



基石药业
CSTONE
PHARMACEUTICALS

2023 Interim Results Presentation

August 16th, 2023

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A Fully Integrated Biopharma With End-to-end Capabilities

5.5 years from inception to the first commercial launch

RESEARCH

Clinical insight driven modular R&D model

45+

IND approvals

10+

Discovery projects ongoing

DEVELOPMENT

Efficient, high-quality and innovative clinical dev. engine

11

NDA approvals

40+

Data presentations /publications

COMMERCIAL

Full capability of in-house commercialization

4 commercialized products

7 indications approved

3 territories coverage

2016

CStone Inception

2018

Record Setting Series B Funding of \$260m

2019

Listed on HKEx

2020

Strategic Partnership with Pfizer

2021

Approval and launch of Gavreto®, Ayvakit®, Cejemly®, Fully integrated biopharma

2022

Approval and launch of Tibsovo®

2023

All 5 registrational trials of sugemalimab succeeded, overseas launch initiated (UK and EU MAA accepted)

01

Business Achievements

2023YTD

2023YTD Achievements

A full-fledged biopharma with strong growth momentum in 2023YTD

Financial

as of June 30, 2023

Total revenue in 1H 2023

261.5

RMB Mn
(Flat YoY)

Sales of pharmaceutical products in 1H 2023

246.9

RMB Mn
(+53% YoY)

Net loss^[1] in 1H 2023

(183.0)

RMB Mn
(Narrowed by 29% YoY)

Research & Development

as of Aug 15, 2023

2 NDA approvals

1L NSCLC



Pralsetinib

NSCLC, MTC/TC



5 NDAs currently under review

R/R ENKTL



1L GC/GEJC



Sugemalimab

1L ESCC



1L stage IV NSCLC



1L stage IV NSCLC



6 Data publications / presentations

CS5001
ROR1 ADC

Ph1 study conducted in the U.S. and Australia, and has now expanded to include China

Lorlatinib
ROS1

Patient recruitment completed in the pivotal study for ROS1-positive NSCLC

Domestic supply

Technology transfer application for avapritinib is under review by CDE; Technology transfer for pralsetinib ongoing with BE study initiated

10+ Discovery projects in progress

Note: Total revenue in 1H2023 includes sales of pharmaceutical products (1H2023: 246.9m vs. 1H2022: 161.4m, +53%) and royalty income of sugemalimab (1H2023: 14.6m vs. 1H2022: 13.1m, +12%), expecting milestone from GC/GEJC and ESCC approval by end of 2023 or early 2024.

[1] Net loss represents the loss for the period excluding the effect of certain non-cash items and onetime events, namely the share-based payment expenses.



Mainland China



Taiwan (China)



United Kingdom



European Union

02

Pipeline Updates

Pioneering Revolutionary Treatments Addressing Critical Unmet Needs

Key Clinical Program

**Significant value driver
with leading position
globally** (Top 2 in position /
best-in-class potential)

CS5001
(ROR1 ADC)

Commercial-stage Programs

Pralsetinib
(RET)

Avapritinib
(KIT/PDGFRA)

Ivosidenib
(IDH1)

Sugemalimab
(PD-L1)

Other Programs

CS1003
(PD-1; Global PhIII)

Pre-clinical
(CS2009, CS5005,
CS5006, etc)

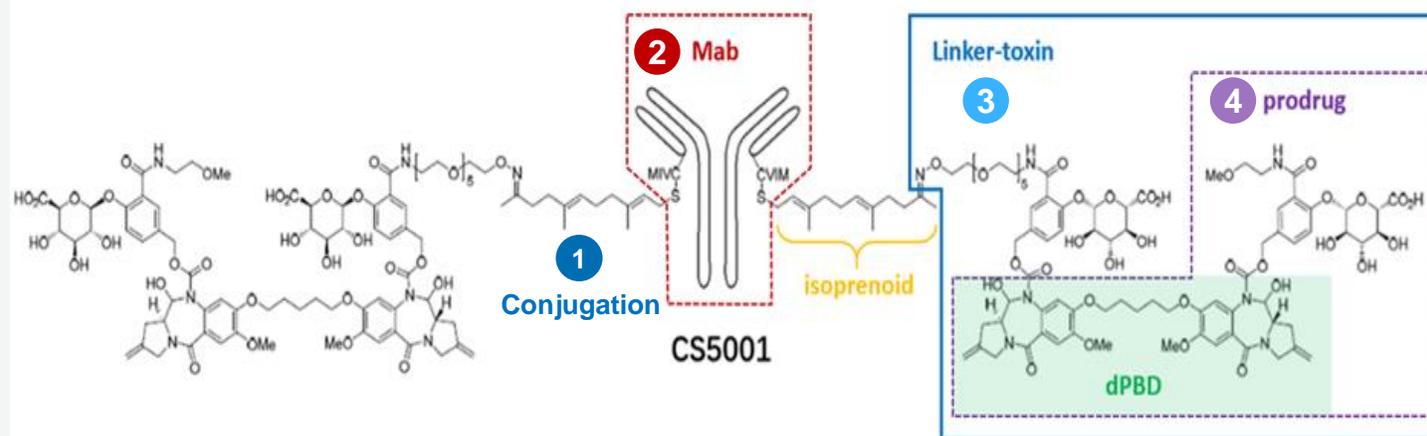
CS5001 (ROR1 ADC) (1/3)

Top 2 in position globally with Ph1 study ongoing in US, Australia and China

An ADC target for both hematological malignancies and solid tumors

- Largely absent in normal blood lymphocytes and adult tissues ¹⁻³
- Embryonic protein over-expressed by many hematological malignancies especially B-cell lymphomas ^{4, 5}
- Broadly expressed by solid tumors such as TNBC, ovarian cancer, and adenocarcinoma (NSCLC) ^{2,6-13}
- First-in-class molecule acquired by Merck for US\$2.75Bn in Nov 2020 at Ph1

4 key differentiators support best-in-class potential:



Controlled quality and production

- 1 **Site-specific** conjugation technology, ConjuAll, enables a **homogenous** drug to **antibody ratio of 2**

Potentially less immunogenicity

- 2 **Fully human IgG1 mAb** v.s. humanized mAb of other ROR1-ADCs

Potentially wider therapeutic window

- 3 Proprietary **tumor-selective cleavable linker** (cleaved by β-glucuronidase), highly stable in serum
- 4 Proprietary **tumor-activated PBD dimer toxin prodrug** (released by β-glucuronidase)

1. Baskar et al, *Clin Cancer Res* 2008, 14(2); 2. Balakrishnan et al, *Clin Cancer Res* 2017 23(12); 3. Uhrmacher et al, *Leukemia Research* 35 (2011) 1360; 4. Borcherdig et al, *Protein Cell* 2014, 5(7):496-502; 5. Daneshmanesh et al, *Leukemia & Lymphoma* 2013, 54(4): 843-850; 6. Zhang et al, *PLoS ONE* 2012 7(3): e31127; 7. Chien et al, *Virchows Arch* 2016, 468(5):589-95; 8. Henry et al, *Transl Oncol.* 2017, 10(3):346-356; 9. Zhang et al, *Sci Rep.* 2014, 24(4):5811; 10. Zheng et al, *Sci Rep.* 2016, 10(6):36447; 11. Liu et al, *PLoS One.* 2015, 10(5):e0127092; 12. Henry et al, *Gynecol Oncol.* 2018, 148(3):576-584; 13. Zhou et al, *Oncotarget* 2017, 8(20):32864-32872

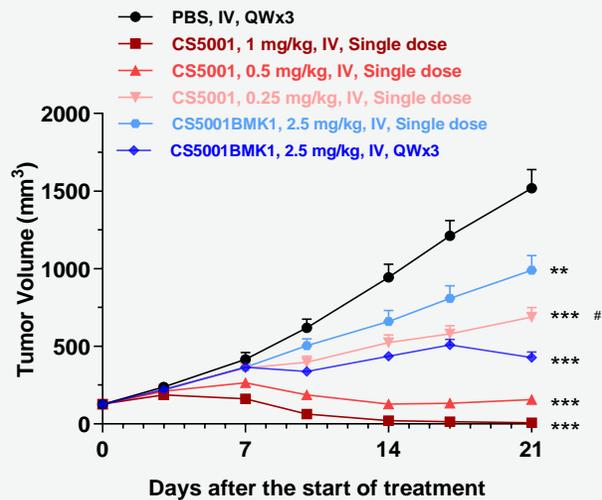
CS5001 (ROR1 ADC) (2/3)

Outstanding pre-clinical data in both solid and hematological cancers

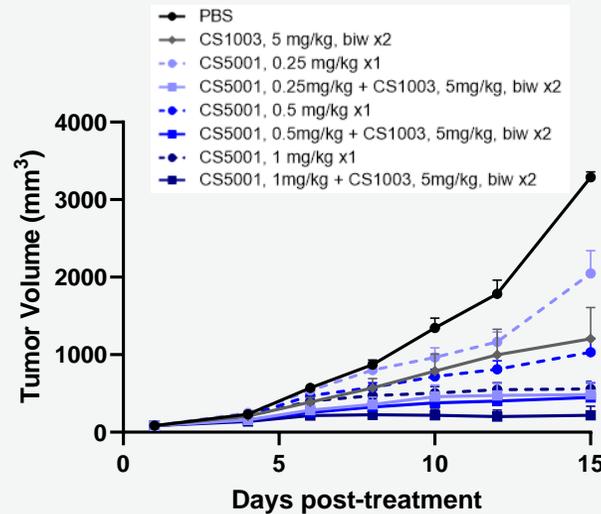
Data Highlights

- Given as a single dose in MCL (mantle cell lymphoma) xenograft models, CS5001 showed **superior efficacy than the benchmark MMAE-based ROR1 ADC** at a higher and more frequent dosing schedule, demonstrating its best-in-class potential
- CS5001 demonstrated synergistic tumor growth inhibition when **combined with CS1003 (an anti-PD-1 mAb)**
- An anti-ROR1 antibody clone has been identified with promising sensitivity and selectivity for immuno-histochemistry (IHC) detection to support **companion diagnostic** development enabling biomarker-driven patient selection
 - CS5001 demonstrated **bystander effect** *in vitro* co-culture systems, suggesting that solid tumors with heterogenous/low expression of ROR1 can also benefit

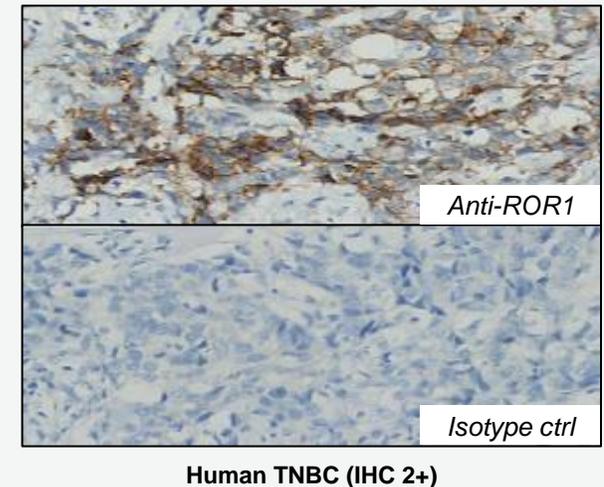
1 Superior in vivo efficacy



2 Combo with PD-1



3 Proprietary IHC mAb developed in house for companion diagnostic



CS5001 (ROR1 ADC) (3/3)

Dose finding Ph1 study ongoing in US, Australia and China

Development Progress

March 2023 ● Translational study results presented at World ADC Conference

April 2023 ● Global multi-regional Ph1 trial expanded to include China

Today ● **Dose escalation to predicted efficacious range;**
Well tolerated safety profile with no DLT observed;
Expected linear PK exposure demonstrating excellent ADC stability;
Anti-tumor activities observed

By end of 2023 ● Update on clinical safety and efficacy

1H 2024 ● Conference presentation on Ph1 data

Registration planned for 2024

Fast-to-market and cost-effective development pathways

Pralsetinib

FIC RET inhibitor supplemental NDA approval for 1L NSCLC in mainland China in 1H 2023



~70K

annual newly diagnosed patients with RET-altered tumors in China^[1]

2L NSCLC	<ul style="list-style-type: none"> • ORR: 66.7%^[4] • mPFS: 11.7mths^[4]
1L NSCLC	<ul style="list-style-type: none"> • ORR: 83.3%^[4] • mPFS: 12.7mths^[4]
1L MTC/TC	<ul style="list-style-type: none"> • ORR: 73.1%^[4] • mPFS: 15.7mths^[4]
Pan-tumor ²	<ul style="list-style-type: none"> • ORR: 57% (PoC)

Drug Profile

Partner with  ^[5]

Development and Regulatory Progress



Commercial Progress

200+ hospitals and DTPs (Direct-to-patient pharmacy) listed as of today	130+ commercial / government insurance programs inclusion	80%+ ^[3] testing rate achieved, with improved accuracy by collaborating with NPQCC; established Lung Cancer Precision Alliance with BeiGene & Merck to maximize testing rate	10 national guidelines, incl. 2023 CSCO NSCLC Clinical, CSCO Primary LC, 2022 CSCO MTC Clinical, etc.
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Market Access

Affordability

RET testing

National Guidelines

● Mainland China
 ● Hong Kong (China)
 ⊘ Taiwan (China)

[1]. Clarivate DRG, 2025; [2]. Broad indications in RET+ solid tumors, i.e., colorectal, gastric, breast, liver, cervical, ovarian, esophageal and pancreatic cancers; [3]. In Top 200 hospitals; [4]. Data for Chinese patient population; [5]. Blueprint Medicines and associated logos are trademarks of Blueprint Medicines Corporation
 Abbr.: FIC = first in class; NSCLC = non-small cell lung cancer, MTC = medullary thyroid cancer, TC = thyroid cancer, PAP = Patient Assistance Program; NPQCC = National Pathology Quality Control Center, CSCO = Chinese Society of Clinical Oncology
 Data source: ESMO Asia 2022, Nature Medicine 2022, ATA 2021, 90th Annual Meeting of the American Thyroid Association 2021

Avapritinib

FIC KIT/PDGFR A inhibitor with potential to expand to indications beyond PDGFR A exon 18 GIST



~45K

annual newly diagnosed patients with **PDGFR A** exon 18 or **KIT** mutation tumors in China

PDGFR A exon 18 GIST	• ORR: 70% ^[1]
Advanced SM	• ORR: 84% • 24m OS: 87.7%
Non-advanced SM	• Statistically significant & clinically meaningful improvement in TSS
KIT D816 or N822 mutant r/r AML	• Data to be published at conference/journal ^[1]
KIT 17/18 mutant GIST (2L-4L)	• mPFS was 19.3mths and ORR was 36.4% in 2L GIST ^[1]

Drug Profile
Partner with 

Development and Regulatory Progress

	GIST		SM		KIT D816 or N822 mutant r/r AML
	PDGFR A exon 18	KIT 17/18 mutant (2-4L)	Advanced	Non-advanced	
	Approved	Robust antitumor activity over SOC via retrospective analysis	Bridging registration trials explored with CDE		Promising efficacy observed in real world. IIT ongoing to generate data to be included in treatment guidelines
 Blueprint	Approved		Approved	Approved ✓	
 Blueprint	Approved		Approved		

Tech transfer application including BE accepted by CDE, domestic supply expected in 2024

Commercial Progress

<h3 style="margin: 0;">80+</h3> <p style="margin: 0;">hospitals and DTPs (Direct-to-patient pharmacy) listed as of today</p>	<h3 style="margin: 0;">100+</h3> <p style="margin: 0;">commercial / government insurance programs</p>	<h3 style="margin: 0;">80%^[3]</h3> <p style="margin: 0;">testing rate achieved, with improved accuracy by collaborating with NPQCC</p>	<h3 style="margin: 0;">5</h3> <p style="margin: 0;">national guidelines, incl. Chinese guideline for diagnosis and treatment of SM</p>
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Market Access

Affordability

PDGFR A exon 18/KIT testing National Guidelines

[1]. Data for Chinese patient population; [2]. Blueprint Medicines and associated logos are trademarks of Blueprint Medicines Corporation; [3]. In Top 100 hospitals

Abbr.: FIC = first in class; GIST = gastrointestinal stromal tumor; SM = systemic mastocytosis; AML = acute myeloid leukaemia; SOC = standard of care; IIT = investigator initiated trial; TSS = total symptom score; NPQCC = National Pathology Quality Control Center; BE = bio-equivalence; CDE = Center for Drug Evaluation

Data source: Clarivate DRG, 2025; ESMO 2021; ASH 2022; AAAAI 2023; ASCO 2023

Ivosidenib

FIC and the only IDH1 inhibitor approved in mainland China with potential for indication expansion



~45K

annual newly diagnosed patients with IDH1 mutation tumors in China^[1]

<i>R/R AML</i>	<ul style="list-style-type: none"> CR: 36.7%
<i>1L AML (Combo)</i>	<ul style="list-style-type: none"> EFS^[2] HR: 0.33 mOS^[3]: 29.3 mths (HR: 0.42)
<i>CCA</i>	<ul style="list-style-type: none"> mPFS: 2.7 mths HR: 0.37
<i>Glioma^[4]</i>	<ul style="list-style-type: none"> mPFS: 13.6 mths (PoC)
<i>R/R MDS</i>	<ul style="list-style-type: none"> CR: 44% ORR: 81% (PoC)
<i>Chondrosarcoma</i>	<ul style="list-style-type: none"> Promising efficacy observed in clinical trial

Drug Profile

Partner with 

Development and Regulatory Progress

	AML		CCA
	R/R ^[1]	1L	
	Approved	In regulatory discussion with CDE	In regulatory discussion with CDE
 Servier	Approved	Approved	Approved
 Servier		Approved	Approved

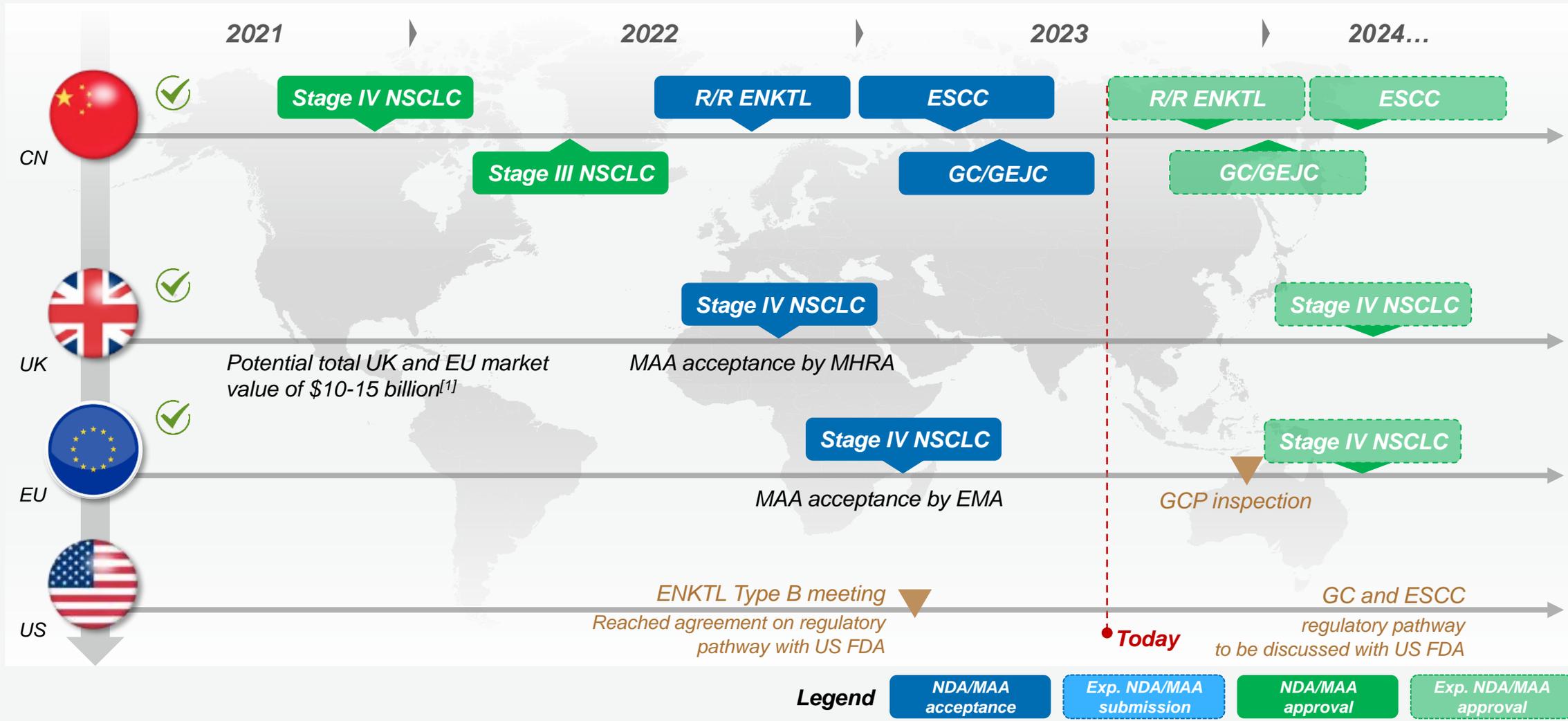
Commercial Progress (Launched in June 2022)

<p style="font-size: 1.5em; font-weight: bold;">~80</p> <p>hospitals and DTPs (Direct-to-patient pharmacy) listed as of today</p> <p style="font-weight: bold;">Market Access</p>	<p style="font-size: 1.5em; font-weight: bold;">~100</p> <p>commercial / government insurance programs</p> <p style="font-weight: bold;">Affordability</p>	<p style="font-size: 1.5em; font-weight: bold;">80%^[5]</p> <p>testing rate achieved, with improved accuracy by collaborating with NPQCC</p> <p style="font-weight: bold;">IDH1 testing</p>	<p style="font-size: 1.5em; font-weight: bold;">6</p> <p>National guidelines, incl. CSCO Hematologic Malignancy, CACA Hematological Oncology, etc.</p> <p style="font-weight: bold;">National Guidelines</p>
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Data source: Clarivate DRG; Globocan 2020; CStone analysis; NEJM; ClarIDHy Trial; J Clin Oncol. 2020 Oct 10; 38(29): 3398–3406.; [1]. Conditional NDA approval for this indication from NMPA; [2]. Event-free survival (EFS) for AGILE: the time from randomization until treatment failure (TF), relapse from remission, or death from any cause, whichever occurs first. TF is defined as failure to achieve CR by Week 24; [3]. Servier presented the updated data from Phase 3 AGILE study at ASCO 2023; [4]. Glioma is not part of the Field in the License Agreement between Servier and CStone; [5] In Top 200 hospitals. Abbr.: FIC = first in class; AML = acute myeloid leukemia, CCA = cholangiocarcinoma, MDS = myelodysplastic syndrome, R/R = Relapsed or Refractory, CR = complete response, NPQCC = National Pathology Quality Control Center, CSCO = Chinese Society of Clinical Oncology, CACA = China Anti Cancer Association; 1L AML: previously untreated IDH1-mutated AML who are not candidates for intensive chemotherapy (not less than 75 years old or who have comorbidities that preclude the use of intensive induction chemotherapy).

Sugemalimab

Expanding into global markets to maximize sugemalimab's asset value, in active discussion with global partners



[1] Data based on EvaluatePharma July 2021 & Cowen PD(L)1 market model update Dec 2019

Abbr.: MAA = marketing authorization application; MHRA = the Medicines and Healthcare products Regulatory Agency; EMA = the European Medicines Agency

Nofazinlimab (PD-1)

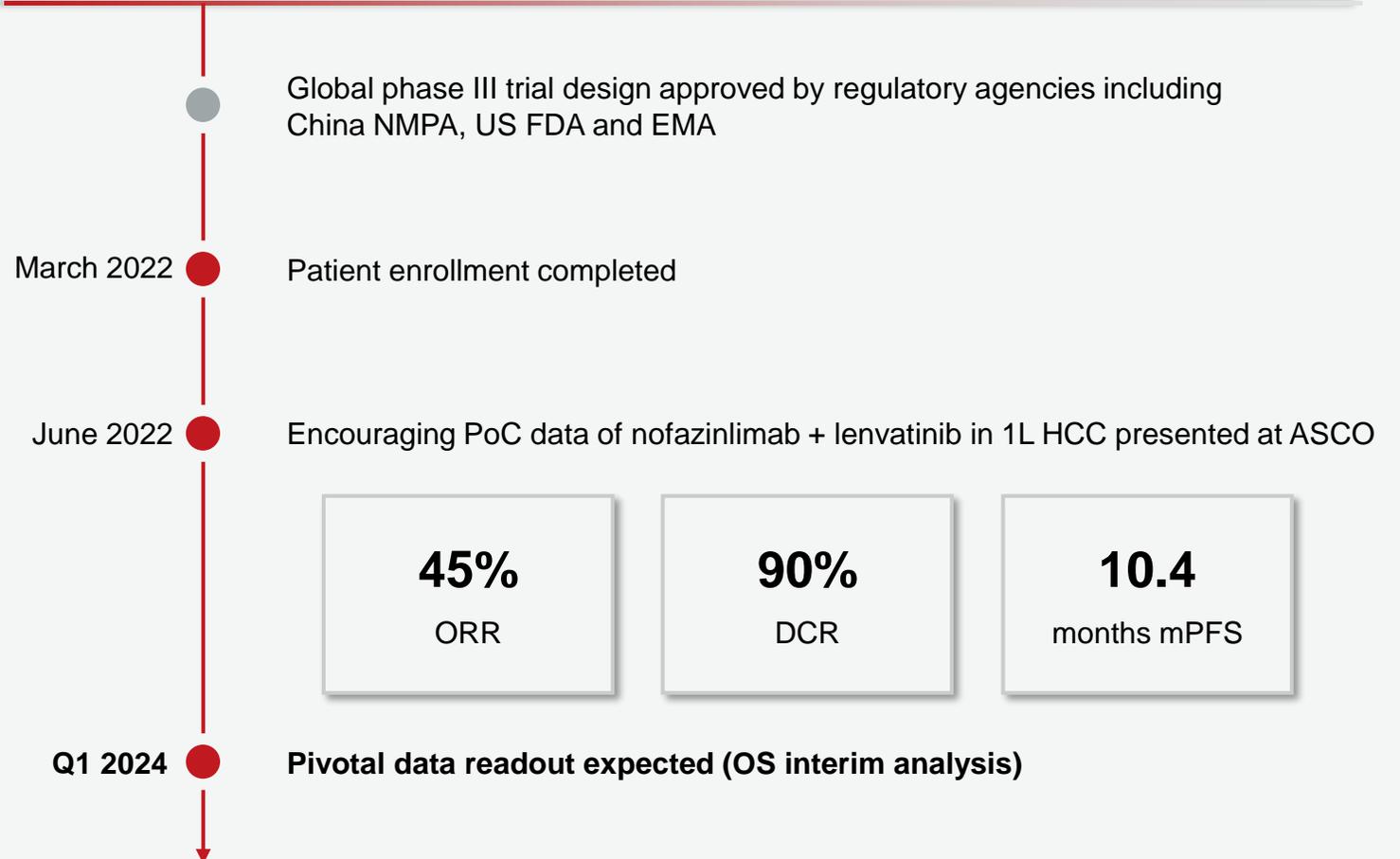
Global registrational study of nofazinlimab + lenvatinib for 1L HCC, with topline readout expected in Q1 2024

Front Runner

- Potentially the first PD-(L)1 + lenvatinib combo treatment approved for 1L HCC
- An attractive treatment option for 1L HCC pts
- Potential cost advantage vs. PD-(L)1 + avastin
- Potentially significant revenue from **global markets**

Drug Profile

Development Progress



New Research Strategy Yields 10+ Discovery Projects

Solid progress on multiple projects, seeking partnership opportunities

Multiple potential FIC/BIC discovery programs are at/near PCC

CS2009

PD-1 x VEGF x another IO target

Potential **FIC** next-generation IO backbone

- ✓ Target **3 critical immune-suppressive pathways** in the tumor microenvironment
- ✓ May **deepen response** of a PD(L)1-based therapy in large tumor types including NSCLC and HCC



Expect IND in 2024

ADCs

CS5005

Potential FIC

- ✓ **Potential FIC ADC** for multiple solid tumors
- ✓ Lead ADC candidate molecule shows **better therapeutic window compared to control drug (a peptide-coupled drug)**



Expect IND in 2024/25

CS5006

Novel ADC target

- ✓ Global FIC, **machine learning multi-omics algorithm** discovered novel tumor-associated antigens, express in multiple tumor types
- ✓ **Novel clinical PoC topoisomerase I inhibitor toxin**, stable hydrophilic linker (DAR8)



Expect IND in 2024/25

EX001

Cell Penetrating Therapeutic Platform

Potentially disruptive drug discovery and delivery platform

- ✓ Intracellularly deliver a variety of drug modalities to address the **“undruggable intracellular targets”**
- ✓ Cell-penetrating therapeutic modules with drug-like *in vivo* PK properties



Multiple PoCs with different drug modalities demonstrated *in vitro*

Current status or progress

CStone's Innovative Portfolio Covers a Broad of Indications with Rapidly Growing Commercial Value

~200K
China annual incidence^[1]

2,000K+
Global annual incidence^[2]

5,000K+
Global annual incidence^[3]

Precision Medicine

- **Pralsetinib** (commercial)
FIC RET inhibitor
- **Avapritinib** (commercial)
FIC KIT/PDGFRα inhibitor
- **Ivosidenib** (commercial)
FIC and the only IDH1 inhibitor
- **Lorlatinib** (clinical)
ROS1/ALK, co-dev with Pfizer

Immuno-oncology

- **Sugemalimab** (commercial)
PD-L1, the first PD-(L)1 approved for stage III & IV NSCLC all comers
- **Nofazimab** (clinical)
PD-1, front runner in PD-(L)1 + Lenvatinib for 1L HCC
- **CS1002** (clinical)
CTLA4, co-dev with Hengrui

Pipeline 2.0

- **CS5001** (clinical)
ROR1-ADC in leading position worldwide
- **CS2009** (pre-clinical)
PD-1 x VEGF x another IO target
- **CS5005** (pre-clinical)
Potential FIC ADC
- **CS5006** (pre-clinical)
Novel ADC target

03

Financial Highlights

1H 2023 Financial Results

Significantly lower operating loss on strong product sales +53% and stringent cost control

<i>Mn RMB</i>	1H 2023	1H 2022	Change
GROUP REVENUES	261.5	261.8	0%
Sales of Pharmaceutical Products ^[1]	246.9	161.4	+53%
Royalty Income ^[1]	14.6	13.1	+12%
License Fee Income	0.0	87.3	-100%
OPERATING EXPENSES (Non-IFRS ^[2] Measures)	(381.2)	(443.3)	-14%
Research and development expenses (Non-IFRS ^[2] Measures)	(198.1)	(218.9)	-9%
Selling, marketing and admin expenses (Non-IFRS ^[2] Measures)	(183.1)	(224.4)	-18%
LOSS FOR THE PERIOD (Non-IFRS ^[2] Measures)	(183.0)	(257.1)	-29%

Total Group Revenues of RMB 261.5Mn

- Sales of Pharmaceutical Products +53% to RMB 246.9Mn
- Royalty Income +12% to RMB 14.6Mn
- Commercial gross profit margin ^[1] increased from 47% to 59%
- Expecting milestone from GC/GEJC and ESCC approval by end of 2023/early 2024

Loss for 1H 2023 down 29% to RMB 183.0Mn

- Lower spending on phase III registrational clinical trials
- Lower SG&A expenses with stringent cost control measures
- Loss for the period reduced by 47%, if adjusted one-time License Fee Income of 87.3Mn in H1 2022 (H1 2023: 183.0Mn vs. adjusted H1 2022: 344.4Mn)

<i>Mn RMB</i>	30 th June 2023	31 st December 2022	Change
CASH BALANCE ^[3]	1,005.4	1,042.1	(36.7)

Cash Balance > RMB 1.0Bn

- Significantly reduced operating cash burn

[1] Commercial gross profit margin represents gross profit margin generated from sales of pharmaceutical products and royalty income. 1H 2022: RMB 81.7Mn (equals to total Gross profit RMB 169.0Mn less Gross Profit from License Fee Income of RMB 87.3m), 47% of commercial revenue vs. 1H 2023: RMB 153.4 Mn, 59% of commercial revenue; [2] IFRS: International Financial Reporting Standards. Non-IFRS Measures represents the loss for the period excluding the effect of certain non-cash items and onetime events, namely the share-based payment expenses; [3] Cash balance includes cash and cash equivalents, and time deposits with original maturity over three months.

04

Catalysts

Expected Catalysts for the Next 12 Months

Assets	Catalysts	Date
Sugemalimab (PD-L1) Marketed	NDA approval for R/R ENKTL in mainland China	By the end of 2023
	★ MAA approval for 1L stage IV NSCLC in EU	1H 2024
	★ MAA approval for 1L stage IV NSCLC in UK	1H 2024
	NDA approval for 1L GC/GEJ in mainland China	Late 2023/1H 2024
	NDA approval for 1L ESCC in mainland China	Late 2023/1H 2024
	Topline readout of the pre-specified OS final analysis for 1L GC/GEJ	3Q 2023
Lorlatinib (ROS1) In pivotal trial	Topline readout and supplemental NDA filing for ROS1-positive NSCLC in mainland China	2024
Nofazinlimab (PD-1) In pivotal trial	★ Topline readout in 1L HCC (in combination with lenvatinib)	1Q 2024
CS5001(ROR1 ADC) In Ph1 trial	★ Update on clinical safety and efficacy	By the end of 2023
	★ Conference presentation on Ph1 data	1H 2024

★ Key value driver
Marketed
In pivotal trial
In Ph1 trial

C1



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JISHI
PHARMACEUTICALS



Thanks





Appendix

Industry Leading Management Team

Proven track record, oncology focus and complementary expertise



Jason Yang
MD, PhD

Chief Executive Officer



Archie Tse
MD, PhD

Chief Scientific Officer



Josh Zhou
MD

Greater China GM



Michael Choi
MBA

Chief Business Officer



Yinghua Zhang

SVP, Operations



Qingmei Shi
MD, PhD

SVP, Clinical Dev.



Jun Cheng

VP, Finance



Nicky Ni
MBA

VP, Board Secretary,
Capital Markets &
Business Planning



Ye Zhao

VP, Head of
Communications





END