



基石药业

CSTONE
PHARMACEUTICALS

2024 Interim Results Presentation

August 26, 2024

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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

15

NDA approvals

50+

Data presentations /publications

COMMERCIAL

Leverage the strength of partners in commercialization

4* commercialized products

9 indications approved

4 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[®], Aynakit[®], 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)

2024

Cejemly[®] MAA approval in EU and overseas strategic partnerships initiated

*the exclusive rights of ivosidenib has been transferred to Servier and the transition is ongoing

01

Business Achievements

2024YTD

2024YTD Achievements

Financial

as of Jun. 30, 2024

Total revenue^[1] in 2024 H1

254.2

RMB Mn

(Flat YoY)

Net profit^[2] in 2024 H1

10.8

RMB Mn

(Turned profitable comparing to a net loss of RMB 183.0 mn in 2023 H1)

Cash balance

813.9

RMB Mn

Research & Development

as of Aug. 26, 2024

2 New NDA approvals

Sugemalimab

1L GC/GEJC



1L stage IV NSCLC



1 NDA currently under review

Sugemalimab

1L stage IV NSCLC



5 Data publications / presentations

CS5001 (ROR1 ADC)

Phase I study ongoing in the U.S., Australia and China; 50+% ORR achieved in HL & DLBCL; PRs & SDs with reduced tumor burden observed in various types of solid tumors during dose escalation (**ASCO 2024 data**)

Lorlatinib (ROS1)

Positive topline readout achieved for pivotal study in ROS1+ advanced NSCLC

10+ Preclinical development projects in progress

Commercial & Partnership

as of Aug. 26, 2024

Manufacturing Localization

- **Avapritinib** manufacturing localization application approved by NMPA
- **Pralsetinib** manufacturing localization application under review by CDE

NRDL

- **Avapritinib** Included in 2023 China's NRDL and implemented from Jan. 1, 2024

BD

- Strategic partnership of **sugemalimab with Ewopharma** in Switzerland and 18 Central Eastern Europe countries
- Exclusive commercialization partnership of **avapritinib with Hengrui** in mainland China

[1] Total revenue in 2024 H1 includes sales of pharmaceutical products (2024 H1 RMB 118.3 mn vs. 2023 H1 RMB 246.9 mn, -52%), license fee income (2024 H1 RMB 122.6 mn vs. 2023 H1 NA) and royalty income (2024 H1 RMB 13.3 mn vs. 2023 H1 RMB 14.6 mn, -9%)

[2] Net profit for the period excluding the effect of certain non-cash items and one-time events, namely the share-based payment expenses.

Abbr.: GC/GEJC, Gastric or Gastroesophageal junction carcinoma; HL, Hodgkin Lymphoma; NRDL, National Reimbursement Drug List;



Mainland China



United Kingdom



European Union



02

Pipeline Updates

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

To drive business growth by maximizing commercial value of products in the market and advancing innovative pipeline 2.0

Commercial-stage Programs

Sugemalimab
(PD-L1)

Pralsetinib
(RET)

Avapritinib
(KIT/PDGFRA)

Key Clinical Program in Pipeline 2.0

CS5001
(ROR1 ADC)

**Top 2 ROR1-ADC globally
with best-in-class potential**

Innovative Early Programs in Pipeline 2.0

CS2009

(PD-1/CTLA4/VEGF trispecific mAb)

CS5005
(SSTR2 ADC)

CS5006
(novel-target ADC)

CS2011
(EGFR/HER3
bispecific mAb)

CS5007
(EGFR/HER3
bispecific ADC)

Autoimmune Assets
(bi/trispecific mAb)

& other exploratory programs

02

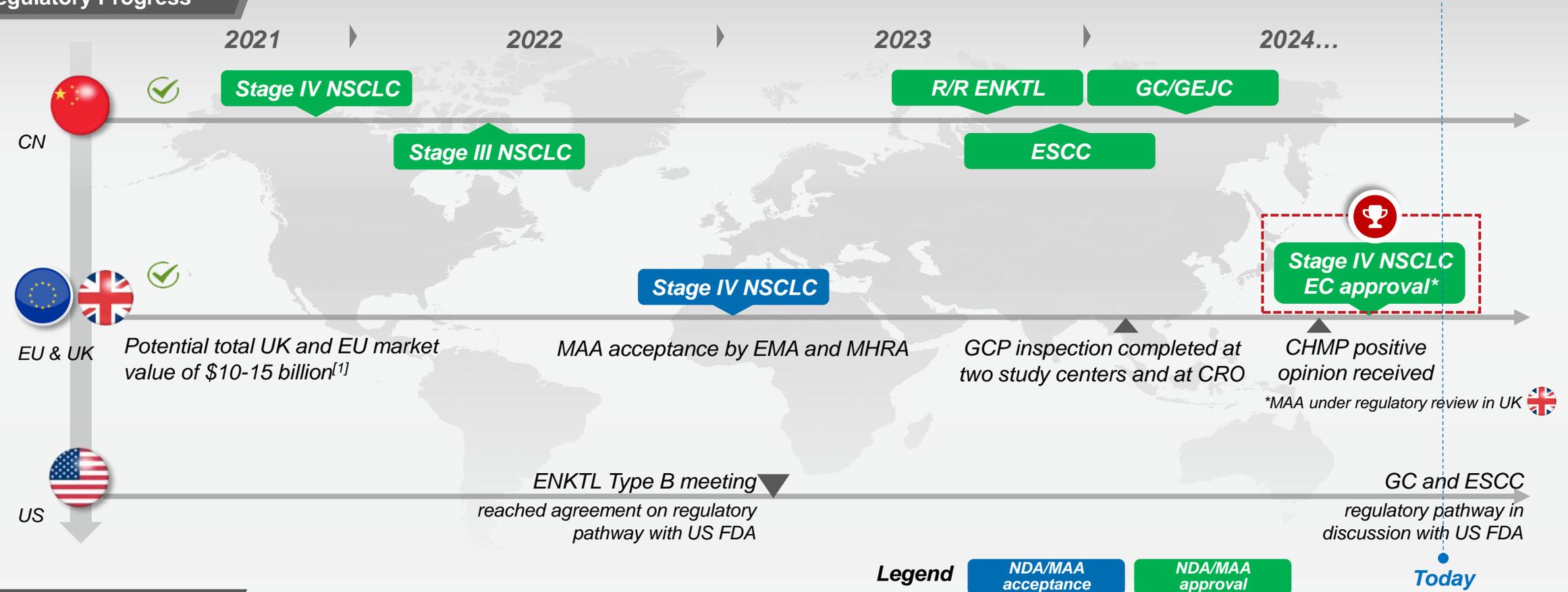
Pipeline Updates

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

Sugemalimab (anti-PD-L1 mAb) (1/2)

All 5 indications approved in mainland China; 1L treatment of NSCLC approved by EC and proceeding smoothly at UK MHRA; in active discussion with global partners

Regulatory Progress



Partnership Progress

- ✓ **Commercial partnership with Ewopharma in Switzerland and 18 Central Eastern European countries (up to USD 51.3 mn total deal size with future revenue through drug supply)**
- ✓ **Negotiations for other regions ongoing and closing expected in 2024**

[1] Data based on Evaluate Pharma 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; 1L = first line; EC = European Commission

Sugemalimab (anti-PD-L1 mAb) (2/2)

EU approval granted; first global partnership achieved and more to come in 2024 H2

MAA approval achieved in EU, positioning CStone as one of the few Chinese biotechs to launch drugs in major global markets



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate D – Medical products and Innovation
D1 – Medicines – policy, authorisation and monitoring
Head of unit

Brussels, 25 July 2024

NOTE TO THE MEMBERS OF THE STANDING COMMITTEE ON MEDICINAL PRODUCTS FOR HUMAN USE/STANDING COMMITTEE ON VETERINARY MEDICINAL PRODUCTS

Subject: Adoption of COMMISSION IMPLEMENTING DECISION granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "Cejemly - sugemalimab", a medicinal product for human use

- ☑ **The *THIRD* Chinese biotech to launch innovative oncology drugs in EU** after Beigene and Hutchmed
- ☑ **The *FIRST* PD-L1 approved in EU for Stage IV NSCLC all comers**
- ☑ **The *FIRST* domestic PD-L1 to be marketed in international markets**
- ☑ **More MAAs of additional sugemalimab indications to be submitted soon to EMA**

Global partnerships to bring significant financial impact via immediate upfront and long-term recurring revenue

Recurring revenue for CStone from sugemalimab sales in global markets:

- Favorable competitive landscape in EU market, only pembrolizumab approved with chemo combo for all comer Stage IV NSCLC

Strategic commercial collaboration with



in Switzerland and
18 Central Eastern Europe
countries

May, 2024

2024 H2

Future ahead

Rising interest level for other regions following EC approval:

- Expecting **sizable upfront** from western Europe, EMEA, South America, SEA, Australia, etc.

Maximize commercial value through partnerships: pralsetinib and avapritinib

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

Commercialization Progress

Pralsetinib 普吉华

RET inhibitor

Nov. 8, 2023

Partner with  艾力斯

for the commercial promotion in mainland China

- Sizable upfront
- CStone to book revenue and Allist to charge service fee
- CStone retains the rights^[1] besides commercial promotion in mainland

Smooth transition to and collaboration with Allist of commercial activities

Avapritinib 泰吉华

KIT/PDGFRα inhibitor

Jul. 3, 2024

Partner with  恒瑞

for the commercial promotion in mainland China

- RMB 35mn upfront
- CStone to book revenue and Hengrui to charge service fee
- CStone retains the rights^[1] besides commercial promotion in mainland China

Included in 2023 China's NRDL and implemented from Jan.1, 2024

Domestic Manufacturing Progress

Manufacturing localization application under review by CDE, to significantly reduce COGS

Manufacturing localization application approved by NMPA, to significantly reduce COGS; domestic supply expected in late 2024/ early 2025

Development and Regulatory Progress

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

 Mainland China
  Hong Kong (China)
  Taiwan (China)

	GIST-PDGFRα exon 18	GIST-KIT 17/18 mutant (2-4L)	SM-Advanced	ISM	KIT D816 or N822 mutant r/r AML
	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
	Approved		Approved	Approved	
	Approved		Approved	Approved	

 Blueprint Medicines
 Blueprint Medicines

Market Potential

~70K annual newly diagnosed patients with RET-altered tumors in China^[3]

~45K annual newly diagnosed patients with PDGFRα exon 18 or KIT mutation tumors in China^[3]

[1]. CStone has an exclusive collaboration and license agreement with Blueprint Medicines for the development and commercialization of avapritinib and pralsetinib in Mainland China, Hong Kong, Macau and Taiwan; [2]. Broad indications in RET+ solid tumors, i.e., colorectal, gastric, breast, liver, cervical, ovarian, esophageal and pancreatic cancers; [3]. Clarivate DRG, 2025; abbr.: CDE, Center for Drug Evaluation; COGS, Cost of Goods Sold; NMPA, National Medical Products Administration; NSCLC, Non-Small Cell Lung Cancer; MTC, Medullary Thyroid Cancer; TC, Thyroid Cancer; GIST, Gastrointestinal-stromal tumor; SM, Systematic Mastocytosis; AML, Acute Myelocytic Leukemia; ISM, Indolent Systemic Mastocytosis

02

Pipeline Updates

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

Pipeline 2.0 – An Innovative Portfolio with Global Right

Drug candidate	Rights	Indication	Discovery	Preclinical Development	IND	FIH	POC	Partner
CS5001 ¹ (ROR1 ADC)		Solid tumors hematologic malignancies						
CS2009 (PD-1xCTLA4xVEGFa trispecific antibody)		Solid tumors						
CS5006 (Undisclosed ADC)		Solid tumors						
CS2011 (EGFRxHER3 bispecific antibody)		Solid tumors						
CS5005 (SSTR2 ADC)		Solid tumors						
CS5007 (EGFRxHER3 bispecific ADC)		Solid tumors						
CS2012 (SSTR2 T-cell engager)		Solid tumors						
CS2013 (Bispecific antibody)		Autoimmune						
EX012 (Bispecific antibody)		Solid tumors						
EX018 (Bispecific antibody)		Autoimmune						

Note: Assets status denotes progress in the region(s) noted in the column titled "Rights"; FIH = First in Human, POC = Proof of Concept, 1. CStone obtains the exclusive global right to lead development and commercialization of LCB71/CS5001 outside the Republic of Korea

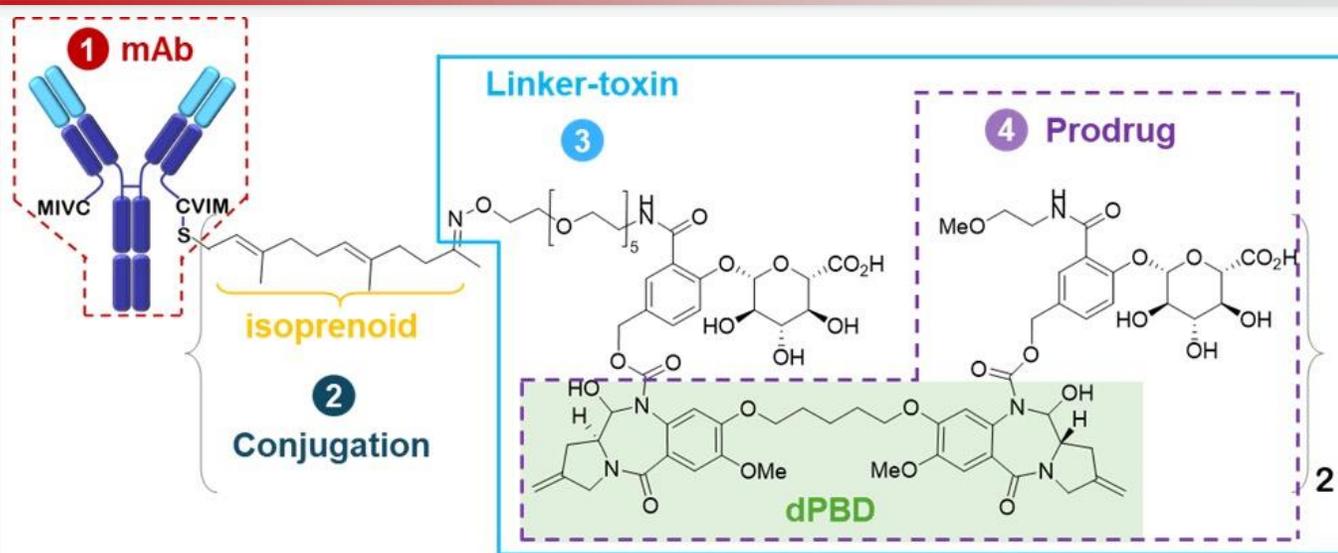
CS5001 (ROR1 ADC)

Top 2 in position globally with phase I 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 adeno-NSCLC ^{2,6-13}
- First-in-class molecule acquired by Merck for US\$2.75Bn in Nov 2020 at phase I

4 key differentiators support best-in-class potential:



1 Fully human anti-ROR1 IgG1 mAb

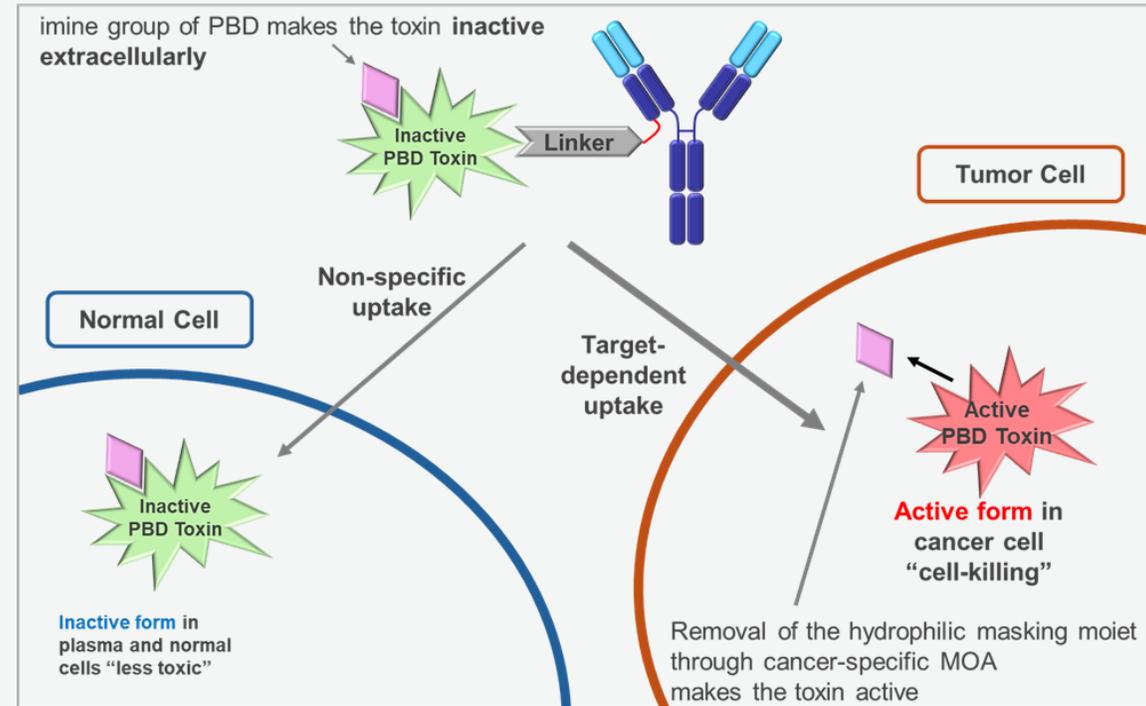
2 Site-specific conjugation technology (“ConjuAll”) enables a homogenous drug to antibody ratio of 2

3 Proprietary tumor-selective cleavable linker (cleaved by β -glucuronidase) shows exceptional stability in serum

4 Proprietary tumor-activated PBD dimer toxin prodrug (released by β -glucuronidase), with advantage in tumor resistance mechanism through DNA crosslinking

Novel prodrug technology minimizes systematic toxicity of conventional PBD

- PBD prodrug is inactive compared to naked PBD
- Prodrug, being in a highly polar form, cannot penetrate and kill normal cells
- Prodrug mitigates toxicity risk associated with systemic exposure of conventional PBD payloads
- Similar IC₅₀ of naked PBD-bearing ADC and PBD prodrug-bearing ADC indicates no loss in payload activity and high efficiency of activating PBD prodrug in cancer cells



Free toxins tested	IC ₅₀ (nM)	
	Tumor cell line	
	72h	168h
Naked PBD free toxin	1.15	0.04
LCB's proprietary PBD prodrug free toxin	>100	>20

Tumor selective activation →

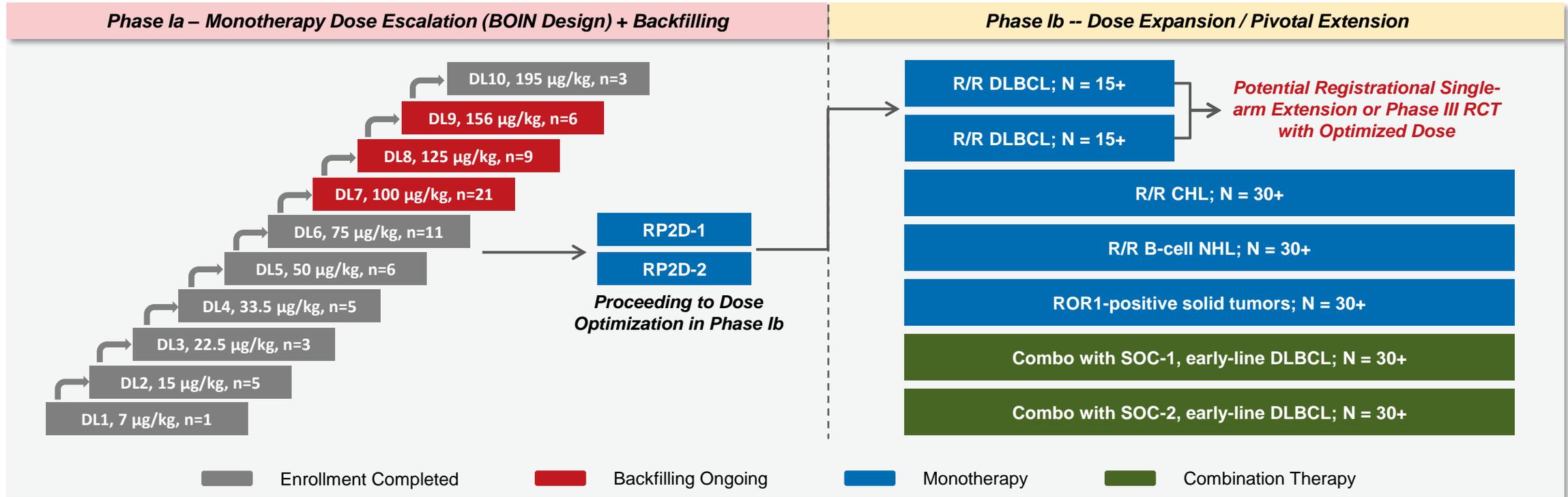
Inactive

ADCs tested	IC ₅₀ (nM)
	Tumor cell line
	144h
Naked PBD-ADC	0.23
PBD prodrug-ADC	0.19

Active

CS5001 phase I trial design and fast-to-market registrational trial plan

A phase I, dose-escalation and dose-expansion study to evaluate the safety, tolerability, pharmacokinetics and antitumor activities of CS5001 in patients with advanced solid tumors and lymphomas



Phase Ia Key Eligibility Criteria

- Age ≥18 years
- 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

Expected Catalysts in Near Term:

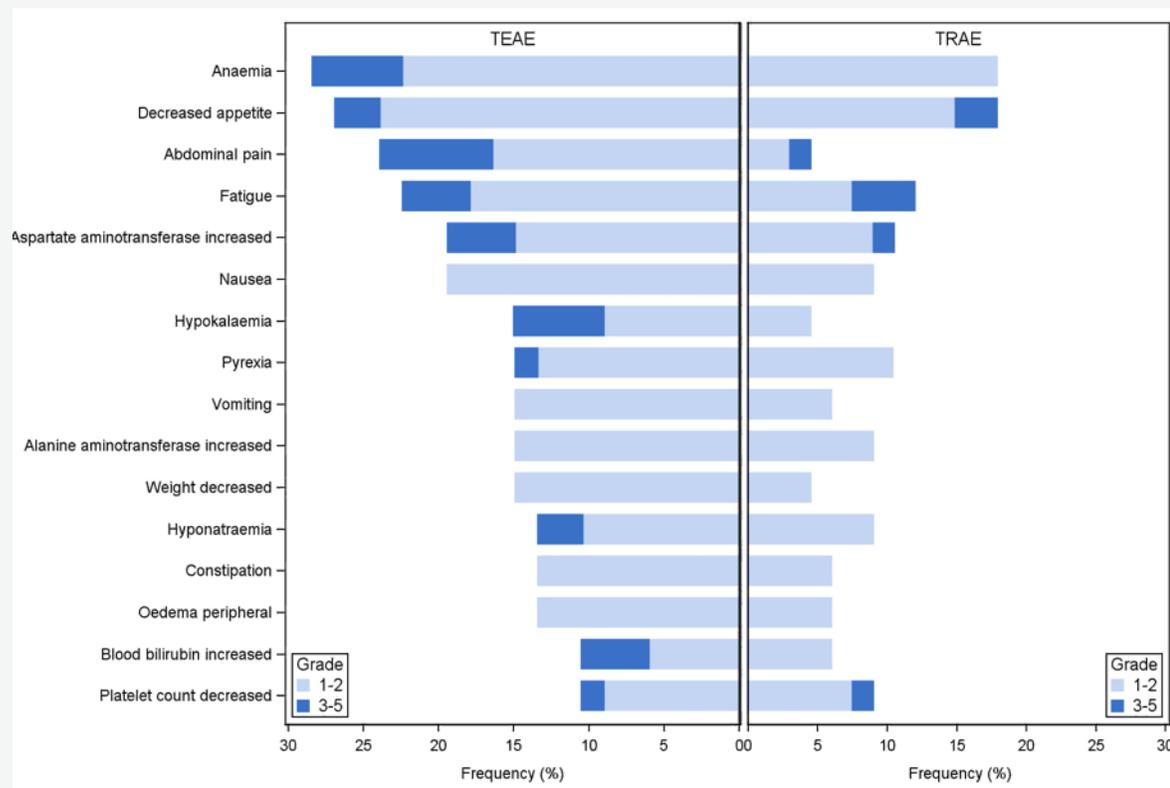
Phase I data presentation at 2024 ASH

Initiation of Phase Ib trial with registrational potential for lymphoma

Exploring ROR1-based combination in phase Ib for early-line lymphoma

CS5001 safety profile (1/3): Well tolerated in heavily pre-treated patients; Most TRAEs of grade 1/2

Most Common TEAEs ($\geq 10\%$) and TRAEs ($\geq 2\%$) (Safety Analysis Set)



▶ 60 (89.6%) patients experienced at least one TEAE; 32 (47.8%) patients had \geq grade 3 TEAEs.

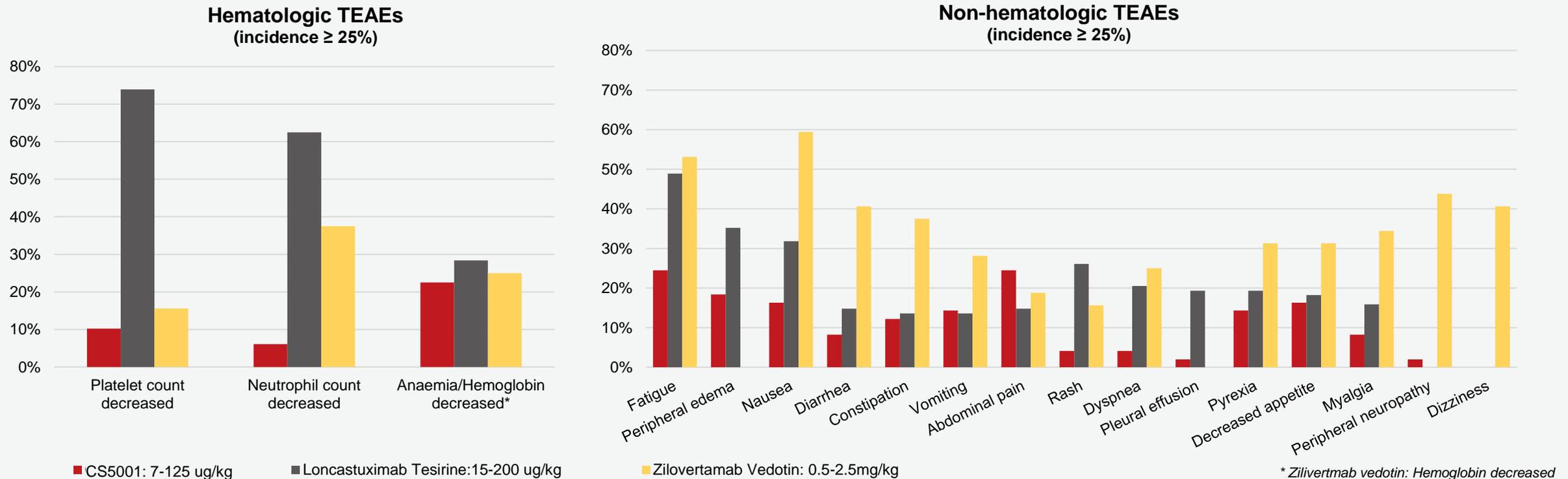
- Most common ($\geq 20\%$) TEAEs were anaemia ($n=19$, 28.4%), decreased appetite ($n=18$, 26.9%), abdominal pain ($n=16$, 23.9%), and fatigue ($n=15$, 22.4%).

▶ TRAEs occurred in 45 (67.2%) patients; 13 (19.4%) patients had \geq grade 3 TRAEs.

- Most common ($\geq 10\%$) TRAEs were anaemia ($n=12$, 17.9%), decreased appetite ($n=12$, 17.9%), fatigue ($n=8$, 11.9%), pyrexia ($n=7$, 10.4%), and aspartate aminotransferase increased ($n=7$, 10.4%).

CS5001 safety profile (2/3): Favorable safety profile of CS5001 vs. two relevant ADCs in phase I trials

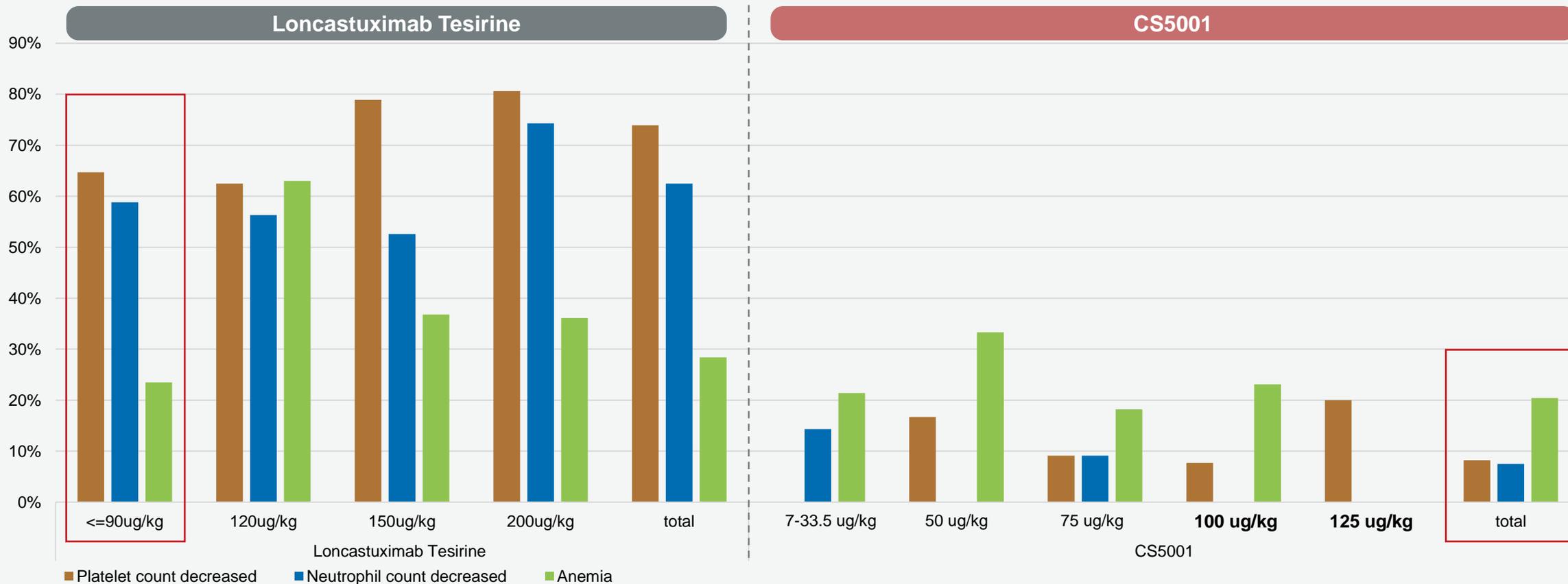
Lower frequency of hematologic and non-hematologic AEs observed for CS5001 up to Dose Level 8 (125 ug/kg)



	CS5001	Zilovertamab Vedotin	Loncastuximab Tesirine
Target	ROR1	ROR1	CD19
Linker	Isoprenoid-β-glucuronide	Mc-vc-PAB	cathepsin-cleavable valine-alanine
Payload	Prodrug of PBD dimer	MMAE	Naked PBD dimer
DAR	2	Avg. 4 (0-8)	Avg. 2.3 (0-6)

CS5001 safety profile (3/3): 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 efficacy profile (1/2): 50+% ORR in multiple types of lymphoma

Best overall response (BOR) in Evaluable Patients with Lymphomas

BOR	DL1-4 7-33.5 µg/kg (n=2)	DL5 50 µg/kg (n=2)	DL6 75 µg/kg (n=5)	DL7 100 µg/kg (n=8)	DL8 125 µg/kg (n=3)	DL9 156 µg/kg (n=1)	All DLs (n=21)
CR	0	0	0	2 (25%)	0	0	2 (9.5%)
PR	0	1 (50%)	1 (20%)	0	3 (100%)	1 (100%)	6 (28.6%)
SD	0	0	0	0	0	0	0
PD	2 (100%)	1 (50%)	4 (80%)	6 (75%)	0	0	13 (61.9%)

▶ Hodgkin Lymphoma

- Objective responses observed from DL5 (50 µg/kg) and above
- 1 CR and 4 PRs among 9 evaluable patients at DL5-9 (**ORR: 55.6%**).

▶ Diffuse large B-cell lymphoma (DLBCL)

- Objective responses observed from DL7 (100 µg/kg) and above
- 1 CR and 2 PRs among 6 evaluable patients at DL7-9 (**ORR: 50.0%**).

Source: 2024 ASCO Poster

Abbr.: DL – dose level; ORR – objective response rate; CR – complete response; PR – partial response; SD – stable disease; PD – progressive disease

CS5001 efficacy profile (2/2): PRs and SDs with reduced tumor burden emerging in various types of solid tumors at higher doses

Best overall response (BOR) in Evaluable Patients with Solid Tumors

BOR	DL1-4 7-33.5 µg/kg (n=9)	DL5 50 µg/kg (n=4)	DL6 75 µg/kg (n=6)	DL7 100 µg/kg (n=10)	DL8 125 µg/kg (n=6)	DL9 156 µg/kg (n=3)	All DLs (n=38)
CR	0	0	0	0	0	0	0
PR	0	0	0	1 (10%)	1 (16.7%)	0	2 (5.3%)
SD	1 (11.1%)	1 (25%)	1 (16.7%)	2 (20%)	2 (33.3%)	2 (66.7%)	9 (23.7%)
PD	8 (88.9%)	3 (75%)	5 (83.3%)	7 (70%)	3 (50%)	1 (33.3%)	27 (71.1%)

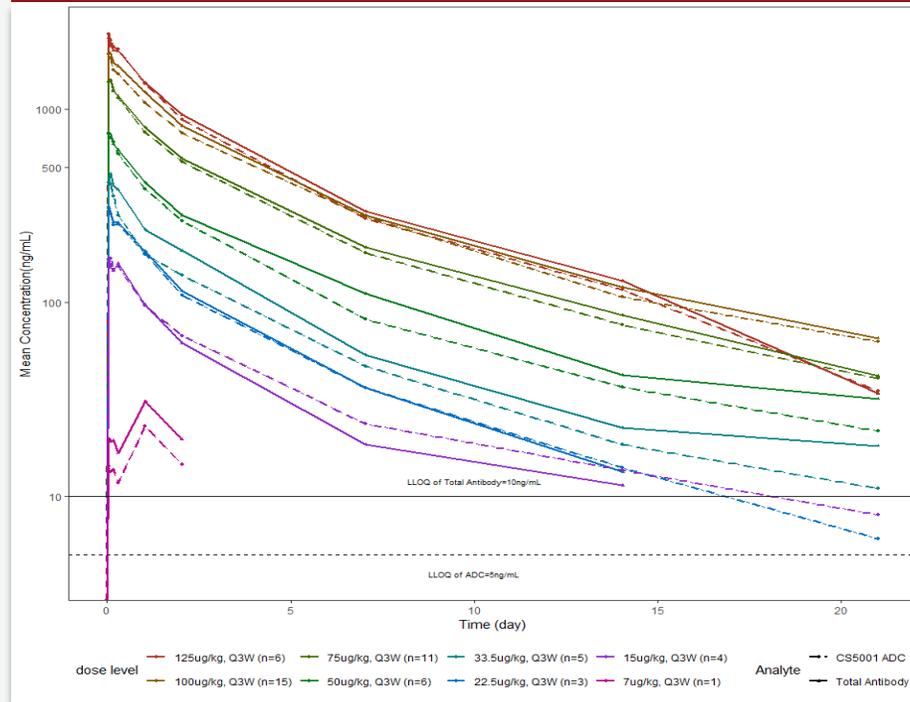
- ▶ PRs and SDs with reduced tumor burden emerging in various types of solid tumors at higher doses
- ▶ Notably in non-small cell lung cancer (NSCLC) (**1 PR and 3 SDs**), triple-negative breast cancer (TNBC) (**1 SD**), pancreatic cancer (**1 PR**), and ovarian cancer (**1 SD**)
- ▶ Most of these patients remain on study for continued treatment and tumor assessment.

Source: 2024 ASCO Poster

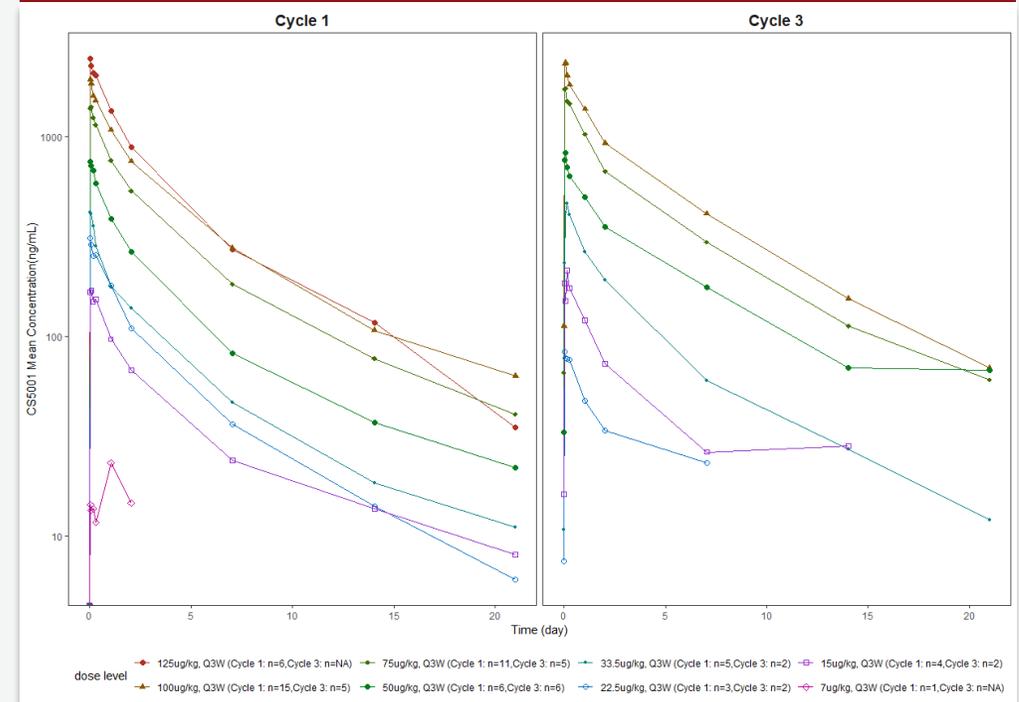
Abbr.: DL – dose level; CR – complete response; PR – partial response; SD – stable disease; PD – progressive disease

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

Mean Serum Concentration of CS5001 and Total Antibody vs. Time Profiles at Cycle 1 (Semi-Log Scale)



Mean Serum Concentration of CS5001 vs. Time Profiles at Cycle 1 and Cycle 3 (Semi-Log Scale)



- Exposure of CS5001 was overall proportional to dose, with an apparent half-life of about 5 days.
- PK profile of CS5001 was similar to that of total antibody.
- Despite fewer patients evaluable for PK from Cycle 3, no significant accumulation was observed at Cycle 3.
- Plasma concentration of free toxin was below the limit of quantification in all samples (lower limit of quantification was 10pg/mL).

Source: 2024 ASCO Poster

Note: Blood specimens were collected for PK analysis at predefined timepoints. PK parameters were derived from non-compartmental analysis from the serum concentration-time profile of CS5001.

CS5001 program summary

1

CS5001, a novel ROR1–directed PBD-ADC, appears well tolerated in heavily pre-treated patients with cancer across doses 7–195 µg/kg in the first-in-human study

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

2

Encouraging anti-tumor activity observed across various tumor types regardless of ROR1 expression

- *Hodgkin lymphoma: ORR: 55.6%; DLBCL: ORR: 50.0%; Solid tumors: PRs and stable diseases (SDs) with reduced tumor burden emerging in various types of solid tumors at higher doses*
- *Correlation between anti-tumor activity and ROR1 expression currently under evaluation*

3

PK profile of CS5001 ADC similar to total antibody, indicating excellent stability of the ADC in circulation

4

Dose escalation and backfilling at higher doses still ongoing to determine preliminary RP2D, followed by phase Ib dose expansion in indication of interest for dose optimization and potential registration.

- *Updated data will be promptly disclosed at academic conferences (e.g. ASH).*

5

Pivotal trials expected to be initiated by end of 2024

02

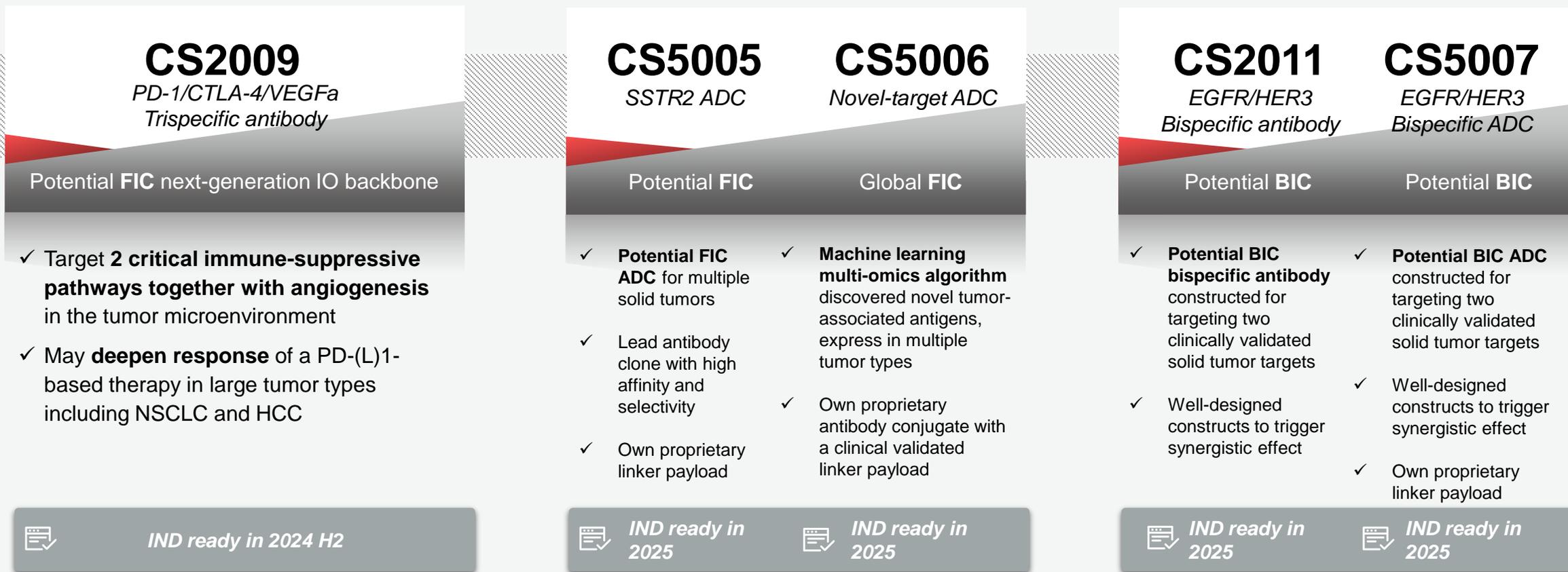
Pipeline Updates

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

A potentially FIC molecule; IND expected in 2024 Q4

A potential FIC trispecific antibody targeting large indications

Molecular design

- A trispecific molecule combining three validated clinical targets
- Preferentially invigorates exhausted TILs
- No attenuation on anti-VEGFa function arm

Target indication

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

Competitive landscape

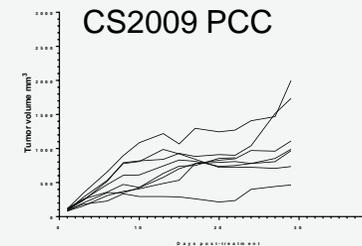
- Potentially first-in-class

Differentiated molecular design

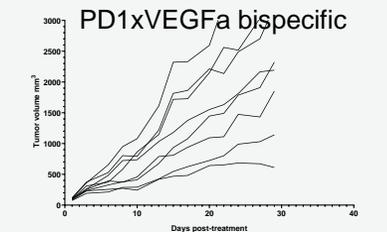
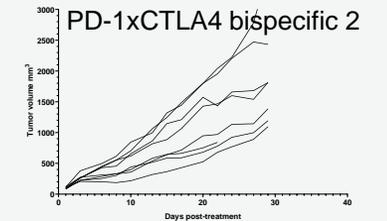
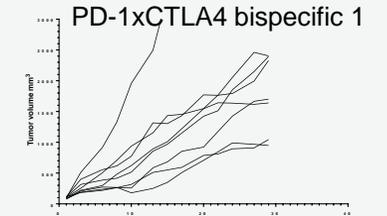


Preclinical data

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 2024 H2
- Fast-to-market trial: single-arm phase II trial for later-line NSCLC, RCC, CC, HCC, GC, etc.
- Global phase III trials: 1L NSCLC, OC, RCC, CC, HCC, GC, etc.

CS5005 (SSTR2 ADC)

A FIC molecule; IND expected in 2025

A novel ADC target with FIC potential

Molecular design

- CStone's own proprietary anti-SSTR2 antibody with high affinity and selectivity
- CStone's own proprietary linker payload

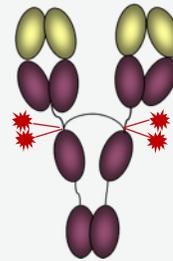
Target indication

- SSTR2 positive tumors including SCLC, NEC, NETs etc..

Competitive landscape

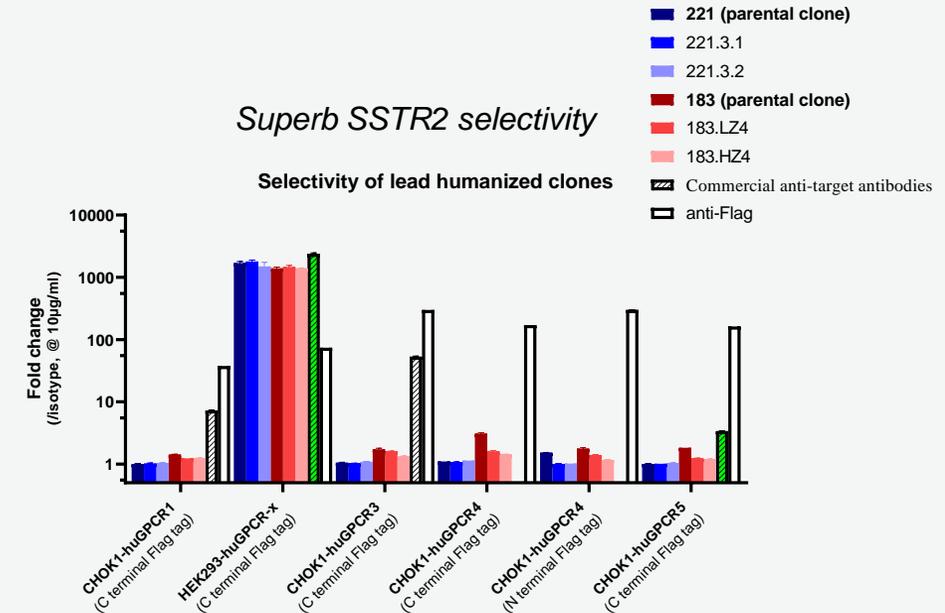
- First-in-class

Differentiated molecular design



FIC SSTR2 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.

Exploring other modalities targeting SSTR2, e.g. RDC, SSTR2/CD3 bispecific antibody, etc.

CS5006 (novel-target ADC)

A FIC molecule; IND expected 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

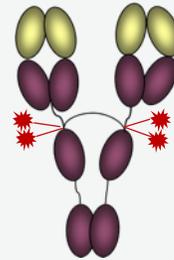
Target indication

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

Competitive landscape

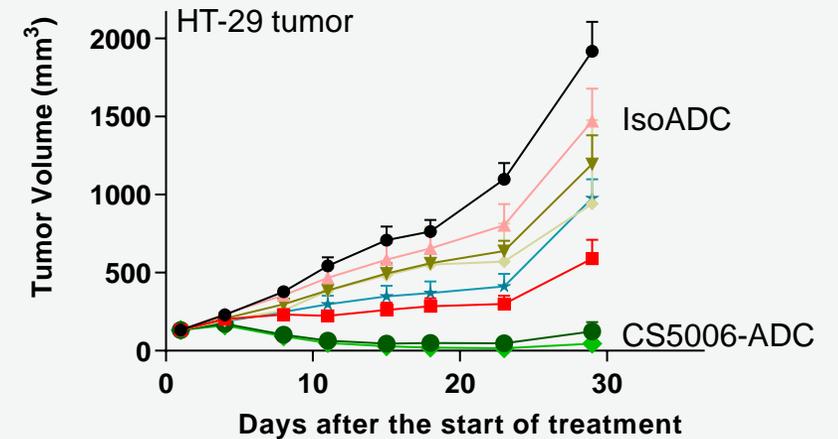
- First-in-class

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.

CS2011 (EGFR/HER3 bispecific antibody) & CS5007 (EGFR/HER3 bispecific ADC)

Potential BIC molecules; IND expected in 2025

Potential BIC

Molecular design

- Full blockage of EGFR and a functional HER3 arm
- Well-designed to trigger synergistic effect
- Better developability and much longer half-life
- Proprietary linker and payload

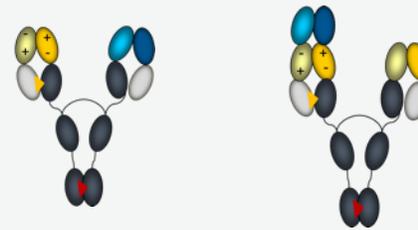
Target indication

- Solid tumors including NSCLC, SCCHN, CRC etc.

Competitive landscape

- Only one competitor currently in phase III clinical trial

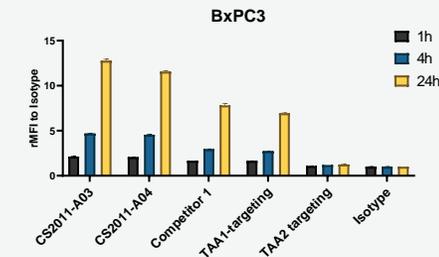
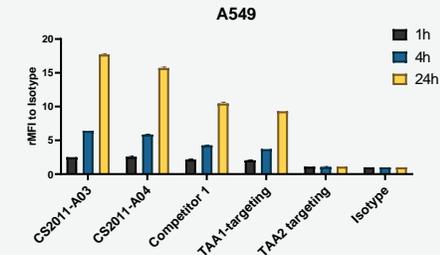
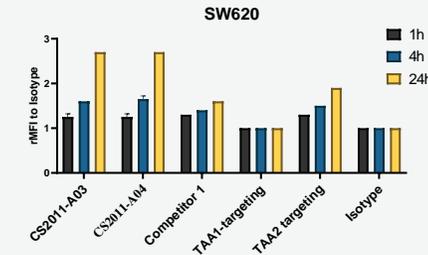
Differentiated Molecular Design



▲ CS2011
▼ CS5007



Preclinical Data



A03, and 04 trigger much higher rate of internalization than the competitor and other antibodies with the relevant targets (SW620 TAA1-TAA2+, A549 TAA1+TAA2-, and BxPC3 TAA1+TAA2+)

Preliminary Development plan

1. CS2011 and CS5007 IND both expected in 2025
2. Fast-to-market: targeting later-line NSCLC & SCCHN patients
3. Global phase III trial: targeting 1L NSCLC, SCCHN, CRC patients versus current SoC

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/PDGFRα 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** (IND-enabling)
PD-1 x CTLA4 x VEGFa trispecific antibody
- **CS5005** (pre-clinical)
SSTR2 ADC
- **CS5006** (pre-clinical)
Novel-target ADC
- **CS2011** (pre-clinical)
EGFR x HER3 bispecific antibody
- **CS5007** (pre-clinical)
EGFR x HER3 bispecific ADC
-and other exploratory programs

03

Financial Highlights

2024 H1 financial results

Achieved profitability for the first time in company history with robust cash reserve

Mn RMB	2024 H1	2023 H1	Change
GROUP REVENUES	254.2	261.5	-3%
Sales of Pharmaceutical Products	118.3	246.9	-52%
License Fee Income	122.6	-	NA
Royalty Income	13.3	14.6	-9%
OPERATING EXPENSES (Non-IFRS ^[1] Measures)	(180.6)	(381.2)	-53%
Research and development expenses (Non-IFRS ^[1] Measures)	(71.0)	(198.1)	-64%
Selling, marketing and admin expenses (Non-IFRS ^[1] Measures)	(109.6)	(183.1)	-40%
OTHER INCOMES/ OTHER GAINS AND LOSSES	27.7	50.6	-45%
Other incomes	14.8	25.8	-43%
Other gains and losses	12.9	24.8	-48%
PROFIT (LOSS) FOR THE PERIOD (Non-IFRS ^[1] Measures)	10.8	(183.0)	NA

Total Group Revenue of RMB 254.2 mn

- Strong contribution from **license fee income** mainly composed of sugemalimab gastric cancer approval milestone in China and ex-China partnership income
- Decrease in **sales of pharmaceutical products** mainly driven by commercial model transition and the divestment of ivosetinib in Dec 2023 which created a total deal value of USD 50 mn

Profit of RMB 10.8 mn – Achieving Profitability for the First Time

- Lower operating expenses across the group with stringent cost control measures and business model transition, while continue to prioritize and focus on high value projects

Mn RMB	30 June 2024	31 December 2023	Change
CASH BALANCE ^[2]	813.9	1,026.7	(212.8)

Cash Balance of RMB 813.9 mn

- Reduced operating cash burn by RMB 153.7 mn (2024 H1: RMB 187.1 mn vs. 2023 H1: RMB 340.8 mn)

[1] IFRS: International Financial Reporting Standards. Non-IFRS Measures represents the profit (loss) for the period excluding the effect of certain non-cash items and onetime events, namely the share-based payment expenses; [2] 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)	★ Phase I data presentation at 2024 ASCO (presented) and ASH	2024 H1 & 2024 H2
		★ Initiation of phase Ib trial with registrational potential	2024 H2
		★ Global BD partnership	2024/2025
Pipeline 2.0	CS2009 (PD1/CTLA4/VEGFa tsAb)	IND submissions	2024 H2
	CS5005 (SSTR2 ADC)	IND submissions	2025
	CS5006 (novel-target ADC)	IND submissions	2025
	CS2011 (EGFR/HER3 bsAb)	IND submissions	2025
	CS5007 (EGFR/HER3 ADC)	IND submissions	2025
Commercial / late-stage programs	Sugemalimab (PD-L1)	★ MAA approval for 1L stage IV NSCLC in EU (achieved) and ex-China partnership (achieved partnership with Ewopharma , more to come)	2024 H1
		★ Regulatory decision for 1L stage IV NSCLC in UK and ex-China partnership	2024 H2
		NDA approval for 1L GC/GEJC in mainland China (achieved)	2024 Q1
	Pralsetinib (RET)	Expected approval of ANDA for manufacturing localization	2025 H1
	Avapritinib (KIT/PDGFRα)	Approval of ANDA for manufacturing localization (achieved)	2024 H2
	Nofazinlimab (PD-1)	Final assessment of OS and ex-China partnership exploration	2025 H1

★ Key value driver

Abbr.: bsAb = bispecific antibody; tsAb = trispecific antibody; 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

Well-balanced portfolio of 16 innovative assets (2/2)

– pipeline 2.0

Drug candidate	Rights	Indication	Discovery	Preclinical Development	IND	FIH	POC	Partner
CS5001 ¹ (ROR1 ADC)		Solid tumors hematologic malignancies						
CS2009 (PD-1xCTLA4xVEGFA trispecific antibody)		Solid tumors						
CS5006 (Undisclosed ADC)		Solid tumors						
CS2011 (EGFRxHER3 bispecific antibody)		Solid tumors						
CS5005 (SSTR2 ADC)		Solid tumors						
CS5007 (EGFRxHER3 bispecific ADC)		Solid tumors						
CS2012 (SSTR2 T-cell engager)		Solid tumors						
CS2013 (Bispecific antibody)		Autoimmune						
EX012 (Bispecific antibody)		Solid tumors						
EX018 (Bispecific antibody)		Autoimmune						

Note: Assets status denotes progress in the region(s) noted in the column titled "Rights"; FIH = First in Human, POC = Proof of Concept, 1. CStone obtains the exclusive global right to lead development and commercialization of LCB71/CS5001 outside the Republic of Korea

Antibody ADC Global Rights

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