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Global Cancer Immunotherapy Market Analysis & Forecast to 2025: Antibody Drug Conjugates (ADCs), Bispecific Monoclonal Antibodies, Cancer Vaccines, Cytokines, Interferons, Chimeric Antigen Receptor (CAR) T-Cell Therapy, PD-1/PD-L1 inhibitors, Dendritic Cells, Checkpoint Inhibitors, Adopted Cell Therapy (ACT) & IDO Inhibitors

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Abstracts

Within the cancer therapeutics space, which today is worth over $160 billion globally, immunotherapeutic drugs have gained worldwide acceptance. This is because they are targeted therapeutics that have high specificity for cancer cells. Today, cancer immunotherapy drugs have captured nearly 50% of the overall oncology drugs market, generating about $75 billion in 2019 alone and are forecast to surpass $143 billion in 2025. This report describes the evolution of such a huge market in 20 chapters supported by over 180 tables and figures in 450 pages.

An overview of cancer immunotherapy that includes: monoclonal antibodies, ADC’s, cancer vaccines and non-specific cancer immunotherapies and CAR T therapies.

Focus on current trends in cancer immunotherapies that include: anti-PD-1 and anti-PDL1 drugs, Dendritic cell vaccines, T-cell therapies and cancer vaccines.

Insight into the challenges faced by drug developers, particularly about the success vs. failure ratios in developing cancer immunotherapy drugs.

Descriptions of more than 23 cancer immunotherapeutics approved and used as

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targeted drugs

Insight into the various immunotherapeutics available for specific cancer types.

Description and data for the prevalence of cancer types that are addressed by cancer immunotherapeutics.

Overall global cancer therapeutics market, leading market players and the best selling cancer drugs.

Detailed account of the market for cancer immunotherapeutics by geography, indication, company and individual drugs.

Profiles, marketed products and products in the pipeline of 79 companies that are located globally

Summary table to identify the category of immunotherapy drug offered by the 79 companies.

Specific chapter on the CAR-T industry detailing manufacturing, regulations and pricing

EXECUTIVE SUMMARY

Immunotherapy is forecast to become the oncology treatment of choice by 2026 with an estimated 60% of previously treated cancer patients likely to adopt immunotherapy in this timeframe. Multiple treatment lines, combination therapy and the opportunity for repeat treatment are likely to accelerate fast growth. Cancer immunotherapy also expands into multiple indications and our analysis indicates that key immunotherapies including anti-PD-1 drugs, dendritic cell vaccines, Tcell therapies and cancer vaccines are all driving the market. The rising incidence and prevalence of numerous cancers globally is a significant accelerator of growth. This is due to more sensitive early detection techniques, higher patient awareness and a growing aging population. Furthermore, the FDA’s pro-science attitude will accelerate development and regulatory approval for these drugs.

To that end, the cancer immunotherapy market is forecast to hit $143 billion by 2025. Overall strong growth rates are expected due to a significant unmet need and

increasing trends of hematological cancers.

Prior to the launching of Yervoy, the five-year survival rate for patients with early stage melanoma was 98%; but the five-year survival rate for late-stage melanoma was just 16%. Yervoy has been reported to have a survival rate of 25% when tested alone. When tested as part of a combination therapy treatment with Bristol's nivolumab, the two-year survival rates rose to 88% for patients with late-stage cancer. Increase in patient survival rates brought about by cancer immunotherapy treatment is similar to that seen when bone marrow transplantation changed our conception on how blood cancer was treated. Other key therapeutic players in this market include Opdivo (nivolumab), Keytruda (pembrolizumab), Tecentriq (atezolizumab), Ibrance (palbociclib) the newly approved Bavencio (avelumab) and Imfinzi (durvalumab) and of course the first CAR-T therapies Kymriah (tisagenlecleucel) and Yescarta (axicabtagene ciloleucel).

Opdivo (nivolumab) from BMS is one of the most exciting agents in the immunotherapy space, and is indicated for melanoma, lung cancer, kidney cancer, blood cancer, head and neck cancer, and bladder cancer. It was given a fast-track approval on December 22, 2014. The majority of immuneoncology agents are anti-programmed death-1 (PD-1) monoclonal antibodies, which will certainly guide the market over the coming years. Projects that currently are valuable include combined immunotherapies on our knowledge of CD137 and PD-1/PDL1 mechanisms. A study on a novel effector activating monoclonal antibody known as IMAB362 for the treatment of solid cancers is also exciting. Other projects comparing CAR-T cell effectiveness against T-cells that target CD19 or mesothelin are interesting in a preclinical setting. Of course, Novartis gained the first CAR-T FDA approval for Kymriah (tisagenlecleucel, CTL019) for children and young adults with B-cell ALL. FDA approved Yescarta (axicabtagene ciloleucel) from Kite Pharma for adult patients large B-cell lymphoma is a major boost for the global and US immunotherapy, and gene therapy markets.

WHAT ARE CAR-T THERAPIES? HOW WILL THEY IMPACT THE MARKET?

CAR T (chimeric antigen receptor T) cells are engineered specificity using antibody fragments directed to the tumor cell, and also T-cell CD8/CD3 plasma membrane proteins that elicit specific activity towards the tumor cell, via intracellular signaling pathways. To date publications have revealed a number of effective intracellular molecules in the engineered T cell including CD28, 4-1BB (CD137) and CD3 zeta. These engineered T cells have numerous advantages including:

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Intracellular domain can be modified to increase efficacy and durability of CAR-T

CAR-T are still subject to the same regulatory and tolerogenic constraints of natural T cells, including checkpoints, Treg, MDSC

CAR-T can be engineered to express cytokines and chemokines that further enhance function and migration

Can be modified to express suicide genes that limit CAR-T population if toxicity occurs

To date, the main challenges associated with CAR T therapy include manufacturing, regulations, pricing and toxicity in patients. Currently there are over 100 recruiting CAR-T clinical trials globally, mainly in the US, China and Europe. To date a number of CAR T Cells (autologous/allogeneic) trials are demonstrating clinical benefit to patients, but others have demonstrated toxicity such as cytokine release syndrome. In July 2017, an FDA advisory panel determined that the benefits of CAR T outperform the risks. Kymriah (tisagenlecleucel) by Novartis is indicated to treat children and young adults with acute leukemia and performed well in the ELIANA trial. The FDA's Oncologic Drugs Advisory Committee (ODAC) recommended this agent for approval and became the first CART cell therapy on the US market. In October 2017, Yescarta (axicabtagene ciloleucel) from Kite Pharma for adult patients large B-cell lymphoma was also given FDA approval.

The CAR-T industry is addressing unmet needs in specific relapsed cancers, and trials have indicated that some patients show long term activity and high remission rates, but there is a large proportion of patients with toxicities such as cytokine release syndrome and neurotoxicity. The main players within the CAR-T market are Novartis, Juno Therapeutics, Kite Pharma and Cellectis. The market is moving ahead, backed by years of R&D, from both academia and industry, investors capitol and small clinical studies. From now on Kelly Scientific forecasts that CAR T therapy will become more streamlined, with faster manufacturing times as advances in technologies take hold and clinical trials provide more robust evidence that this immunotherapy is robust. These factors, plus strategies to reduce adverse reactions and toxicities and larger players like Novartis taking stage will push CAR-T therapy ahead. However, recent deaths in the Juno ROCKET trial are creating questions amongst investors. How will the CAR T space influence the total immunotherapy industry going forward? This comprehensive report scrutinizes the total market and provides cutting-edge insights and analysis.

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KEY QUESTIONS ANSWERED IN THIS REPORT

What is the global market for cancer immunotherapeutics by product class such as MAbs, vaccines and non-specific immunotherapies, through 2025?

What is the global market for cancer immunotherapeutics by geography, through 2025?

What is the global market for cancer immunotherapeutics by indication, through 2025?

What is the global market for MAbs by type such as naked MAbs and ADCs, through 2025?

What are the market values for Herceptin, Avastin, Erbitux, Yervoy, Mabthera, Adectris, and Keytruda?

What is the global market for cancer vaccines?

What is the global market for cytokines in cancer immunotherapy?

The projected market values for Nivolumab, Tecentriq, DCVax-L, Imfinzi?

What immunotherapies have been approved to date?

What monoclonal antibodies (MAbs) were approved by the FDA to treat different types of cancers?

What are naked MAbs and how many of them have been approved by the FDA?

What are antibody-drug conjugates (ADCs) and how many of them are available in the market?

What are the common cytotoxic “wareheads” used in ADCs?

What are the important clinical assets in ADCs?

How many bispecific MAbs are in late-stage development?

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What are the common side effects of MAbs in cancer immunotherapy?

What are cancer vaccines and how many of them have been licensed to be marketed?

How many cytokines have been approved for being used in cancer immunotherapy?

What are the major checkpoint inhibitors in clinical development?

What is the current status of anti-PD-1 drugs, dentritic cell therapies, T-cell therapies and cancer vaccines?

What are the most valuable R&D projects in cancer immunotherapy and what would be their approximate sales revenues in 2025?

Number of melanoma drugs approved to date?

Number of lung cancer drugs approved to date?

Number of brain cancer drugs approved to date?

What is CAR T Therapy?

What are the main challenges associated with CAR T therapy?

What is the status of CAR T therapeutic approval?

What are the current regulations for immunotherapies in USA, Europe & Japan?

What are the main manufacturing steps in CAR T therapy?

What challenges lie ahead for CAR T production?

DATA SOURCES AND METHODOLOGY

Based in Locations in Europe and Asia, our analyst team are all PhD-level experts and

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industryexperienced professionals. They pool resources, contacts, business acumen and technical experience to provide cutting edge insights for all of Kelly Scientific reports. Our senior analysts have at least ten years' experience in major strategic corporations. Our methodologies are clearly defined from the outset. Initially a number of clear objectives are set, e.g., to identify the market size, segmentation, key players, SWOT analysis, influential technologies, and business and economic environments:

By Company (e.g., Merck, Novartis, BMS, Juno, Kite, Cellectis)

By Geography (US, UK, EU)

By Segment (Cancer type, Product Class, Vaccine, Monoclonal Antibody, CAR T therapy)

Key Strengths, Weaknesses and Threats Influencing Leading Player Position within the Market:

Technologies Driving the Market

Top Fastest Growing Market Segments and Emerging Opportunities

Top Pharmaceutical Companies within the by Market Share and Revenue

Comprehensive Product Portfolios, R&D Activity and Pipeline Therapeutics

M&A Activity and Future Strategies of Top Pharmacos

Following this, we determine key financial data & business strategy information to give clients the most accurate information required to identify areas of profitable growth and what technical advantages are required in a competitive landscape:

Company Financials, Sales & Revenue Figures

Business Model Strategies for Diagnostic, Pharmaceutical and Biotechnology

Companies

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Market analysis is initiated using primary research tools such as speaking directly with endusers, identifying their needs and any un-met needs in the market place. This exploratory research identifies any specific requirements in the market, and is tailored specifically to niche markets such as immunotherapy, personalized medicine, targeted therapeutics and companion diagnostics, drug delivery systems, cosmetic surgery and services, and cancer biomarkers. At Kelly Scientific, we have a wide range of contacts within these niche areas that provide us with cutting edge insights to a marketplace that is beyond the reach of many.

We also travel to a wide range of international conferences quarterly to source new data and trends from global experts.

Secondary research performed by Kellyscipub.com is meticulously scrutinized and analysed prior to integration into a final report. We only use validated and confirmed sources of information from company specific corporate websites, annual reports, press-releases, international scientific and medical journals and research reports. All graphical and numerical data included in our reports are referenced and sourced accordingly. Specific websites are consulted and referenced throughout the including that of the Food and Drug Association (www.fda.gov), the National Cancer Institute, World Health Organization, PubMed, Clinicaltrials.gov and other government agencies worldwide. Kelly Scientific utilises the most recent statistical and numerical data available.

Together both primary and secondary research and also unique insights from the chief analysts and editor alike provide the client with a report that exceeds its competitors. We strive to out-perform our competitors, just like our clients.

The project leader and author of this report is a retired college professor with 32 years of experience in teaching biochemistry, biotechnology, pharmacology, cell biology and molecular biology. He also has written 35 healthcare-related market research reports covering medical devices, pharmaceuticals and biotechnologies. Data for this report were collected and compiled from company websites, annual reports, press releases, international scientific journals and FDA documents. Data on the incidence of different types of cancers were collected from authentic sources and they have been appropriately indicated. Kelly Scientific has used the latest available data from reliable sources only; however we cannot guarantee complete accuracy or completeness from secondary information sources.

The senior editor of this research obtained a Ph.D. in Medicine/Genetics/Immunology

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from the Royal College of Surgeons in Ireland, following completion of a M.Sc. in Biotechnology (NUIG) and an honours degree in Biochemistry from Trinity College Dublin. With many years of medical writing and publishing the senior editor also has extensive experience and knowledge of molecular biology, immunology, bioinformatics and diagnostic testing. As a pharma/biotech industry analyst she has significant expertise in laboratory diagnostic testing and instrument and reagent development technology

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