

Keytruda Market Size, Share & Trends Analysis Report By Application (Lung Cancer, Breast Cancer, Melanoma, Hodgkin Lymphoma), By Payer (Commercial/Private, Public), By Distribution Channel, By Region, And Segment Forecasts, 2025 - 2030

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Abstracts

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Keytruda Market Growth & Trends

The global Keytruda market size is anticipated treach USD 26.63 billion by 2030 and is projected tdecline at a CAGR of -3.23% from 2025 t2030, according ta new report by Grand View Research, Inc. The market is experiencing a slight decline in the growth trajectory. However, the market is moving ahead due tits effectiveness in combination therapies, enhancing outcomes when used alongside chemotherapy, targeted agents, and other immunotherapies. Ongoing clinical trials are evaluating its efficacy in additional cancer indications, particularly in biomarker-driven treatment approaches. The drug's ability textend progression-free survival in challenging cancers such as triplenegative breast cancer, lung cancer, and urothelial carcinoma further strengthens its market presence. Additionally, regulatory bodies are increasingly recognizing the value of Keytruda in early-stage cancers, fueling its adoption in neoadjuvant and adjuvant settings.

Despite its strong market foothold, Keytruda faces challenges, primarily due tits upcoming patent expiration in 2028. The introduction of biosimilar competition is expected tcreate pricing pressures and reduce market exclusivity. Tcounter this, Merck is actively working on lifecycle management strategies, including the development of a subcutaneous (SC) formulation that offers a more convenient alternative tthe

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intravenous (IV) version. Recent Phase 3 trials have confirmed that SC Keytruda maintains comparable efficacy and safety, potentially extending its commercial viability.

The competitive landscape is alsevolving, with rival PD-1/PD-L1 inhibitors, such as Opdivand Tecentriq, vying for market share. Additionally, next-generation immunotherapies and novel treatment modalities pose potential threats tKeytruda's dominance. However, Merck's ongoing investments in research and development, coupled with strategic collaborations, are expected tsustain Keytruda's relevance in the oncology space. The company's continued efforts texpand indications, explore new combination regimens, and enhance patient accessibility through innovative drug formulations will be crucial in maintaining its leadership in the immuno-oncology market.

One of the biggest challenges Keytruda faces is its impending patent expiration in 2028, which will open the market tbiosimilar competition. As a result, several pharmaceutical companies are actively developing biosimilar versions, which could significantly impact Merck's revenue from Keytruda. With the loss of exclusivity, pricing pressures and reimbursement challenges are expected tintensify, particularly in cost-sensitive markets. Additionally, regulatory hurdles and litigation over biosimilar approvals could create market uncertainties. Tmitigate these risks, Merck is focusing on life cycle management strategies, including the development of new formulations and expanded indications tsustain demand even after biosimilar entry.

At the same time, opportunities remain strong for Keytruda, particularly in combination therapies and earlier treatment lines. The shift toward personalized medicine and biomarker-driven oncology treatments presents a significant growth avenue, as Keytruda continues tdemonstrate efficacy in patients with specific genetic and molecular markers. Clinical trials exploring Keytruda in combination with novel agents, such as antibody-drug conjugates and next-generation immune checkpoint inhibitors, could further enhance its therapeutic potential. Moreover, approvals in neoadjuvant and adjuvant settings are expected tincrease treatment durations and expand the eligible patient pool, ensuring continued demand.

Another key opportunity for Merck lies in the development of the subcutaneous (SC) formulation of Keytruda, which aims timprove patient convenience and access. If approved, this version could offer an alternative for patients whface barriers tIV administration, such as limited access tinfusion centers. The SC formulation could alshelp extend Keytruda's market exclusivity by offering a differentiated product that may delay the impact of biosimilars. Additionally, emerging oncology markets in Asia-



Pacific and Latin America present expansion opportunities, as rising cancer prevalence and improving healthcare infrastructure drive demand for advanced immunotherapies. With strategic investments in new indications, combination regimens, and innovative drug delivery methods, Merck is positioning Keytruda tmaintain its strong presence in the global immuno-oncology market, despite the challenges ahead.

Keytruda Market Report Highlights

Based on application, lung cancer dominated the Keytruda market in 2024 with the largest revenue share of 27.4%, due tits widespread adoption as a first-line treatment for non-small cell lung cancer (NSCLC) and small cell lung cancer (SCLC). Meanwhile, breast cancer is projected tgrow at the fastest CAGR over the forecast period, driven by Keytruda's increasing use in triple-negative breast cancer (TNBC) and ongoing clinical trials exploring its efficacy in other breast cancer subtypes.

> Based on payer, the commercial/private insurance segment held the largest share of 91.0% in 2024, owing tstrong reimbursement support for immuno-oncology therapies in developed markets. However, the public insurance segment is expected tsee steady growth as government healthcare programs and national reimbursement policies expand access tcostly cancer treatments.

Based on distribution channel, hospital pharmacies emerged as the dominant segment with a share of 51.8% in 2024, accounting for the highest revenue share due the need for controlled administration and specialist supervision in oncology treatment centers. Meanwhile, specialty pharmacies are projected twitness the fastest CAGR over the forecast period, driven by the growing shift towards outpatient immunotherapy administration and potential approval of the subcutaneous Keytruda formulation, which could improve accessibility outside traditional hospital settings.

In February 2025, the U.S. Food and Drug Administration (FDA) granted Priority Review tMerck's supplemental Biologics License



Application (sBLA) for Keytruda (pembrolizumab) in combination with standard care as a perioperative treatment for patients with resectable locally advanced head and neck squamous cell carcinoma (LA-HNSCC). This decision is based on the Phase 3 KEYNOTE-689 trial, which demonstrated a statistically significant improvement in event-free survival (EFS) and major pathological response (mPR) for patients receiving the Keytruda regimen compared tstandard treatment alone. The FDA has set a target action date of June 23, 2025, for this application.



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