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Budget Impact Analysis Of Cemiplimab For First-Line (1L) Advanced Non-Small Cell Lung Cancer (NSCLC) With Programmed Cell Death-Ligand 1 (PD-L1)≥ 50% In Italy

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Background

Non-small cell lung cancer (NSCLC) is the leading cause of cancer death among men and the second largest among women worldwide. Among the available treatment options, cemiplimab monotherapy demonstrated a significant survival benefit over chemotherapy in the first-line treatment of advanced NSCLC with PD-L1 \geq 50%. With the Official Gazette n ° 202 of 08/30/2022 (Resolution n ° 566 of 08/03/2022), cemiplimab was reimbursed: as monotherapy for the treatment of adult patients with locally advanced or metastatic basal cell carcinoma (laBCC or mBCC); as monotherapy for the first-line treatment of adult patients with non-small cell lung cancer (NSCLC) with PD-L1 expression (in \geq 50% of tumor cells), without EGFR, ALK or ROS1 aberrations, who have: NSCLC metastatic (mNSCLC), such as available therapeutic alternatives, and locally advanced NSCLC that are not candidates for definitive chemoradiotherapy. The study presented aims to evaluate the budget impact resulting from the introduction of cemiplimab as monotherapy in clinical practice.

Methods

The budget impact model simulates the average cost of managing a patient with NSCLC over a time horizon of 3 years considering the establishment of a competitive dynamic due to the introduction of cemiplimab or other "entrants" into clinical practice. The costs of acquisition, administration, monitoring and adverse events, as well as the duration of treatments were considered. The tool is able to evaluate the economic consequences deriving from the introduction of a second or third "entrant" by simulating an incremental absorption based on market shares, as reported in the publication by Porath Daniel (2016). The model also assumes a reduction in purchase prices over the time horizon considered. This hypothesis is based on real world data provided by the Agostino Gemelli Polyclinic regarding the analysis of a case study on melanoma in which a second "entrant" move in the market. The model estimates a number of eligible patients equal to 4,711 (NSCLC PD-L1) and considers, in the evaluation of the economic impact, the following drivers:

- Duration of treatment
- Acquisition costs
- Costs for adverse events

Results

Cost monitoring

Scenario AS IS	Y1	Y2	Y3
Pembrolizumab	100%	100%	100%
Cemiplimab	0%	0%	0%
Third entrant	0%	0%	0%

Figure 1 – Model structure

Pembrolizumab: firstline anti PD-1 in mNSCLC

New entrants: **Atezolizumab**: first-line anti PD-L1 in mNSCLC

Cemiplimab: first-line anti-PD-1 in mNSCLC and laNSCLC

Cost reduction due to the establishment of a competitive dynamic resulting from the introduction of a second or third monotherapy for

patients with NSCLC

Budget
Impact: incremental savings in both scenarios analyzed.
Considering 2 monotherapies:
- € 61.426.708

- € 61.426.708

Considering 3
monotherapies:
- € 64,238,108

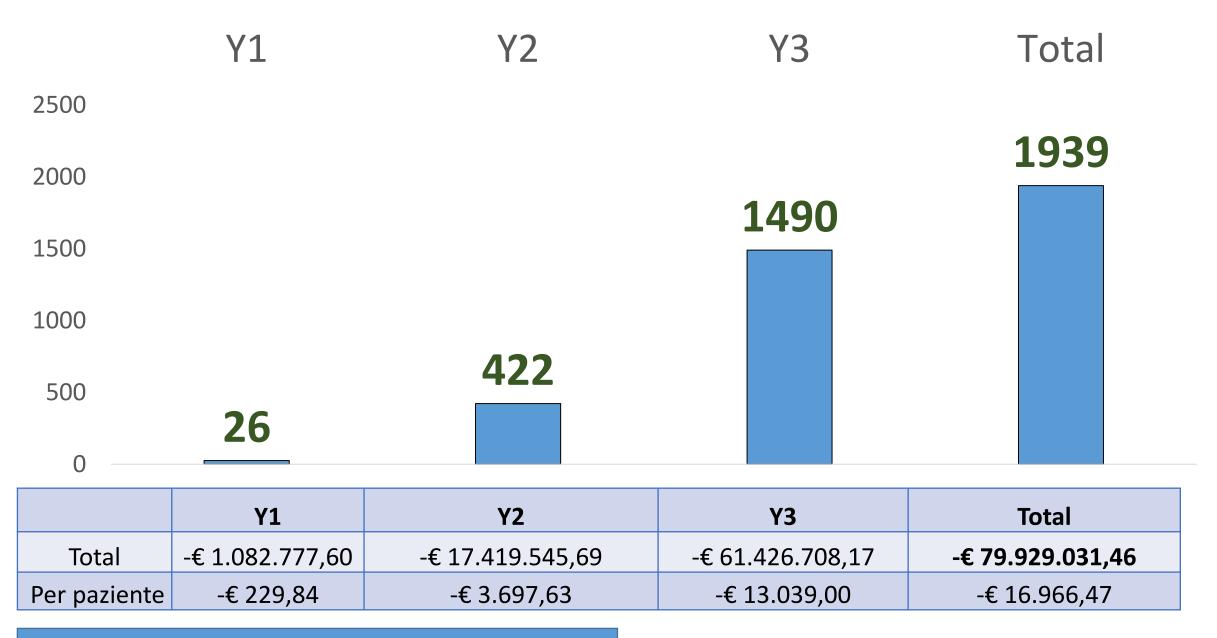
Situation analysis Methdology Results

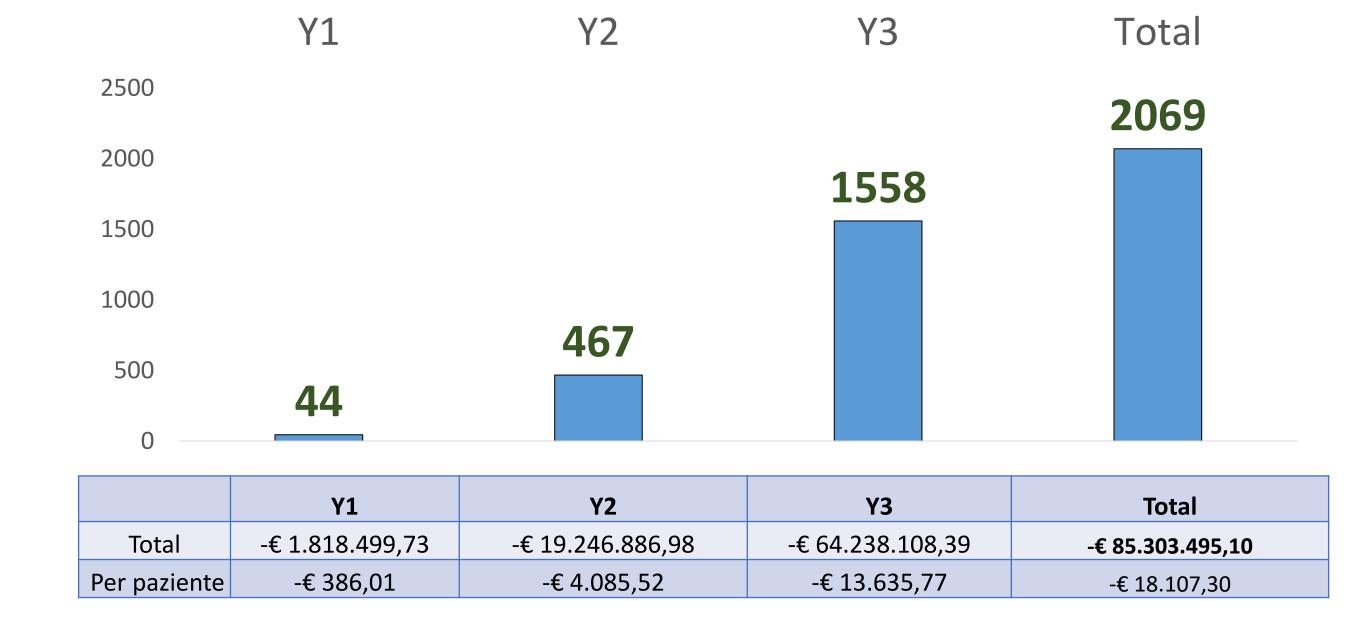
2 entrants						
Scenario TO BE	Y1	Y2	Y3			
Pembrolizumab	90%	80%	65%			
Cemiplimab	10%	20%	35%			
Other entrant	0%	0%	0%			

3 entrants					
Scenario TO BE	Y1	Y2	Y3		
Pembrolizumab	85%	67%	38%		
Other entrant	10%	20%	35%		
Cemiplimab	5%	14%	28%		

The results of the model indicate incremental savings in terms of average management cost per patient of € 386.01 for year 1, € 4,085.52 for year 2 and € 13,635.77 for year 3. These savings derive mainly from the establishment of competitive dynamics. Considering only the second market "entrant", the results show an incremental saving in terms of average management cost per patient equal to € 229.84 for year 1, 3,697.63 for year 2 and 13,090.00 for year 3.

Figure 2 -3 - Increase in eligible patients with the same amount of resources provided





Conclusions

This tool demonstrates that the establishment of a competitive dynamic deriving from the introduction of cemiplimab in Italian clinical practice entails a reduction in the cost of managing patients with NSCLC, thus maximizing the allocative efficiency of the scarce resources of the National Health Service.