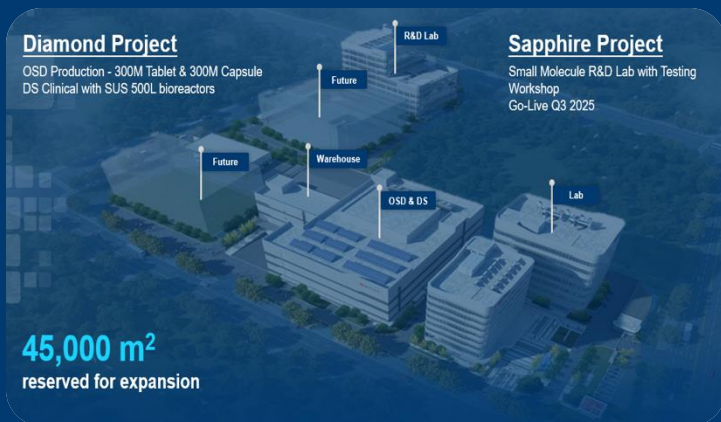




Suzhou Manufacturing Campus

Feb 2024

Multi-Functional Clinical & Commercial Manufacturing Facility



Global Quality Track Record

> 30 Of Approvals and Inspections in 5+ Years
(US FDA, EMA, China NMPA, ANVISA, TGA, MFDS, and more)

Inspections with Zero Critical Observations

Suzhou, China Site



Oral Solid Dosage

- *600M Capsule & Tablet Production Capacity
 - Blending & Sieving, Wet & Dry Granulations, Capsule Filling & Tableting, and Film Coating
 - Primary Packaging (Bottle & Blister)
 - Label & Packaging

*Total capacity expandable to 1 billion capsule/tablet per year in 6-12 months



Drug Substance

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



Lab & CMC

- QC: Analytical Method Validation & Transfer and Testing
 - Raw Material, IPC, Release, Environmental Monitoring, Utility Monitoring
 - Stability & Reference Standard Management
- PD: Process Development, Lab Process Validation, and Transfer
- MST: Tech Transfer to Continuous Process Verification



Warehouse

- Storage Conditions:
 - 15 - 25°C, 2 - 8°C, - 40°C, - 70°C

BeiGene Global Manufacturing Capabilities Overview

South Campus

North Campus



48,000 m²
reserved for expansion

Diamond Project

Sapphire Project



45,000 m²
reserved for expansion

Phase I

156,000 m²
reserved for expansion



Q2 2024 Opening
First US Manufacturing Base

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

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)

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

BeiGene Confidential



Global Quality Track Record

> 30 Of Approvals and Inspections In 5+ Years

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



QC & MST Lab with Global Platform

Analytical Method Validation & Transfer

Global Stability & Reference Standard Center



Global PD Lab & CMC Management

Cell Line & Process Development (incl. Formulation)

CMC & Project Management