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CSTONE
PHARMACEUTICALS

CSTONE PHARMACEUTICALS (2616.HK)

2020 INTERIM RESULTS PRESENTATION

August 19th, 2020

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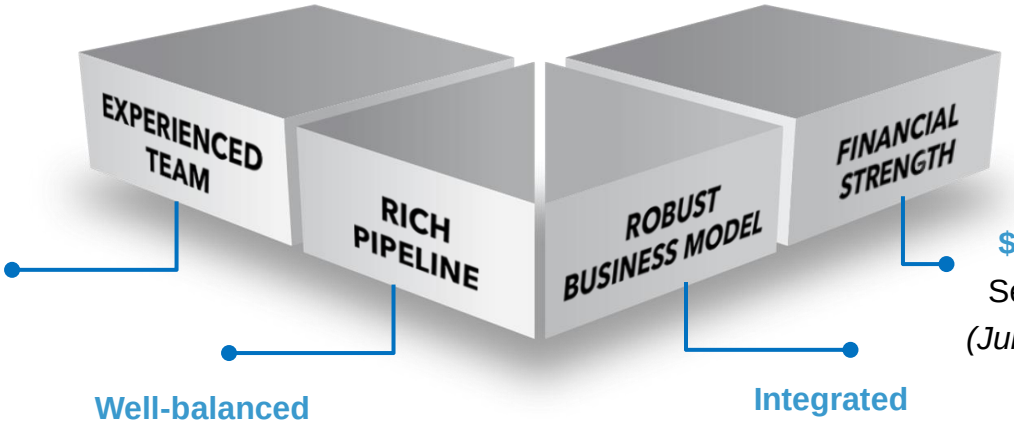
To Become **Globally** Recognized as the **Leading Chinese** Biopharma

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 and Transitioning into Commercial Stage

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

Note: NDA = New Drug Application

CStone is rapidly transitioning into a fully-fledged biopharma within ~4 years of inception

2016 — **Company Inception (Dec 2015)**

2017 — **Series A**

Translational Medicine Research Center established

2018 — **Series B**

Sugemalimab (CS1001, PD-L1 antibody) Ph1 first patient dosed

2019 — **IPO on HKEx**

In-license deals with **Blueprint** & **Agios**

Ivosidenib (IDH1 inhibitor) NDA filing in Taiwan

2020

In-license & collaboration with **Numab**

Global clinical collaboration with **Bayer**

Avapritinib (KIT/PDGFRA inhibitor) NDA filing in Taiwan and mainland China

State-of-the-art manufacturing facility construction commenced

Pralsetinib (RET inhibitor) pivotal trial success in 2L RET-fusion NSCLC in China

Sugemalimab (CS1001, PD-L1 antibody) pivotal trial success in 1L Stage IV NSCLC (sq & nsq) in China

Commercial capability **rapid ramp-up**

Note: Ph = Phase, NSCLC = non-small cell lung cancer, sq = squamous, nsq = non-squamous

Critical clinical and regulatory milestones achieved in 2020YTD, propelling CStone to near commercial stage

- **Exceptionally positive readout for 3 pivotal trials**
- **Significantly de-risked CStone's late stage assets**

Sugemalimab (CS1001, PD-L1 antibody)

- Ph3 trial met primary endpoint with highly positive topline data as 1L treatment in Stage IV squamous and non-squamous NSCLC
- NDA submission in preparation

Pralsetinib (RET inhibitor)

- Pivotal study in 2L RET-fusion NSCLC in Chinese cohort demonstrated deep and durable anti-tumor activity consistent with global data
- NDA submission in mainland China in preparation

Avapritinib (KIT/PDGFRA inhibitor)

- NDA submissions accepted by China NMPA and Taiwan FDA for PDGFRA exon 18 mutation GIST

Note: YTD = year to date, GIST = gastrointestinal stromal tumor, NMPA = National Medical Products Administration, FDA = Food and Drug Administration

Other notable achievements in 2020YTD for late-stage assets

Sugemalimab (PD-L1 antibody)	■ 5 pivotal trials on track, including Stage III NSCLC, 1L gastric cancer, 1L esophageal cancer and r/r-ENKTL, with r/r-ENKTL trial received IND approval from US FDA and expanded to the US
CS1003 (PD-1 antibody)	■ Global Ph3 trial in 1L HCC ongoing and received orphan drug designation (ODD) from US FDA
Pralsetinib (RET inhibitor)	■ Completed enrollment in China for pivotal trial in 1L RET mutant MTC ■ Initiated pivotal trial in 1L RET fusion-positive NSCLC ■ Enrolling patients in a basket cohort in other RET-altered solid tumor types
Ivosidenib (IDH1 inhibitor)	■ Received NDA approval from Taiwan FDA for the treatment of r/r AML adult patients with IDH1 mutation, and marketing approval is expected in 2H 2020

Note: IND = Investigational New Drug, AML= acute myeloid leukemia, HCC = hepatocellular carcinoma, ENKTL = extranodal natural killer / T-cell lymphoma, NSCLC = non-small cell lung cancer, MTC = medullary thyroid cancer, r/r = relapsed or refractory

Remarkable speed towards commercialization

Expect 5+ NDA approvals for 4 products by 2021

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Ivosidenib (IDH1 inhibitor)	Avapritinib (KIT/PDGFRA inhibitor)	Pralsetinib (RET inhibitor)	Sugemalimab (PD-L1 antibody)
IDH1 r/r AML	**PDGFRA exon 18 GIST**	**RET 2L NSCLC**	**1L Stage IV NSCLC (sq & nsq)**
Taiwan, China *Singapore*	*Mainland China* *Taiwan, China*	*Mainland China* *Taiwan, China*	*Mainland China*

Significant strides in 2020YTD for early-stage assets

TWO Combo Trial Initiation	■ CS1002 (CTLA-4 antibody) and CS1003 (PD-1 antibody) combo expansion cohorts in selected tumor types ■ Fisogatinib (FGFR4 inhibitor) and sugemalimab (PD-L1 antibody) combo initiated Ph2 study for FGF19+ HCC
TWO IND Approvals	■ Donafenib and sugemalimab combo China IND approval in Apr 2020 ■ NM21-1480 (PD-L1×4-1BB×HSA tri-specific molecule) US IND approval in Jun 2020 (Numab), and Taiwan IND approval in Aug 2020
TWO Mono Trial Dose Escalation FPFD	■ CS3002 (CDK4/6 inhibitor) IND approved by China NMPA; mono Australia dose escalation FPFD in Jan 2020 ■ CS3005 (A2aR antagonist) IND approved by China NMPA; mono Australia dose escalation FPFD in Jan 2020
Pre-clinical Data Release	■ Pre-clinical data release of sugemalimab (PD-L1 antibody), CS3002 (CDK4/6 inhibitor) and CS3003 (HDAC6 inhibitor) at 2020 AACR virtual annual meeting II

Note: FPFD= First Patient First Dose

Compelling progress achieved in 2020YTD for commercial operations, BD and manufacturing

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Commercial Operations

- Rapidly ramped up commercial capabilities with seasoned functional leaders including Taiwan & Hong Kong GM, Sales, Marketing, MED and Market Access head onboard
  - All leaders have >15 years of China pharma industry experience and strong network with key stakeholders
  - Highly competent core sales team established to cover target hospitals in mainland China and Taiwan
- Successfully listed pre-commercial products ivosidenib (IDH1 inhibitor) and avapritinib (KIT/PDGFRA inhibitor) in CSCO guideline
- Extensively interacted and communicated with target HCPs on diseases, diagnostics and products via multichannel engagements
- Signed 1st commercial agreement for Hainan Bo'ao Early Access Program to boost brand's share of voice and pave way for successful mainland China launch in near future

海南自由贸易港 博鳌乐城国际医疗旅游先行区 HAINAN FREE TRADE PORT BOAO HOPE CITY

Business Development

- Engaging potential partners for multiple partnership opportunities that will accelerate our value creation, including in-licensing, out-licensing and strategic partnership
- Extended our territory beyond Greater China to Singapore to develop and commercialize ivosidenib (IDH1 inhibitor)

Manufacturing

- Commenced the construction of the state-of-the-art manufacturing facility in Suzhou with roof-sealing of the main building expected in 2H 2020

Note: GM = general manager, MED = medical affairs, CSCO = Chinese Society of Clinical Oncology, HCP = healthcare professional

Sugemalimab (PD-L1) Ph3 study highly positive results

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

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Achievement

- Interim analysis showed that sugemalimab (PD-L1 antibody) combined with chemotherapy demonstrated a statistically significant and clinically meaningful prolongation of PFS, reducing the risk of disease progression or death by 50% (HR=0.5, p<0.0001)
- Clinical benefits shown across all subgroups including histology subtypes and PD-L1 expression levels
- Sugemalimab in combination with chemotherapy was well tolerated, with no new safety signal detected
- NDA submission expected in Q4 2020

Significance

Competitive positioning

- 1st PD-L1 antibody to demonstrate overwhelming efficacy as 1L treatment of Stage IV sq & nsq NSCLC in a randomized, double-blinded Ph3 trial

Innovative design

- 1 registrational trial to cover both key histologies (sq & nsq), with smaller trial patient size (n=480), faster completion and lower trial cost

Execution excellence

- Approx. 20 months vs. industry benchmark of ~25 months to complete the 480-patient trial despite fierce competition and COVID-19 outbreak, and less than 3 years from Ph1 to first Ph3 topline report

Note: PFS = Progression-Free Survival, HR = Hazard Ratio

Pralsetinib (RET) pivotal trial showed deep and durable efficacy in Chinese cohort

2L NSCLC (RET fusion-positive)

Achievement

- Deep and durable anti-tumor activity observed in 2L RET fusion-positive NSCLC in Chinese cohort patients, data to be released in a scientific conference in near future
- Efficacy and safety results are consistent with global data, pralsetinib was well-tolerated in the Chinese patient population
- NDA submission in mainland China expected in Q3 2020

Significance

Competitive positioning in local market

- Potentially 1st RET inhibitor available in China for RET fusion-positive NSCLC patients

Execution excellence

- Approx. 2 years from licensing to topline data readout of the bridging registrational trial
- 11 months from First Patient In to the topline data readout, with an enrollment rate ~4 times higher than the global average rate

Avapritinib (KIT/PDGFRA) NDA accepted in mainland China and Taiwan

PDGFRA exon 18 GIST

Achievement

- NDA accepted in mainland China in April for treatment of adults with unresectable or metastatic GIST harboring a PDGFRA exon 18 mutation
- Priority review status granted by China NMPA
- NDA accepted in Taiwan in March for GIST harboring a PDGFRA exon 18 mutation
- Preliminary efficacy and safety data in Chinese cohort patients presented at ASCO 2020

Significance

Competitive positioning in local market

- Potentially 1st treatment targeting PDGFRA exon 18 mutation GIST in mainland China

Execution excellence

- Approx. 20 months from in-licensing deal to NDA submission in mainland China and Taiwan
- 2 quarters ahead of initial schedule for NDA filing

Note: ASCO = American Society of Clinical Oncology

The unique MoA of sugemalimab (PD-L1) and the distinct design of our tri-specific molecule (NM21-1480) renders both the potential to be the "best-in-class" immune checkpoint inhibitors

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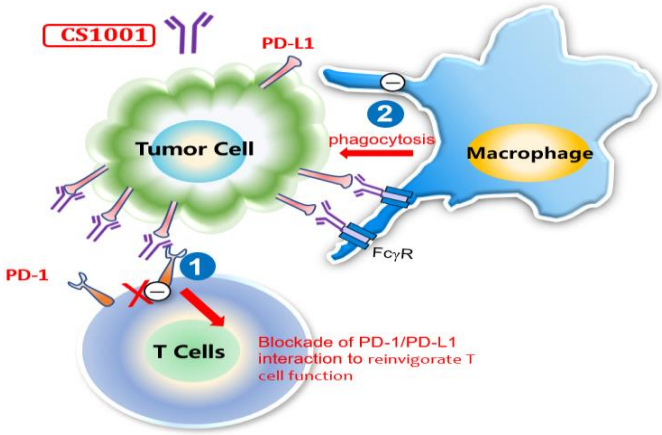
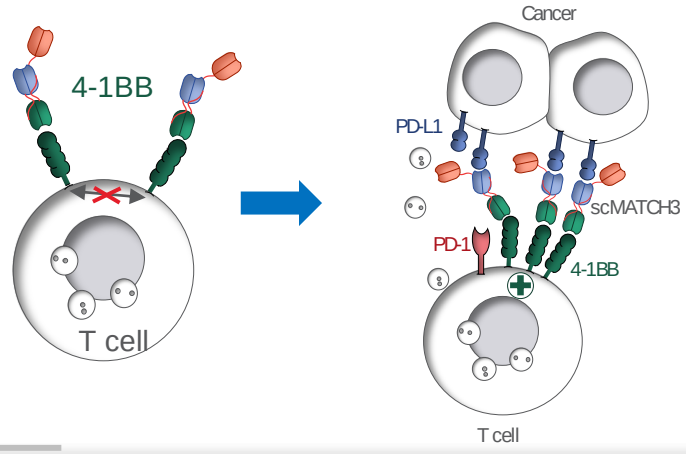
1 Unique MoA of sugemalimab



- **Fully human, full length IgG4** antibody – minimal possibility of generating ADA
- *Naturally* lacks of ADCC/CDC activity that leads to better safety and avoids unwanted attack of T cells
- ***Retains ADCP activity*** that potentially induces direct tumor killing by macrophages and enhances tumor antigen presentation for long-term anti-tumor immunity
- In additional to **NKTL**, this novel MoA possibly explains the higher clinical activity of Sugemalimab observed in our **NSCLC and EC** clinical trials

2 NM21-1480 (PD-L1x4-1BBxHSA)

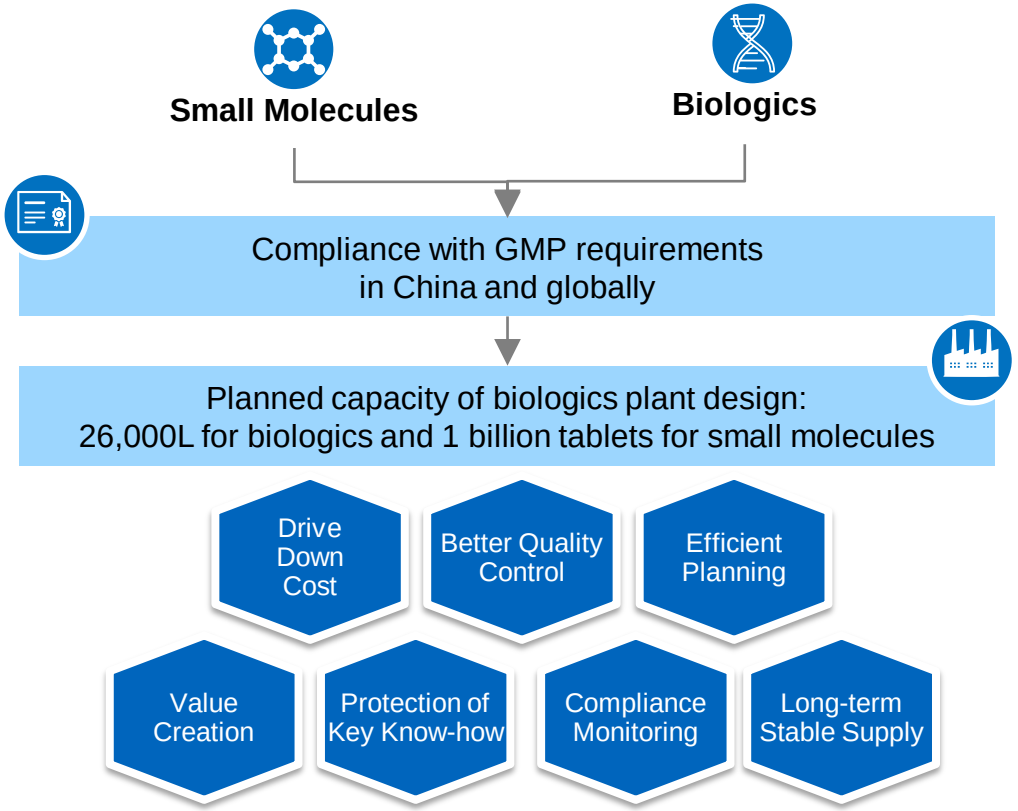


- CStone's **leading next-generation PD-L1 candidate** in co-development with Numab
- **Monovalent tri-specific molecule** binds to PD-L1 (immune checkpoint), 4-1BB (immune agonist) & HSA (half-life extension)
- Conditional activation of 4-1BB occurs only at tumor sites when PD-L1 arm is engaged via ultra-high affinity
- IND approved by US FDA (June 2020) and Taiwan FDA (August 2020)
- Patient **recruitment ongoing** for the multi-center Ph1 study in US and Taiwan

Note: MoA = Mechanism of Action, IgG4 = Immunoglobulin G4, ADCP = Antibody-Dependent Cellular Phagocytosis
ADCC = Antibody-Dependent Cell-Mediated Cytotoxicity, CDC = Complement Dependent Cytotoxicity, EC = Esophageal Cancer

State-of-the-art manufacturing facility in construction to be in full operation by next year

- In August 2019, CStone entered into an agreement with Sungent (state-owned controlled by Suzhou Industrial Park) to build manufacturing facility
- Commencement of the construction in the first half of 2020 with roof-sealing of the main building in 2H 2020 and full operation in 2021
- Planned building area of approximately 100,000 sqm
- Capabilities: once completed, the complex will be equipped with integrated capabilities for R&D, pilot plant, and full commercial scale manufacturing
- Planned capacity: 26,000L for macromolecule biologics and 1 billion tablets and capsules for small molecule drugs
- Strategic partnership with Wuxi Biologics on clinical and commercial stage manufacturing



Financial summary for 1H 2020

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Cash Balance

- **RMB2,124 million of cash, cash equivalents, and time deposits** as of June 30, 2020 vs. RMB2,726 million as of December 31, 2019
- Cash position decreased by RMB602 million mainly due to R&D expenses, administrative and selling expenses

Sources of Cash

- **IPO proceeds**: HK$2,394 million (post greenshoe)
- **Bank borrowing**: Available bank loan facility up to RMB200 million for working capital improvement and the construction of the manufacturing facility and other facilities

Uses of Cash

- **R&D expenses** (non-IFRS[1]): RMB470 million
- **Administrative and selling expenses** (non-IFRS[1]): RMB100 million

Note: 1. Adjusted for share-based compensation

Outstanding execution in 2020YTD with multiple thrilling milestones achieved and more to come

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	Milestones achieved in 2020YTD	To be achieved for rest of 2020
Clinical Development	**NDA Submission** ■ Avapritinib (KIT/PDGFRA): **PDGFRA exon 18 GIST** accepted by NMPA in April and **PDGFRA exon 18 GIST** submitted to Taiwan FDA in March **Pivotal Trial Data Readout** ■ Sugemalimab (PD-L1): **Stage IV NSCLC** registrational trial topline readout in August ■ Avapritinib (KIT/PDGFRA): **PDGFRA exon 18 GIST** registrational trial data published at ASCO 2020 ■ Pralsetinib (RET): **2L RET NSCLC** registrational trial topline readout in July **Key Data at Int'l Conference** ■ **Stage IV NSCLC** sq and nsq **Ib trial** data published at ASCO 2020	**Marketing Approval** ■ Ivosidenib (IDH1): **r/r AML, Taiwan** **NDA Submission** ■ Sugemalimab (PD-L1): **Stage IV NSCLC, China** ■ Pralsetinib (RET): **2L RET NSCLC, China** ■ Ivosidenib (IDH1): **r/r AML, Singapore** **Pivotal Trial Data Readout** ■ Sugemalimab (PD-L1): **Stage III NSCLC** registrational trial data by Q4 2020 / Q1 2021 ■ Pralsetinib (RET): **1L MTC** registrational trial data by Q4 2020
Research, Commercial, BD and Manufacturing	**Research** ■ NM21-1480 IND approval in US and Taiwan ■ Pre-clinical data release of sugemalimab (PD-L1), CS3002 (CDK4/6) and CS3003 (HDAC6) at 2020 AACR virtual annual meeting II **Commercial** ■ Solid brand plan for launch readiness ■ Fully fledged commercial capability ramped up **Business Development** ■ Singapore rights obtained for ivosidenib (IDH1)	**Commercial** ■ Product launch of TIBSOVO (ivosidenib) in Taiwan for r/r AML[1] **Business Development** ■ Continue engaging potential partners for multiple partnership opportunities i.e. in-licensing, out-licensing and strategic partnership **Manufacturing** ■ Roof-sealing of the main building expected in 2H 2020

Note: 1. Depending on marketing approval

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Business Overview

Industry leading management team with proven track record and complementary expertise

Frank Jiang, MD, PhD
Chairman, Chief Executive Officer

SANOFI Lilly

Shirley Zhao, MD, MBA
Greater China GM,
Head of Commercial

Bristol-Myers Squibb Lilly
Allergan SANOFI GENZYME

Jason Yang, MD, PhD
Chief Medical Officer

BeiGene COVANCE
Pfizer AMGEN

Bing Yuan, PhD, MBA
Chief Strategy and
Business Officer

MERCK NOVARTIS Eisai

Jon Wang, PhD
Chief Scientific Officer

MERCK Biogen
MedImmune

Archie Tse, MD, PhD
Chief Translational
Medicine Officer

MERCK Daiichi-Sankyo

Jingrong Li, PhD
SVP, Product Development
& Manufacturing

先声药业 Simcere
BioSpecifics Roche

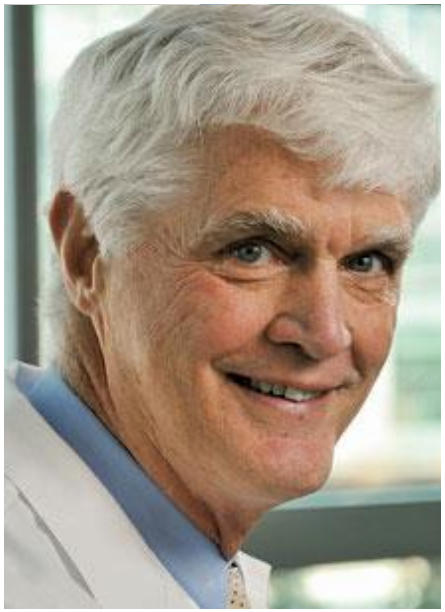
Sanhu Wang, MPH
SVP, Government and
Regulatory Affairs

饿了么 mindray迈瑞
国家药品监督管理局
National Medical Products Administration

Yinghua Zhang
VP, Operations

先声默沙东 SMSD
先声药业 Simcere

Distinguished world-class scientific advisory board with deep oncology and IO expertise



Paul Bunn
MD

Former ASCO President
2002-2003
Distinguished Professor,
University of Colorado

Elizabeth Jaffee
MD

Former AACR President
2018-2019
Professor of Oncology,
Johns Hopkins
University

Weiping Zou
MD, PhD

Chair, AACR Cancer
Immunology
Charles B.de Nancrede
Professor,
University of Michigan

Richard Finn
MD

Former International
Liver Cancer
Association President
Clinical Professor,
UCLA

Note: ASCO = American Society of Clinical Oncology; AACR = American Association for Cancer Research.

Well-balanced oncology portfolio with a focus on immuno-oncology and precision medicine

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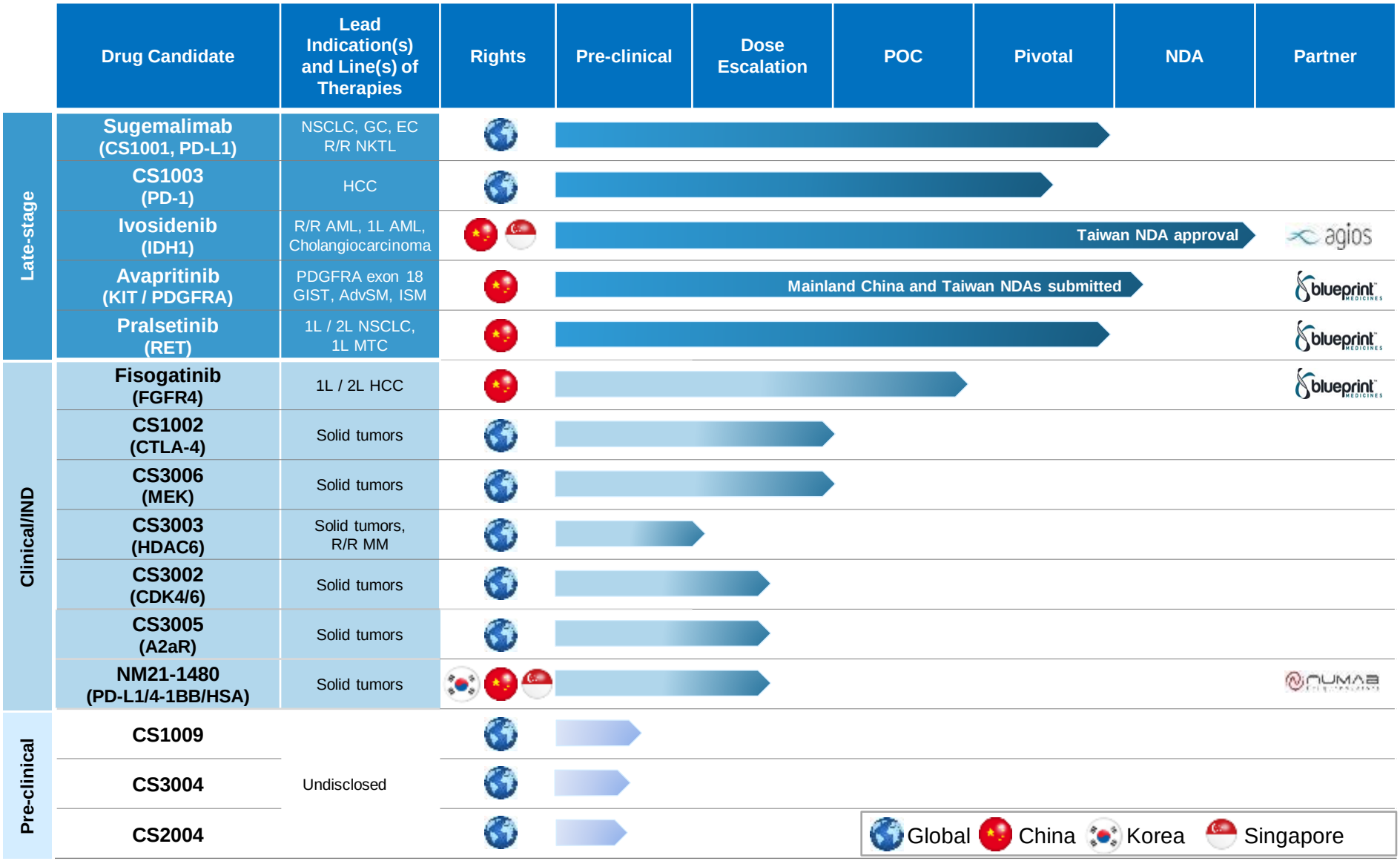

Source: Company

Note: Assets status denote progress in the region noted in the column titled "Rights". AML= Acute Myeloid Leukemia, AdvSM = Advanced Systemic Mastocytosis, GIST = Gastrointestinal Stromal Tumor, HCC = Hepatocellular Carcinoma, ISM = Indolent Systemic Mastocytosis, NKTL = Natural KILLER/T Cell Lymphoma, NSCLC = Non-small Cell Lung Cancer, MTC = Medullary Thyroid Cancer, R/R = Relapsed or Refractory, SM = Systemic Mastocytosis, MM = Multiple Myeloma.

Focus on China's largest indications, covering 55%+ of total cancer incidences

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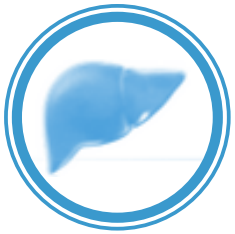


Cancer type	Lung Cancer	Colorectal Cancer	Gastric Cancer	Liver Cancer	Esophagus Cancer
New cases (2018)	774,323	516,859	456,124	392,868	307,359
5-year prevalence (2018)	716,411	1,237,145	603,851	296,780	284,163
Ongoing and planned clinical trials	PD-L1 Mono Stage III NSCLC	PD-L1+Regorafenib Advanced CRC	PD-L1 + Chemo Advanced GC/GEJ	PD-1 + VEGFRi Advanced HCC	PD-L1 + Chemo Advanced ESCC
	PD-L1 + Chemo Stage IV NSCLC	PD-1+Regorafenib Advanced CRC	PD-L1+Regorafenib Advanced GC/GEJ	Fisogatinib FGF19+ HCC	
	Pralsetinib RETm 1L NSCLC & 2L NSCLC		PD-1+Regorafenib Advanced GC/GEJ	PD-L1 + Fisogatinib FGF19+ HCC	

registrational
exploratory

Source: Globocan 2018, represents estimated data in China
Note: NSCLC = non-small cell lung cancer; GC = gastric adenocarcinoma; GEJ = gastro-esophageal junction adenocarcinoma; HCC = hepatocellular carcinoma; ESCC = esophageal squamous cell carcinoma; CRC = colorectal cancer; VEGFRi = inhibitor of vascular endothelial growth factor receptor

Differentiated Combo Strategy - driven by sizable portfolio anchored around 3 I/O backbone agents

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3 IO backbone agents

- Only company in China owns clinical stage ***PD-L1, PD-1 and CTLA-4***

15 assets in the pipeline

- ***10*** in-house developed de-risked assets plus ***5*** in-licensed FIC/BIC assets

1 potential 2nd generation of PD-(L)1

- ***PD-L1x4-1BB*** *provides more flexible combo and potential better efficacy*

De-risked Combo

- PD-(L)1 + Chemo/RT (S3 NSCLC, S4 NSCLC, 1L GC, 1L EC) — *Ph3*
- PD-1 + CS1002 (CTLA-4)
- PD-(L)1 + Regorafenib (VEGF)
- PD-(L)1 + Lenvatinib (VEGF) — *Ph3*
- And more…

Novel Combo Unique to CStone

- PD-L1 + Fisogatinib (FGFR4)
- PD-L1 + CS3002 (CDK4/6)
- PD-1 + CS1002 (CLTA-4) + CS3005 (A2aR)
- And more…

Multi-specific

- NM21-1480 (PD-L1 x 4-1BB)
- And more…

11 combo trials, including 5 registrational trials

I/O+Chemo/ RT | I/O+I/O | I/O+TT (targeted therapy)

Note: FIC = First-in-Class; BIC = Best-in-Class

Clinical Development Engine: Strong in-house team led by experienced leaders and supported by global CROs

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Frank Jiang, MD, PhD
Chairman and CEO

- Former Head of APAC R&D for Sanofi
- Led a **21,000** patient mega-trial
- Led **79** clinical trials and **30** NDAs within five years

Jason Yang, MD, PhD
CMO

- Former SVP and Head of Clin Dev for Beigene, led development of PD-1, BTK, PARP and RAF dimer inhibitors
- Led **40+** global and China trials

Archie Tse, MD, PhD
CTMO

- Former Executive Director of Early Clin Dev at MSD (US)
- Led **30+** FIH oncology trials
- Led **20+** I/O combination trials

Responsible for late stage clinical development and regulatory affairs

- Clinical Development & PV [1]
- Regulatory Affair
- Biometrics & Medical Writing
- Quality Assurance
- Clinical Operations

Responsible for early stage clinical development and diagnostics/biomarkers

- Molecular Diagnostics
- Translational Medicine & Biomarker
- Clinical Pharmacology
- Early Development

Strong in-house team with ~180 clinical staff, representing ~55% of total employees, of which ~75% hold advanced degrees[2] and ~72% have clinical development experience at MNCs

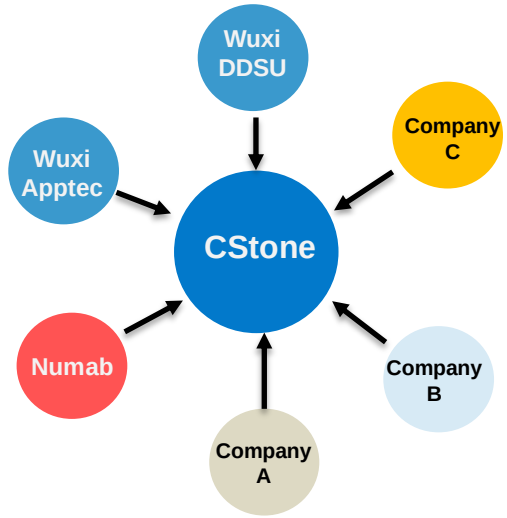
IMS Health & Quintiles are now IQVIA™ | PAREXEL® | COVANCE SOLUTIONS MADE REAL® | Syneos Health

Keep clinical strategy planning & development oversight in-house, while outsourcing day-to-day execution to global CROs to ensure optimal balance between efficiency and scalability

Note:
1. Includes GI cancer, lung cancer, hematology & other solid tumors, and pharmacovigilance
2. Master and above

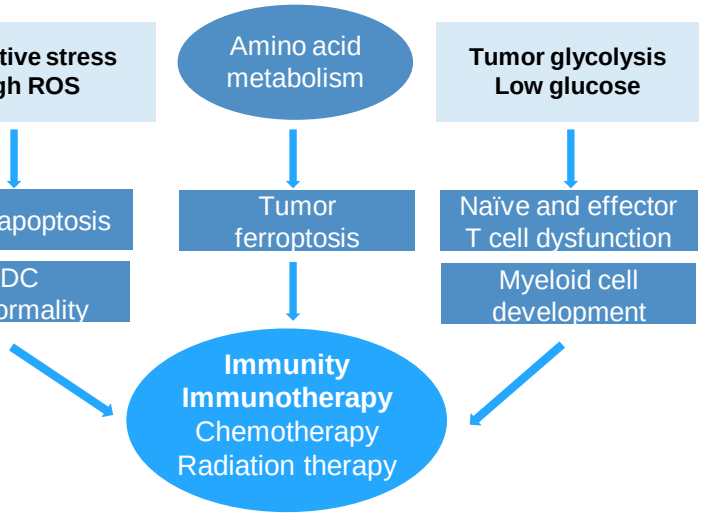
*Focus areas: n*ovel biology, multi-functional biologics, cancer vaccines

- **CStone Internal Discovery Platform**
  - "**Hub & Spoke**" models for internal projects
    - *CStone names the targets; Internal **Project Leader and Project Manager** to run projects*
    - *Lead discovery & optimization done at CRO or platform companies until **PCC**, then bring back to CStone*
  - Work with leading academic labs to identify lead candidates, then bring to CStone for development



Novel Biology

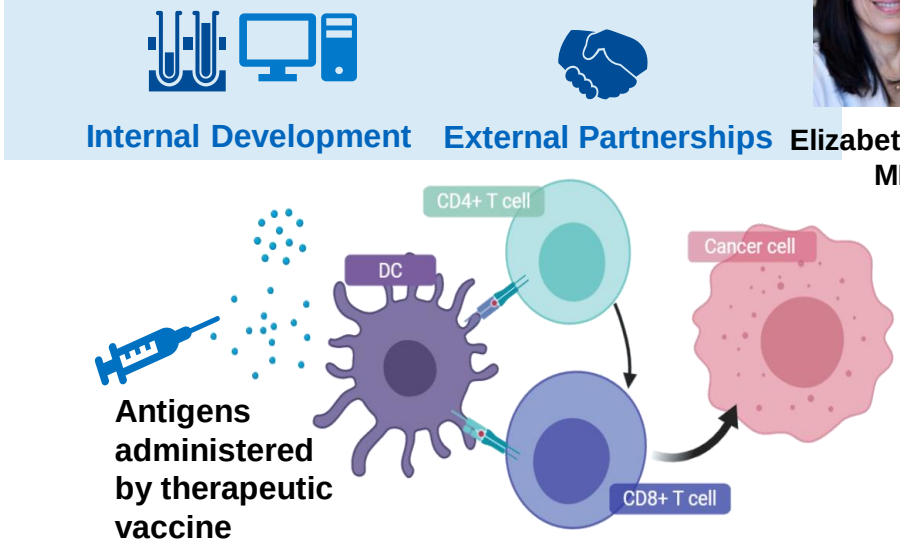
Weiping Zou MD, PhD



Targeting **ferroptosis pathway** may sensitize and improve immunotherapy efficacy

Cancer Vaccines

Elizabeth Jaffee MD



Note: L Jiang et al. Ferroptosis as a p53-mediated activity during tumour suppression Nature 2015, 520: 57–62, PCC = pre-clinical candidate

We will focus on precision medicine in the near-term, followed by PD-(L)1 across China prevalent indications in the longer term

Near-term (2020~2021)	Mid-term (2022~2025)	Long-term (2026~)
Expect 4 products Across 4+ indications[1]	**Expect ~6 products Across 14+ indications[1]**	**Expect ~13 potentially approved products Across 20+ indications[1]**
AYVAKIT avapritinib tablets	PDGFRA GIST	AYVAKIT avapritinib tablets	PDGFRA GIST, SM	AYVAKIT avapritinib tablets	PDGFRA GIST, SM
Pralsetinib	2L NSCLC	Pralsetinib	1L NSCLC 1L, 2L NSCLC, 1L MTC	Pralsetinib	1L NSCLC, 2L NSCLC, 1L MTC
TIBSOVO ivosidenib	r/r AML	TIBSOVO ivosidenib	r/r AML, NIC AML	TIBSOVO ivosidenib	r/r AML, NIC AML
Sugemali-mab (PD-L1)	S4 NSCLC (sq & nsq)	**Sugemali-mab (PD-L1)**	S4 NSCLC (sq & nsq), S3 NSCLC, ESCC, GC NKTL	**Sugemali-mab (PD-L1)**	S4 NSCLC (sq & nsq), S3 NSCLC, ESCC, GC NKTL
		CS1003 (PD-1)	HCC	**CS1003 (PD-1)**	HCC
		Fisogatinib	HCC	Fisogatinib	HCC
				CTLA-4; CDK4/6; A2A; PD-L1/4-1BB/HSA; CS1009, CS3004, CS2004	

We are constantly filling our pipelines that fit with our pipeline 2.0 approach

Note:1. For in-licensed assets NDA approval time will depend on our partners' NDA approval time by US FDA

基石药业
CSTONE
PHARMACEUTICALS

Thank you!