REGULATORY ENVIRONMENT

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The Westin Hotel, Cape Town
INTRODUCTION

Strategy to get a COVID-19 vaccine approved in South Africa

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REGULATORY PATH FOR AFRIGEN BIOLOGICS

Regulatory Path 1:

Section 22C license for Afrigen Biologics (PTY) Ltd

Regulatory Path 2:

A Successful CTA application for a Phase I/II Clinical trial
The facility is designed to complement the **platform-based strategy** that ensures the development of a wide range of products with a depth in science.

These platforms are the following:
- R&D and Production of mRNA,
- Innovative Nano Technology Product Design and Manufacturing
- Analytical and Micro laboratories.

**Challenges:**
- Facility design
- Suppliers
- Timelines
- SAHPRA Inspectorate
Without Technology Transfer the Afrigen team stood up for the challenge in building AfriVac 2121.

Based on research work available in public domain the Afrigen team developed the Drug Substance and the Drug Product.

In collaboration with other research institutions:
- University of Witwatersrand
- Vaccine Research Centre (VRC)/ National Institute of Health (NIH)

A series of development batches had been completed and now moving into upscaling and Technical batches before the Engineering batches scheduled in 2nd half of 2023.

Following GMP approval from SAHPRA, the GMP batch planned for early 2024.
Afrigen Regulatory Plan

Objectives of High-Level Plan:
• Outline the regulatory activities for a successful CTA approval of the proposed Phase I/II Clinical Trial
• Identify specific steps and action to meet regulatory activities

CTA pre-submission meeting:
A CTA pre-submission meetings are conducted with an approximately 3 months frequency to ensure an alignment with SAHPRA on the proposed CMC, pre-clinical and clinical plan.

The purpose of the meeting will be:
• To establish clear objectives and to identify what Afrigen aims to accomplish.
• Identify questions that are critical to investigational product development and submission approval.
• To reach consensus on key scientific and technical issues that have arisen during various stages of product development.
• To discuss issues that directly relates to regulatory requirements and guidance documents.
Clinical Trial Protocol

- SAMRC presented the Afrigen Clinical development pathway to SAHPRA and Clinical Trial Committee (CTC).
- SAHPRA and CTC were satisfied with the study design and hypothesis.
- SAHPRA encouraged Afrigen to complete the Clinical Trial Application (CTA).
- Target date for the completion and submission of the CTA is Q3 – Q4 2023.
- Target date for Clinical trial Phase I/II start is Q1 2024
Timelines – Jan 2023

- **First lab scale mRNA vaccine batch**
- **80% Funding secured**
- **Identification of initial 14 technology recipients (spokes)**
- **Clinical trial Phase I/II start**
- **mRNA vaccine GMP clinical trial batch**
- **SAHPRA Regulatory approval to produce GMP Phase I/II material**
- **mRNA vaccine engineering batch**
- **Tech transfer Package 1 complete**
- **Industrialized mRNA platform engineering batches**
- **Industralized mRNA platform GMP validation batches**

**2021**
- Q3: mRNA hub established
- Q3: Mapping IP constraints

**2022**
- Q1: Support to Technology Transfer to 14 spokes
- Q3: GMP Facility, Quality Management System and equipment readiness
- Q3: Technology Transfer (Packages 1-3) to 14 spokes
- Q3: Introductory Training on mRNA technology (9/15 spokes)

**2023**
- Q1: Support design and implementation of Hub manufacturing facilities and processes
- Q3: Establish the R&D mRNA technology platform to manufacture Phase I/II clinical trial material
- Q3: R&D mRNA technology platform transfer from Afrigen
- Q3: mRNA technology platform scale-up and validation

**2024**
- Q1: Evaluation and development of improved 2nd generation mRNA technology

**2025**
- Q1: Evaluation and development of mRNA vaccines for other diseases
Next steps

Preparation for final inspection of SAHPRA

• Virtual inspection by SAPHRA inspectorate to establish a training platform for Africa

Preparation of CTA dossier

• Investigators Brochure

• Pre-clinical documentation (Immunogenicity, Challenge study and Tox study)

• Preparation and compile of Module 3 in support of the Phase I /II Clinical Trial
Thank you!