



基石药业

CSTONE
PHARMACEUTICALS

2023 Annual Results Presentation

March 28th, 2024

Stock Code: 2616. HK

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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

14

NDA approvals

50+

Data presentations /publications

COMMERCIAL

Full capability of in-house commercialization

4* commercialized products

9 indications approved

3 territories coverage

2016

CStone Inception

2018

Record Setting Series B Funding of \$260m

2019

IPO at SEHK

2020

Global Strategic Partnership with Pfizer

2021

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

2022

Approval and launch of Tibsovo®

2023

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

01

Business Achievements

2023 & 2024YTD

2023 and 2024YTD Achievements

A full-fledged biopharma with strong growth momentum in 2023

Financial

as of Dec. 31, 2023

Total revenue^[1] in FY2023

463.8

RMB Mn

(Flat YoY)

Other gains and loss in FY2023

199.5

RMB Mn

(Mainly from BD income)

Net loss^[2] in FY2023

(330.2)

RMB Mn

(Narrowed by 57% YoY)

Cash balance



1026.7

RMB Mn



Research & Development and Partnerships

as of Mar. 27, 2024

5 New NDA approvals

Pralsetinib 1L NSCLC 
NSCLC, MTC/TC 

Sugemalimab R/R ENKTL 

1L ESCC 
1L GC/GEJC 

2 NDAs currently under review

Sugemalimab 1L stage IV NSCLC 

1L stage IV NSCLC 

10+ Data publications / presentations

CS5001 ROR1 ADC Ph1 study ongoing in the U.S., Australia and China, with promising efficacy observed in multiple tumor types

Lorlatinib ROS1 Positive topline readout achieved for pivotal study in ROS1-positive advanced NSCLC

Ava & Pral COGS reduction Avapritinib manufacturing localization application under review by CDE; Pralsetinib manufacturing localization application submitted to CDE

NRDL Avapritinib Included in 2023 China's National Reimbursement Drug List

BD Exclusive commercialization partnership of pralsetinib with Allist in mainland China
Exclusive licensing of nofazinlimab to 3SBio in mainland China
Exclusive rights transfer of ivosidenib to Servier in Greater China and Singapore

[1] Total revenue in 2023 includes sales of pharmaceutical products (2023: 336.7m vs.2022: 364.3m, -8%) , license fee income (2023: 95.7m vs.2022: 87.3m,+10%) and royalty income of sugemalimab (2023: 31.4m vs. 2022: 29.8m, +5%)

[2] Net loss represents the loss for the year 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

- 1. Key Clinical Program***
- 2. Innovative Early Programs***
- 3. Commercial-stage Programs***

To drive business growth by advancing innovative pipeline 2.0 and maximizing commercial value of mature products

Key Clinical Program in Pipeline 2.0

CS5001
(ROR1 ADC)

**2nd clinical stage ROR1-
ADC with best-in-class
potential globally**

Innovative Early Programs in Pipeline 2.0

CS2009

(PD-1/CTLA4/VEGF tri-specific mAb)

CS5005

(GPCR-x ADC)

CS5006

(novel-target ADC)

CS5007, CS2011, etc.
(other exploratory programs)

Commercial-stage Programs

Pralsetinib
(RET)

Avapritinib
(KIT/PDGFRA)

Ivosidenib
(IDH1)

Sugemalimab
(PD-L1)

02

Pipeline Updates

- 1. Key Clinical Program***
- 2. Innovative Early Programs***
- 3. Commercial-stage Programs***

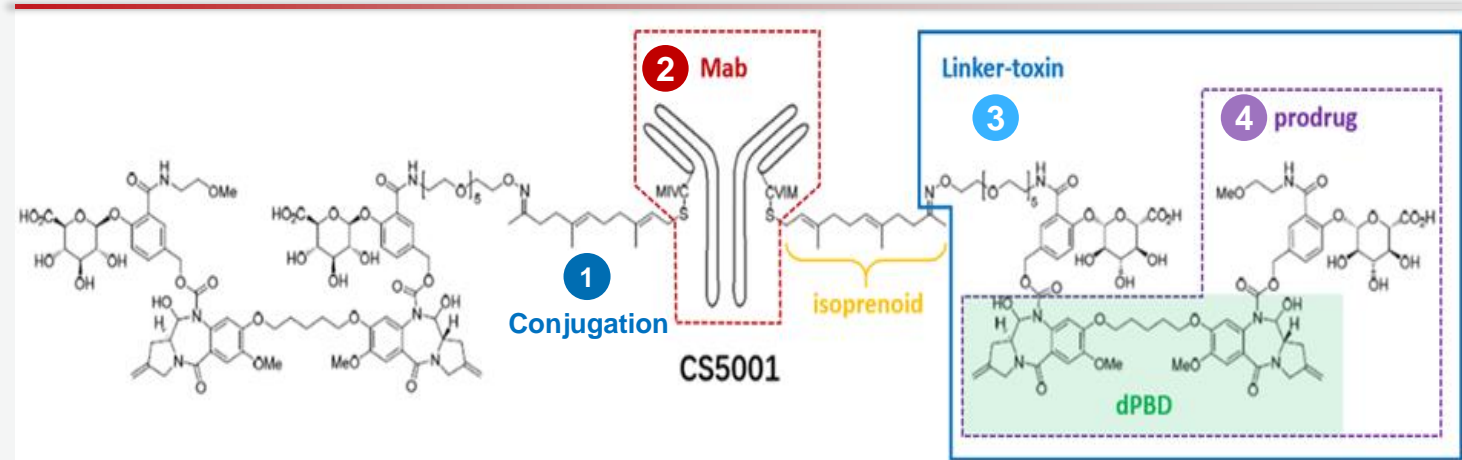
CS5001 (ROR1 ADC)

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 tissues¹⁻³
- 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 adeno-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 in clinical stage

Potentially wider therapeutic window

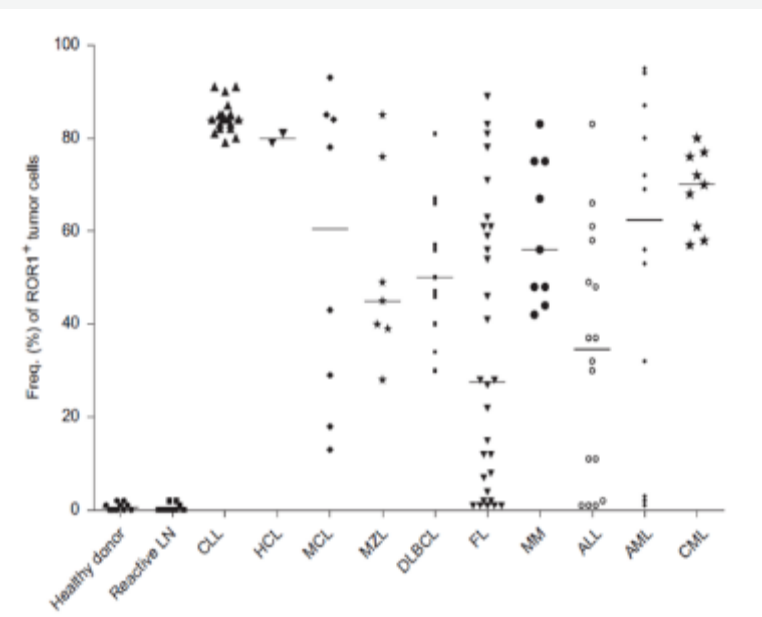
- 3 Proprietary **tumor-selective cleavable linker** (cleaved by β -glucuronidase), highly stable in blood circulation
- 4 Proprietary **tumor-activated PBD dimer (dPBD) toxin prodrug** (released by β -glucuronidase)

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

ROR1 is a promising target for multiple malignancies

- Receptor tyrosine kinase-like orphan receptor 1 (ROR1) is a member of the receptor tyrosine kinase family
- Broad expression of ROR1 in both solid tumor and hematological malignancies (e.g., TNBC, lung cancer, ovarian cancer, pancreatic cancer, CLL, MCL, etc.)
- Predominantly absent from normal blood lymphocytes and adult tissues, indicating minimal off-target activity

ROR1 expression in different hematological malignancies



Leuk Lymphoma. 2013 Apr;54(4):843-50

ROR1 expression in different solid tumor types

Tumor type	Positive rate
TNBC	56% (n=56)
Lung cancer	42% (n=137)
Ovarian cancer	50% (n=159)
Pancreatic cancer	15% (n=38)

TNBC

LC

Ovarian cancer

Pancreatic cancer

ROR1 expression is homogeneous, defined as definite membranous staining of over 50% of tumor cells

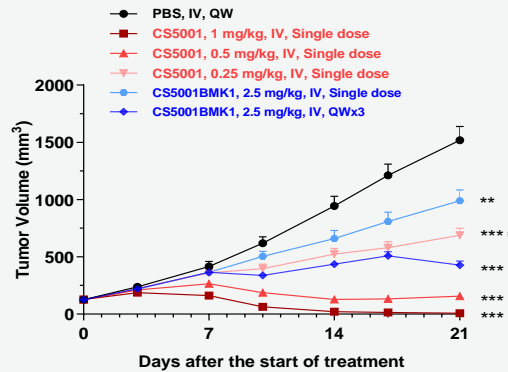
Clin Cancer Res. 2017 Jun 15;23(12):3061-3071

CS5001 (ROR1 ADC) preclinical data overview (1/2)

Robust antitumor activities observed in both solid tumors and hematological cancers

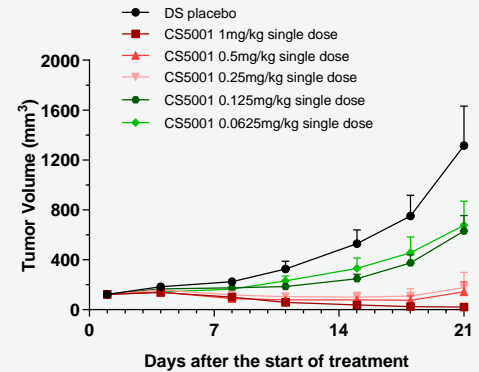
CS5001 remarkably killed tumor cells in CDX models, superior in vivo efficacy

Jeko1 (Mantle cell lymphoma)



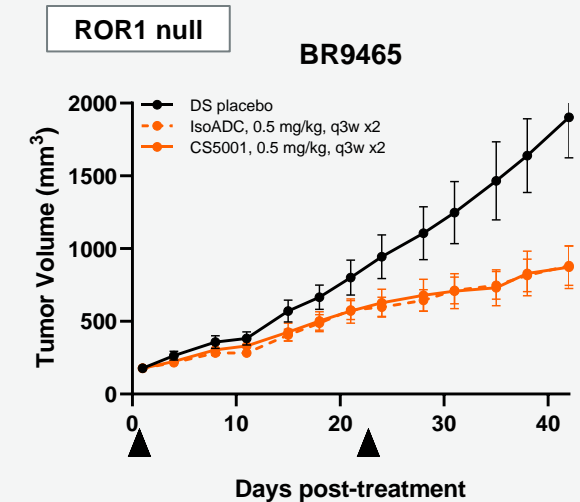
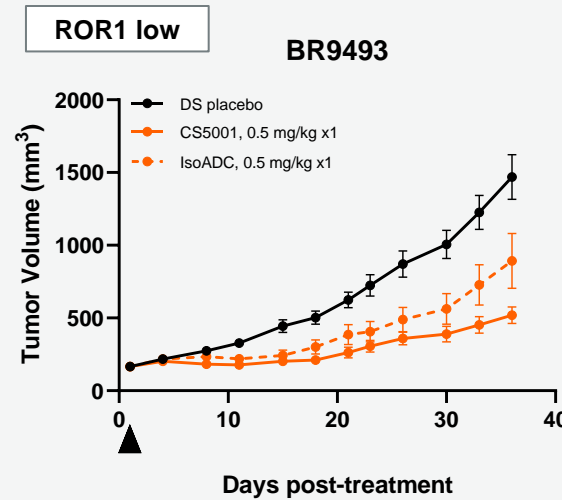
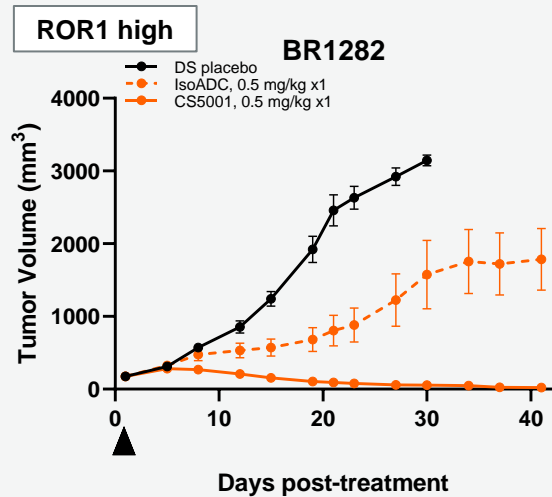
Treatment	TGI %	CR
CS5001, 1 mg/kg, Single dose	109	2/8
CS5001, 0.5 mg/kg, Single dose	98	0/8
CS5001, 0.25 mg/kg, Single dose	60	0/8
CS5001BMK1, 2.5 mg/kg, Single dose	38	0/8
CS5001BMK1, 2.5 mg/kg, QWx3	78	0/8

PA-1 (Ovarian cancer)



Treatment	TGI %	CR
CS5001, 1 mg/kg, Single dose	108	2/8
CS5001, 0.5 mg/kg, Single dose	98	1/8
CS5001, 0.25 mg/kg, Single dose	95	0/8
CS5001, 0.125 mg/kg, Single dose	57	0/8
CS5001, 0.0625 mg/kg, Single dose	53	0/8

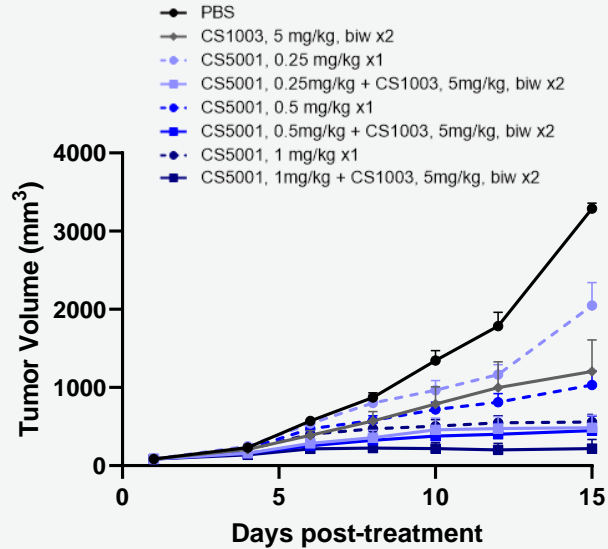
ROR1-dependent anti-tumor activity was demonstrated in solid tumor PDX models



Note: $p < 0.01$, ***, $p < 0.001$ vs PBS; #, $p < 0.05$, vs CS5001BMK1 single dose; TGI: tumor growth inhibition; CR: complete regression is defined as ≤ 13.5 mm³ for 3 consecutive measurements; CS5001BMK1: benchmark1, an MMAE-based ROR1 ADC (same sequence, linker & toxin as VLS-101)

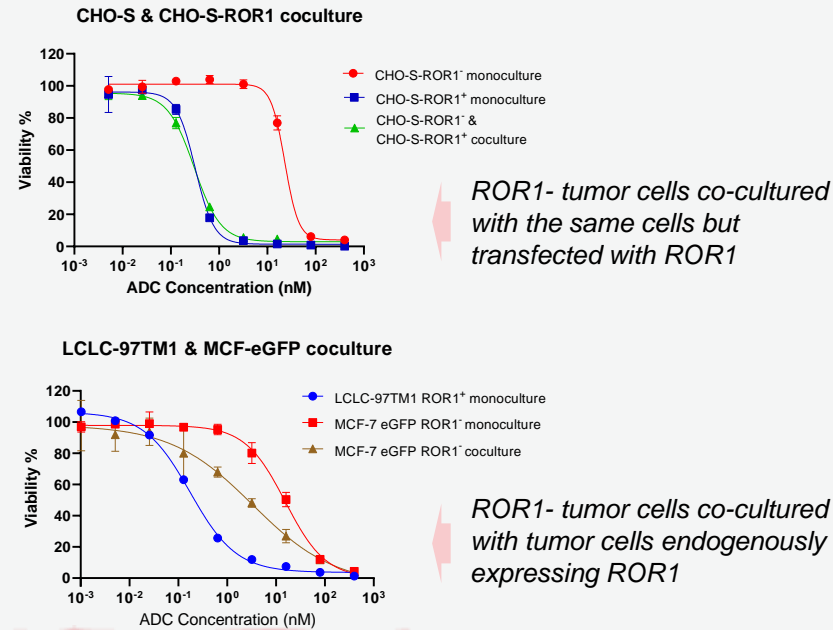
CS5001 (ROR1 ADC) preclinical data overview (2/2)

Synergistic with checkpoint inhibitors



CS5001 demonstrated synergistic tumor growth inhibition when **combined with CS1003 (an anti-PD-1 mAb)**

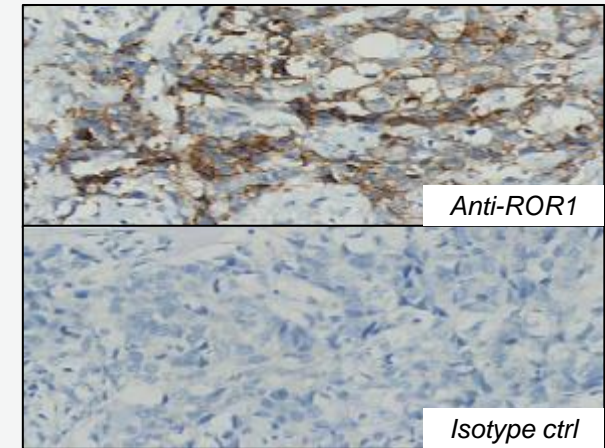
Remarkable bystander effect



CS5001 demonstrated **robust bystander killing effect** in co-culturing assays with ROR1+/- cells

Proprietary IHC mAb

developed in house for companion diagnostic



Human TNBC (IHC 2+)

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 phase 1 trial design and fast-to-market registrational trial plan

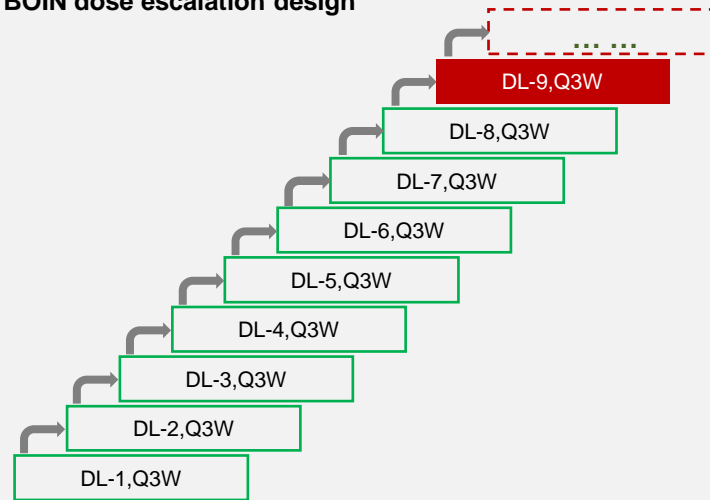
A Phase 1, Dose-Escalation and Dose-Expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Antitumor Activities of CS5001, an Anti-ROR1 Antibody Drug Conjugate, in Patients with Advanced Solid Tumors and Lymphomas

Phase 1a Dose Escalation (BOIN Design) + Backfill

Key eligibility criteria

- Age 18 years or older
- Patients with advanced solid tumor or lymphoma who progressed or were intolerant to all available standard therapies known to confer clinical benefit
- ≥ 1 evaluable lesion
- Adequate organ function
- Available tumor samples for biomarker analysis

MRCT phase 1 trial is ongoing in the USA, AUS and China
BOIN dose escalation design



Tentative RP2D

Phase 1b Dose Expansion/pivotal Extension

- A** B cell lymphoma 1; N = up to 80
- B** B cell lymphoma 2; N = up to 124
- C** Solid tumor 1; N = up to 82
- D** Solid tumor 2; N = up to 100
- E** Exploration in ROR1-positive solid tumors (including TNBC, endometrial cancer, ovarian cancer, NSCLC, gastric cancer and pancreatic cancer);

The enrollment of dose escalation portion of this MRCT phase 1 trial is ongoing in the USA, Australia and China

Expected catalysts in the near term:

Ph1 data presentation at 2024 ASCO and ESMO / ASH

Initiation of Ph1b trial with registrational potential

Phase 1 update: CS5001 is well-tolerated and has demonstrated promising anti-tumor activities in both solid tumors and hematological malignancies

A Escalated to Dose Level 9 (DL9) with no DLT events

- DLT evaluation completed at prior 8 dose levels, DL9 currently under evaluation
- DLT not observed, suggesting the drug being safe and well-tolerated
- Adverse events observed to date mostly Grade 1 or 2

B Anti-tumor activity observed in both lymphoma and solid tumor

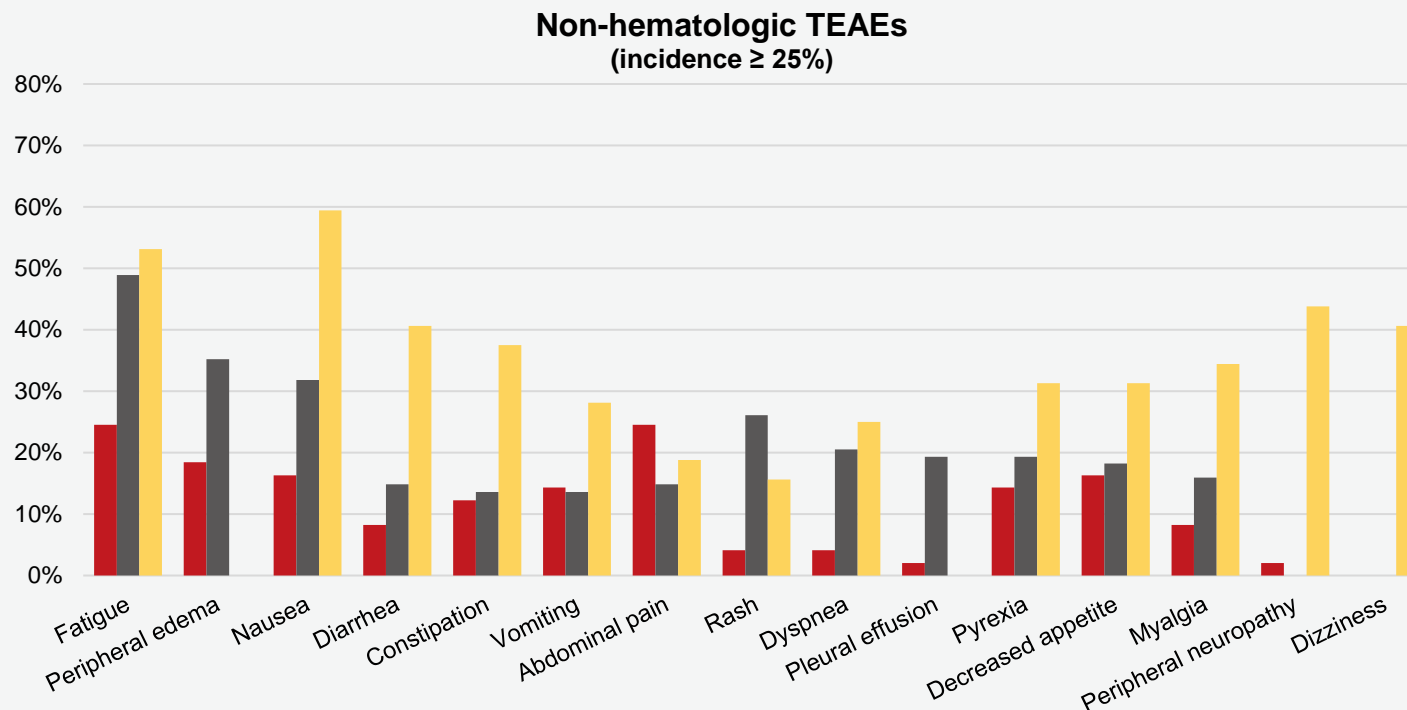
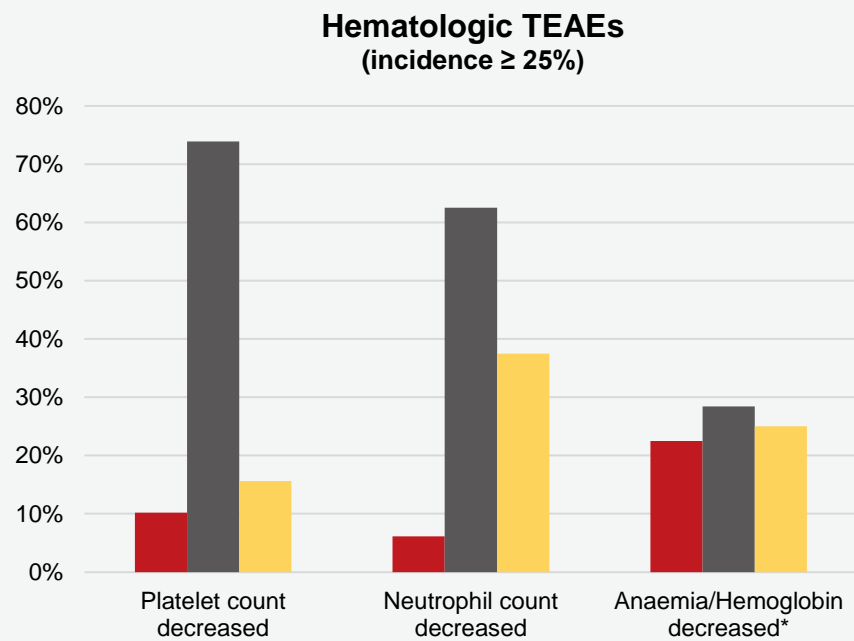
- Encouraging antitumor activities observed among patients at DL5 or above, including PRs or CRs in both advanced solid tumor (e.g. lung cancer and pancreatic cancer) and lymphoma (e.g. Hodgkin lymphoma, DLBCL)
- Efficacy at higher dose levels being evaluated, to disclose detailed data at upcoming international conferences, e.g. ASCO, ESMO, ASH

C Clinical pharmacokinetics profile as expected

- PK data demonstrated a dose-proportional exposure of CS5001
- Excellent linker stability – ADC and total antibody demonstrate similar exposure

CS5001 safety profile (1/2): favorable safety profile of CS5001 vs. two relevant ADCs in phase I trials

Lower frequency of hematologic and non-hematologic AEs observed for CS5001 up to Dose Level 8



■ CS5001: DL1-DL8

■ Loncastuximab Tesirine: 15-200 ug/kg

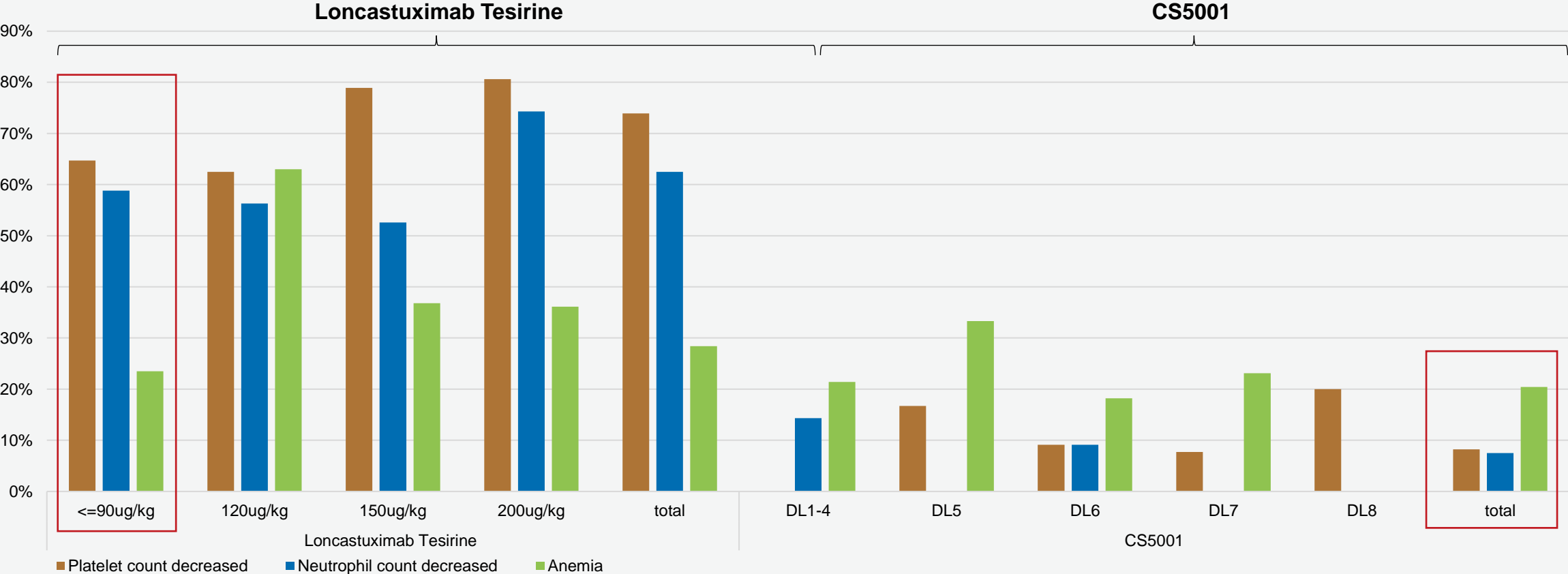
■ Zilovetamab Vedotin: 0.5-2.5mg/kg

* Zilivertmab vedotin: Hemoglobin decreased

	CS5001	Loncastuximab Tesirine	Zilovetamab Vedotin
Antibody	Fully human ROR1 mAb	Humanized CD19 mAb	Humanized ROR1 mAb
Linker	Isoprenoid-PEG-β-glucuronide PAB	MC-PEG-VA-PAB	MC-VC-PAB
Payload	Prodrug of dPBD	Naked dPBD	MMAE
Linker cleavage mechanism	By β-glucuronidase (tumor selective)	By cathepsins	By cathepsins
Conjugation	Site specific and homogeneous	Randomized	Randomized

CS5001 safety profile (2/2): CS5001 exhibited fewer hematologic toxicities vs. a commercial-stage PBD-based ADC at similar dose levels

Hematologic TEAEs by Dose Levels - Loncastuximab Tesirine vs. CS5001

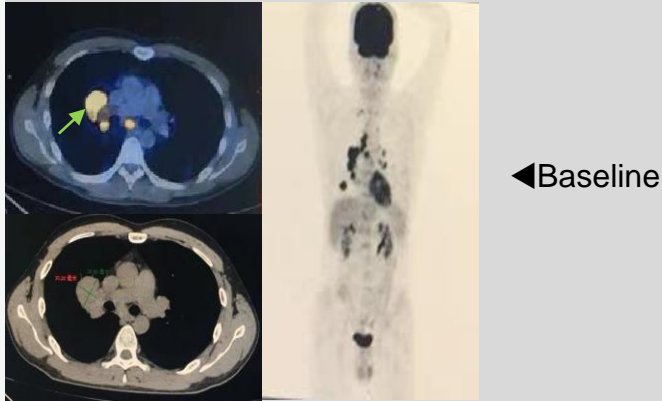


Wang ML, et al. NEJM Evidence. DOI: 10.1056/EVIDoa2100001; Brad S Kahl 1, Clin Cancer Res. doi: 10.1158/1078-0432.CCR-19-0711.

CS5001 case reports of antitumor activities

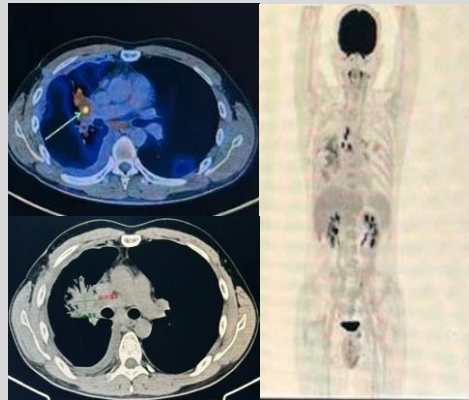
Patient 0104003 (DL5): 33-year-old male, Stage IV Hodgkin Lymphoma

Patient's disease relapsed following two prior lines of chemotherapies, including ABVD and RCHOP. After receiving 4 cycles of CS5001 treatment, a **partial response** was observed per Lugano 2014.



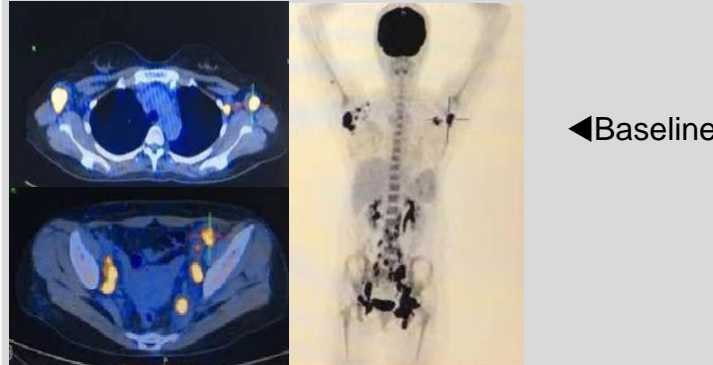
◀ Baseline

After 4 cycles treatment of CS5001 ▶



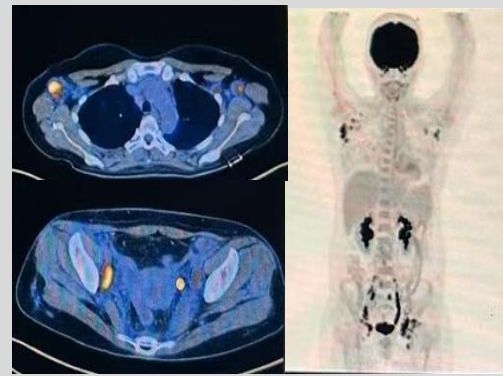
Patient 0104002 (DL6): 34-year-old female, Stage IV Hodgkin Lymphoma

Patient had a refractory disease after undergoing five lines of chemotherapy, including ABVD, GVD, Sintilimab+Decitabine, ICE+Sintilimab, and IBI-322. Following 4 cycles of CS5001 treatment, a **partial response** was observed as per Lugano 2014



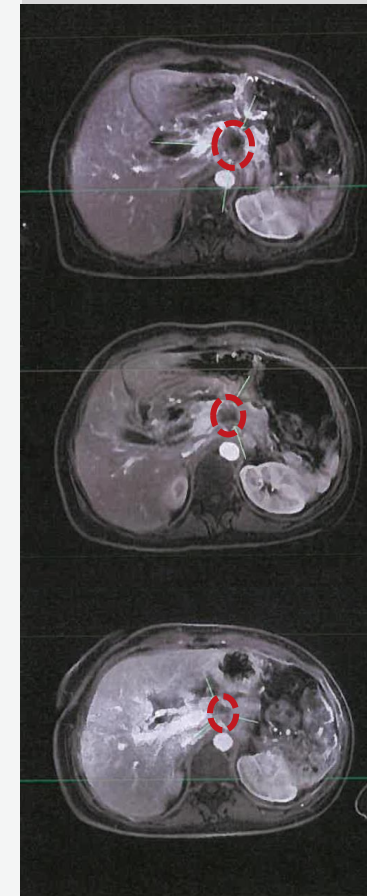
◀ Baseline

After 4 cycles treatment of CS5001 ▶



Patient 0201010 (DL7): 52 y/o female with advanced pancreatic adenocarcinoma

52 y/o female with advanced pancreatic adenocarcinoma



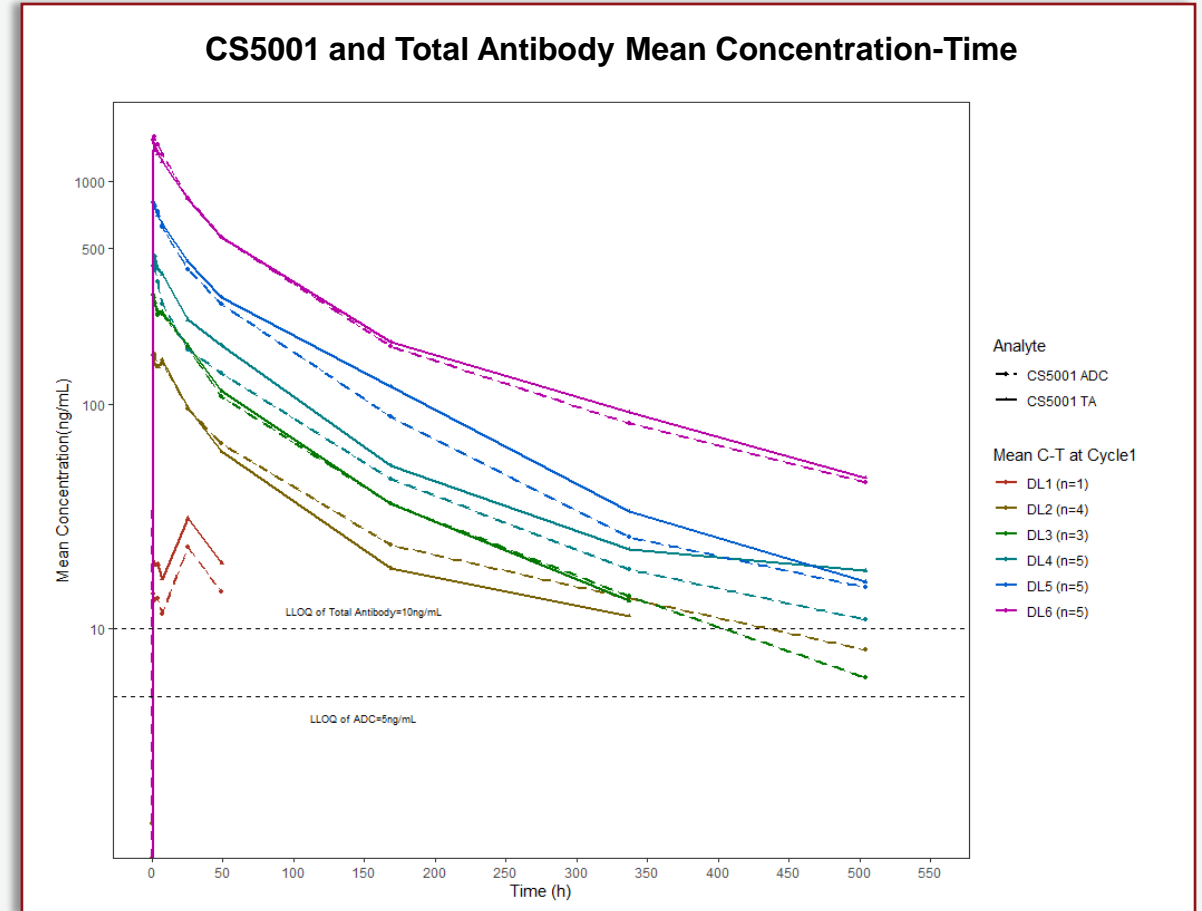
◀ Baseline MRI: target lesion pancreatic surgical bed soft tissue mass with a longest diameter of **37 mm**

◀ After 9 weeks of CS5001 treatment, the longest diameter of target lesion reduced to **28 mm (24% reduction)**, the overall response is **SD**

◀ After 18 weeks of CS5001 treatment, the longest diameter of target lesion reduced to **24 mm (35% reduction)**, the overall response is **PR**

CS5001 PK profile: excellent linker stability with dose-proportional exposure

- PK data suggested a dose proportional exposure of CS5001 following *i.v.* administration
- Immunoconjugate exhibited excellent linker stability, with close similarity observed between ADC and total antibody PK profiles
- The levels of toxin and prodrug in plasma are below the limit of quantification
- No anti-drug antibody formation has been detected



CS5001 phase 1 clinical program summary

1

CS5001, a novel ROR1–directed PBD-ADC, appears well tolerated and safe in the first-in-human phase 1 study

- *No DLT was observed and MTD was not reached*
- *Lower toxicities were observed comparing to other relevant ADCs*

2

CS5001 demonstrated promising antitumor activities in both solid tumor and lymphoma. Detailed and updated data to be disclosed in ASCO and other conferences in 2024

3

PK data suggested a dose-proportional exposure and excellent linker stability

4

Enrolment in the dose escalation portion is ongoing, with continued evaluation of tolerability and efficacy in both solid tumors and lymphomas

5

Pivotal trials expected to be initiated by end of 2024

02

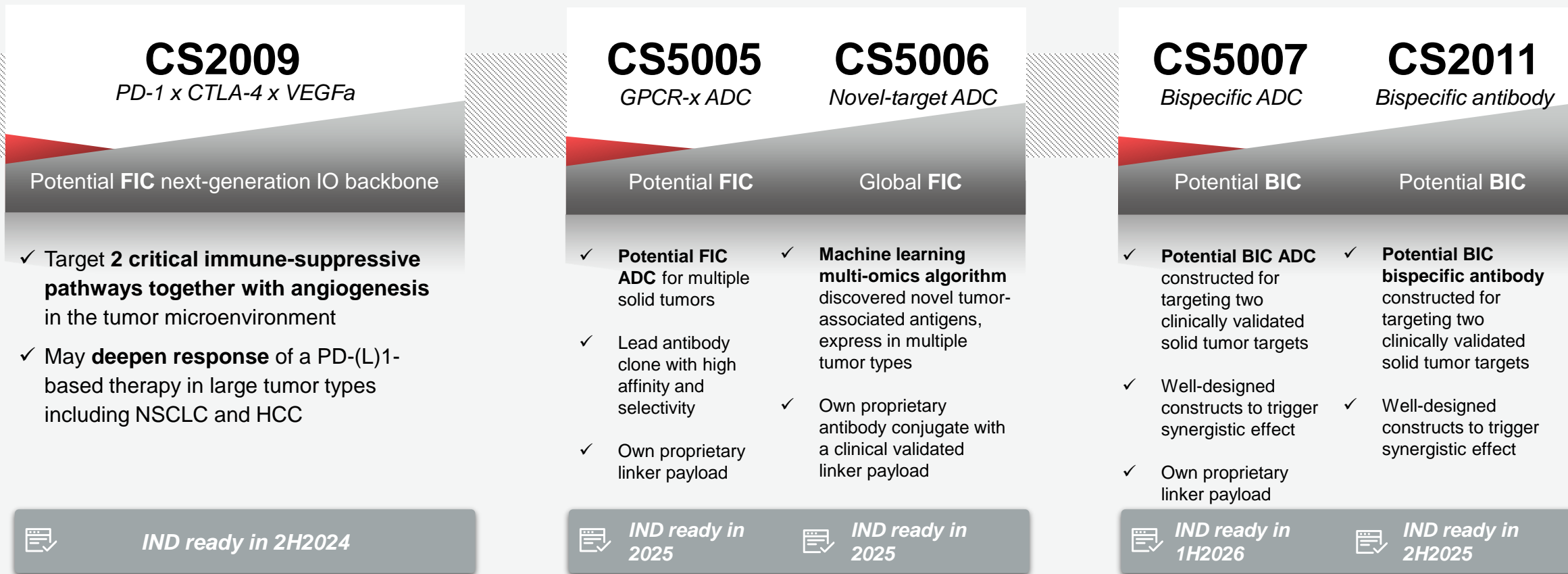
Pipeline Updates

- 1. Key Clinical Program***
- 2. Innovative Early Programs***
- 3. Commercial-stage Programs***

Innovative early programs in pipeline 2.0: multiple internally developed assets to drive future growth

Making rapid progress on multiple projects, seeking partnership opportunities

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



Current status or progress

Abbr.: FIC = first in class; BIC = best in class; IO = immune-oncology; PCC = preclinical candidate compounds; PoC = proof of concept; IND = investigational new drug

CS2009 (PD-1, CTLA-4, VEGFa tri-specific antibody)

A FIC molecule estimated IND in Q4 2024

A potential FIC tri-specific antibody targeting large indications

Molecular design

- A tri-specific molecule combining three validated clinical targets
- Preferably invigorates exhausted TILs
- No attenuation on anti-VEGFa function arm

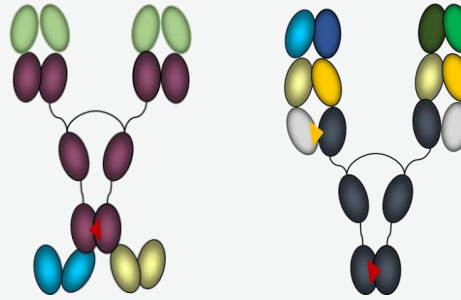
Target indication

- Tackling broader patient populations including NSCLC, HCC, GC etc.

Competitive landscape

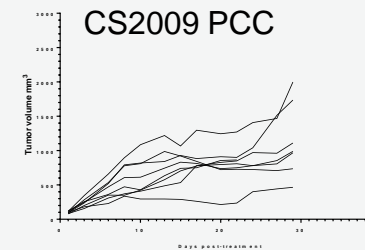
- Potentially first-in-class

Differentiated molecular design

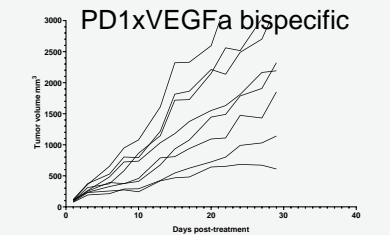
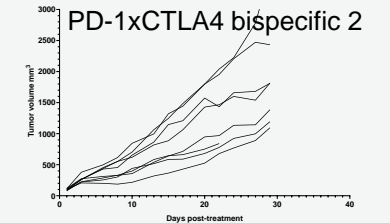
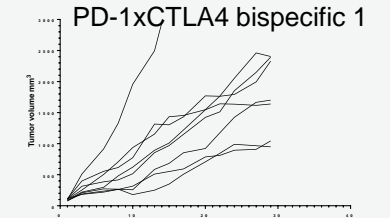


Preclinical data

In the immune-competent model, CS2009 exhibits greater antitumor activities versus competitors



X: days post-treatment
Y: tumor volume, mm³



Preliminary clinical development plan

- IND expected in 2H2024
- Fast-to-market trial: single-arm phase II trial for later-line HCC, NSCLC, GC, RCC, CC, etc.
- Global phase III trials: 1L NSCLC, HCC, GC, RCC, CC, etc.

CS5005 (GPCR-x ADC)

A FIC molecule to be IND-ready in 2025

A novel ADC target with FIC potential

Molecular design

- CStone's own proprietary anti-GPCR-x antibody with high affinity and selectivity
- CStone's own proprietary linker payload

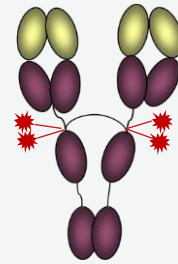
Target indication

- GPCR-x positive tumors including SCLC, NEC, NETs etc..

Competitive landscape

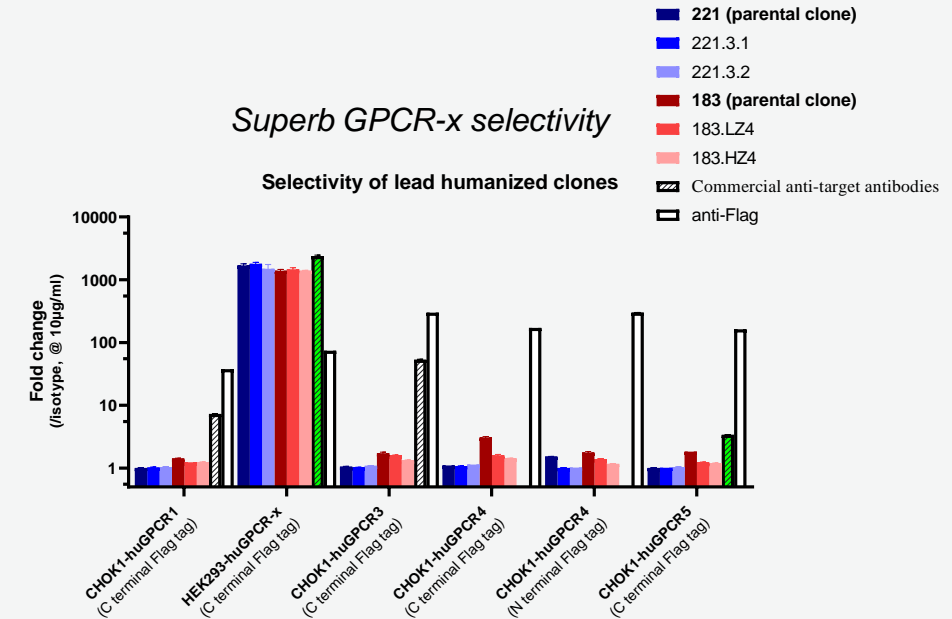
- First-in-class

Differentiated molecular design



FIC anti-GPCR-x ADC (DAR4 or 8)

Preclinical data



Preliminary clinical development plan

- IND expected in 2025
- Fast-to-market trial: single-arm phase II trial for later-line SCLC, 3L NEC, Gr3 NET, etc.
- Global phase III trials: 1L SCLC, 2L NET, etc.

CS5006 (novel-target ADC)

A FIC molecule to be IND-ready in 2025

An ADC with novel target and FIC potential

Molecular design

- CStone's own proprietary antibody with high affinity and selectivity
- Clinically validated linker payload

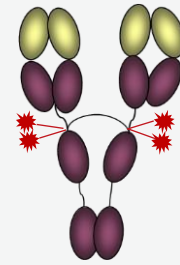
Target indication

- Covering broad indications, including NSCLC, SCCHN, ESCC, etc.

Competitive landscape

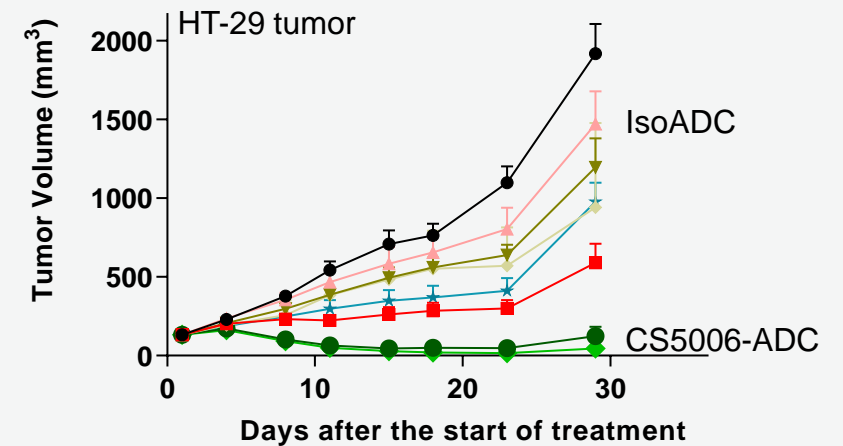
- First-in-class

Differentiated molecular design



FIC novel target ADC (DAR4 or 8)

Preclinical data



Preliminary clinical development plan

- IND expected in 2025
- Fast-to-market trial: single-arm phase II trial for later-line SCCHN, ESCC, etc.
- Global phase III trials: 1L NSCLC, SCCNH, ESCC, etc.

02

Pipeline Updates

- 1. Key Clinical Program***
- 2. Innovative Early Programs***
- 3. Commercial-stage Programs***

Pralsetinib and ivosidenib: maximize commercial value through partnerships

Leverage the strength of partners in commercialization to maximize the value of commercial pipeline

Commercial Collaboration

Pralsetinib



Nov. 8th, 2023

RET inhibitor

Granted exclusive commercial promotion right to



- Sizable upfront
- CStone to book revenue and Allist to charge service fee
- CStone retains the rights besides commercial promotion in mainland China

Domestic Manufacturing Progress

Manufacturing localization application submitted to CDE, to reduce COGS by 70%+

Development and Regulatory Progress

	1L NSCLC	2L NSCLC	1L MTC/TC	Pan-tumor ^[1]
	Approved	Approved	Approved	Excellent efficacy in Ph2 trial (ORR: 57%)
	Approved	Approved		
	Approved	Approved	Approved	

Mainland China Hong Kong (China) Taiwan (China)

Market Potential

~70K

annual newly diagnosed patients with RET-altered tumors in China^[2]

Ivosidenib



Dec. 21st, 2023

IDH1 inhibitor

Transferred exclusive rights to



- USD 50 million
- CStone to transfer to Servier the exclusive right to develop and commercialize TIBSOVO[®] in Greater China and Singapore

	AML		CCA
	R/R ^[3]	1L	
	Approved		
	Approved	Approved	Approved
		Approved	Approved

~45K


annual newly diagnosed patients with IDH1 mutation tumors in China^[4]



[1]. Broad indications in RET+ solid tumors, i.e., colorectal, gastric, breast, liver, cervical, ovarian, esophageal and pancreatic cancers; [2]. Clarivate DRG, 2025; [3]. Conditional NDA approval for this indication from NMPA; [4]. Clarivate DRG; Globocan 2020

Avapritinib


FIC KIT/PDGFRα inhibitor with potential to expand to indications beyond GIST; **partnership** negotiation ongoing






~45K

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

PDGFRA exon 18 GIST	<ul style="list-style-type: none"> ORR: 70%^[1]
Advanced SM	<ul style="list-style-type: none"> ORR: 84% 24m OS: 87.7%
Non-advanced SM	<ul style="list-style-type: none"> Statistically significant & clinically meaningful improvement in TSS
KIT D816 or N822 mutant r/r AML	<ul style="list-style-type: none"> Data to be published at conference/journal^[1]
KIT 17/18 mutant GIST (2L-4L)	<ul style="list-style-type: none"> 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
	PDGFRA 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		

Manufacturing and supply

Manufacturing localization application under review by CDE, to reduce COGS by ~50%, domestic supply expected in late 2024

Commercial Progress

<h3>80+</h3> <p>hospitals and DTPs (Direct-to-patient pharmacy) listed as of today</p> <p>Market Access</p>	<h3>NRDL</h3> <p>Included in 2023 China's National Reimbursement Drug List</p> <p>Affordability</p>	<h3>80%^[3]</h3> <p>testing rate achieved, with improved accuracy by collaborating with NPQCC</p> <p>PDGFRA exon 18/KIT testing</p>	<h3>5</h3> <p>national guidelines, incl. Chinese guideline for diagnosis and treatment of SM</p> <p>National Guidelines</p>
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[1]. Data for Chinese patient population; [2]. Blueprint Medicines and associated logos are trademarks of Blueprint Medicines Corporation; [3]. In Top 100 hospitals

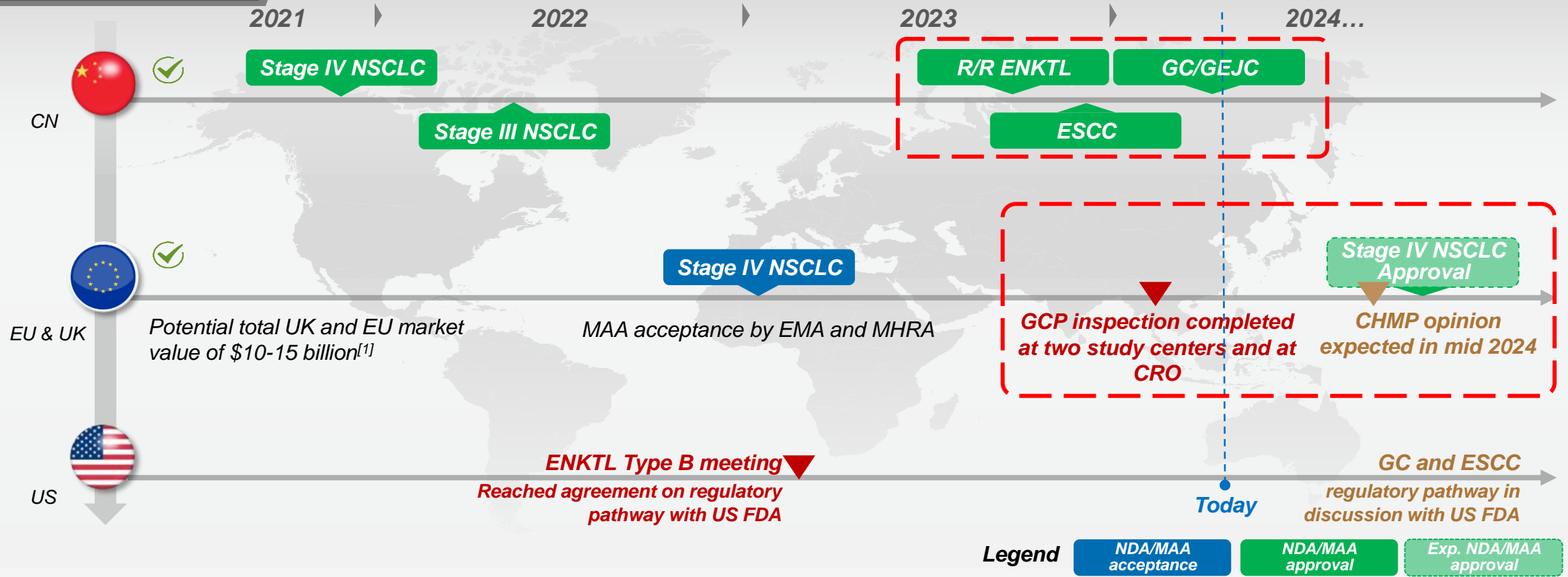
Abbr.: FIC = first in class; GIST = gastrointestinal stromal tumor; SM = systemic mastocytosis; AML = acute myeloid leukaemia; SOC = standard of care; IIT = investigator initiated trial; TSS = total symptom score; NPQCC = National Pathology Quality Control Center; BE = bio-equivalence; CDE = Center for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

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

Sugemalimab (PD-L1 mAb)

All 5 indications approved in China; MAA under regulatory review in EU and UK; in active discussion with global partners

Regulatory Progress



Partnership Progress

Partnership negotiation for ex-China rights ongoing, with multiple deals to be closed through the end of 2024

[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

CStone's Mature and 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/PDGFRA 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
- **Nofazinlimab** (clinical)
PD-1, front runner in PD-(L)1 + Lenvatinib for 1L HCC
- **CS1002** (clinical)
CTLA4, co-dev with Hengrui, received IND approval for 1L late-stage nsq-NSCLC

Pipeline 2.0

- **CS5001** (clinical)
ROR1-ADC in leading position worldwide
- **CS2009** (pre-clinical)
PD-1 x CTLA4 x VEGFa
- **CS5005** (pre-clinical)
GPCR-x ADC
- **CS5006** (pre-clinical)
Novel-target ADC

03

Financial Highlights

FY2023 financial results

Significantly lower loss for the year from BD income with robust cash reserve

Mn RMB	FY2023	FY2022	Change
GROUP REVENUES	463.8	481.4	-4%
Sales of Pharmaceutical Products ^[1]	336.7	364.3	-8%
License Fee Income	95.7	87.3	+10%
Royalty Income ^[1]	31.4	29.8	+5%
OPERATING EXPENSES (Non-IFRS ^[2] Measures)	(872.8)	(1048.6)	-17%
Research and development expenses (Non-IFRS ^[2] Measures)	(534.7)	(559.2)	-4%
Selling, marketing and admin expenses (Non-IFRS ^[2] Measures)	(338.1)	(489.4)	-31%
OTHER INCOMES/ OTHER GAINS AND LOSSES	250.1	17.9	+1297%
Other incomes	50.6	18.7	+171%
Other gains and losses	199.5	(0.8)	+25038%
LOSS FOR THE YEAR (Non-IFRS ^[2] Measures)	(330.2)	(760.7)	-57%

Total Group Revenues of RMB 463.8Mn

- Sales of Pharmaceutical Products -8% to RMB 336.7Mn
- License Fee Income +10% to RMB 95.7Mn
- Royalty Income +5% to RMB 31.4Mn
- Commercial gross profit margin ^[1] increased from 49% to 57%

Loss for FY2023 down 57% to RMB 330.2Mn

- Higher other gains mainly due to net gain of 179.5Mn related to transfer of Ivosidenib license
- Lower spending on phase III registrational clinical trials
- Lower SG&A expenses with stringent cost control measures

Mn RMB	31 st December 2023	31 st December 2022	Change
CASH BALANCE ^[3]	1,026.7	1,042.1	(15.4)

Cash Balance > RMB 1.0Bn

- Lower operating cash burn by RMB 21.9m (FY2023: RMB 588.8Mn vs. FY2022: RMB 610.7Mn)
- Cash inflow from equity offering and BD

[1] Commercial gross profit margin represents gross profit margin generated from sales of pharmaceutical products and royalty income. FY 2022: RMB 191.2Mn (equals to total Gross profit RMB 278.5Mn less Gross Profit from License Fee Income of RMB 87.3m), 49% of commercial revenue vs. FY 2023: RMB 208.6 Mn, 57% of commercial revenue; [2] IFRS: International Financial Reporting Standards. Non-IFRS Measures represents the loss for the year 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 in the near term

	Assets	Catalysts	Date
Key clinical program	CS5001 (ROR1 ADC)	★ Ph1 data presentation at 2024 ASCO and ESMO / ASH	1H2024 & 2H 2024
		★ Initiation of Ph1b trial with registrational potential	2H2024
		★ Global BD partnership	2024/2025
Pipeline 2.0	CS2009 (PD1xCTLA4xVEGFa)	IND submissions	2H2024
	CS5006 (novel-target ADC)	IND submissions	2025
	CS5005 (GPCR-x ADC)	IND submissions	2025
Commercial / late-stage programs	Sugemalimab (PD-L1)	★ Regulatory decision for 1L stage IV NSCLC in EU and ex-China partnership	1H 2024
		★ Regulatory decision for 1L stage IV NSCLC in UK and ex-China partnership	2H 2024
		NDA approval for 1L GC/GEJ in mainland China (achieved)	Q1 2024
	Pralsetinib (RET)	Expected acceptance of ANDA for manufacturing localization	1H 2024
	Avapritinib (KIT/PDGFRα)	Expected approval of ANDA for manufacturing localization	2H 2024
	Nofazinlimab (PD-1)	Final assessment of OS and ex-China partnership exploration	1H 2025

★ Key value driver

Abbr.: IND = investigational new drug; NDA = new drug application; ENKTL = Extranodal Natural KILLER/T Cell Lymphoma; NSCLC = non-small cell lung cancer; MAA = marketing authorization application; GC/GEJ = gastric adenocarcinoma/gastroesophageal junction adenocarcinoma; ESCC = esophageal squamous cell carcinoma; HCC = hepatocellular carcinoma

C1



基石药业
JISHI
PHARMACEUTICALS



Thanks





Appendix

Experienced management team



Jason Yang
M.D., Ph.D.

Chief Executive Officer, President of R&D



Michael Choi
MBA

Chief Business and Strategy Officer



Qingmei Shi
M.D., Ph.D.

Chief Medical Officer



Yujuan La
Ph.D.

Head of Product Dev.



Min Liao
EMBA

Head of Commercial



Nicky Ni
MBA, CFA

Chief Financial Officer



Yinghua Zhang

Head of Operations





END