

基石药业  
CSTONE  
PHARMACEUTICALS

# Strategic Collaboration between CStone and Pfizer

September 2020

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# Table of Contents



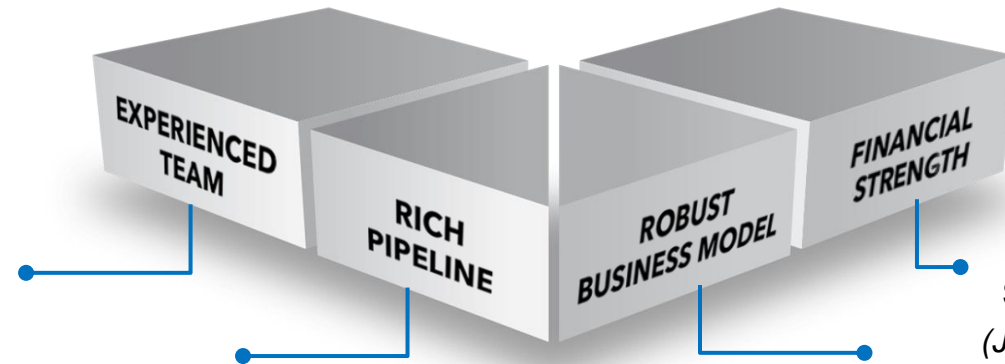
- 1** Opening Remarks
- 2** Transaction Overview
- 3** Key Collaboration Highlights
- 4** Implications For CStone Post Transaction
- 5** Q&A



To Become **Globally** Recognized as the **Leading Chinese Biopharma**

**4 Years Since Company Inception**

**HKEx listed**  
**2616.HK**



**Industry-leading**  
management team

**Well-balanced**  
oncology portfolio with a focus  
on immuno-oncology and  
precision medicine with **5+ NDA**  
**submissions** in 2020

**Integrated**  
biopharma with clear focus  
on clinical development, fast  
ramp-up of manufacturing  
capability, and transitioning  
into commercial stage

**\$150M** + **\$262M** + **\$328M**  
Series A + Series B + HK IPO  
(July 2016) (May 2018) (Feb 2019)

Note: NDA = New Drug Application

# Rapid progress towards commercialization

Expect 5+ NDA approvals for 4 products by 2021



- Robust positive-readout for 3 pivotal trials
- Sugemalimab in Stage IV NSCLC, pralsetinib in RET 2L NSCLC, avapritinib in PDGFRA exon 18 GIST
- Materially de-risked CStone's late-stage assets

**Ivosidenib**  
(IDH1 inhibitor)

**Avapritinib**  
(KIT/PDGFR  
inhibitor)

**Pralsetinib**  
(RET inhibitor)



**Sugemalimab**  
(PD-L1 antibody)

**IDH1**  
r/r AML

**PDGFRA exon 18**  
GIST

**RET**  
2L NSCLC

**1L Stage IV NSCLC**  
(squamous & non-  
squamous)

*Taiwan, China*  
*Singapore*

*Mainland China*  
*Taiwan, China*

*Mainland China*  
*Taiwan, China*

*Mainland China*

**NDA regions**

# Table of Contents



- 1 Opening Remarks
- 2 Transaction Overview
- 3 Key Collaboration Highlights
- 4 Implications For CStone Post Transaction
- 5 Q&A

# Transaction overview



A strategic and multifaceted collaboration with Pfizer, a leading multinational biopharmaceutical company

## Equity investment: \$200mm

- Pfizer to invest \$200mm in CStone for use in research and development, at approximately HK\$13.37 per share
- Pfizer to own 9.90% of CStone's enlarged capital post transaction

1

### China commercialization of sugemalimab

- Pfizer to **in-license sugemalimab (PD-L1 antibody)** from CStone, a potential best-in-class PD-L1 antibody, in mainland China
- In addition to the equity investment premium, CStone is entitled to receive **up to \$280mm** in milestone payments and tiered, **mid-to-high teens** royalties

2

### Co-development of Pfizer's assets

- CStone and Pfizer to together select **post proof-of-concept ("POC") oncology assets** for co-development, for which CStone will lead clinical development and Pfizer will lead commercialization in Greater China
- CStone to receive **low double-digit royalties** for Pfizer's assets

3

### Joint in-licensing of global innovative drugs

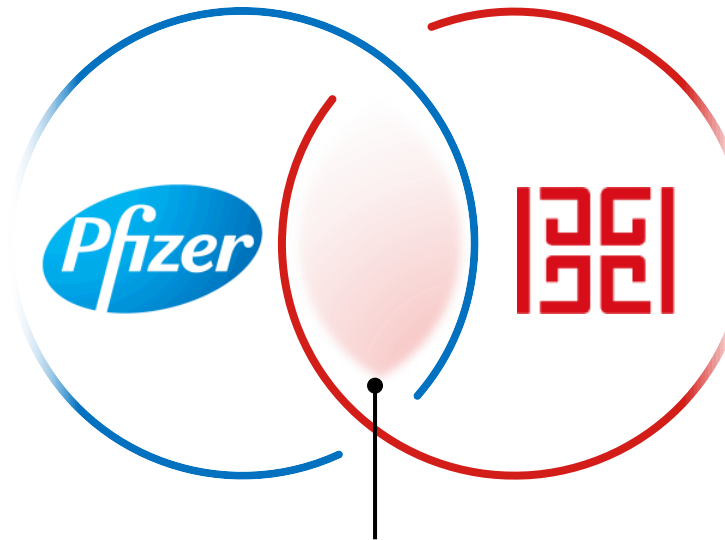
- CStone and Pfizer to **jointly in-license other oncology therapies for Greater China market**
- CStone and Pfizer to determine responsibilities on an asset-by-asset basis, while retaining an **option for CStone to participate in co-promotion**

# A collaboration based on complementary strengths



## Pfizer

- A global pharmaceutical leader with prestigious brand value
- Extensive commercialization network in China
- Leading oncology franchise with robust pipeline of drug candidates



## CStone

- An emerging leader in the biopharmaceutical industry in China
- Sugemalimab, a commercial-ready, potential best-in-class PD-L1 asset for large indications
- Superior clinical capabilities with strong execution

## Synergistic Collaboration

Long-term collaboration solidified through equity investment

Faster and broader commercialization of sugemalimab in China

Competitive platform for in-licensing deals to allow rapid expansion of pipeline



# Compelling financial benefits and strategic rationale



## Significant Financial Benefits

- Bolsters CStone's ability to fund development of sugemalimab
- Frees resources to focus on broader strategic development objectives

## Maximizing Potential of Sugemalimab in China; Retaining Ex-China Rights

- Boosts the addressable market of sugemalimab by harnessing Pfizer's industry leading commercialization capabilities in China
- CStone to retain all development and commercialization rights of sugemalimab outside mainland China

## Innovative Collaboration Model

- Framework for CStone and Pfizer to collaborate on co-development and joint in-licensing in ways that leverage each other's strengths
- Additional source of innovation secured for pipeline development of both companies

## Advancing CStone into a Fully Integrated Biopharma

- Further built on a well-established clinical engine and rapidly ramped-up manufacturing capability, this transaction will enhance:
  - CStone's capability to execute Pipeline 2.0 strategy with dual sourcing of innovation focusing on first-in-class and best-in-class assets with global rights
  - CStone's capability of building a full-fledged commercial organization with near-term ambitions to reach "critical mass"

## Importance for the Patient Community

- Patients to obtain faster and broader access to a highly differentiated PD-L1 treatment and future first-in-class and best-in-class treatments
- CStone to become a key player in addressing China's critical public health needs

# Table of Contents



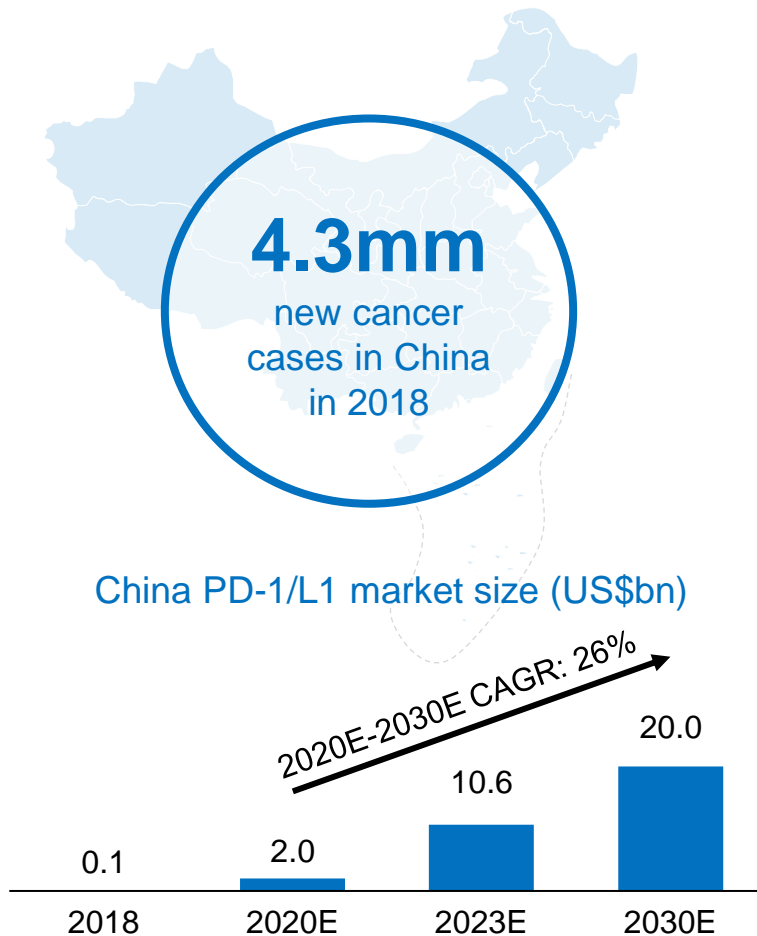
- 1 Opening Remarks
- 2 Transaction Overview
- 3 Key Collaboration Highlights
- 4 Implications For CStone Post Transaction
- 5 Q&A

# 1 China commercialization of sugemalimab

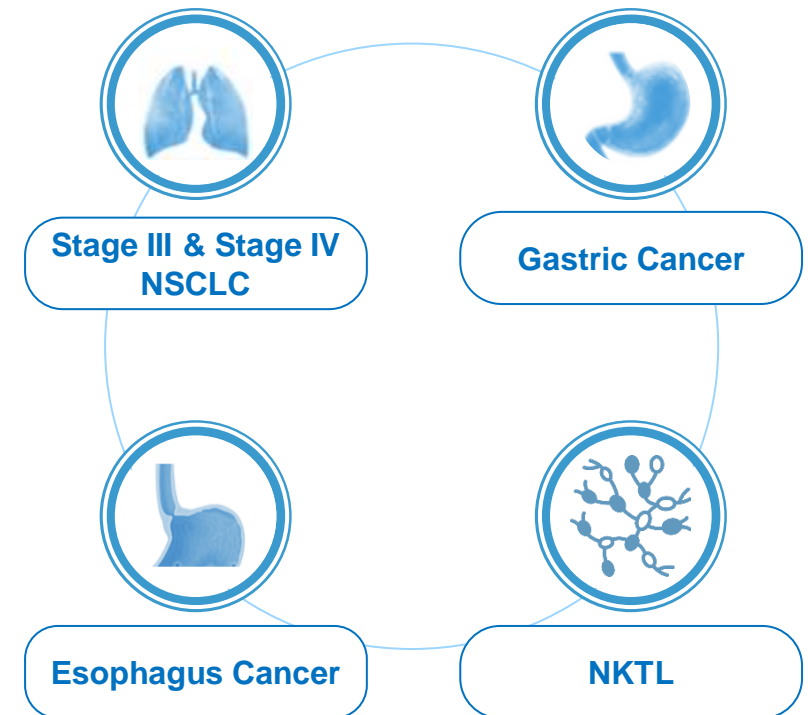


Sugemalimab is strategically positioned in large oncology indications in China

## PD-(L)1 is a huge and burgeoning market in China



## Sugemalimab's indication coverage includes high-incidence indications in China



Note: NKTL = Natural killer /T-cell lymphoma  
Source: Globocan 2018, Frost & Sullivan

# 1 China commercialization of sugemalimab



Pfizer is the ideal partner to maximize commercial success of sugemalimab in China

## Four key success factors to win in this market



Proven leading commercial capability in China



Broad and deep coverage in local market



Established commercial relationship with hospitals



Rich experience in NRD negotiation

## Pfizer's leading oncology franchise in China



Note: <sup>1</sup> Breast cancer, lung cancer, renal cell carcinoma, gastrointestinal cancer, and hematology

## 2 Co-development of Pfizer's assets

Fully leveraging synergistic strengths of CStone and Pfizer



By leveraging CStone's clinical development capability and Pfizer's commercialization capability, both parties will together bring innovative oncology therapies to the patient community in China

### Collaboration framework



- Near-term timeline clearly defined
- Post POC assets only in the scope
- Low double-digit royalties on Pfizer's assets



### Leverages each company's strengths



- ✓ Proven execution excellence in clinical development
- ✓ Deep knowledge of regulatory pathway and oncology market in China



- ✓ Expansive commercialization infrastructure in China
- ✓ Exceptional multi-national brand
- ✓ Rich pipeline of oncology assets

### 3 Joint in-licensing of global oncology assets



Maximizing in-licensing competitiveness for highly sought-after opportunities



- *An innovative collaboration model between a China biotech and a MNC*
- *Target highly sought-after, late-stage or commercial stage assets*



Proven track record of in-licensing late-stage, global first-in-class assets in China market



Exceptional brand value and China commercial capabilities

#### Advantages of joint in-licensing model

- ✓ Complementary strengths and portfolio synergies to maximize financial return
- ✓ Potential for CStone to participate in commercialization
- ✓ Flexibility maintained to in-license and commercialize separately

# Significance of the collaboration to CStone



- 1** Significant financial benefits from \$200mm equity investment at approximately HK\$13.37 per share, up to \$280mm milestone payments and additional tiered royalties
- 2** Maximizes commercial potential of sugemalimab, a potential best-in-class PD-L1 antibody in China
- 3** Further solidifies clinical development leadership in China with additional avenues for cash flow generating arrangement
- 4** Vote of confidence by a MNC in a leading China biotech platform
- 5** Allows patients faster access to a highly differentiated PD-L1 treatment

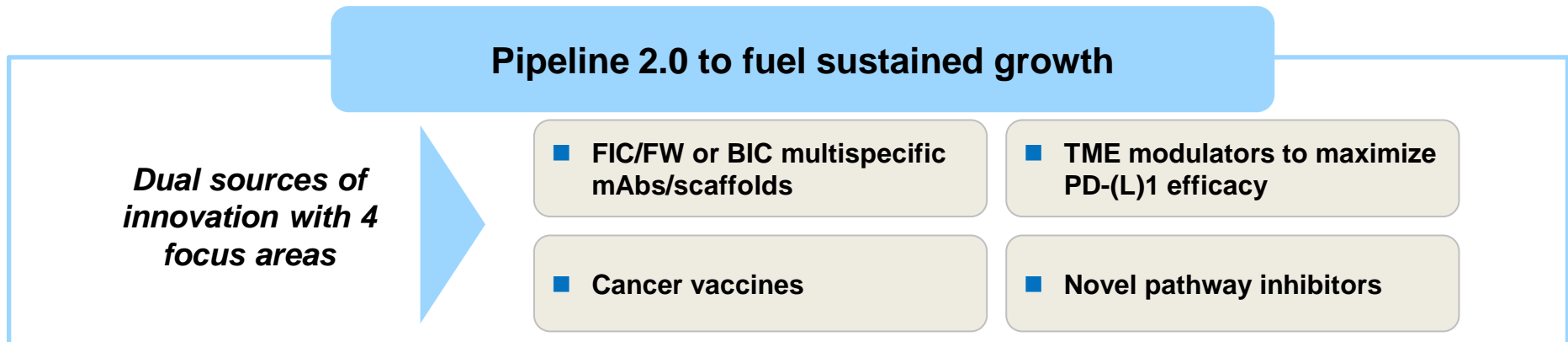
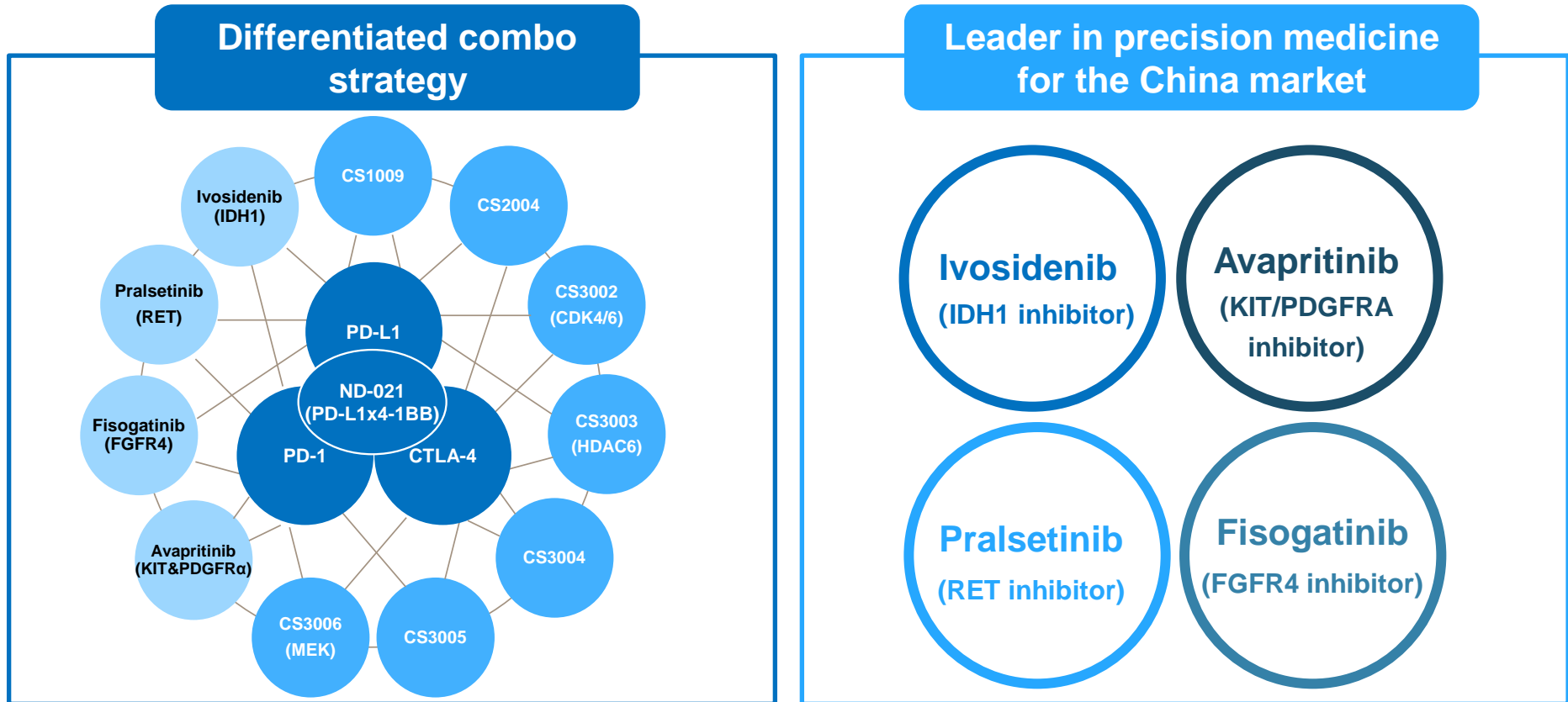
# Table of Contents



- 1 Opening Remarks
- 2 Transaction Overview
- 3 Key Collaboration Highlights
- 4 Implications For CStone Post Transaction**
- 5 Q&A



# The strategic deal enhances our ability and resources to pursue our winning portfolio strategy



Note: FIC = first-in-class; FW = first-wave; BIC = best-in-class; TME = tumor microenvironment

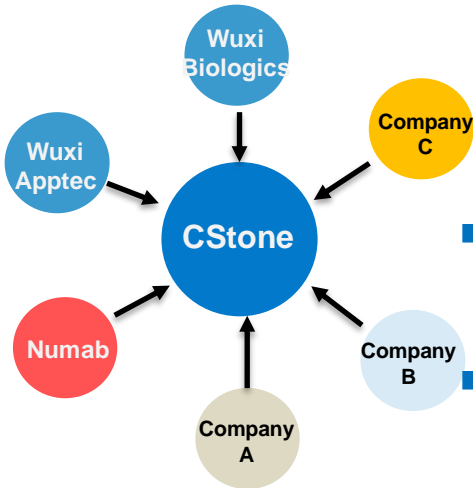
# Better equipped to execute pipeline 2.0 with dual sourcing of innovation focusing on FIC / BIC assets with global rights



1

## Internal Research

CStone research model – “**Hub & Spoke**”:  
**40** INDs delivered for 12 assets since company’s formation



- A fully integrated research team composed of cancer biology, pharmacology, DMPK/Tox and bioinformatics. All functional leaders have over 10 years’ experience in drug discovery and IND filing
- CStone initiates projects, identifies targets and leads the process from lead identification to IND
- Leverage leading technology platforms from CROs or biotech partners for lead discovery and optimization

### Upcoming for pipeline 2.0

- Multiple targets identified and having on-going discussions with platform partners
  - Multi-specifics
  - Target B
  - ...

2

## Partnerships

- Proven track record of licensing global FIC / BIC assets
- Active partnership discussions anticipated to come to fruition in near future



### Strong pipeline of potential partnerships

- ADC
- Novel fusion protein
- Cancer vaccine

# Further solidified clinical development leadership in China



## Early stage

### Transition to late stage

**1**  
Asset

Fisogatinib  
(FGFR4)

- Global FIC
- Explore registration pathway for mono

### Advance to combination POC

**5**  
Combos

CS1002  
(CTLA-4) +  
CS1003 (PD-1)

Fisogatinib +  
CS1003

Donafenib +  
sugemalimab

Regorafenib+  
Sugemalimab  
/ CS1003

NM-1480  
(PD-L1/4-  
1BB/HSA)

### Continue to identify mono RP2D

**2**  
Assets

CS3005  
(A2a)

CS3002  
(CDK4/6)

## Late stage

### 2 potential BIC I/O assets

**6**  
Indications

Sugemalimab  
(PD-L1)

CS1003  
(PD-1)

### 3 FIC / FTC precision medicines

**7**  
Indications

Pralsetinib  
(RET)

Avapritinib  
(PDGFRA)

Ivosidenib  
(IDH1)

### New post-POC assets under Pfizer co-development

**Additional assets**

Asset 1

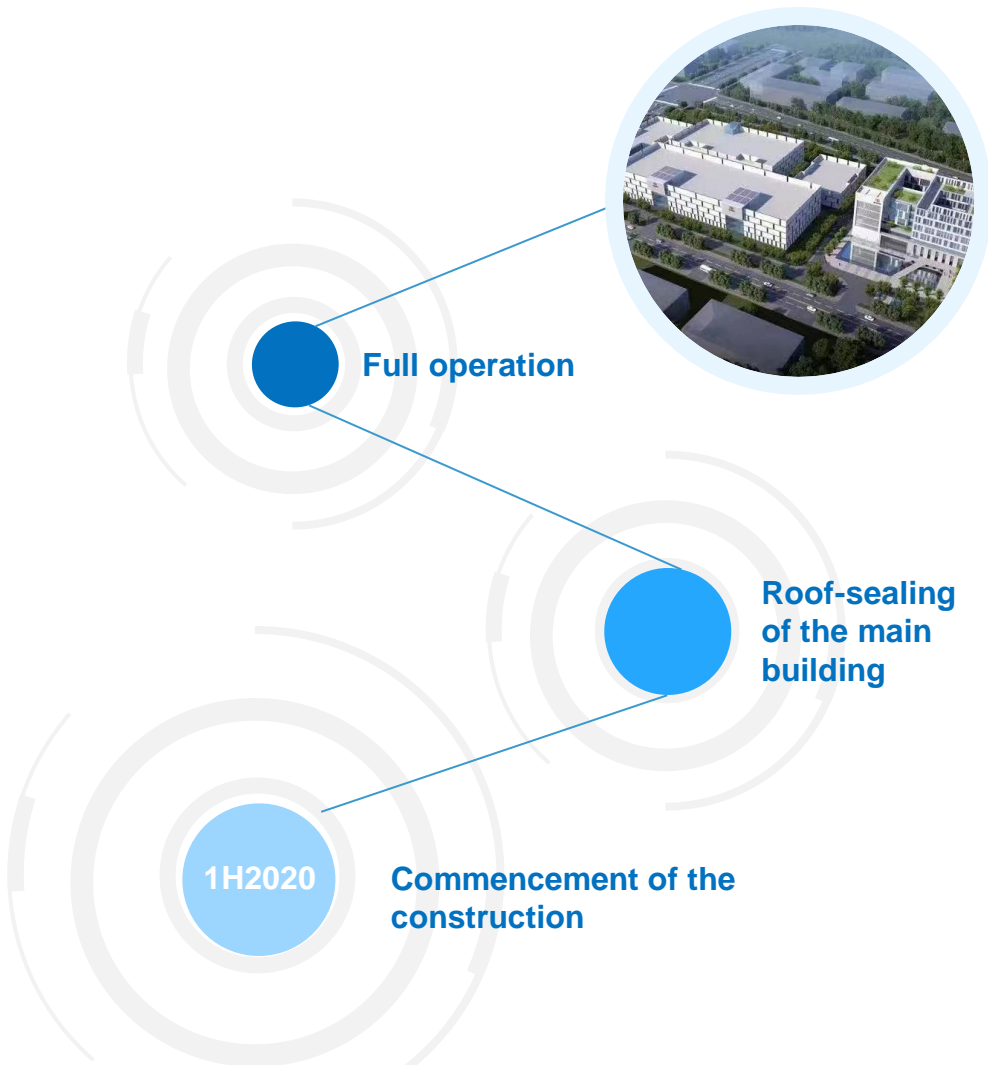

Asset 2

More to come...


# State-of-the-art manufacturing facility to secure supply for sugemalimab and other CStone assets




■ CStone will be responsible for manufacturing sugemalimab and commercial supply to Pfizer <sup>1</sup>

**1 billion** tablets for small molecules



**26,000L** for biologics



Planned building area of approximately **100,000 sqm**

Compliance with GMP requirements in China and globally



R&D



Pilot Plant



Full Commercial Scale Manufacturing

Strategic partnership with **WuXi Biologics** Global Solution Provider on clinical and commercial stage manufacturing

Note: <sup>1</sup>Subject to the terms and conditions set forth in the Collaboration Agreement

# Clear strategy towards building a full-fledged commercial organization with near-term ambitions to reach “critical mass”



## Stage 1 (2020)

### Develop “Full-Fledged” commercial organization

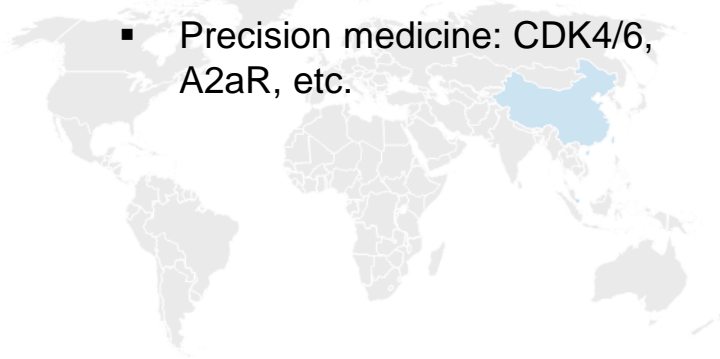
- **Strategically** out-license sugemalimab in mainland China
- Focus on launching precision medicines. **Bo’ao EAP** precision medicine pilot program in Hainan
- Commercial organization with **core competencies and team** ready by 2020 year end



## Stage 2 (in 3-5 years)

### Reach “Critical Mass” with strong commercial platform

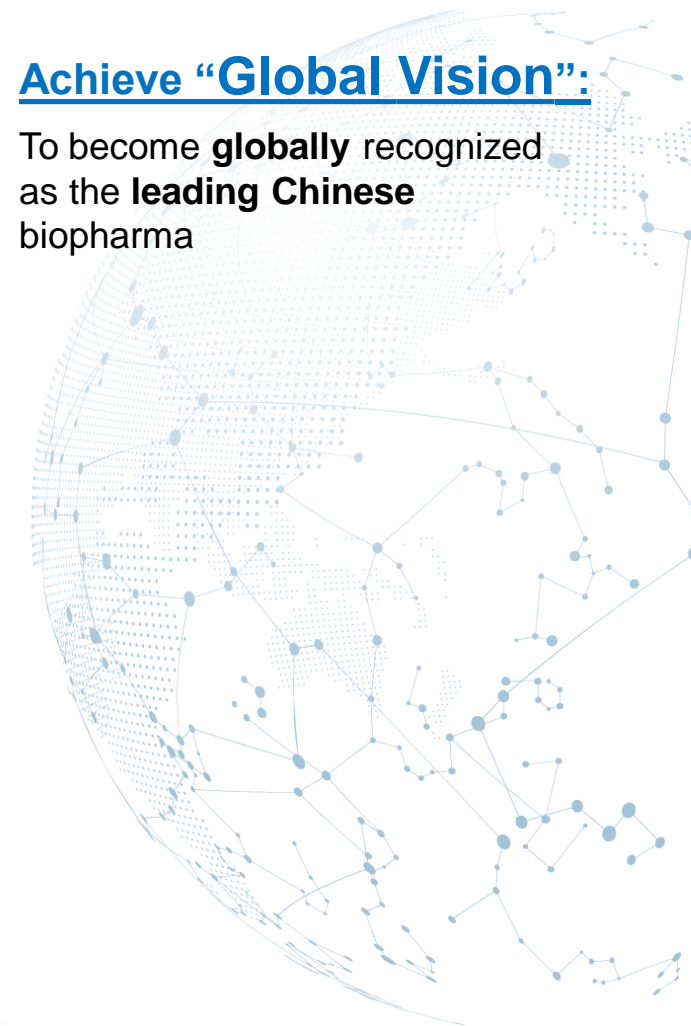
- **Oncology focused** portfolio with 3+ precision medicine and multiple I/O combos
- Well-established sales team with broad hospital coverage in China
- Commercial **partnership with global company** for value creation, pipeline assets with **ex-China rights** in hand
  - I/O: sugemalimab, CS1003 (PD-1), CS1002 (CTLA-4)
  - Precision medicine: CDK4/6, A2aR, etc.



## Stage 3 (beyond)

### Achieve “Global Vision”:

To become **globally** recognized as the **leading Chinese** biopharma



Note: I/O = immuno-oncology; EAP = early access program

# Table of Contents



- 1 Opening Remarks
- 2 Transaction Overview
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**Thank you!**

