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Cell and Gene Therapy Manufacturing

INVESTMENT OPPORTUNITY

Biotechnology and Pharma

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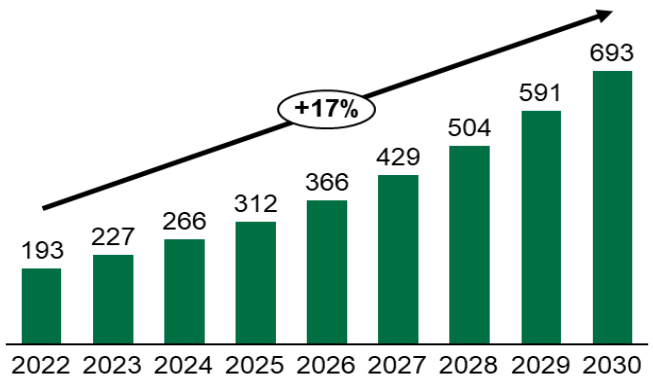
High Potential | Moderate Potential | Low Potential

OPPORTUNITY DESCRIPTION: CGT encompasses a group of novel therapies involving either the manipulation of cells to improve the immune system (cell therapy), or the transfer of genetic material to treat disease (gene therapy). This opportunity addresses the manufacturing of CAR-T and gene therapies[2]

DEMAND

MIDDLE EAST MARKET SIZE, USD M



INVESTMENT OVERVIEW

INVESTMENT HIGHLIGHTS

- Expected Investment size of USD: 25M – 50M
- Manufacturing capacity: 500 – 5000 doses annually
- Expected IRR: 15 – 20%
- Job Creation: ~50 high skilled postgraduate level jobs (e.g., manufacturing science and tech., assay development, regulatory affairs), with average salaries of $70K+ p.a.
- GDP Impact USD: 17M[2]
- Location (Examples): KFSH-RC, NEOM, Dammam

VALUE PROPOSITION

- Commitment to biopharma manufacturing across multiple entities and areas incl. viral vectors, mRNA, and mAbs
- Strong network of specialized clinical providers, with KFSH- RC the largest specialized center in the region and has a dedicated medical genetics department
- Dedicated push on enhancing pharma supply security, with efforts across entities and programs including Industrial Clusters and National Industrial Development Program
- Robust set of ecosystem entities, such as NHIC, SNIH, SFDA, and NUPCO, all of which contribute to strong research, regulatory and execution capabilities required for CGT

MARKET OVERVIEW

KEY DEMAND DRIVERS

- Increasing incidence of cancer, chronic and rare genetic cases (genetic and lifestyle related), driving CGT interest
- Above average occurrences of auto - somal recessive disorders, e.g. cong-enital heart disease, sickle-cell anemia, which can specifically be targeted by gene therapies
- KSA is being developed as a hub for innovative treatments, driving regional demand

EQUIPMENT AND REAGENTS

Gene Therapy
- Cells (e.g., HEK293T cells)
- Media (for cell cultivation)
- Cell handling system
- Chamber
- Bioreactor
- GMP grade plasmids
- Transfection Reagents
- Harvesting system
- Clarification, purification, formulation, and filtration systems

Cell Therapy
- Cell isolation and activation systems
- Viral vectors
- Transduction reagent
- Cell handling systems
- Chambers and flasks
- Harvesting system
- Cryobags and freezing systems

GLOBAL TRENDS

- Oncology, CNS disorders and infectious diseases account for majority of CGT clinical trials, with 2,093 clinical trials in progress globally and 200 in phase 3 (as of June 2022)
- Demand for viral vectors outstripping supply, with 70% of clinical trials in progress requiring viral vectors – low supply driven by complex manufacturing methods and shortage of manufacturing capacity
- Increased focus on improving CGT manufacturing cost and time, through improved supply chains, industrial collaboration and iterative improvements to reduce costs

1) GDP impact solely associated with establishment of the R&D facility. Larger GDP impacts are associated with CGT as a driver of additional research, improved health adjusted life years and other wider health economic impacts
2) This opportunity addresses CGT manufacturing/ product processing specifically, and does not include clinical delivery activities

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SUPPLY

SCALABILITY AND LOCALIZATION

Grade: Low | **Medium** | High

- Supported by multiple biotech manufacturing efforts/ hubs across KSA, presenting opportunities for localization, increasing number of doses produced and introducing additional CGT products
- Notable efforts in KSA to increase security of pharma supply and localize manufacturing
- Ability to serve cumulative demand of GCC, Organization of Islamic Countries (OIC) and MENA as regional pioneer of CGT

CURRENT ACTIVITIES

- Key treatment center involved in delivering CGT (specifically CAR-T therapy) is King Faisal Specialist Hospital and Research Center (KFSH-RC), including clinical trials delivery

VALUE CHAIN

Gene Therapy

R&D and Clinical Trials	Manufacturing: Cell Expansion	Manufacturing: Transfection with plasmids	Manufacturing: Viral Vector Production, and Virus Extraction	Manufacturing: Viral Vector Fill and finish
Early stage and clinical research	Establish cell lines e.g., in bioreactor	Adding DNA plasmids into cells	Harvesting and chromatography	Ultrafiltration and filling vials

Cell Therapy

R&D and Clinical Trials	Manufacturing: Cell Collection and Transport	Manufacturing: T – Cell Isolation	Manufacturing: Viral Transduction	Manufacturing: T – Cell Expansion, Harvesting and Formul.
Early stage and clinical research	Isolation of cells Leukapheresis	T – Cells separated using cell processors	Introduction of new DNA via viral vector	Automated expansion and therapy formulation

KEY STAKEHOLDERS

المجلس الصحي السعودي
Saudi Health Council

وزارة الصحة
Ministry of Health

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

ENABLING FACTORS

ENABLERS & INCENTIVES

- Fixed incentives in place for pharma industry, and potential for customized incentive packages based on discussions with MISA
- Access to established specialized provider network for manufacturing sites (e.g., KFSH-RC)

COST OF DOING BUSINESS IN KSA

Factor	Ranking amongst regional peers
Electricity tariffs for industrial players	$48 /MWh
Productivity adjusted wages	$3.3 /hour
Logistics Performance Index (1-5)	3.2
Construction Costs (Indexed to US, % 0 is cheapest)	74
Ease of getting credit (0-100)	50

Bottom 25% | Top 75% | Top 50% | **Top 25%**

DEFINITIONS

#	SCORECARD SECTION	DEFINITIONS
1	Market size	Size of market in value/volume in KSA and/or Region (MENA/GCC) covering future projections based on available estimates from published /government sources
2	Business drivers	A select number of factors that will influence future demand for the related product/service
3	Investment highlights	An overview of key financial metrics summarizing the investment opportunity along with the expected return based on the suggested investment size
4	Value proposition	Summary of key differentiators that position KSA as a strategic choice over other regional/global peers
5	Market readiness	An overview of KSA market structure, market maturity and level of participation by local and global players
6	Global trends	Latest business developments within the sector/product category
7	Scalability and localization	Ease of scaling the business across the value chain or into new adjacent products or geographies that would maximize the opportunity's investment returns and the ability and potential to locally manufacture the product and its components
8	Import dependency	An overview of the countries from which Saudi Arabia is importing the product and their value/volume and share in total imports
9	Value chain analysis	The process or activities that would potentially need to be carried out to deliver the underlying product or service
10	Key stakeholders	Government institutions, organizations, and/or authorities that participate or influence the market for the underlying product/service
11	Enablers	Factors that enable investment in the underlying opportunity
12	Cost of doing business in KSA	Key factors that position KSA as a competitive destination for investment in the region. Productivity adjusted wages do not include cost of $1.23/hour towards annual recurring charges including work permit, resident identity (iqama) and health insurance

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