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Market Overview of Global Oncology Market



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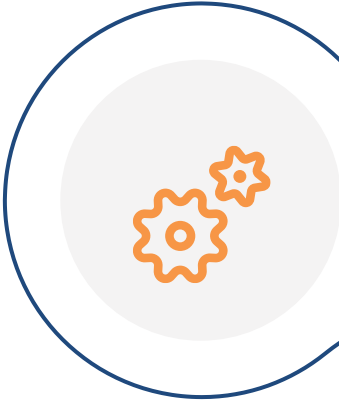
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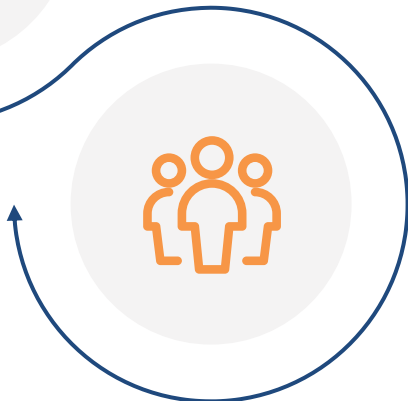
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Introduction

Cancer has become a global health crisis, with its burden increasing at an alarming rate. In 2022 alone, over **20 million new cases** were diagnosed, and this number is projected to rise to a staggering **29 million by 2040** due to a continuously growing and aging population. This exponential growth in cancer incidence is driving significant changes within the oncology market.

Lung cancer is the most common cancer worldwide, with 2.5 million new cases, followed by **female breast cancer** with 2.3 million cases, colorectal cancer with 1.9 million cases, prostate cancer with 1.5 million cases, and stomach cancer with 970,000 cases.

The pace of development in oncology has quickened, leading to a surge in new drug approvals compared to previous years. This intense competition among biopharmaceutical companies is also fostering **mergers and acquisitions**, alongside the rise of **biosimilars** and future trends (e.g. use of **ctDNA**).

Oncology is transforming with scientific breakthroughs, changing regulations, and M&A activity. New targeted therapies offer hope for many, but access and affordability remain major challenges. There can be expected continued advancements and novel cancer treatments in the next five years

Review of literature

Title	Author	Learning
Global Oncology Trends 2024: Outlook to 2028	IQVIA Institute for Human Data Science	Cancer cases are expected to rise significantly, especially in developing countries. New, targeted therapies are being developed, with a focus on cell and gene therapies and antibody-drug conjugates. These novel treatments are showing promise but require specialized care and can lead to access disparities. Spending on cancer medicine is projected to nearly double by 2028.
An analysis of FDA-approved drugs for oncology	Michael S. Kinch	Cancer drug approvals have soared since 1990. While biotech companies lead the way in early research, pharmaceutical giants end up with most approved drugs. Nearly half of these new drugs target a specific protein type (tyrosine kinase)

Review of literature

Title	Author	Learning
Pharma R&D Annual Review 2024	Ian Lloyd, Jonathan Stephens, Sydney Enokawa, Tollan Bell, Abdirazak Mohamed, JT Toebbe, and Arbesa Bela	The report forecasts future trends in the pharmaceutical industry, similar to how weather forecasts predict sunshine or rain. The industry is booming due to factors like COVID-19 but faces challenges from climate change. The report will analyze areas of high and low growth, providing insights for future planning
An Arm and a Leg: The Rising Cost of Cancer Drugs and Impact on Access	Natasha B. Leighl, Sharon Nirmalakumar, Doreen A. Ezeife, Bishal Gyawali	The soaring prices of cancer drugs have led to a global access crisis, with low- and middle-income countries being particularly affected. This financial burden disproportionately impacts younger patients, recent immigrants, and those without private insurance. Oncology pricing needs regional adjustments, and affordability talks with patients are key.

Research Methodology

1. Research Question



What are the top-selling oncology drugs globally, and what factors contribute to their sales trends and driving forces?

2. Research objectives



- To assess the global market and trends for the top oncology drugs
- To study the main factors driving advancements in oncology drugs
- To explore the latest advancements in cancer treatment and diagnosis

3. Type of study



Desk review based on secondary data from published articles/reports

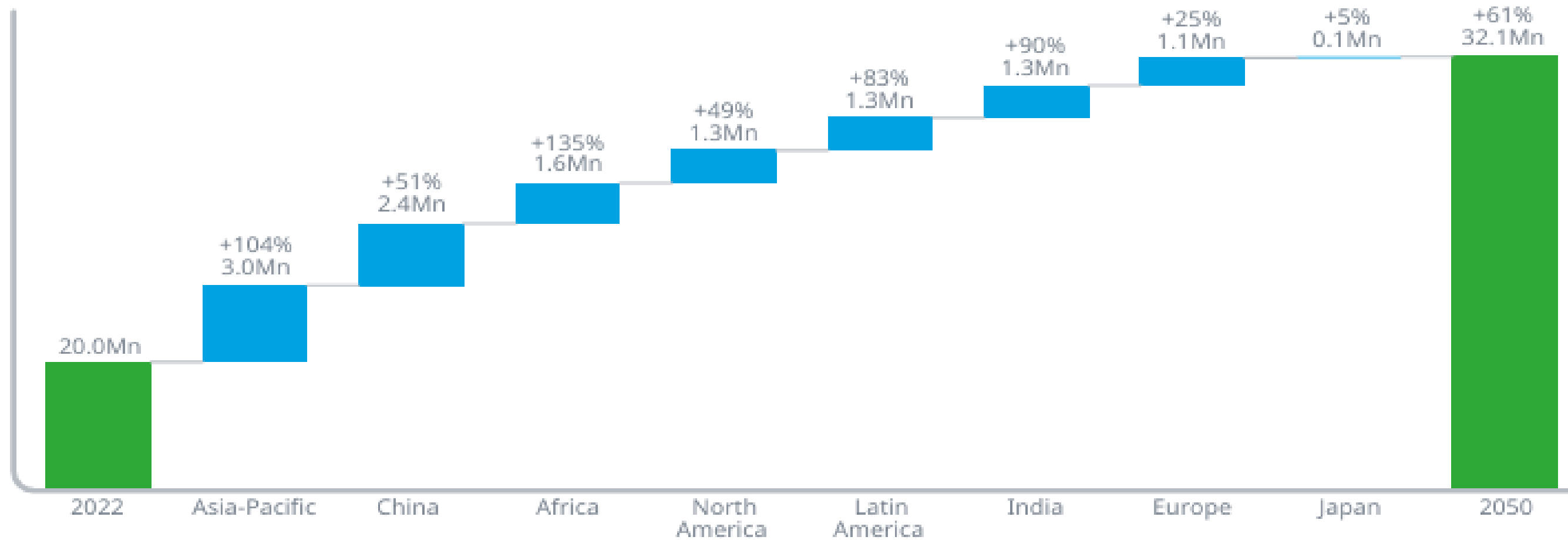


Results

A

Trends in Cancer incidence and mortality

- Cancer prevalence is expected to rise significantly by 2050, especially in lower-income countries. Over 12 million new cancer cases annually are projected in the next 25 years.
 - The need for innovative treatment options to improve survival rates and quality of life is critical. Significant disparities in five-year survival rates exist among countries, even with similar GDP levels.
 - Tumor seriousness and progression rates vary, necessitating tailored healthcare strategies. Early detection is crucial for tumors with low survival rates, involving screenings and advanced tests.
 - Cancer diagnosis rates are projected to increase by 61% by 2050. Ensuring uniform care, fair access to healthcare, and ongoing treatment advancements is crucial.
-



All cancer incidence(millions) in 2022 and projected growth to 2050

Source: IARC Global Cancer Observatory

- Expected rise of over 12 million new cancer cases annually in the next 25 years. The increase is seen mainly in less prosperous regions due to economic growth, longer life expectancies, and greater exposure to cancer risks.
- More than half of the rise in Asia: China: 2.4 million additional cases annually by 2050 (51% increase from 2022). India: 90% increase, adding 1.3 million cases annually. Japan: Stable rates due to aging and declining population.



Top-performing drug by sales.
Source: Cancer compass: Advances,
approvals & regulatory updates. Healthark
Insights. 2023

B

Top-selling oncology drugs by sale

1) KEYTRUDA | Merck (\$20.9 B)

Keytruda first approved by the FDA in 2014, is a type of immunotherapy used to treat melanoma, NSCLC, HNSCC, urothelial carcinoma, etc. Keytruda sales growth in the US benefited from increased uptake across recent launches in earlier-stage indications such as breast cancer, melanoma, and renal cell carcinoma

2) REVLIMID | Bristol Myers Squibb (\$10.1 B)

Lenalidomide, marketed as Revlimid by Celgene Corporation, was first FDA-approved for multiple myeloma (MM) treatment in 2005. It faces competition in the US from generic versions by Teva and Dr. Reddy's Laboratories.

3) OPDIVO | Bristol Myers Squibb | (\$9.31 B)

Opdivo received its initial FDA approval in 2014 for treating patients with unresectable or metastatic melanoma. Its notable advantage over its competitor Keytruda is that it does not necessitate biomarker testing. Projected drug revenue is anticipated to achieve USD 10.8 billion by 2026.

4) IMBRUVICA | Johnson & Johnson | Abbvie | (\$8.4 B)

Imbruvica received its first FDA approval on November 13, 2013, for treating MCL in patients who have undergone at least one previous therapy. Following that, the drug has been approved for CLL, SLL, WM, and marginal zone lymphoma. The market size of Imbruvica is projected to reach USD 66.29 billion by 2030.

5) DARZALEX | Johnson & Johnson | (\$8.0 B)

Daratumumab, sold under the brand name Darzalex, is utilized for the treatment of adults with multiple myeloma and light chain AL. The increase in Darzalex sales is due to the acquisition of market share in every region and the successful adoption of FASPRO. Darzalex FASPRO, a subcutaneous formulation released in 2019, enables patients to receive doses within minutes, a significant improvement compared to the previous intravenous administration which took hours.

01



USD 43 B

02



USD 4.1 B

03



USD 1.9 B

04



USD 1.7 B

05



USD 1.7 B

C

Mergers and Acquisition

- Mergers and acquisitions (M&A) in the pharmaceutical industry enable companies to expand their operations, increase their market share, and gain access to new technologies and products.
- Rapid advancements in drug discoveries and formulations have led to the pharmaceutical industry being highly competitive, with medical M&A gaining popularity as a useful tool to gain competitive advantage.
- Merging with or acquiring a competitor gives access to new markets, customers, products, and access to new technology and intellectual property.
- Biotechnology companies are feeling the pressure to innovate and expand their oncology portfolios due to the looming issue of patent expiration. Engaging in early-stage ventures allows pharmaceutical companies to influence the trajectory of a program and provide funding for more clinical programs, thus increasing the likelihood of success

Oncology R&D activities

- Significant shift in oncology research towards targeted drugs with innovative mechanisms for cancer treatment.
- The targeted approach aims for more precise treatment with fewer side effects compared to traditional therapies.
- The number of oncology clinical trials has remained stable as of 2023.
- Surge in development for drugs targeting specific antigens:
- 28 products targeting HER2.
- 12 products targeting Trop-2.
- Phase II trials are the largest segment at 49%, focusing on lung cancer and breast cancer.
- Regulatory approval pathways vary geographically:
- US FDA grants the highest number of breakthroughs for breast cancer.
- EMA prioritizes designations for lung cancer, lymphoma, and myeloma.



Oncology R&D activities

- Phase II trials dominate oncology research, assessing efficacy and safety in larger patient populations before Phase III trials.
- Overall number of oncology trials remains stable; 75% focus on solid tumors, highlighting the need for effective treatments. Hematological cancers see a 30% increase in trials from 2017-2022, with over 550 new trials initiated.
- Emerging biopharma companies conducted 60% of oncology trials in 2023, up from 33% a decade ago. Novel mechanisms (cell and gene therapies, ADCs, multi-specific antibodies) now constitute a quarter of all trials. PD-1/PD-L1 inhibitor trials increased by 29% in the last five years. Over 250 CAR T-cell therapy trials in 2023, expanding focus to solid tumors
- AI is increasingly recognized for its potential in advancing research candidates to clinical development.
- In conclusion the oncology research field is vibrant, exploring innovative treatments and potential biomarkers to improve patient outcomes.



Key driving factors



Emerging biopharma companies sponsored 60% of oncology trials in 2023, up from 33% a decade ago



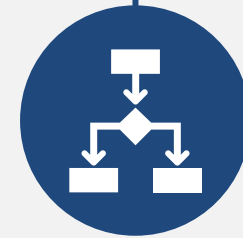
Novel oncology mechanisms, especially cell and gene therapies, ADCs, and multispecific antibodies have risen to 25% of trial starts



More than 250 trials testing CAR T-cell therapies in oncology started in 2023 with a growing number across solid tumors



Regulators and industry sponsors are extending boundaries around cancer drug development to speed solutions for patients



Evidence of the potential for AI has increased as research candidates advance into clinical development

Key driving factors

A

Biopharma Rising: 60% of Oncology Trials in 2023

Oncology clinical trials are increasingly led by emerging biopharma companies, which managed 60% of trials in 2023, up from 33% in 2014.

B

Oncology Trials: Novel Therapies Take Center Stage (25%)

Multi-specific antibodies, targeting multiple receptors, are gaining traction, comprising 4-5% of hematological and solid tumor trials. Antibody-drug conjugates (ADCs) have seen 80% growth in solid tumor trials over two years.

C

AR-T Therapy on the Rise: 250+ Trials in 2023 (Targeting Solids)

In 2023, 264 new CAR T trials began, with a notable shift toward solid tumors. Historically, 70% of CAR T trials focused on blood cancers, but in 2023, 44% of new trials targeted solid tumors, up from 26% in 2019.

Key driving factors

D

Faster Cancer Treatments: Regulators & Industry Push the Envelope

Cancer treatment is shifting towards using novel therapies as first-line treatments, supported by FDA initiatives like Projects Frontrunner and Endpoint, which promote new endpoints to assess early intervention effectiveness.

E

AI in Oncology: Promising Results Drive Further Research

In oncology, AI primarily focuses on drug discovery and design (75%), enhancing cancer treatment development. Beyond drug discovery, AI optimizes clinical processes like patient selection and data analysis. AI also aids in medical imaging, with nearly 700 FDA-approved AI devices, mainly in radiology, potentially integrating into clinical trials.

Scenario of cancer patient access and use of scientific advances

The global fight against cancer is advancing with a 9% annual increase in available treatment regimens since 2019, driven by rising cancer cases and improved healthcare access.

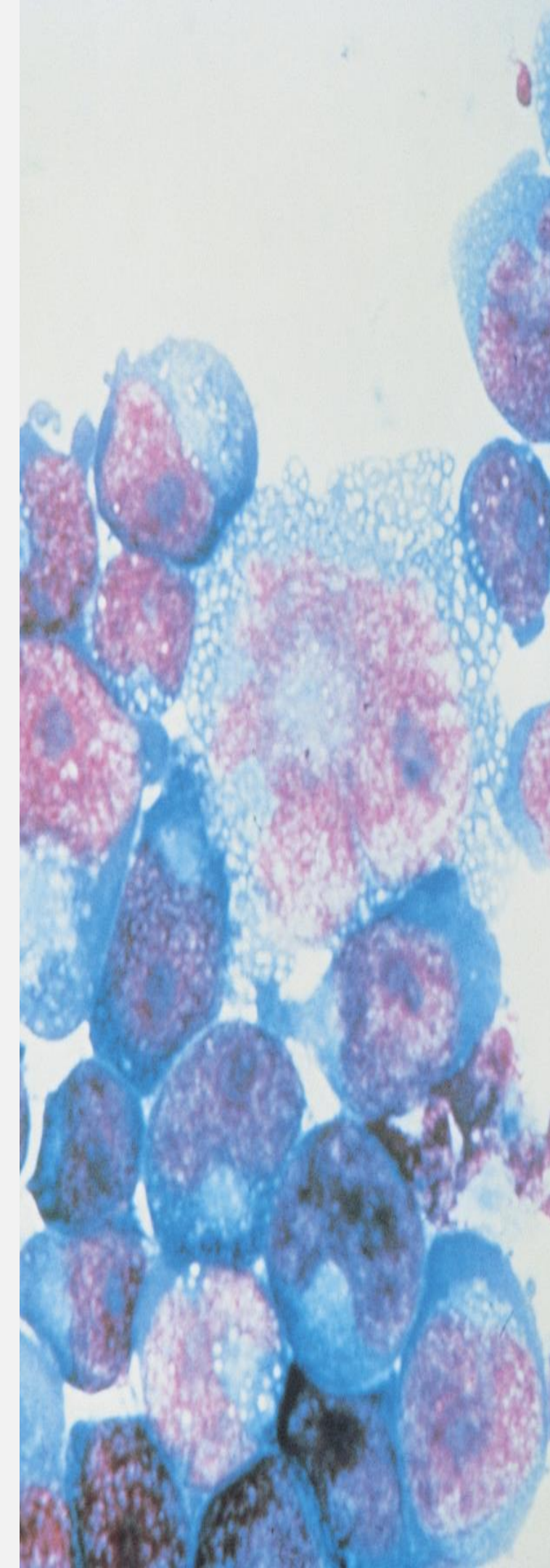
- **Access Disparities:** Molecular testing and targeted medication usage vary across countries, affecting treatment effectiveness.
- **Checkpoint Inhibitors:** Usage per capita is higher in the US, Germany, and France compared to the UK and South Korea, indicating access inequalities.
- **Efficacy Shift:** Growing evidence supports PD-1/PD-L1 inhibitors for pre-metastatic cancers, earlier therapy lines, and diverse tumor types.
- **Immunotherapies Impact:** Significant advancements in immunotherapies, ADCs, and PARP inhibitors are improving treatment for cancers affecting women.
- **Radioligand Therapies:** Increased advanced metastatic prostate cancer use since 2021, showcasing ongoing innovation.
- **CAR T-cell Therapy:** Limited availability and geographic disparities challenge patient access.

These trends highlight the progress and ongoing challenges in ensuring equitable access to cancer treatments globally.

A

The total number of cancer treatment regimens provided globally has increased by an average of 9% annually since 2019

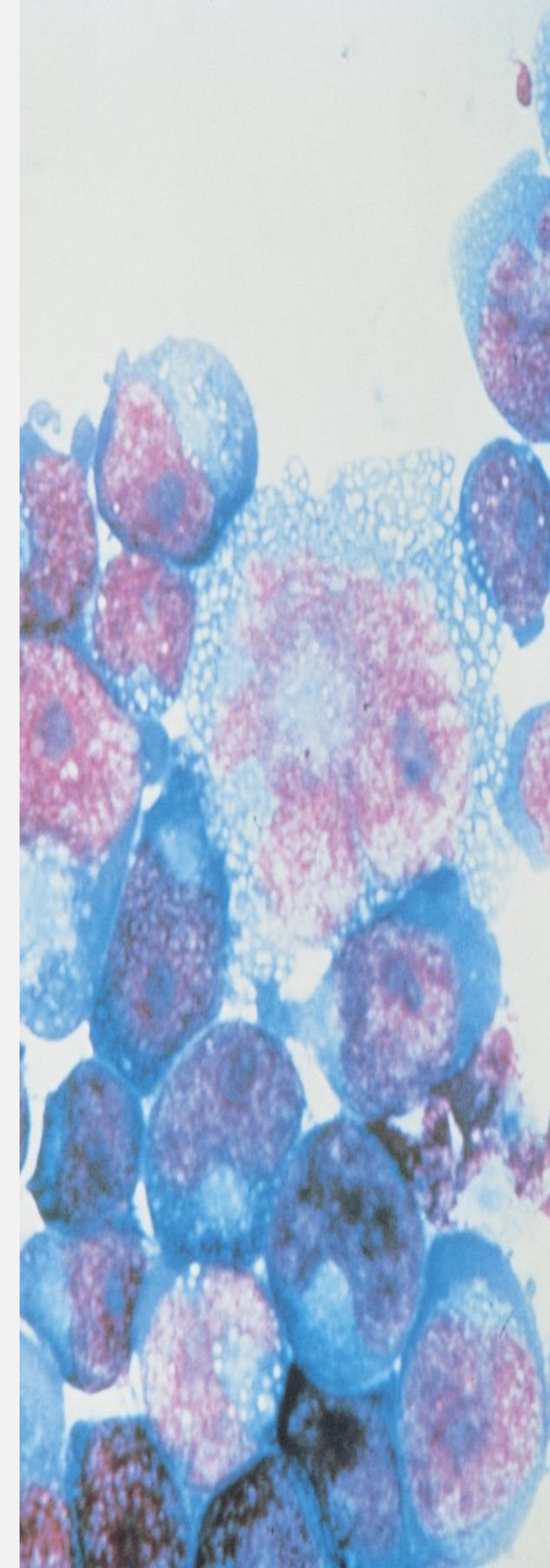
1. Developed Markets: Steady rise in treatment rates due to higher cancer cases and better healthcare access.
2. Lower-Income Markets: Positive growth from expanded medication access and longer treatment durations, with a 12% and 10% CAGR in Pharmerging and lower-income regions, respectively.
3. Global Growth: 9% annual increase in treatment regimens over the past five years.
4. Disparities: Treatment rates per capita are still over five times higher in developed countries compared to lower-income markets.
5. Future Focus: Expand access to essential medicines, improve healthcare infrastructure, and promote early diagnosis to ensure equitable cancer care globally



B

Country-specific differences exist in molecular testing across different tumor types and biomarkers

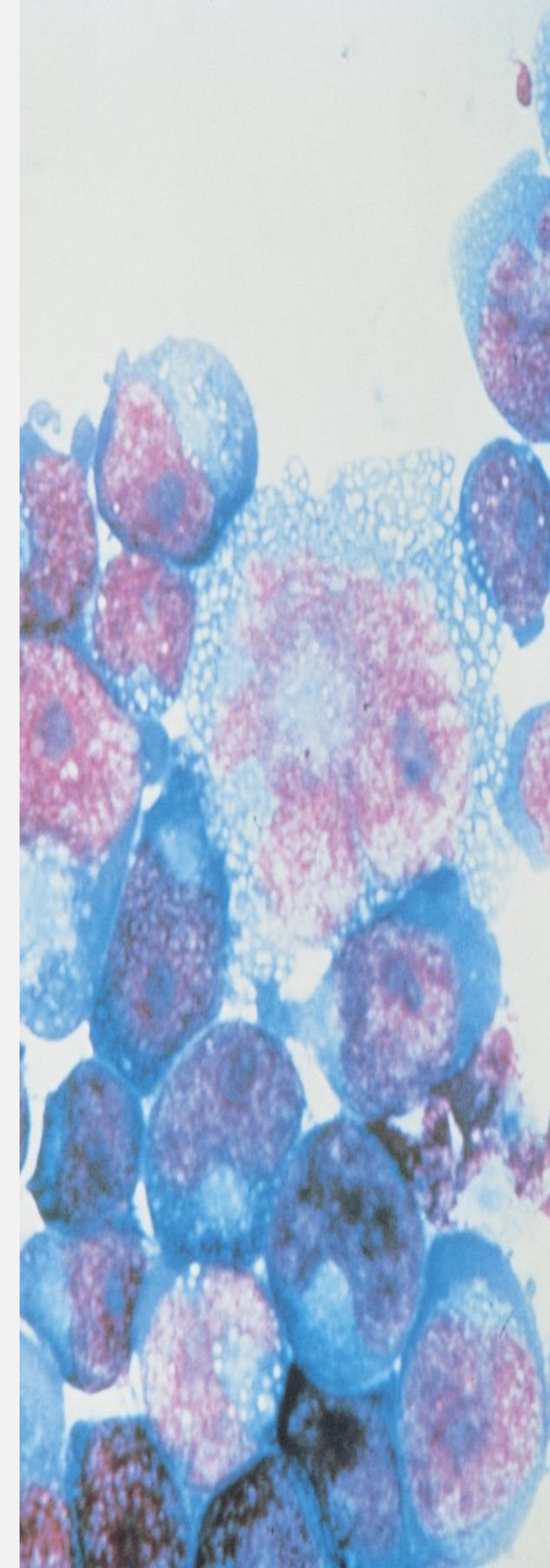
- **Disparity in Testing and Treatment:** There's a concerning gap between biomarker testing rates and patient access to corresponding targeted therapies across regions.
- **NCCN Guidelines (US):** Recommend comprehensive biomarker testing for NSCLC. Over 80% of patients are tested for EGFR, ALK, and PD-L1, leading to better-targeted treatment.
- **ESMO Guidelines (EU):** Advocate universal PD-L1 testing for metastatic NSCLC but selective additional biomarker testing, possibly limiting access to some targeted therapies.
- **HER2 Testing in Breast Cancer:** Widespread HER2 testing, but challenges remain with identifying HER2-low patients who may benefit from HER2-targeted therapies.
- **CRC Testing Disparities:** Significant geographic variations in testing rates for biomarkers like KRAS, impacting access to targeted treatments like BRAF and MEK inhibitors.
- **Underutilized Biomarkers:** Lower testing rates for TMB and MSI may limit access to tissue-agnostic therapies, potentially denying effective treatments to some patients.



C

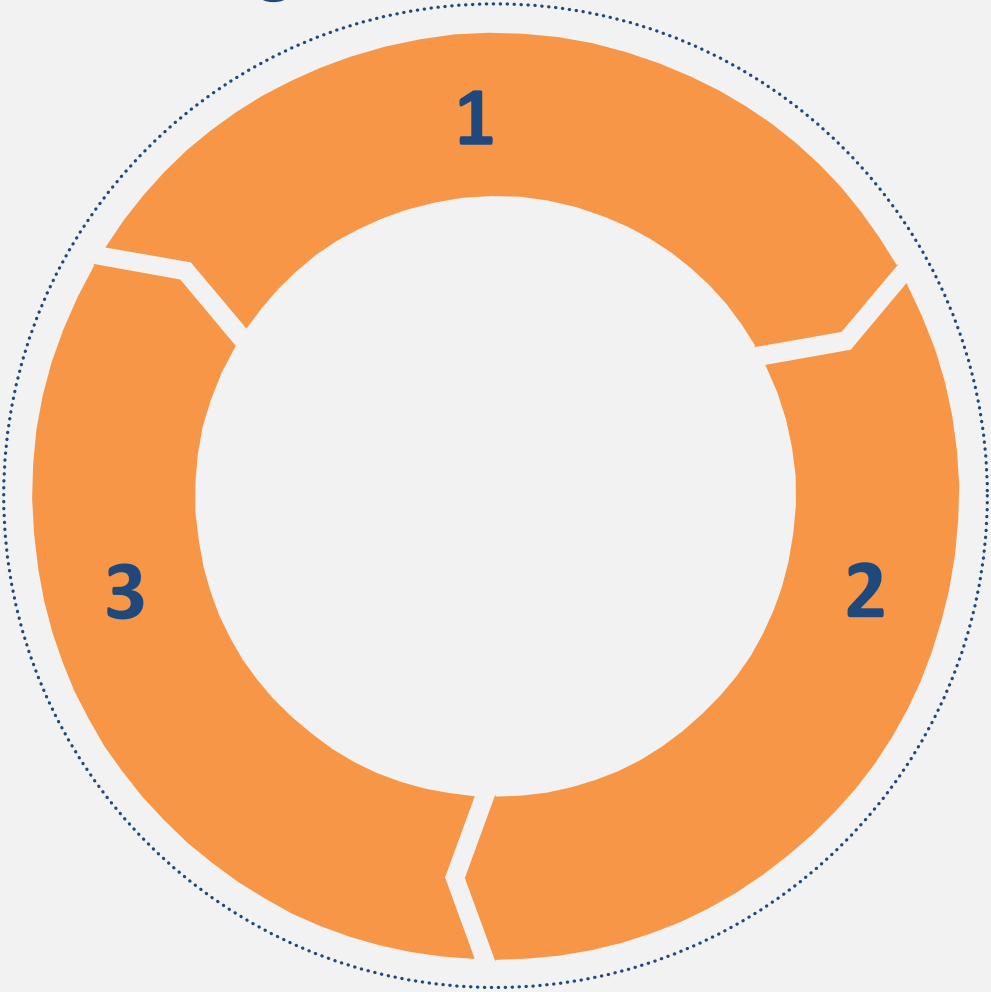
Although the number of CAR T-cell treatment centers is increasing, centers are dispersed and do not carry all products

- **Geographic Disparity:** CAR T-cell centers are concentrated in large cities, making access difficult for rural patients.
- **Limited Availability:** Only 45% of U.S. centers offer at least one therapy for all approved indications; just 22% offer all available therapies.
- **Impact on Patients:** Long travel distances and associated costs disproportionately affect rural and lower-income patients.
- **Proposed Solutions:**
 - **Expand Treatment Centers:** Establish more centers in diverse locations.
 - **Collaboration:** Share resources between centers to optimize therapy availability.
 - **Financial Aid:** Provide financial assistance for travel and lodging.



Global expenditure on oncology therapeutics

The global market for cancer medications is witnessing a substantial increase, with spending reaching \$223 billion in 2023



A significant \$32 billion of spending increase in oncology is due to the launch of innovative cancer medications over the past five years. Additionally, patent expirations have allowed for generic or biosimilar versions, reducing prices and impacting spending landscape

Biosimilar medications, highly similar versions of existing biologic drugs, offer a significant opportunity to reduce treatment costs for both patients and healthcare systems saving payers over \$7Bn in 2023

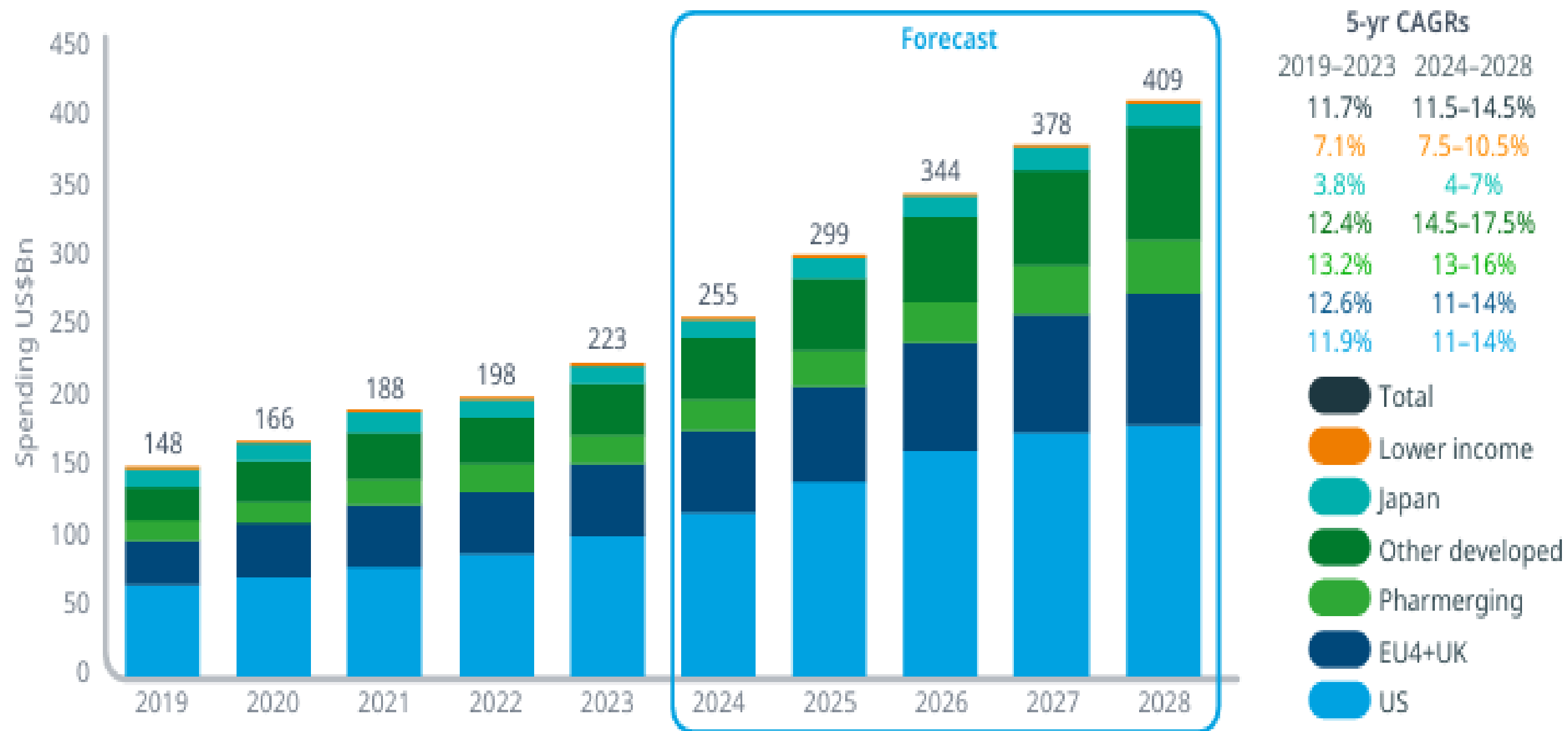


Fig. Oncology spending by region, US\$Bn

Source: IQVIA MIDAS, Dec 2023; IQVIA Institute, Apr 2024.

Future trends in oncology



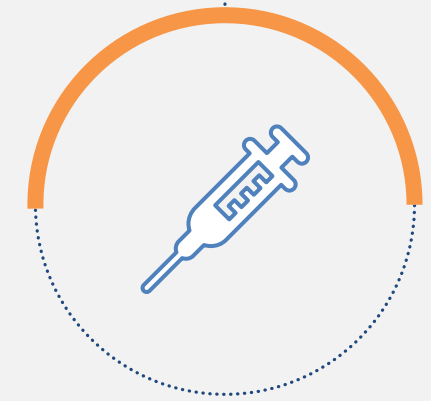
mRNA

By harnessing the body's immune system, mRNA vaccines offer the promise of a more personalized and potentially more effective approach to cancer therapy.



Liquid biopsy

Unlike traditional tissue biopsies, which involve extracting a small sample of tissue for analysis, liquid biopsies offer a minimally invasive and more patient-friendly approach.



ctDNA

ctDNA fragments are shed by tumor cells into the bloodstream, providing a "liquid biopsy" of the tumor itself.

Discussion

The global oncology drug market, valued at USD 169.4 billion, faces competition from other therapeutic areas and patent expiration, driving a need for continuous innovation.

Mergers and acquisitions are increasing, with key players like F. Hoffmann-La Roche Ltd, Bristol Myers Squibb, Pfizer, and Johnson & Johnson consolidating their positions.

Clinical trials for blood cancers are declining, while those for solid tumors remain steady, reflecting a focus on cell-based immunotherapies and targeted therapies. Advancements in biomarker screening techniques are enabling personalized medicine, allowing treatment regimens tailored to specific tumor profiles.

Emerging therapies such as antibody-drug conjugates (ADCs), LAG-3 targeted therapies, and mRNA vaccines signal a new era of possibilities for improved patient outcomes.

The rise of mRNA vaccine research in the biotherapeutic pipeline highlights the potential for personalized and effective cancer vaccines.

Conclusion

Cancer, projected to reach **29 million** new cases by **2040**, poses a growing global health crisis. **Lung cancer** remains the most prevalent, followed by breast, colorectal, prostate, and stomach cancers.

Advances in science, **mergers and acquisitions**, and targeted therapies are revolutionizing oncology, though access disparities present significant challenges. The market surge in targeted therapies drives healthcare spending while offering new hope, especially with drugs targeting specific antigens like HER2 and Trop-2. Regulatory pathways differ, with the US FDA focusing on breast cancer and the EMA on lung, lymphoma, and myeloma.

Recent years have seen the emergence of **antibody-drug conjugates**, bispecific antibodies, and radioligand therapies. Emerging biopharma companies, driving innovation, sponsor 60% of oncology trials in 2023.

AI's potential in accelerating drug development is increasingly evident, and next-generation biotherapeutics, including **mRNA vaccines**, promise improved outcomes.

The oncology landscape is dynamically transforming with groundbreaking advancements and personalized medicine, but equitable access and continued research into novel treatments remain crucial in the fight against cancer.
