



Researchers have developed a formulated prototype monoclonal antibody generated from *Nicotiana benthamiana* plants grown in controlled conditions.

PLANT-MADE MONOCLONAL ANTIBODIES TO TREAT AND PREVENT A RANGE OF DISEASES

A portfolio of therapeutic and protective monoclonal antibodies

Addressing a problem and fulfilling a market demand

An increasing demand for monoclonal antibodies and an attractive alternative to costly mammalian options

Monoclonal antibodies (mAbs) are immune system proteins that are used in targeted drug therapy and prophylaxis and are in high demand around the world to fight diseases.

Despite advancements in biomedical technology, current methods for producing mAbs – primarily mammalian cell cultures – can be costly, time-consuming, and pose scalability challenges. Additionally, potential risks like viral contamination in these cultures further complicate matters.

With the global mAbs market expected to exceed USD300 billion by 2025, there is a pressing demand for innovative production methods that can meet the increasing global need. Our combination of non-communicable and infectious disease mAbs will supply an enormous African and global market and impact global health. In the African context, the need for locally produced, affordable mAbs is even more pressing due to the continent's unique health challenges, and barriers to accessing expensive imported treatments. As such, a local, efficient and cost-effective method of mAb production is critically needed.

The technology on offer

A portfolio of therapeutic and protective monoclonal antibodies

CSIR researchers have developed a pipeline of mAb products using an innovative plant-based platform. This technology leverages fleetingly agroinfiltrated plants to produce mAbs with an efficiency and scalability that significantly outpaces current methods. Desired antibody genes are introduced into plants, which then serve as bioreactors, expressing the antibodies in a cost-effective, environmentally friendly and animal-free way, while retaining their critical quality attributes, including post-translational modifications. As part of the portfolio of products, researchers engineered humanised glycosylation and tyrosine sulfation into CSIR-developed HIV mAbs, resulting in potent efficacy. The research team has produced a series of mAbs for treating cancer, autoimmune disorders and infectious diseases like HIV/Aids, rabies and Covid-19.

Value proposition and competitive advantage

Safer, cheaper and faster than other production methods

The plant-based mAb production platform offers a transformative solution to the global demand for these vital therapeutics and prophylactics. By harnessing the power of plant systems, the CSIR-developed approach produces mAbs at a fraction of the current cost (a reduction of up to 50% in the cost of goods), dramatically reducing production time and providing unparalleled scalability. Moreover, plant systems offer an animal-free and lower risk of viral and prion contamination compared to mammalian cultures, ensuring safer products. The technology is set to democratise access to these essential therapeutics across Africa, where they are needed most.

The CSIR-developed antibodies hold several competitive advantages. They offer a safer, faster, more affordable and scalable alternative to current mAb production methods. With the advanced transient agroinfiltration techniques and engineered plants, the reduced upstream capital expenditure costs significantly surpass competitors. For example, the CSIR's leading pipeline product, Rabivir, will be available at a highly cost-competitive price to the public health sector of developing countries. Moreover, the technology enables rapid scalability to meet surges in demand, making it highly responsive to market needs, including emergencies like outbreaks, pandemics, biological warfare, or emerging disease threats.

Market opportunity

Monoclonal antibodies: The fastest-growing class of pharmaceuticals

With the global mAbs market projected to grow annually at a rate of 11%, and reach over USD300 billion by 2025, the opportunity is tremendous. The South African monoclonal antibodies market was valued at USD403.96 million in 2022 and is expected to reach USD969.72 million by 2028, growing at a compound annual growth rate of 15.76%. Monoclonal antibodies represent the fastest growing class of pharmaceuticals and their global access is currently patchy. By focusing on the African region, this innovation addresses a market that is currently overlooked, thus reducing competition and increasing the growth potential.

Business opportunity

Secure a licence to produce biopharmaceutical products using plant-based production know-how or negotiate a production contract

Various business collaboration opportunities are available for uptake of the CSIR-developed monoclonal antibodies through CSIR C³. These include licensing agreements stipulating royalties on the sale of mAb biopharmaceutical products for rabies, HIV and cancers.

Investment and return on investment

Invest to capitalise on the world's pursuit of monoclonal antibodies and an under-served African market

An initial investment of R25 million is required to conduct pre-clinical studies for the leading products. This funding will be used to further mature the pipeline and recruit key talent, expediting the commercialisation timeline.

Milestones and timelines

During the first two years, the investigational new drug-enabling studies for the leading prototype will be finalised. In years three and four, a pilot production facility will be expanded and licensed in collaboration with the CSIR and a clinical trial application for phase I studies will be submitted. Year five and six plans centre on penetration of key African markets; commencement of revenue generation through contracts and licensing agreements; and investment in research and development for potential expansion into other plant-based therapeutics. Year six and onwards will see operational profitability; possible expansion into other global markets, or acquisition by big pharma; and clinical development of the next pipeline molecule.

A team of experts in plant-based production of biopharmaceuticals

The technical team is a highly experienced biotechnology team. The project chief researcher is a PhD-level biomanufacturing expert with a focus on plant genetic engineering and bioprocess development, with numerous patents and publications to his name. The team brings more than 15 years of research and industry experience. The technical business development staff has a successful track record in establishing and nurturing partnerships in the biopharmaceutical industry, both in Africa and globally.

The project has an advisory board comprising prominent researchers, clinicians and pharmaceutical industry leaders in the field of monoclonal antibodies and bioproduction systems.

The diverse project team has the necessary knowledge, skills and experience to help bring this innovative technology to the African market, thereby making a significant impact on the continent's healthcare landscape and health product self-sufficiency.

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