Presentation Content

1. Overview about BioGeneric Pharma “BGP”
2. Production capabilities & Capacities
3. Products and Pipeline
4. mRNA TT project status at BGP
BioGeneric Pharma “BGP” is an Egyptian private company with multi-national shareholders:

- **Egyptian Private Investors**
- **Saudi Private Investors**
- **Pharco Corporation**
  - "Ranked No. 1 in the Egyptian market in 2019"
- **Amoytop Biotech China**
  - "Listed in the Stock Market"
- **BioGeneric Ltd. USA**
To become a leading biopharmaceutical company in development & production of therapeutic biological products and preventive vaccines

To provide high quality therapeutic biopharmaceutical products and preventive vaccines for saving lives
**BioGeneric Pharma S.A.E**

**Integrated Quality Management System Policy**

**Sys-PY01**


BGP is considered to be a world class biological production facility that operates under global regulatory, quality and safety standards guaranteeing products’ quality accompanied by an environment-friendly production and testing system and providing a safe workplace.

BGP’s aim is to develop, manufacture, analyse and market biopharmaceutical drug products and preventive vaccines in a consistent affordable price all the way through products’ life cycle, focusing on continual improvement through programs appropriate to the nature and scale of risks and aspects and ensuring customer satisfaction, preservation of the environment; avoiding pollution, injury and ill health and complying with laws, regulations and other requirements.

BGP is built on an experienced team of experts from various areas of biotechnology and quality capable of facing any challenges that may occur within the fast growing biotech field.

BGP believes in the diverse contributions of employees and provides extra ordinary value to the customers, community, shareholders and other relevant interested parties.

Dr. Mohamed R. Sayed
CEO BioGeneric Pharma S.A.E
BGP Production Capabilities & Capacities
Brief overview on drug substance production areas’ capabilities

➢ Mixers (50 L to 1500 L)

➢ Tissue culture flasks up to 2000 ml

➢ Bioreactors from 25 L to 2000 L

➢ Clarification systems with depth filters up to 20 m²

➢ Single-use dual chromatography/TFF systems up to 3600 L/h

➢ Systems for the final drug substance filtration up to 2.0 m²

All equipment operate via single use technology & are supplied by PALL®
Formulation and Filling Line (Robotic 3 Lines in 1; Vial, Cartridges and Pre-filled syringes):

Constructed on 850 m²

Pre-formulation, formulation, filtration and filling by using single use technology, supplied by Syntegon® and single use formulation tanks supplied by Merck®

<table>
<thead>
<tr>
<th>Container</th>
<th>Working Capacity/Hour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-filled Syringe</td>
<td>7,536</td>
</tr>
<tr>
<td>Cartridge</td>
<td>5,472</td>
</tr>
<tr>
<td>6R Vial</td>
<td>4,032</td>
</tr>
<tr>
<td>20R Vial</td>
<td>2,120</td>
</tr>
<tr>
<td>50R Vial</td>
<td>1,120</td>
</tr>
</tbody>
</table>
Formulation and Filling Conventional Vial Line:

Constructed on 650 m²
Pre-formulation, formulation, filtration and filling with 300 L and 600 L pre-formulation tanks and 600L sterile receiving tank supplied by Syntegon®

<table>
<thead>
<tr>
<th>Container</th>
<th>Working Capacity/Hour</th>
</tr>
</thead>
<tbody>
<tr>
<td>2R Vial</td>
<td>19,200</td>
</tr>
<tr>
<td>6R Vial</td>
<td>16,000</td>
</tr>
<tr>
<td>10R Vial</td>
<td>13,824</td>
</tr>
<tr>
<td>20R Vial</td>
<td>8,208</td>
</tr>
<tr>
<td>50R Vial</td>
<td>3,072</td>
</tr>
</tbody>
</table>
Brief overview on inspection, labelling and packaging capabilities

Automatic visual inspection machine & 2\textsuperscript{ry} packaging line with track & trace system supplied by Syntegon\textsuperscript{®}

Used for vials, syringes & cartridges.

Capacity of 2\textsuperscript{ry} packaging line is around 100 cartoon/minute
Products’ Overview
### Approved products

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Generic Name</th>
<th>Concentration</th>
<th>Dosage Form</th>
<th>Pack</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BioBeva</strong></td>
<td>Bevacizumab</td>
<td>25 mg/ml</td>
<td>Concentrate for solution for I.V. infusion</td>
<td>Single-dose vial of 4 ml</td>
</tr>
<tr>
<td></td>
<td></td>
<td>100 mg/4 ml</td>
<td></td>
<td>Single-dose vial of 16 ml</td>
</tr>
<tr>
<td></td>
<td></td>
<td>400 mg/16 ml</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Rituxigen</strong></td>
<td>Rituximab</td>
<td>10 mg/ml</td>
<td>Concentrate for solution for I.V. infusion</td>
<td>2 Single-dose vials of 10 ml</td>
</tr>
<tr>
<td></td>
<td></td>
<td>100 mg/10 ml</td>
<td></td>
<td>Single-dose vial of 50 ml</td>
</tr>
<tr>
<td></td>
<td></td>
<td>500 mg/50 ml</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>TrastuThera</strong></td>
<td>Trastuzumab</td>
<td>150 mg</td>
<td>Lyophilized Powder for concentrate for solution for I.V. infusion</td>
<td>Single-dose vial of 150 mg powder</td>
</tr>
<tr>
<td></td>
<td></td>
<td>440 mg</td>
<td></td>
<td>Multi-dose vial of 440 mg powder + 20 ml vial of bacteriostatic WFI</td>
</tr>
<tr>
<td><strong>Finlimod</strong></td>
<td>Fingolimod</td>
<td>0.5 mg</td>
<td>Hard Gelatin Capsules</td>
<td>Pack of 28 capsules</td>
</tr>
</tbody>
</table>

* Toll manufactured
<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Generic Name</th>
<th>Dosage Form</th>
<th>Pack</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biogensulin R Vial</td>
<td>Insulin regular</td>
<td>Solution for S.C.&amp;I.V. injection</td>
<td>Multi-dose vial</td>
</tr>
<tr>
<td>Biogensulin R Cart</td>
<td>Insulin regular</td>
<td>Solution for S.C. injection</td>
<td>Cartridge</td>
</tr>
<tr>
<td>Biogensulin Mix</td>
<td>Human Insulin 30/70</td>
<td>Suspension for S.C. injection</td>
<td>Multi-dose vial</td>
</tr>
<tr>
<td>Biogensulin Mix Cart</td>
<td>Human Insulin 30/70</td>
<td>Suspension for S.C. injection</td>
<td>Cartridge</td>
</tr>
<tr>
<td>Genupart</td>
<td>Insulin aspart</td>
<td>Solution for S.C.&amp;I.V. injection</td>
<td>Multi-dose vial</td>
</tr>
<tr>
<td>Genupart Pen</td>
<td>Insulin aspart</td>
<td>Solution for S.C. injection</td>
<td>Pre-filled disposable pen</td>
</tr>
<tr>
<td>Genupart Cart</td>
<td>Insulin Aspart</td>
<td>Solution for S.C. injection</td>
<td>Cartridge</td>
</tr>
<tr>
<td>Genupart Mix</td>
<td>Insulin Aspart biphasic</td>
<td>Suspension for S.C. injection</td>
<td>Cartridge</td>
</tr>
<tr>
<td>Genupart Mix Pen</td>
<td>Insulin Aspart biphasic</td>
<td>Suspension for S.C. injection</td>
<td>Cartridge</td>
</tr>
<tr>
<td>Glarsulin</td>
<td>Insulin glargine</td>
<td>Solution for S.C. injection</td>
<td>Multi-dose vial</td>
</tr>
<tr>
<td>Glarsulin Pen</td>
<td>Insulin glargine</td>
<td>Solution for S.C. injection</td>
<td>Pre-filled disposable pens</td>
</tr>
<tr>
<td>Glarsulin Cart</td>
<td>Insulin glargine</td>
<td>Solution for S.C. injection</td>
<td>Cartridge</td>
</tr>
</tbody>
</table>
## Under registration products (Continued)

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Generic Name</th>
<th>Concentration</th>
<th>Dosage Form</th>
<th>Pack</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Filgrastim</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biofilgragen</td>
<td>Filgrastim</td>
<td>300 mcg/ml</td>
<td>Solution for S.C, I.V injection &amp; Infusion</td>
<td>Single-dose vial of 1 ml solution</td>
</tr>
<tr>
<td>Biofilgragen PFS</td>
<td>Filgrastim</td>
<td>300 mcg/0.5 ml</td>
<td>Solution for S.C. injection</td>
<td>PFS of 0.5 ml solution</td>
</tr>
<tr>
<td>Enoxaparin</td>
<td>Enoxaparin sodium</td>
<td>20 mg/0.2 ml</td>
<td>Solution for injection</td>
<td>PFS of 0.2 ml solution</td>
</tr>
<tr>
<td></td>
<td></td>
<td>40 mg/0.4 ml</td>
<td></td>
<td>PFS of 0.4 ml solution</td>
</tr>
<tr>
<td></td>
<td></td>
<td>60 mg/0.6 ml</td>
<td></td>
<td>PFS of 0.6 ml solution</td>
</tr>
<tr>
<td></td>
<td></td>
<td>80 mg/0.8 ml</td>
<td></td>
<td>PFS of 0.8 ml solution</td>
</tr>
<tr>
<td>Inactivated Poliomyelitis Vaccine, Sabin Strains (Vero Cell)</td>
<td>Each 0.5 ml dose contains:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Type I (Sabin) 15 DU</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Type I (Sabin) 45 DU</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Type I (Sabin) 45 DU</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Suspension for injection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Single-dose vial Multi-dose vial</td>
</tr>
</tbody>
</table>
Products (Continued)

Technology Transfer Multi-stage Projects:
- Monoclonal antibodies
- Vaccine products

Local Production “Formulation & Filling”
- Fingolimod
- Filgrastim
- Enoxaparin
- Insulin products & analogues “Full-range portfolio”
mRNA Technology Transfer Programme current status at BGP
Visits from WHO/MPP to BGP

- **WHO announcement**
- **Feb - 2022**
  - WHO Headquarter
  - (PQ Team & LPA Unit)
  - WHO RO “EMRO”
  - WHO CO “Egypt”
  - EDA

- **June - 2022**
  - Director general of WHO “Dr. Tedros Adhanom”
  - H.E. Egyptian Minister of Health

- **October - 2022**
  - MPP
  - WHO Headquarter
  - WHO RO “EMRO”
  - WHO CO “Egypt”
  - EDA

- **Jan - 2023**
mRNA Activities Classification at BGP

1. Training on lab-scale mRNA technology at Afrigen in August 2022  - Done
2. Document received regarding introduction to mRNA Technology in December 2022  - Done
3. Gap analysis has been performed by BGP team to identify the needed equipment and tools  - Done
4. Received TT Package 1a on 04/04/2023, and started gap analysis  - Ongoing
5. Preparation for receiving the pilot/commercial scale from the mRNA hub in South Africa  - Waiting
Documents received regarding introduction to mRNA Technology on 04/12/2022
BGP dedicated 2 R&D labs with surface area around 65 m² for mRNA R&D activities
### Gap Analysis with reference to introductory package

#### Gap analysis evaluation form

<table>
<thead>
<tr>
<th>Reference</th>
<th>Requirement</th>
<th>Current state</th>
<th>Gap identified</th>
<th>Description of identified gap (if applicable)</th>
<th>Action needed</th>
<th>Responsibility</th>
<th>Due date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction to the mRNA Technology</td>
<td>Manual for Laboratory Scale Preparation of a COVID-19 Vaccine no. 2022_mRNA2020_001, version 1 Item no. 3 R&amp;D Lab-scale process steps for the production of COVID-19 mRNA vaccine</td>
<td>Equipment, materials and consumables required for R&amp;D Lab-scale process steps for the production of COVID-19 mRNA vaccine</td>
<td>Refer to attachment B</td>
<td>Refer to attachment B</td>
<td>Yes</td>
<td>QC department</td>
<td>Q2/2023</td>
</tr>
</tbody>
</table>

**Conclusion:** Upon performing gap analysis for equipment, materials and consumables required for R&D Lab-scale process steps for the production of COVID-19 mRNA vaccine, some gaps were identified. Most suppliers for missing equipment/materials/consumables were contacted for financial offers as shown in attachment B. For remaining items, suppliers are being contacted to fill in gaps. Change will be reported and assessed in a change control to approve and start implementation.

**Prepared by:**
- Nourhan Hassan
- Eve Nabil

**Revised by:**
- Fawzi Hassan

**Approved by:**
- Fawzi Hassan

---

**05-01-2023_Gap analysis Attachment B_List of requirements to support mRNA lab scale project.docx**
BGP investments in equipment to support mRNA lab-scale activities

After receiving the training at Afrigen, and upon receiving the intro package, BGP started procuring a lot of equipment to support the mRNA TT project.

**mRNA lab-scale equipment availability status at BGP**

- 55% Equipment procured by BGP
- 45% Missing equipment still required to be procured
Equipment supporting mRNA project

- Incucell, Friocell & CO2 Cell Incubators (MMM)
- Biosafety Cabinets (Thermo Fisher)
- Microplate Reader (Tecan)
- Microplate Washer (Tecan)
Equipment supporting mRNA project (Continued)

- Fully automated liquid handling robot System (Tecan)
- Automated Cell Counter (DeNovix)
- Liquid Nitrogen Tanks (Thermo Fisher)
- Inverted Microscope with High Resolution Camera (Olympus)
- (qPCR) Real Time PCR CFX OPUS 96 (Bio-Rad)
Equipment supporting mRNA project

2 Photo stability chambers 404 L (MMM) + 4 Stability chambers 1212 L (MMM) = 6 stability chambers of the German Brand (MMM)
Equipment supporting mRNA project (Continued)

ICP (Agilent)

Liquid particle counter (Beckmann Coulter)

Analytical balances (Sartorius)

Moisture analyzer (Sartorius)

GC (Agilent)

FTIR (Agilent)

UV Spectrophotometer (Agilent)
Equipment supporting mRNA project

- **Sciex PA800 Capillary Electrophoresis**
  - UV Detector
  - DAD

- **Agilent 1290 Infinity II UHPLC**
  - DAD
  - FLD

- **Agilent 1260 Infinity II Bio-Inert HPLC**
  - DAD
  - ELSD

- **Agilent 1260 Infinity II HPLC**
  - UV Detector
  - RID

- **Agilent 1290 Infinity II Bio UHPLC**
  - DAD

- **Agilent Cary 60 UV Spectrometer**
  - Xenon lamp
  - Thermostated Multicell holder
Other Supporting Equipment (Continued)

- Milli-Q IQ 7005 Water Purification System
- Sartorius Analytical Balances
- Vacuum pump
- Ultra sonicator
- pH-meter
- Dry Block Thermostat
- Water Bath
- Hot plate/Magnetic Stirrer
- Vortex Mixer
- Vacuum Concentrator/Lyophilizer
- Thermo Scientific Centrifuges
- Gilson Micropipettes
### Other steps done towards mRNA R&D Activities

<table>
<thead>
<tr>
<th>mRNA activities classification</th>
<th>Identification of target antigen through:</th>
<th>Collaboration agreement with Badr University in Cairo, Faculty of Biotechnology, research centre</th>
<th>Agreement with laboratory animal facility for pre-clinical studies</th>
<th>Agreement with CRO for clinical studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>COVID-19</td>
<td>• Preventive healthcare department MOH</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• EMRO WHO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Africa CDC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Academy of Scientific Research &amp; Technology to identify priorities of researches in Egypt’s healthcare</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non COVID-19</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. On-going
2. Done
3. Done
4. Done
BGP’s strategy for the mRNA platform

**For Covid-19 vaccine:**

- Design for a fit for purpose mRNA pilot production area to be revised in reference to the GMP layout in Afrigen
- Produce pilot batch(es) to ensure implementation & validation of the process
- Waiting to receive commercial-scale package of mRNA COVID-19 to start performing gap analysis
- Complete training for technology transfer of mRNA COVID-19 from South African hub

**For non-Covid:**

- BGP prepared an estimated budget for remaining missing equipment in the lab-scale gap analysis
- BGP dedicated and partially equipped two labs for R&D activities
- Decide along with the Egyptian government, Africa CDC and other entities to identify priorities of target antigens to start R&D activities
Thank you

For more information, check our website:
www.biogenericpharma.com