BioNTainer-based manufacturing in Kigali, Rwanda

Building a resilient vaccine ecosystem

There is still a lack of global access to vaccines: Africa produces less than 1% of the human vaccines it uses. The African Union has set a target for the African vaccine manufacturing industry to develop, produce and supply over 60 percent of the total vaccine doses required on the continent by 2040.

BioNTech believes that mRNA is a powerful new drug class that can help address the global challenge of vaccine access. We aim to contribute by building mRNA-manufacturing capacities where they are needed.

Achieving this target requires a globally coordinated effort. BioNTech is working closely with partner countries from the African Union and local authorities, such as the Africa CDC and Rwanda FDA, European partners, including the European Commission and the European Medicines Agency, as well as global institutions and scientific partners such as WHO, CEPI and the Gates Foundation.

1) https://www.nature.com/articles/d41586-021-01048-1
**The Challenge**

Establishing GMP production for mRNA-based vaccines is complex and time-consuming

Technical solutions for manufacturing sites must comply with internationally harmonized GMP standards

Complex mRNA manufacturing encompassing approximately 50,000 steps that have highest quality standards, including about 40 quality control tests for each manufactured batch to ensure safety and efficacy

Transferring complex processes keeping the systems up-to-date and employing highly qualified personnel

**The Solution**

Modular production units, GMP-compliant set-up and personnel training

Container-based approach with modular design, standardized equipment and software components that can be regularly updated with the aim to remain one of the most sophisticated mRNA manufacturing facilities

Facilitating GMP process implementation and maintenance through validation packages, automation, digital solutions, as well as local and global quality control

Staffing of the BioNTainers and training of local employees

**BioNTainers as a solution to help promote vaccine equity for Africa**

<table>
<thead>
<tr>
<th>Funding</th>
<th>Fully funded by BioNTech to date (committed investment of approximately $150 million)</th>
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</thead>
<tbody>
<tr>
<td>Structure</td>
<td>6-8 containers = 1 module&lt;br&gt;6 containers = 1 drug substance module&lt;br&gt;8 containers = 1 drug product module</td>
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<tr>
<td>Container size</td>
<td>ISO sized (2.6m x 2.4m x 12m)</td>
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<tr>
<td>Shipment</td>
<td>Plane, freighter, truck or train</td>
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<tr>
<td>Production volume</td>
<td>Commercial-scale facility, could manufacture up to 50 million doses annually of a product with an RNA process similar to that of the Pfizer-BioNTech COVID-19 Vaccine</td>
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<td>Associated capabilities</td>
<td>E.g. logistics, quality, control labs, quality assurance set-up, warehousing, cold and frozen storage</td>
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Developing the BioNTainers

16 February 2022
First presentation of the BioNTainers in BioNTech’s innovation center

2024
Plans to complete the set-up and technical installation of the BioNTainers as well as the training of personnel

January 2021
Start of the BioNTainer development (“project Barracuda”)

13 March 2023
Arrival of the first BioNTainer in Kigali, Rwanda

2025
BioNTainers are expected to start operating and manufacture test batches for the validation and regulatory authorization of the facility

27 August 2021
Signing of a Joint Communiqué to build up manufacturing capacities in Africa

18 December 2023
Inauguration of the BioNTech site in Kigali, Rwanda

23 June 2022
Groundbreaking of the first BioNTainer-based facility in Kigali, Rwanda

Construcing a commercial-scale mRNA facility in Africa

The Rwandan facility has a total size of about 35,000 sqm

of which 800 square meters will be occupied by the initial two BioNTainers.

Approximately 190,000 cubic meters of soil were moved during the construction process to level the ground.

A total of 6 buildings are being constructed at the BioNTech site in Kigali.

2 stationary cranes & 2 mobile cranes were needed to build the manufacturing hall, the taller one having a height of 35 m.

The team in Kigali currently consists of 20 members and is planned to grow to 60 members by the end of 2024.

The BioNTainers could in principle produce a range of mRNA-based products, including investigational malaria and tuberculosis vaccines if successfully developed and approved.

Achieved milestones
Current milestone
Future milestones
Manufacturing mRNA-based vaccines in a BioNTainer

1. mRNA production
2. mRNA purification & concentration
3. Drug product formulation
4. Filling & packaging

DS module
6 containers = 1 BioNTainer for drug substance

DP module
8 containers = 1 BioNTainer for drug product