Pitch Deck study for:

Development & Production of Oncology Monoclonal Antibody Drugs

(Nivolumab Biosimilar Development)

Pharmaceutical Technology Centre
PTC ONCOLOGY®

Agenda

- Project summary
- Scope
- Idea and Innovation
- Justification for investment
- Financial summary
- Delivering My Project
- Patent/Market Landscape
- Define Biosimilar
- Develop a new cell line for Pembrolizumab
- Financial summary
- Further costs post cell line development of Nivolumab
- Biosimilar Development Gantt Chart-Pembrolizumab
- Global Sales of Pertuzumab
- Nivolumab Market Outlook
- Nivolumab Market Size and Projections
- Global Nivolumab Market Segmentation Analysis
- Nivolumab Market Drivers

Project summary

My project is based on developing formulation, process design, analytical and manufacturing technology development of monoclonal antibodies as final anti-cancer medicines (injectable dosage forms). Our target will be the development of Nivolumab.

This project will be processed through PTC Oncology along with our technical partner, The Antibody Company-TAC, and will consist of the following three major steps: -

- ***Cell Line for Production of oncology monoclonal antibodies*:**

Cell culture process development starts with cell line generation and selection, followed by process and media optimisation in small-scale systems, including 96-well plates, shaker flasks, and bench-scale bioreactors, for high-throughput screening purposes. Once conditions are defined, the process is often transferred to a pilot scale to test scalability, produce material for preclinical toxicology studies, and then larger-scale manufacturing for producing clinical material under current good manufacturing practices (cGMP) regulations.

- ***Formulation and Manufacturing Process Development of Oncology Monoclonal Antibody Drugs* :**

Pharmaceutical monoclonal drugs will be formulated in specific dosage forms to be administered to cancer patients effectively. Typical pharmaceutical dosage forms for monoclonal antibody drugs are parenteral injections (intravenous -IV), which will be pre-formulated and formulated by high technical standards.

- ***Analytical Method Development and Validation of Anti-cancer Monoclonal Drugs:***

Pharmaceutical analysis method development is essential to support monoclonal product validation, quality, and safety from an early phase of development (R&D) through to the manufacturing process and post-marketing. Analysis method development will reveal the required characterisation, identification, and determination of the start-up materials used in the manufacturing of final monoclonal anti-cancer drug products (as dosage form), as well as the specifications and assays of final monoclonal anti-cancer drug products.

SCOPE

Immunotherapy is a type of biological therapy that uses substances made from living organisms to treat cancer. Immunotherapy is considered a good cancer treatment that helps the immune system fight cancer.

Monoclonal antibodies are proteins produced in the laboratory that bind specifically to targets on cancer cells. Some monoclonal antibodies target cancer cells, allowing them to be more easily identified and destroyed by the immune system. Such monoclonal antibodies are a type of immunotherapy. Monoclonal antibodies may also be called therapeutic antibodies.

Monoclonal antibodies are created in the lab. Antibodies are produced naturally by your body and help the immune system recognise germs that cause disease, such as bacteria and viruses, and mark them for destruction. Like your body's own antibodies, monoclonal antibodies recognise specific targets.

So, these monoclonal antibodies are also immunotherapy because they help turn the immune system against cancer. For example, some monoclonal antibodies mark cancer cells so that the immune system will better recognise and destroy them. An example is rituximab, which binds to a protein called CD20 on B cells and some cancer cells, triggering the immune system to kill them. B cells are a type of white blood cell. Fc receptors for IgG (FcγRs) provide a key link between therapeutic antibodies and the cellular immune system and enable monoclonal antibodies to induce adaptive immune responses. Antibody-induced antitumour adaptive immunity against tumour-specific antigens might already contribute to the patterns of delayed and prolonged antitumour responses seen when antibodies are used alone or in combination with chemotherapy.

Idea and Innovation

The concept behind my innovation focuses on the development of Nivolumab, an oncology monoclonal antibody drug. This involves designing and conducting all necessary pharmaceutical industrial studies required for the development and manufacturing of Nivolumab to obtain marketing authorisation from the MHRA. Once approved, the drug can be produced for commercial use in the UK and globally.

Justification for investment

Why is my innovation and proposal suitable for investment?

This project is considered vital and life-saving for some people suffering from cancer. The innovation of developing and manufacturing monoclonal antibodies for fighting cancer cells deserves more care and attention, in addition to expanding investment in it, due to its valuable effects on alleviating the suffering of cancer patients, accelerating the recovery rate, and reducing mortality. I, with my partner, established Pharmaceutical Technology Centre-PTC Oncology in September 2022 to be the nucleus through which the development and manufacturing of this project. We have made a strong technical collaboration with The Antibody Company-TAC, which is specialised in developing monoclonal antibodies in the UK, to enhance and support PTC Oncology in developing effective monoclonal antibody drugs for oncology use. TAC already has one monoclonal antibody drug in clinical trials that it made for a client. Others are in the pipeline.

The required start-up studies have been conducted for this project, which will enable the success of this project within the required time frame and with the capabilities necessary to complete it. The benefit of investing in this innovative project will be reflected in setting up a highly developed laboratory with up-to-date equipment and employing skilled staff to produce high-quality oncology monoclonal antibody drugs..

Delivering My Project

Who are in the project team? Why do we have the right skills and experience to succeed, and how will we successfully deliver your project?

1-Managing Director, Sameh Qanadilo. Of PTC Oncology. - Rich experience in pharmaceutical formulation and manufacturing process techniques for over 20 years. especially in the formulation and compounding of sterile injectable medicines. • Pharmaceutical Development Expert throughout professional life, has been a result-oriented scientist and a leader with pharmaceutical R&D expertise across dosage forms. Solid Orals. Successfully developed and launched more than 20 liquid injectable products. Developed complex and unconventional technology-driven products, involving, Hot Melt Extrusion, Oral osmotic drug delivery systems, Spray drying, Dry Powder Layering, Immediate release formulations and Delayed release formulations, Capsules, Tablets, Powder for Suspension, Liquid dosage forms, etc. Process Development studies based on QbD and DOE concepts. Developing the drug products for the global market and troubleshooting.

2-Project Director, Eric Wagner is a life-sciences entrepreneur and antibody specialist, and the founder of The Antibody Company, supporting biotech, diagnostics, and research organisations with high-quality antibody and immunoassay solutions. With a strong background in immunology and protein science, he has hands-on experience across antibody discovery, development, purification, characterisation, and assay development. He is particularly skilled at resolving complex technical challenges—such as aggregation, poor assay performance, and scalability—through rigorous yet practical optimisation. Bringing a clear commercial perspective to scientific work, Eric partners closely with clients to translate early-stage concepts into robust, scalable workflows. Known for clear communication and thoughtful problem-solving, he helps teams make confident technical decisions and move programmes forward efficiently.

Patent/Market Landscape

Confirm market

- Market analysis
- What is the market size?
- Competitors

Commission a patent landscape analysis to define

- Market entry strategy
- Expiration current IP
- Its indications
- Formulations
- Dosage formats
- Strengths?

Define Biosimilar

Source originator material and patents

- Sequence originator material (5-10 lots)
- Define consensus protein sequence to take forward (from sequences and public information)
- Define key parameters of Ab, eg N-glycan, charge variants

Develop a new cell line for Nivolumab

Can direct development ourselves

exclusivity

slower

medium risk

TIME: ~8 months

COST: ~1.4M £

Further costs post cell line development of Nivolumab

Enter clinical trial 5-6M £

Phase I clinical trial 10M £

EMA white paper to get rid of clinical phase III

Financial summary

Travel and subsistence

Purpose of journey or description of subsistence cost	Number of times	Cost each (£)	Total
For marketing the oncology monoclonal antibody drugs	15	1,150	£17,250
Total travel and subsistence			£17,250

Financial summary

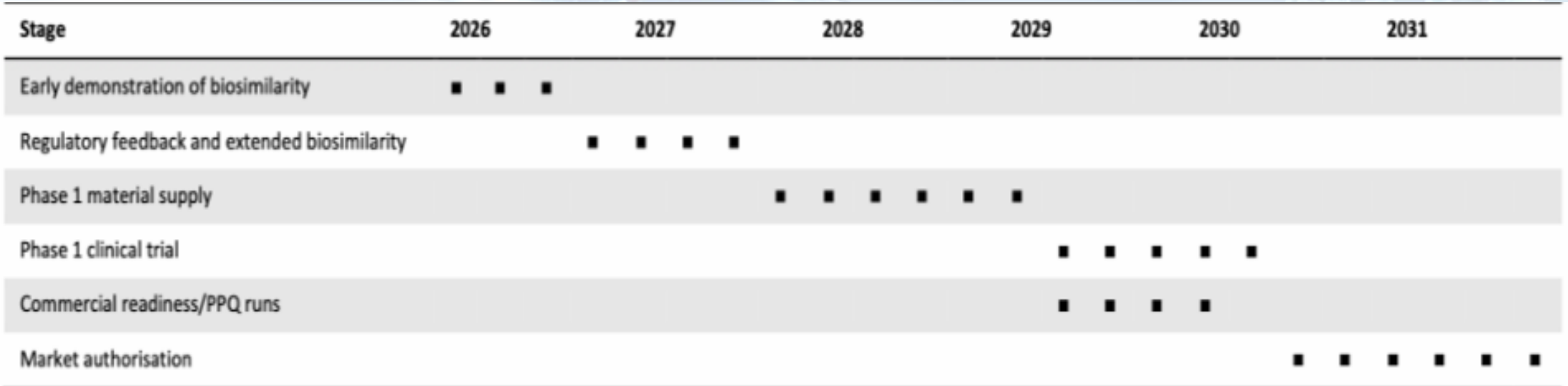
Other costs

Description and justification of the cost	Estimated cost (£)
Overhead costs	£3,026
General administration cost	£20,736

Total Cost

Total project cost	**£ 17,441,012**

Biosimilar Development Gantt Chart-Nivolumab



Global Sales of Nivolumab

The drug's global market was an estimated £3.43 billion in 2025.

And market growth by 2029 will be (15.5%) £ 3.96 billion

(GCC), Sales of Nivolumab are 30,000 - 40,000 vials, = 71,020,600 GBP yearly.

Nivolumab Market Outlook

The global pembrolizumab market size was valued at approximately USD 17 billion in 2023 and is projected to reach around USD 35 billion by 2032, exhibiting a robust CAGR of 8.5% during the forecast period. This significant growth is driven by the increasing incidence of various types of cancers worldwide, coupled with the expanding therapeutic applications of Nivolumab. This monoclonal antibody has shown substantial efficacy in cancer immunotherapy. With its ability to enhance the body's immune response against cancer cells, pembrolizumab has become a cornerstone in the treatment of multiple cancer indications, thereby propelling market expansion.

A key growth factor in the Nivolumab market is the rising prevalence of cancer globally. As lifestyle changes, environmental factors, and genetic predispositions contribute to a higher incidence of cancer, the demand for effective treatment options has surged. Nivolumab, known for its effectiveness in treating advanced melanoma, non-small cell lung cancer (NSCLC), and other forms of cancer, is increasingly being integrated into cancer treatment protocols. The drug's ability to target the PD-1 pathway, thereby enabling the immune system to detect and attack cancer cells more effectively, underscores its pivotal role in cancer therapy. As more oncologists and healthcare providers advocate for immunotherapy as a frontline treatment, the market for Nivolumab is expected to witness substantial growth.

Another significant driver for the Nivolumab market is the continuous research and development activities aimed at expanding its therapeutic indications. Clinical trials exploring Nivolumab effectiveness in a broad spectrum of cancers, such as head and neck cancer, bladder cancer, and Hodgkin lymphoma, are underway. Such studies not only aim to validate its efficacy in new indications but also strive to optimise dosing regimens and combination therapies. The promising results from these trials have spurred interest among pharmaceutical companies and research institutes, further boosting the market. Additionally, ongoing efforts to enhance the drug's effectiveness through combination therapies with other Immunotherapeutics or chemotherapy agents are expected to provide new avenues for market expansion.

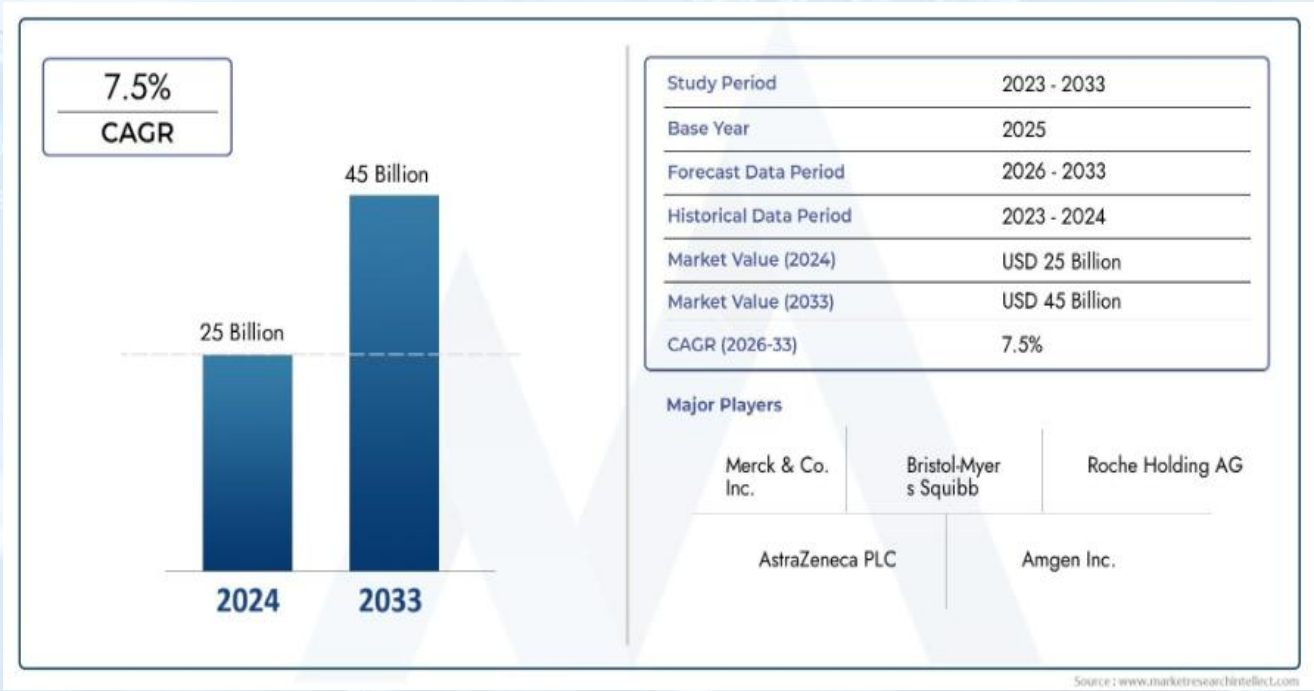
Regulatory approvals and favourable reimbursement policies are also pivotal in shaping the growth trajectory of the Nivolumab market. The approval of Nivolumab by regulatory authorities such as the FDA and EMA for multiple cancer indications reflects its recognised safety and efficacy profile. These approvals not only facilitate market entry in different regions but also enhance the drug's credibility among healthcare providers. Moreover, the inclusion of Nivolumab in national and international treatment guidelines, coupled with reimbursement support from healthcare payers, makes this therapy more accessible to patients. As countries around the world increasingly recognise the importance of immunotherapy in cancer treatment, the market for Nivolumab is poised for significant growth.

Nivolumab Market Size and Projections

The Nivolumab Market was valued at USD 25 billion in 2024 and is predicted to surge to USD 45 billion by 2033, at a CAGR of 7.5% from 2026 to 2033.

The Nivolumab Market is undergoing a major transformation, fuelled by rapid technological innovation, shifting consumer behaviour, and the growing need for smarter, more connected digital environments. As organisations adapt to a more agile and tech-driven landscape, Nivolumab Market solutions are emerging as essential tools to streamline operations and drive strategic growth.

Businesses are leveraging Nivolumab Market technologies to break down silos, automate routine tasks, and better serve customers across both physical and digital channels.
Globally, companies are recognising the value of investing in Nivolumab Market tools, not only to improve performance today, but also to prepare for future demands. Whether it's improving service, supporting hybrid work, or enabling smarter decision-making, the Nivolumab Market is a core part of modern enterprise infrastructure.



Global Pembrolizumab Market Segmentation Analysis

The Global Nivolumab Market is Segmented based on Indication, Administration Route, Distribution Channel and Geography.

Nivolumab Market Drivers

Several influential trends are driving the rapid expansion of the Nivolumab Market :

- Accelerated Digital Transformation - As businesses fast-track their strategies, the demand for robust Nivolumab Market segments is rising. These platforms support automation in their intelligent workflows and real-time data integration, empowering organisations to be more agile and data-driven across all industries.
- Widespread Adoption of Cloud Technologies- Cloud-native Nivolumab Market solutions provide unmatched scalability, flexibility, and lower total cost of ownership, making them particularly attractive for businesses navigating rapid change and growth.
- Rise of Remote and Hybrid Work Models - With remote work now a standard feature of the modern workplace, the Nivolumab Market plays a critical role in supporting distributed teams, ensuring secure access, and maintaining operational continuity.
- Operational Efficiency Through Automation- From automating repetitive tasks to optimising resource allocation, these technologies in the Nivolumab Market help businesses save time, cut costs, and boost productivity across every department.
- Customer Experience as a Competitive Advantage- In an era where customer expectations are at an all-time high, Nivolumab Market tools enable companies to deliver fast, personalised, and consistent service or product, ultimately strengthening brand loyalty and retention.