



# GZ Manufacturing Campus

Feb 2024

# First Biologics Manufacturing Facility



## North Campus: Clinical & Commercial Biologics production

## (New) South Campus: Clinical & Commercial ADC production



### Drug Substance

- DS Suite 1-3 with Single-use 2kL and Stainless 5kL
  - Batch and Fed-batch
- Mammalian (mAb, BsAb/TsAb, Fabs, Fusion, Recombinant proteins)

- + ADC Conjugation Room with 250L Stainless-Steel Tank
  - Partnership with CMOs for Linker & Payload supply
- + ADC Purification area equipped with Chromatography and UF/DF systems



### Drug Products

- Isolators
- Liquid vials (clinical & commercial)
- Lyophilized vials
- Pre-filled Syringes (clinical & commercial)
- Label & Packaging

- + Lyophilized vials (ADC)
- + Label & Packaging (ADC)



### Lab & CMC

- QC: Analytical Method Validation & Transfer, Stability & Reference Standard Management
- PD: Cell Line & Process Development (USP to Formulation)
- MST: Tech Transfer to Continuous Process Verification

- + PD (ADC): Conjugation & Purification Process Development, Analytical Development, Fill Finish and Lyo Process Development
- + Linker and Payload Process Development underway to internalize supply in future



### Warehouse

- ASRS (Automatic Search & Retrieval System)
- Storage Conditions:
  - 15 - 25°C, 2 - 8°C, - 40°C, - 70°C

# BeiGene Global Manufacturing Capabilities Overview

## South Campus

## North Campus



48,000 m<sup>2</sup>  
reserved for expansion

## Guangzhou, China Site | Clinical & Commercial Biologics production



### Drug Substance

- DS Suite 4 with Single-use 500L, 2kL and Stainless 5kL
  - Batch and Fed-batch
- Mammalian (mAb, BsAb/TsAb, Fabs, Fusion, Recombinant proteins)
- **ADC (PD and Manufacturing)**



### Drug Products

- Liquid vials & **Pre-filled Syringes**
- Lyophilized vials
- Label & Packaging



### Global Quality Track Record

**> 30 Of Approvals and Inspections In 5+ Years**

(US FDA, EMA, China NMPA, ANVISA, TGA, MFDS, and more)

## Diamond Project

## Sapphire Project



45,000 m<sup>2</sup>  
reserved for expansion

## Suzhou, China Site | Multi-functional Clinical & Commercial Production



### Oral Solid Dosage

- Tablet & Capsule Production
- Primary Packaging (Bottle & Blister)
- Label & Packaging



### Drug Substance

- DS Suite with Single-use 500L
  - Batch and Fed-batch
- Mammalian (mAb, BsAb/TsAb, Fabs, Fusion, Recombinant proteins)



### QC & MST Lab with Global Platform

Analytical Method Validation & Transfer

Global Stability & Reference Standard Center

## Phase I

156,000 m<sup>2</sup>  
reserved for expansion



Q2 2024 Opening  
First US Manufacturing Base

## Hopewell, NJ Site | Clinical & Commercial Biologics production



### Drug Substance

- DS Suite with Single-use 2kL
  - Batch, Fed-batch, and Perfusion
- Mammalian (mAb, BsAb/TsAb, Fabs, Fusion, Recombinant proteins)



### Drug Products

- Liquid vials & Lyophilized vials
- Label & Packaging



### Global PD Lab & CMC Management

Cell Line & Process Development (incl. Formulation)

CMC & Project Management