

administration and adverse event management costs were included in the model. The base-case analysis used a time horizon of 20 years. Costs and health outcomes were discounted at a rate of 3% per year.

**Results:** Base case results project for PD-L1 positive (TPS $\geq$ 50%) patients treated with pembrolizumab a mean survival of 2.25 years. For docetaxel, a mean survival time of 1.07 years was estimated. Weekly disease management costs observed in KN010 for the progression-free state were \$866 and \$1,298 for pembrolizumab and docetaxel, respectively. Weekly disease management costs for the progressive disease state were \$1,938 based on a US healthcare claim database. Results projected total disease management costs to be \$166K per patient treated with pembrolizumab compared with \$93K for docetaxel because of extended progression-free and post-progression survival with pembrolizumab. Nearly half (45%) of total expected cost differences between pembrolizumab and docetaxel are due to the incremental disease management costs. Further analyses that exclude drug treatment costs show that the additional disease management costs associated with extended progression-free and overall survival exceed \$50,000 per LY gained (\$61,864).

**Conclusion:** Pembrolizumab improves outcomes compared to docetaxel in PD-L1 positive (TPS $\geq$ 50%) pre-treated advanced NSCLC patients in the US. The improved overall survival with pembrolizumab is accompanied by the economic reality of additional non-pembrolizumab costs that represent their own substantial economic burden.

**Keywords:** Cost-effectiveness, PD-L1, advance NSCLC

Scottsdale/AZ/United States of America, <sup>4</sup>HCOR Cancer Center, São Paulo/Brazil

**Background:** Delivering high quality cancer care at an affordable cost is one of the main challenges for health care professionals and policy makers, especially in low- and middle-income countries. The objective of our study is to assess the economic impact of nivolumab and pembrolizumab with and without the use of PD-L1 as a biomarker in Brazil.

**Methods:** We developed a decision-analytic model to determine the cost-effectiveness of PD-L1 assessment and the second-line treatment with NIVO or PEMBRO versus docetaxel. The model used outcomes data from randomized clinical trials and drug acquisition costs were estimated using current prices in Brazil. Thereafter, we used Brazilian epidemiologic data to estimate the economic impact.

**Results:** We included three RCTs (two with NIVO and one with PEMBRO). The estimated number of cases eligible for therapy with immune checkpoint inhibitors is 4,733. Treating all patients with NIVOLUMAB would cost US\$ 173 million dollars each year, representing an increase of 21% in current Brazilian expenses for cancer drugs acquisition. Treating only patients with PD-L1 > 1% with NIVOLUMAB would cost 93 million dollars every year, leading to an increase of 11.3% in expenses for cancer drugs acquisition. However, with such selection, up to 46% of cases would not be treated and 315 years of life would be lost compared to treating all patients regardless of PD-L1 expression. The cost of each year-of-life saved was improved by PD-L1 selection (from US\$ 196,000 to US\$ 164,000). Table 1 summarizes our findings for five different scenarios of treatment. The results were similar with NIVOLUMAB and PEMBROLIZUMAB.

**Conclusion:** The use of PD-L1 expression as a biomarker for treatment with immune checkpoint inhibitors decreases the overall economic impact and the cost per life-year saved. Further study and societal discussion is needed in order to find the optimal strategy for patient selection.

**Keywords:** Pharmacoeconomy, Policy Maker, Immunotherapy, biomarker

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**An Estimate of the Economic Impact of Immunotherapy Relative to PD-L1 Expression in Brazil - An Update with Brazilian Costs**



**Pedro Aguiar Jr.,<sup>1</sup> Ramon De Mello,<sup>2</sup> Hakaru Tadokoro,<sup>1</sup> Hani Babiker,<sup>3</sup> Gilberto Lopes<sup>4</sup>**

<sup>1</sup>Universidade Federal de São Paulo, São Paulo/Brazil, <sup>2</sup>Universidade Do Algarve, Faro/Portugal, <sup>3</sup>Honor Health,

| SCENARIO              | QALY GAIN | ICER (US\$) | LIFE-YEARS SAVED | YEARS OF LIFE NOT SAVED | % NOT TREATED | TOTAL COST (US\$) | IMPACT ON TOTAL CANCER DRUG EXPENDITURE | COST/LYS (US\$) |
|-----------------------|-----------|-------------|------------------|-------------------------|---------------|-------------------|---|-----------------|
| NIVO ALL COMERS       | 0.148     | 129 K       | 885              | 0                       | 0%            | 173 Million       | 21.1%                                   | 196 K           |
| NIVO PD-L1 > 1%       | 0.201     | 108 K       | 570              | 315                     | 46%           | 93                | 11.3%                                   | 164 K           |
| PEMBRO PD-L1 > 1%     | 0.138     | 137 K       | 666              | NA                      | 34%           | 100               | 12.1%                                   | 150 K           |
| NIVO ALL SQ/ > 1% NSQ | 0.216     | 99 K        | 738              | 147                     | 35%           | 116               | 14.0%                                   | 157 K           |
| PEMBRO PD-L1 > 50%    | 0.164     | 116 K       | 285              | NA                      | 72%           | 43                | 5.2%                                    | 151 K           |