HPR131

Launches of Oncology Products in LATAM Versus the United States

A Comparative Analysis of FDA-Approved Oncology Drug Access in the United States, Brazil and Argentina

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1 OBJECTIVES

Despite increasing oncology needs in Latin America, timely access to innovative therapies remains limited[1]. This analysis evaluates regulatory approval timelines and treatment costs for top-selling oncology products in Brazil and Argentina, compared to their initial launch in the United States, to understand the access gap across key LATAM markets.

2 METHODS

Ten leading oncology drugs in the U.S. were selected based on 2024 revenue rankings, based on their annual financial reports. Each product's first FDA-approved indication was selected to define treatment dosing and estimate annual pricing using at-launch Wholesale Acquisition Cost data for each country, sourced from GlobalData. Official sources (ANVISA, ANMAT, and FDA) were reviewed to determine local approval dates. Time differences from FDA approval to local authorisation and annual treatment cost differentials (in USD) were calculated for Brazil and Argentina.

Table 1. Top 10 Oncology Drugs by U.S. Revenue in 2024[2-10]

ONCOLOGY PRODUCT*	U.S. REVENUE (USD)
pembrolizumab	$17.8 billion
daratumumab	$6.58 billion
nivolumab	$5.35 billion
abemaciclib	$5.31 billion
lenalidomide	$5.27 billion
palbociclib	$2.85 billion
osimertinib	$2.76 billion
durvalumab	$2.60 billion
ibrutinib	$2.44 billion
atezolizumab	$2.0 billion

*Original brand products

3 RESULTS

On average, oncology drugs received marketing authorisation in Brazil **945 days** (range 239-4382 days) and Argentina **986 days** (range 314-2798 days) after U.S. FDA approval[11-13]. Annual treatment costs were significantly lower in LATAM, with an average percentage difference of **~63% lower in Brazil** and **~99% lower in Argentina**, compared to the U.S., and an average price differential of $85,573 in Brazil and $132,941 in Argentina (mean annual cost in the U.S.: **$134,933**, Brazil: **$49,360**, and Argentina: **$1,992**)[14-15].

Figure 1. Launch Year in U.S., BR and AR[11-13]

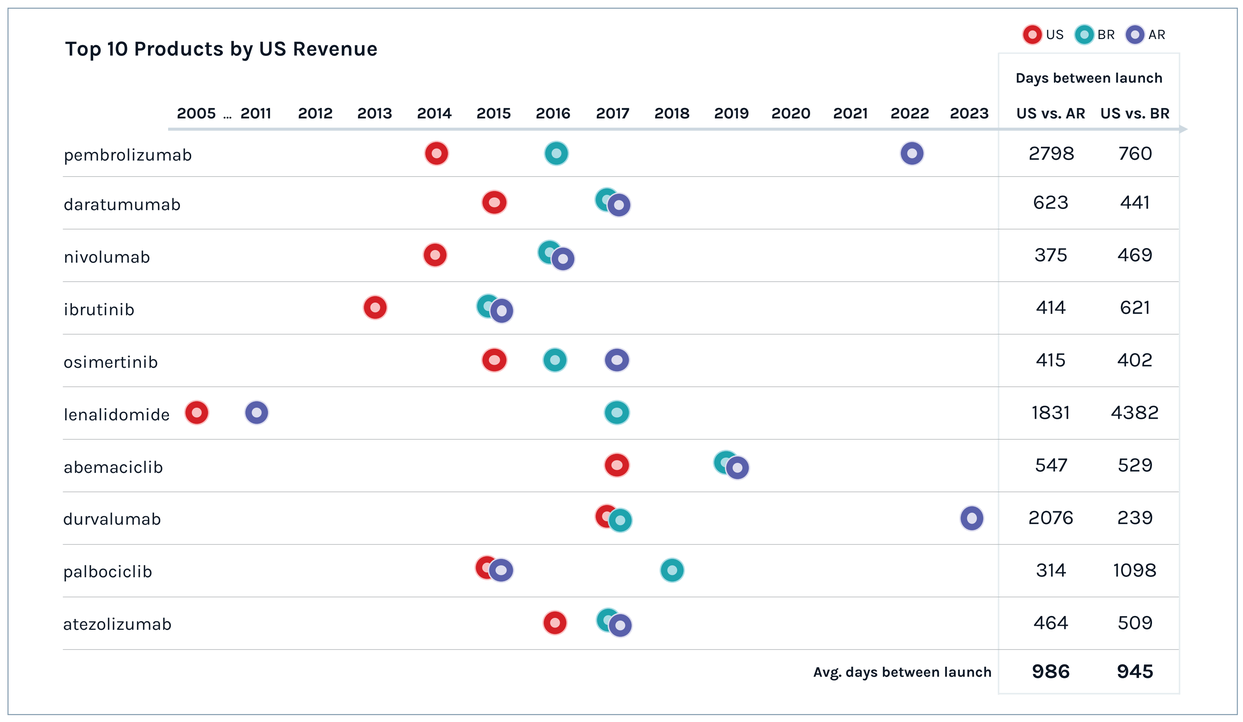
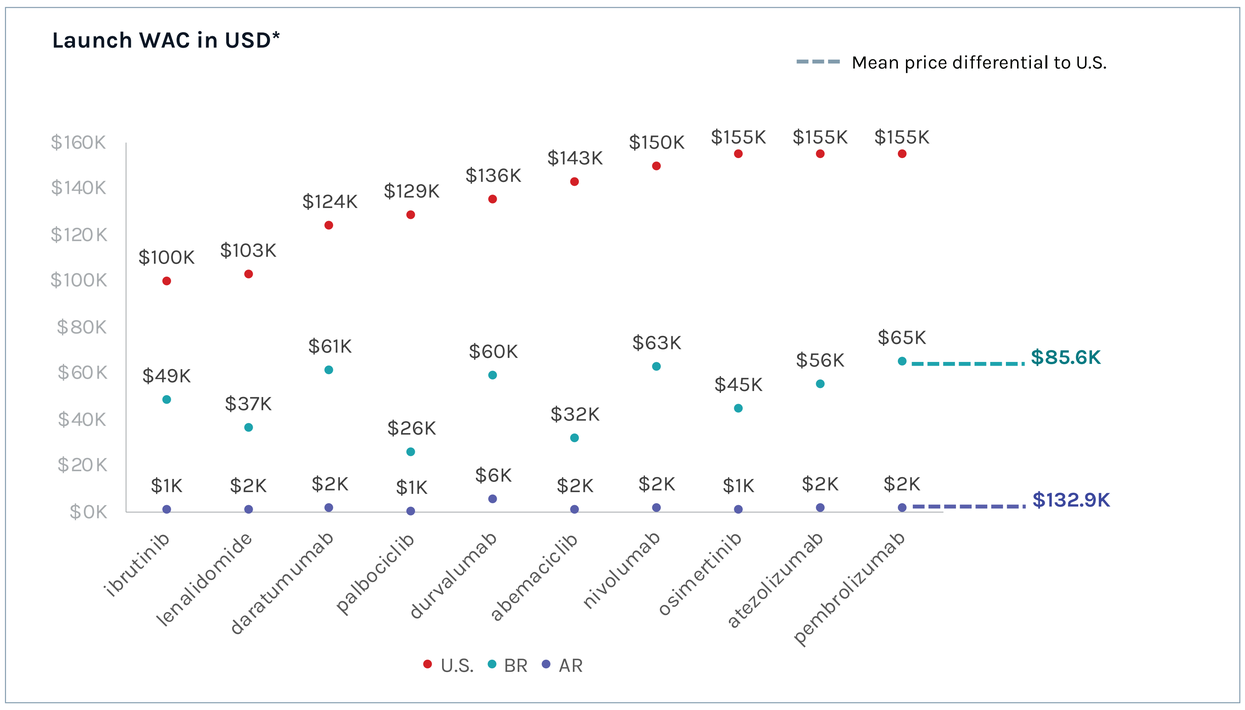


Figure 2. Annual Treatment Cost[14-15]



*Exchange rate: 1 USD = 1174.01 ARS and 5.51 BRL

4 CONCLUSIONS

The analysis reveals significant access delays and wide pricing disparities for oncology drugs in Brazil and Argentina versus the U.S. Access delays may diminish the clinical value of early innovations. Pricing variability suggests differences in procurement strategies, local economic constraints, and regulatory processes. These findings highlight the importance of regulatory harmonisation, early dialogue with health authorities, and value-based pricing strategies to accelerate access and improve equity in cancer care across LATAM markets. These insights can support manufacturers, policymakers, and stakeholders in shaping future access strategies that close the gap between innovation and availability in emerging markets.

5 REFERENCES

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