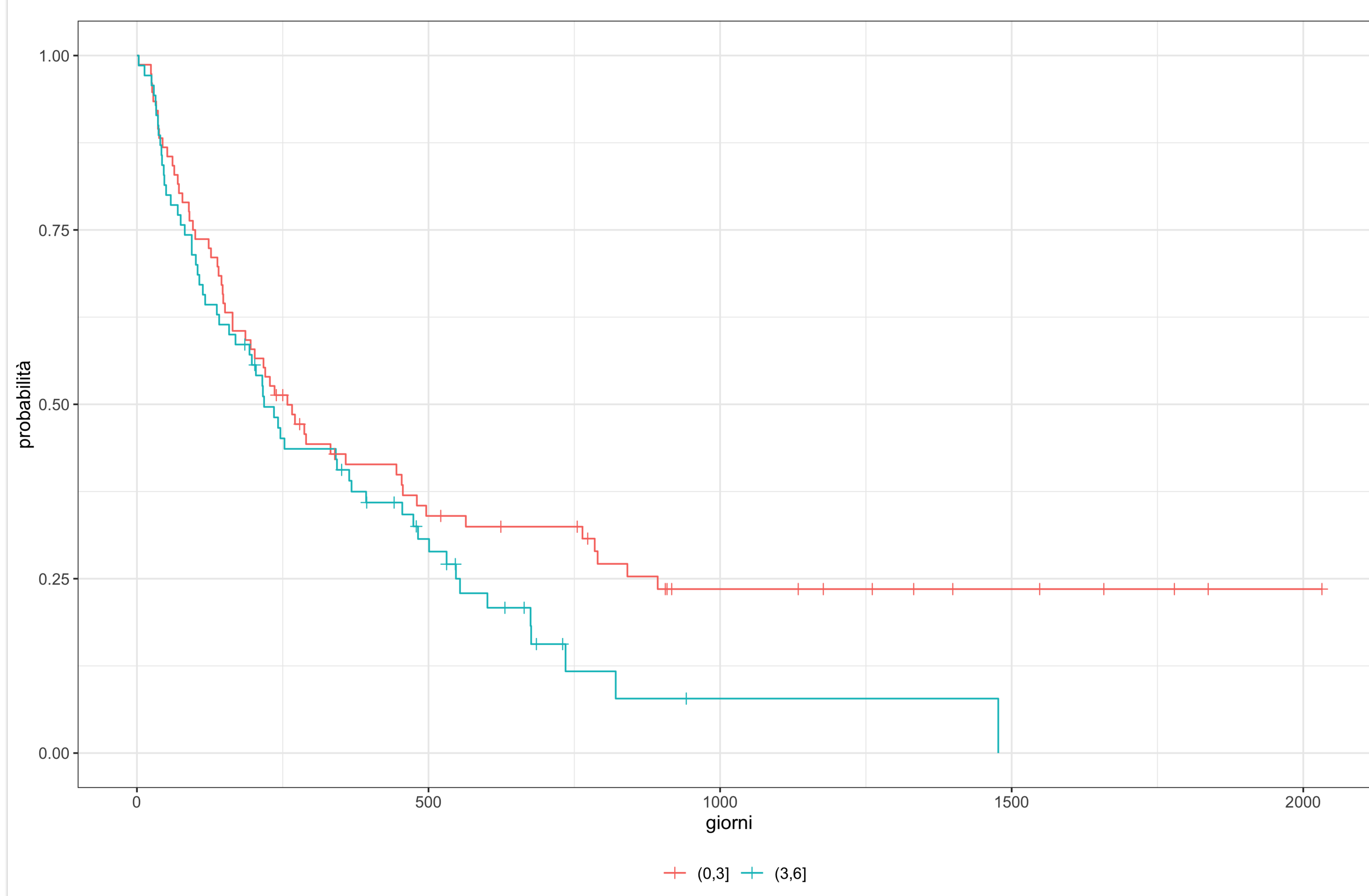


Figure 2. Progression-free survival of the two groups of patients who received pembrolizumab at doses <3 mg/kg and \geq 3 mg/kg.

REFERENCES

- Gazzetta Ufficiale Repubblica Italiana n°328, 2019
- ClinicalTrials.gov ID NCT02142738. Study of Pembrolizumab (MK-3475) compared to Platinum-Based Chemotherapies in participants with metastatic Non-Small cell Lung Cancer. (KEYNOTE-024)

Abstract Number 4CPS-120
ATC code: L01- ANTINEOPLASTIC AGENTS

