Oncology 2025
The Cancer Control Challenge:
Better Understanding It to Better Face It

IMMUNE CHECKPOINT INHIBITORS USED IN CANCER TREATMENT IN BRAZIL: AN OVERVIEW UP TO 2023

Debora Cristina Viana Pereira[1], Andrei Stéfano Queiroz Gonçalves[1], Zenilde da Silva Alves[1], Ádila Marina Ramos Santana[1], Louise Sousa De Souza[1], Jade Dias Valente[1], Beatriz Modesta Moreira[1], Maria Izabel Florindo Guedes[2], Paulo Pimentel de Assumpção[1], Lívia Érika Carlos Marques[1]

[1]Oncology Research Center (NPO), Federal University of Pará (UFPA), Brazil
[2]Laboratory of Biotechnology and Molecular Biology (LBBM), State University of Ceará (UECE), Brazil

Introduction: In cancer treatment, immunotherapy aims to reactivate immune cells to restore their action against malignant cells. Immune checkpoint inhibitors (ICIs) are currently considered one of the most promising approaches, acting on targets such as cytotoxic T-lymphocyte antigen 4 (CTLA-4) and programmed cell death 1 (PD-1) receptors and their PD-L1 ligand. Since the approval of the first ICI in 2011, Ipilimumab (anti-CTLA-4), several antibodies directed at these targets have been approved by the Food and Drugs Administration (FDA), such as Nivolumab, Pembrolizumab, Cemiplimab, Dostarlimab, Retifanlimab and Tislelizumab (anti-PD-1); Atezolimumab, Durvalumab, Avelumab, Adebrelimab, Cosibelimab, Envafolimab and Sugemalimab (anti-PDL-1); Tremelimumab (anti-CTLA-4). **Objectives**: To analyze the immune checkpoint inhibitor monoclonal antibodies used in cancer immunotherapy in Brazil with active registration with the National Health Surveillance Agency (ANVISA) and their procurement profile by the Federal Government between 2014 and 2023. **Methods**: This study is a retrospective descriptive analysis of ICIs registered with ANVISA, categorized by the target of action, type and clinical indication, and a search for purchasing data from the Integrated General Services Administration System (SIASG), considering brand, year of registration and number of items purchased. **Results**: In 2023, 9 ICIs were identified with active registration with ANVISA, of which 8 had procurement registrations in the period analyzed, 5 of which are fully human and 3 humanized. As for the targets of action, it was identified that: CTLA-4 has 2 antibodies (Ipilimumab and Tremelimumab) with active registration, all of which are human; PD-1 has 4 antibodies, two human (Cemiplimab and Nivolumab) and two humanized (Pembrolizumab and Dostarlimab); and PD-L1 has 3 antibodies, two human (Durvalumab and Avelumab) and one humanized (Atezolizumab). In total, 104,840 units have been approved for purchase in these nine years, with Nivolumab (77,251 units) and Pembrolizumab (14,265 units) standing out, followed by Durvalumab (6,564 units), Ipilimumab (3,276 units), Atezolizumab (2,141 units), Avelumab (1,027 units), Cemiplimab (251 units) and Dostarlimab (65 units).

Tremelimumab was not registered during this period. There has been a progressive increase in antibody purchases over the years, with the highest volume recorded in 2023 (61,960 units). The main clinical indications for ICIs were: melanoma, liver cancer, cutaneous squamous cell carcinoma, endometrial cancer, non-small cell lung cancer, bladder cancer and Merkel cell carcinoma. **Conclusion**: The study provides an overview of the purchases of immune checkpoint inhibitors made available by SUS between 2014 and 2023, highlighting Nivolumab and Pembrolizumab as the most purchased antibodies. Pembrolizumab, approved by the FDA for solid tumors with high microsatellite instability (MSI-H) and mismatch repair deficiency (dMMR), was the first antibody authorized for agnostic use, allowing for a wide range of oncological indications, which may justify its significant volume of purchases. However, despite these advances, access to immunotherapy in Brazil is still limited, with only 9 of the 15 internationally approved ICIs registered with ANVISA, and there are no biosimilars available in the country. These findings highlight the need to expand the availability and accessibility of these innovative therapies, promoting greater equity in cancer treatment and improving public health policies.

Keywords: Immunotherapy; monoclonal antibodies; cancer.