



基石药业

CSTONE  
PHARMACEUTICALS

# 2024 Annual Results Presentation

March 28<sup>th</sup> 2025

Stock Code: 2616. HK

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# An Innovative Biopharma Driven by Globally Recognized R&D Capability

*Proven track record for high-quality and efficient drug development worldwide*

## RESEARCH

**Clinical insight driven modular R&D model**

**45+**

IND approvals

**10+**

Discovery projects ongoing

## DEVELOPMENT

**Efficient, high-quality and innovative clinical dev. engine**

**16**

NDA approvals

**50+**

Data presentations /publications

## COMMERCIAL

**Leverage the strength of partners in commercialization**

**4\*** commercialized products

**9** indications approved

**5** 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)

2024

**Sugemalimab MAA approval in EU & UK** overseas strategic partnerships progressing

2025

**Sugemalimab global expansion & Pipeline 2.0 advancement**

**01**

# ***Business Achievements***

**2024 & 2025YTD**

# FY2024 and 2025YTD achievements: encouraging data for key clinical assets and steady progress towards commercial partnerships

Profitability for the first time in 2024H1; significant yoy improvement in FY2024 financial performance

## Financial

as of Dec. 31, 2024

Total revenue<sup>[1]</sup> in FY2024

**407.2**

RMB Mn

Net loss<sup>[2]</sup> in FY2024

**(94.0)**

RMB Mn

(Significantly narrowed by 72% yoy)

Cash balance

**672.9**

RMB Mn

## R&D and Commercial Progress

as of Mar. 27, 2025

**CS5001**  
ROR1 ADC

- Encouraging anti-tumor activity observed in both lymphomas and solid tumors
- Global phase Ib trial ongoing for potential registration in r/r DLBCL (mono), evaluations in front-line DLBCL (combo), and explorations in solid tumors and other lymphomas (mono and combo)

**CS2009**  
PD-1/VEGF/CTLA-4  
trisppecific antibody

- Global, first-in-human trial initiated and first patient dosed in Australia

**Sugemalimab**  
Anti-PD-L1 antibody

### 3 New NDA approvals:

- 1L stage IV NSCLC — EU & UK
- 1L GC/GEJC — mainland China

### 1 NDA submission:

- Stage III NSCLC — EU

### 3 commercial partnerships covering 40 countries<sup>[3]</sup>:



**Avapritinib**  
KIT/PDGFRα inhibitor

- Manufacturing localization application approved by NMPA in Aug 2024
- Exclusive commercialization partnership of avapritinib with Hengrui in mainland China

**Pralsetinib**  
RET inhibitor

- Manufacturing localization application accepted and under review since Feb 2024

**Other achievements**

- 17 data publications / presentations
- 10+ discovery projects in progress

[1] Total revenue in 2024 includes sales of pharmaceutical products (2024: 175.1m vs. 2023: 336.7m) , license fee income (2024: 204.0m vs. 2023: 95.7m,+113%) and royalty income of sugemalimab (2024: 28.1m vs. 2023: 31.4m, -10%); [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; [3] Commercial partnerships with EwoPharma in Switzerland and 18 Central Eastern European countries ; with Pharmalink in 12 Middle East and South Africa countries; with SteinCares in 10 Latin American countries

Abbr: DLBCL, diffused large B cell lymphoma; r/r, relapse and refractory; GC/GEJC, ; r/r, relapsed/refractory; GC/GJEC, gastric cancer/gastroesophageal junction carcinoma; NSCLC, non-small cell lung cancer

# 02

## ***Pipeline Updates***

### ***1. Commercial-stage Programs***

### ***2. Key Clinical Programs***

***CS5001 (ROR1 ADC)***

***CS2009 (PD-1/VEGF/CTLA-4 trispecific mAb)***

### ***3. Innovative Early Programs***

***EGFR/HER3, SSTR2, ITGB4, Autoimmune***

# 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/PDGFR)

Recurring revenue to fuel pipeline advancement

## Key Clinical Programs in Pipeline 2.0

**CS5001**  
(ROR1 ADC)

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

**CS2009**  
(PD-1/VEGF/CTLA-4 trispecific antibody)

*Global first-in-class / best-in-class potential*

Strong growth momentum in near term

## Innovative Early Programs in Pipeline 2.0

**CS2011**  
(EGFR/HER3 bispecific mAb)

**CS5007**  
(EGFR/HER3 bispecific ADC)

**CS5005**  
(SSTR2 ADC)

**CS5005-R**  
(SSTR2 RDC)

**CS5008**  
(SSTR2/DLL3 bispecific ADC)

**CS5006**  
(ITGB4 ADC)

**CS5009**  
(B7H3/PD-L1 bispecific ADC)

**CS2013**  
(undisclosed autoimmune bispecific mAb)

**CS2015**  
(undisclosed autoimmune bispecific mAb)

& other exploratory programs

Robust growth engine in the long run

**02**

*Pipeline Updates*

# ***Commercial-stage Programs***

# First-line stage IV NSCLC approved in EU & UK for all-comers population; three global partnerships established with additional collaborations anticipated in H1 2025

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

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

All **FIVE** indications have been approved in China



- ✓ Stage IV NSCLC
- ✓ Stage III NSCLC
- ✓ R/R ENKTL
- ✓ ESCC
- ✓ GC/GEJC

The **FIRST** PD-L1 developed by a Chinese biopharmaceutical company to be marketed in international markets



- ✓ The **THIRD** Chinese biotech to launch innovative oncology drugs in EU after Beigene and Hutchmed
- ✓ The **FIRST** PD-L1 approved in EU for first-line Stage IV NSCLC all comers
- ✓ New indication application submitted for stage III NSCLC, expecting to become the **SECOND** PD-(L)1 approved in Europe for this indication
- ✓ More MAAs of additional sugemalimab indications to be submitted soon to EMA



- ✓ The **FIRST** domestic PD-L1 approved in UK for 1L Stage IV NSCLC all comers

**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



**Additional partnerships in western Europe, SEA, Australia, Canada, etc** in active progress and expect to close soon.

# Latest milestone highlighting our continuing progress to advance sugemalimab global strategy



If this new indication is approved, sugemalimab would address a critical unmet need in stage III NSCLC, **where only one PD-L1 antibody is currently approved in Europe.** The drug's dual utility in stage III and IV NSCLC could solidify its role as a cornerstone immunotherapy in lung cancer.



## New Indication Application for Sugemalimab in Stage III NSCLC Submitted to the EMA



This marks CStone's second regulatory submission for sugemalimab to the EMA, following its initial approval in Europe for metastatic squamous and non-squamous NSCLC in 2024

Results supported this submission were previously published in *The Lancet Oncology*:

- **36% reduction in risk of disease progression or death**, significantly improved progression-free survival (PFS).
- **56% reduction in risk of death**, with a strong positive trend toward overall survival (OS) benefit.
- Consistent clinical benefits across subgroups, regardless of prior CRT modality (concurrent or sequential).
- Favorable safety profile, no new safety signals identified.

# ESMO guideline recommendation and JAMA publication further supporting sugemalimab's adoption by physicians and reimbursements



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ESMO

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## ESMO Non-Oncogene-Addicted Metastatic Non-Small-Cell Lung Cancer Living Guideline

To cite this living guideline, please include the original Clinical Practice Guideline citation "Ann Oncol. 2023;34(4):358-376" and this online publication, including date and version number: "ESMO Non-Oncogene-Addicted Metastatic Non-Small-Cell Lung Cancer Living Guideline, v1.2 January 2025"

Export references (RIS)

This living guideline was prepared by L Hendriks, F Cortiula, E Mariamidze, L Castelo-Branco, D Martins-Branco, C Sessa, G Pentheroudakis and M Reck, on behalf of the Clinical Practice Guideline author group.

v1.2 was prepared by L Hendriks, F Cortiula, E Mariamidze, D Martins-Branco, M Reck and S Popat, and has been peer reviewed.

### Sugemalimab has been included in the **ESMO Guideline** and is recommended as a first-line combination therapy for both sq & nsq NSCLC, with substantial benefits

*Supported by GEMSTONE 302 trial:*

- Significant benefits in PFS and OS compared with control group
- Sustained and consistent benefits across various histological subtypes and PD-L1 expression levels



JAMA Network

JAMA

Search All Enter Search Term

### Original Investigation

February 24, 2025

## First-Line Sugemalimab Plus Chemotherapy for Advanced Gastric Cancer

### The GEMSTONE-303 Randomized Clinical Trial

Xiaotian Zhang, MD<sup>1</sup>; Jufeng Wang, MD<sup>2</sup>; Gang Wang, MD<sup>3</sup>; Yanqiao Zhang, MD<sup>4</sup>; Qingxia Fan, MD<sup>5</sup>; Chuangxin Lu, MD<sup>6</sup>; Changlu Hu, MD<sup>7</sup>; Meili Sun, MD<sup>8</sup>; Yiye Wan, MD<sup>9</sup>; Sanyuan Sun, MD<sup>10</sup>; Junye Wang, MD<sup>11</sup>; Li Zhang, MD<sup>12</sup>; Yongqian Shu, MD<sup>13</sup>; Jie Luo, MD<sup>14</sup>; Dan Zhu, MD<sup>14</sup>; Zhenwei Shen, MD<sup>14</sup>; Sheng Yao, PhD<sup>14</sup>; Qingmei Shi, MD<sup>14</sup>; Jason Yang, MD<sup>14</sup>; Lin Shen, MD<sup>1</sup>; for the GEMSTONE-303 Investigators

Author Affiliations

JAMA. Published online February 24, 2025. doi:10.1001/jama.2024.28463

### Publication of the GEMSTONE-303 study results of sugemalimab in **JAMA**

*Key Highlights:*

- Sugemalimab is the world's first anti-PD-L1 mAb approved for G/GEJ adenocarcinoma
- GEMSTONE-303 supports sugemalimab in combination with chemo as a new 1L SoC for patients with CPS  $\geq 5$  G/GEJ.
- Sugemalimab is the first anti-PD-L1 mAb demonstrating superior OS and PFS with a manageable safety profile in combination with chemo in first-line CPS  $\geq 5$  G/GEJ.

# Strengthening strategic collaboration on pralsetinib and avapritinib to maximize commercial value

Actively advancing manufacturing localization and patient access

**Pralsetinib** 普吉华

Nov 8 2023

RET inhibitor

Partner with



for the commercial promotion in mainland China

**Avapritinib** 泰吉华

Jul 3 2024

KIT/PDGFRα inhibitor

Partner with



for the commercial promotion in mainland China

Market potential

**~70K**

annual newly diagnosed patients with RET-altered tumors in China<sup>[2]</sup>

Registration & development

- Approved for **1L & 2L treatment of NSCLC** and **1L treatment of MTC/TC** among RET-altered tumors
- Excellent efficacy observed in phase II trial among **pan-tumor patients** (ORR 57%)

Market potential

**~45K**

annual newly diagnosed patients with PDGFRA exon 18 or KIT mutation tumors in China<sup>[2]</sup>

Registration & development

- Approved for treatment of **GIST, advanced SM and ISM** among PDGFRA exon 18 or KIT mutated tumors
- Promising efficacy observed in real-world for **r/r AML, to be included in guidelines**

Domestic manufacturing progress

**Manufacturing localization application accepted and under review since Feb 2024; expecting significant gross margin increase**

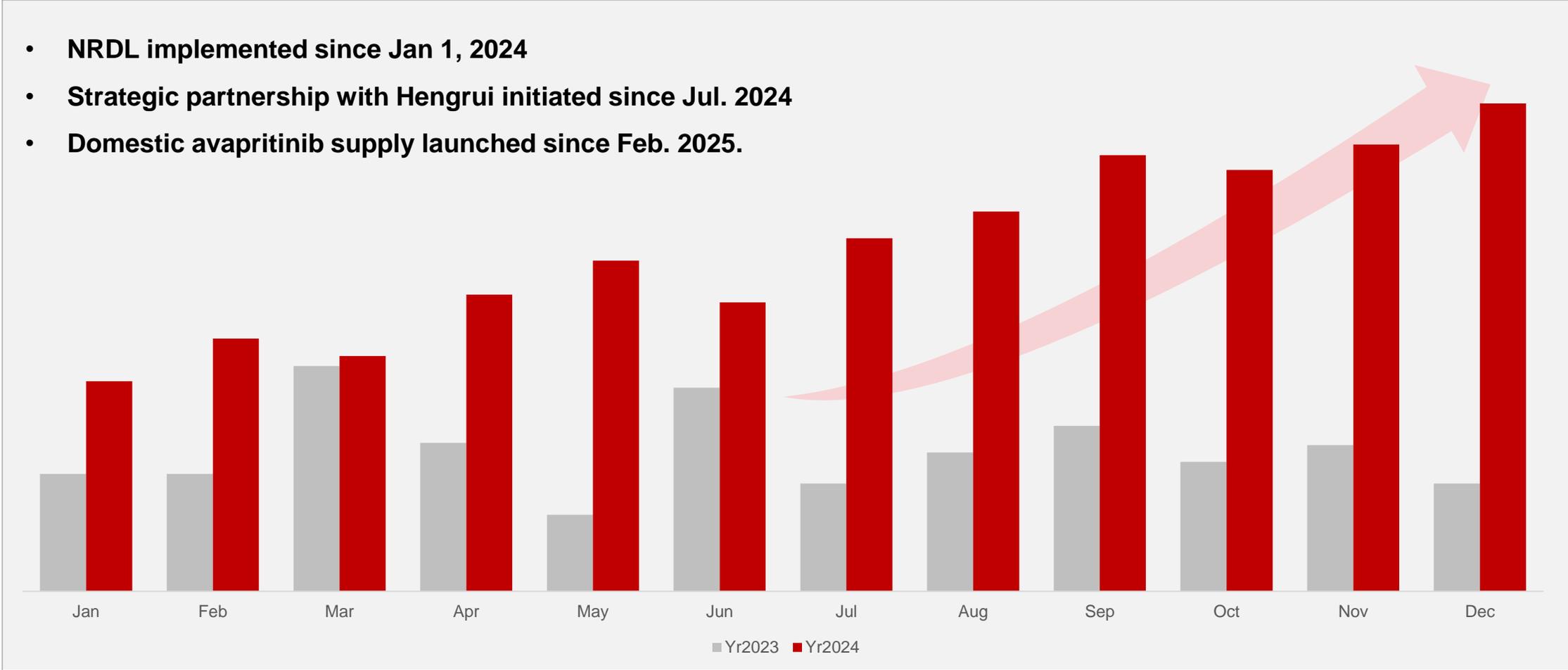
Domestic manufacturing & NRDL progress

**Included in 2023 NRDL (implemented since Jan 2024); domestic supply launched in Feb 2025, with significant gross margin increase anticipated**

[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]. Clarivate DRG, 2025; [3]. Broad indications in RET+ solid tumors, i.e., colorectal, gastric, breast, liver, cervical, ovarian, esophageal and pancreatic cancers; abbr.: NSCLC, Non-Small Cell Lung Cancer; MTC, Medullary Thyroid Cancer; TC, Thyroid Cancer; GIST, Gastrointestinal-stromal tumor; SM, Systemic Mastocytosis; AML, Acute Myelocytic Leukemia; ISM, Indolent Systemic Mastocytosis

# Significant volume increase for avapritinib in the first year after entering NRDL and partnership with Hengrui

Avapritinib's 2024 in-market sales more than doubled compared to 2023



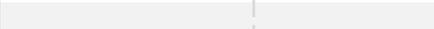
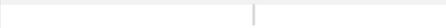
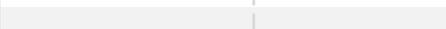
# 02

*Pipeline Updates*

## ***Key Clinical Programs*** ***CS5001 (ROR1 ADC)***

# Pipeline 2.0: an innovative portfolio with global rights

CS5001: No. 2 position globally with first-to-market potential

Drug candidate	Right	Indication	Discovery	Preclinical Development	IND-Enabling	FIH	POC
CS5001 <sup>1</sup> (ROR1 ADC)		Solid tumors hematologic malignancies					
CS2009 (PD-1/VEGF/CTLA-4 trispecific antibody)		Solid tumors					
CS2011 (EGFR/HER3 bispecific antibody)		Solid tumors					
CS5007 (EGFR/HER3 bispecific ADC)		Solid tumors					
CS5005 (SSTR2 ADC)		Solid tumors					
CS5008 (SSTR2/DLL3 bispecific ADC)		Solid tumors					
CS5005-R (SSTR2 RDC)		Solid tumors					
CS5006 (ITGB4 ADC)		Solid tumors					
CS5009 (B7H3/PD-L1 bispecific ADC)		Solid tumors					
CS2013 (Bispecific antibody, undisclosed targets)		<b>Autoimmune</b>					
CS2015 (Bispecific antibody, undisclosed targets)		<b>Autoimmune</b>					

Note: Assets status denotes progress in the region(s) noted in the column titled "Rights"; FIH = First in Human, POC = Proof of Concept,

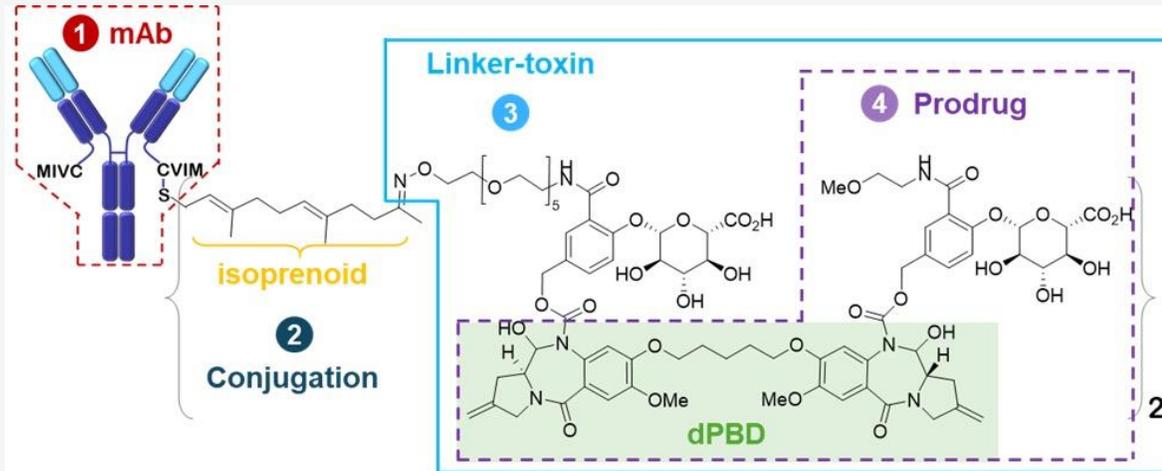
1. CStone obtains the exclusive global right from LigaChem Biosciences, Inc. (LCB) to lead development and commercialization of LCB71/CS5001 outside the Republic of Korea

 Antibody  ADC  RDC  Global Rights

# CS5001, a ROR1-ADC with optimized design to enhance efficacy and tolerability

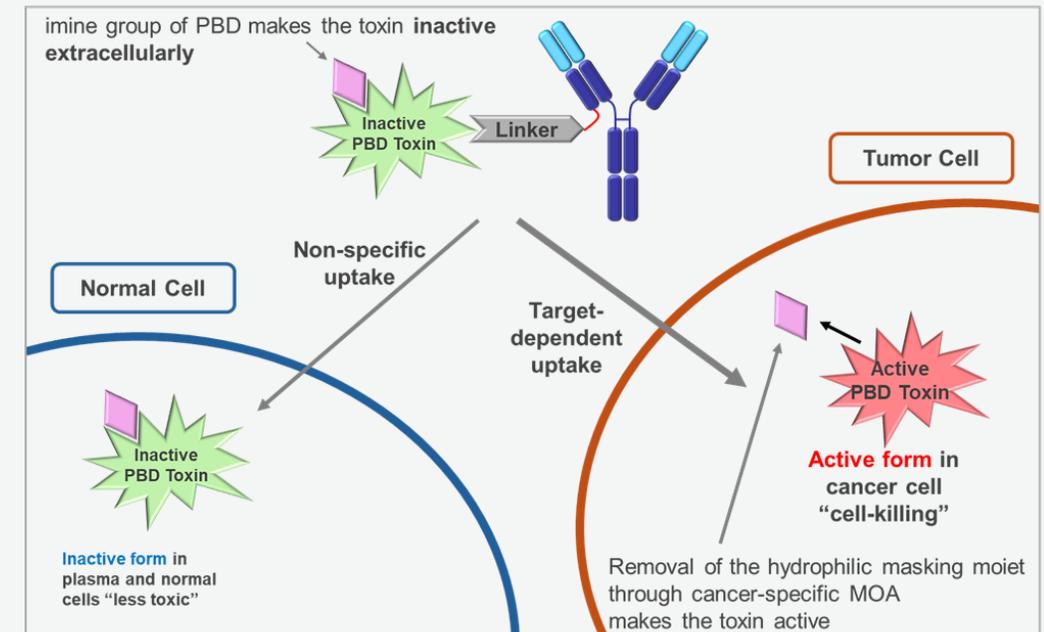
No. 2 position globally with phase Ib study ongoing in US, Australia and China

## 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  $\beta$ -glucuronidase) shows exceptional stability in serum
- 4** Proprietary tumor-activated PBD dimer toxin prodrug (released by  $\beta$ -glucuronidase), with advantages: **a)** much higher potency than MMAE/DXd/Exatecan, etc.; **b)** stronger ability of killing slowly-growing tumors through DNA-crosslinking mechanism than MMAE/DXd/Exatecan, etc.; **c)** less likely to induce tumor resistance

## Novel prodrug and linker technology minimizes systemic toxicity of conventional PBD



Free toxins tested	IC <sub>50</sub> (nM)		ADCs tested	IC <sub>50</sub> (nM)
	Tumor cell line			Tumor cell line
Naked PBD free toxin	1.15	0.04	Naked PBD-ADC	0.23
LCB's proprietary PBD prodrug free toxin	>100	>20	PBD prodrug-ADC	0.19

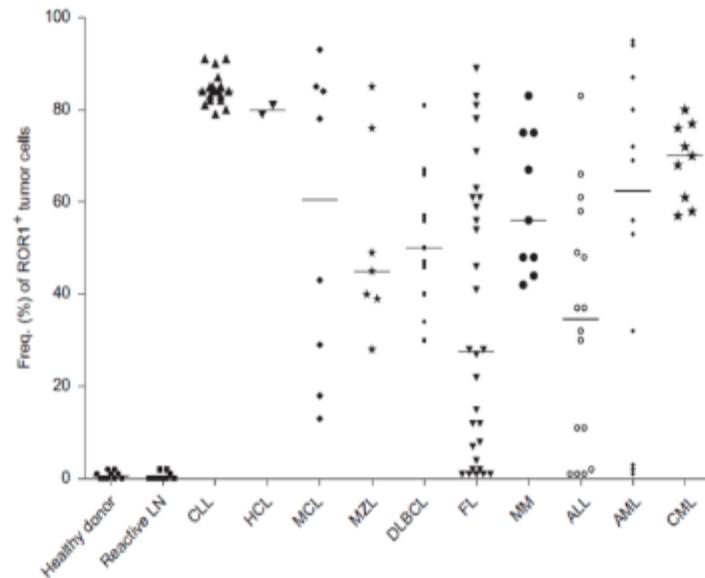
Inactive
➔
Active

Tumor selective activation

# ROR1 is a promising target for multiple hematological malignancies and solid tumors

- 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

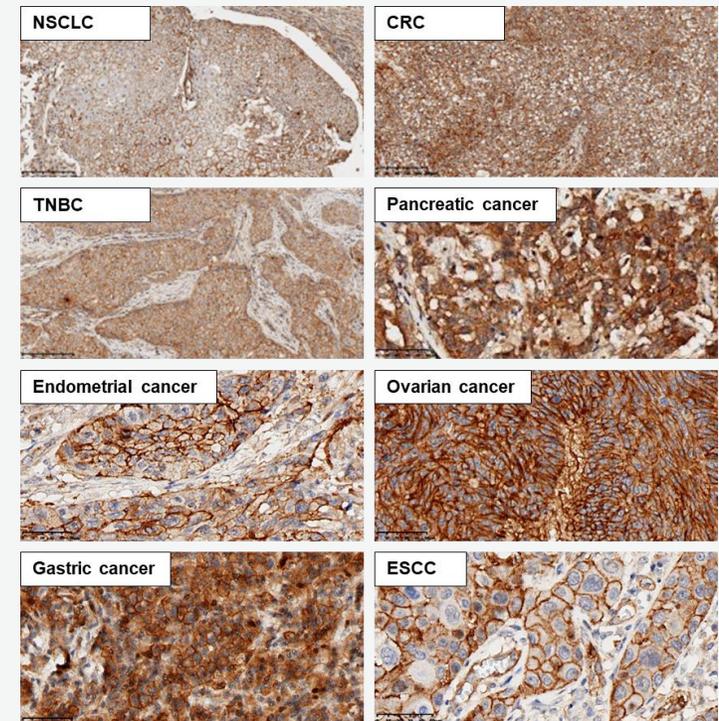


Leuk Lymphoma. 2013 Apr;54(4):843-50

## Validated by IHC with CStone's proprietary mAb which is being developed into a CDx

Tumor type	H-Score (M)≥50	H-Score (M)≥10	H-Score (M)≥1
NSCLC	45% (9/20)	55% (11/20)	75% (15/20)
CRC	60% (6/10)	60% (6/10)	60% (6/10)
TNBC	50% (5/10)	60% (6/10)	60% (6/10)
PC	30% (6/20)	60% (12/20)	70% (14/20)
EC	40% (4/10)	40% (4/10)	40% (4/10)
OC	50% (5/10)	70% (7/10)	90% (9/10)
GC	60% (6/10)	60% (6/10)	70% (7/10)
ESCC	40% (4/10)	50% (5/10)	90% (9/10)

ROR1 expression in tumor membrane: H-Score (M)=1x (% of 1+ cells) + 2 x (% of 2+ cells) + 3 x (% of 3+ cells).



# Global hematologic market holds vast potential: CS5001 poised to target multiple billion-dollar lymphoma indications

Sizable value in solid tumor market in parallel, given CS5001's promising anti-tumor activity observed in various solid tumors

By 2029, global market potential for hematologic malignancies expected to reach:

**\$139 bn<sup>[1]</sup>**

Global annual incident lymphoma patients<sup>[2]</sup>:

**~635K**

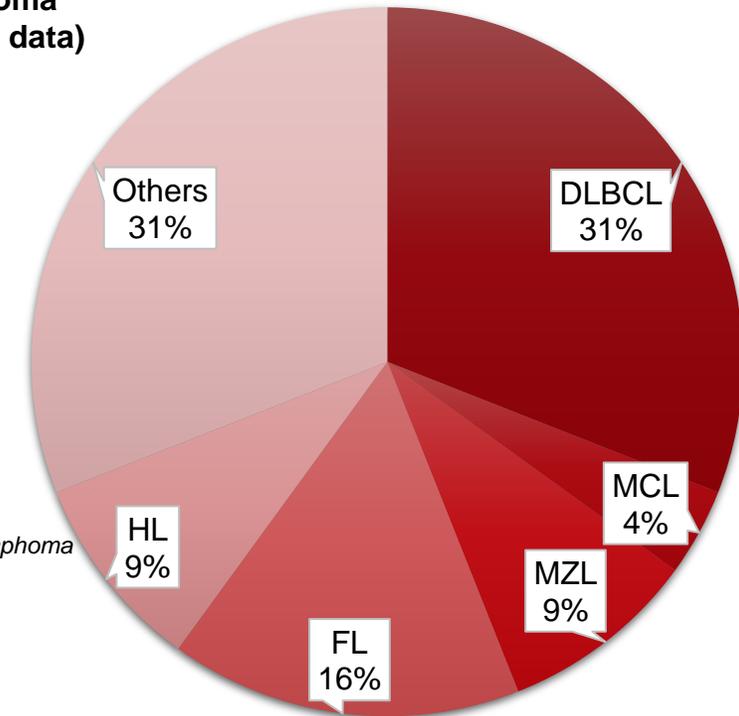
Annual incident lymphoma patients in the US<sup>[2]</sup>:

**~89K**

Annual incident lymphoma patients in China<sup>[2]</sup>:

**~85K**

Proportion of different lymphomas in total lymphoma (based on US data)



*DLBCL, diffused large B cell lymphoma*

*MCL, mantal cell lymphoma*

*MZL, marginal zone lymphoma*

*FL, follicular lymphoma*

*HL, Hodgkin lymphoma*

# CS5001 may redefine DLBCL treatment paradigm, unlocking greater clinical benefit and commercial value

## DLBCL treatment landscape<sup>[1]</sup>

Treatment lines	Regimen 1	Regimen 2
<b>1L treatment</b>	<p><b>R-CHOP</b> Rituximab+Cyclophosphamide+Doxorubicin +Vincristine+Prednisone</p> <p>2y PFS rate: 70.2% 2y OS rate: 88.6% ORR 83.8%; CR 74% (POLARIX)</p>	<p><b>POLA-R-CHP</b> Polatuzumab vedotin+Rituximab+Cyclophosphamide +Doxorubicin+Prednisone</p> <p>2y PFS rate: 76.7% 2y OS rate: 88.7% ORR 85.5%; CR 78% (POLARIX)</p>
<b>2L treatment</b>	<p><b>R-GemOx<sup>[3]</sup></b> Rituximab+Gemcitabine+Oxaliplatin</p> <p>mOS 12.9 mths; mPFS 3.6 mths; CR 25.3% (STARGLO)</p>	<p><b>Glofitamab (CD3/CD20 bsAb) -GemOx</b> Glofitamab+Gemcitabine+Oxaliplatin</p> <p>mOS 25.5 mths; mPFS 13.8 mths; CR 58.5% (STARGLO)</p>
<b>3L or later treatment</b>	<p><b>loncastuximab tesirine (CD19 ADC)</b></p> <p>ORR: 48.3%; CR: 24.1% (LOTIS-2)</p>	

## Peak sales for DLBCL related drugs <sup>[2]</sup>

Rituximab (peak sales) :

**~\$7.5 bn**

Polatuzumab (est. peak sales) :

**~\$2.4 bn**

# CS5001 demonstrates higher ORR as monotherapy in non-Hodgkin lymphoma

	CS5001	Zilovertamab Vedotin	
<b>Molecule Property</b>			
Target	ROR1	ROR1	
Linker	Isoprenoid-β-glucuronide	Mc-vc-PAB	
Payload	Prodrug of PBD dimer	MMAE	
DAR	2	Avg. 4 (0-8)	
<b>Clinical Data</b>			
Disease	<b>Aggressive and indolent advanced NHL</b> , including r/r DLBCL, r/r MCL, r/r MZL, r/r FL, etc.	<u>r/r DLBCL</u>	<u>r/r MCL</u>
	Anti-tumor activities observed in solid tumors including <b>pancreatic cancer, ovarian cancer, NSCLC, TNBC</b> , etc.	Anti-tumor activity in solid tumor not reported	
Prior lines of therapy	≥ 3 (82%)	3 (median)	4 (median)
ORR	<p><i>2024 ASCO poster</i></p> <ul style="list-style-type: none"> <li>Across dose levels 7-9: <b>50.0%</b> (n=6)</li> </ul> <p><i>2024 ASH poster</i></p> <ul style="list-style-type: none"> <li>Across dose levels 7-9: <b>56.3%</b> (n=16)</li> <li>At tentative RP2D: <b>70%</b> (n=10)</li> </ul>	<p><i>2023 ASCO abst.:</i></p> <ul style="list-style-type: none"> <li>At RP2D: <b>30%</b> (n=20)</li> </ul> <p><i>2024 ASH abst.:</i></p> <ul style="list-style-type: none"> <li>At RP2D: <b>29%</b> (n=79)</li> </ul> <p><i>2024 ASH poster:</i></p> <ul style="list-style-type: none"> <li>At RP2D: <b>28%</b> (n=103)</li> </ul>	<p><i>2024 ASH abst.:</i></p> <p><b>40%</b> (n=40)</p>
Safety	Well tolerated, no DLT up to DL10; manageable safety profile	Notable neurotoxicity, e.g., peripheral neuropathy	

# Data from MSD's waveLINE-007 demonstrated ROR1 ADC's potential in frontline DLBCL

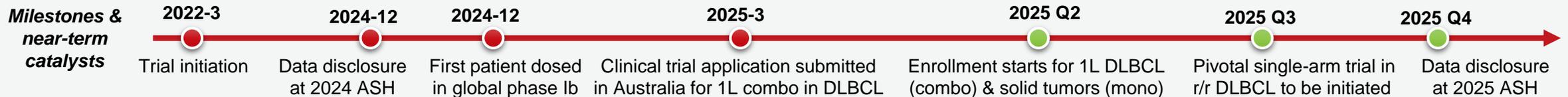
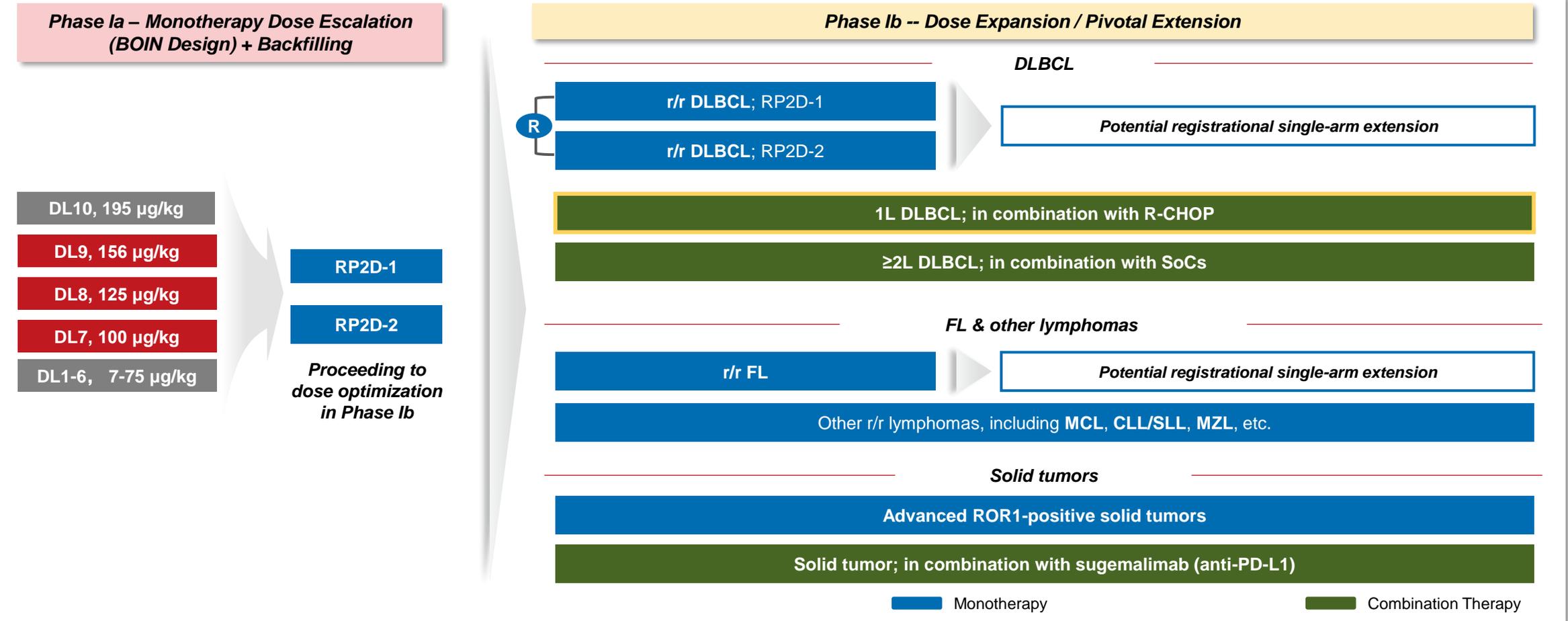
Zilovertamab vedotin (ZV) + R-CHP (phase II clinical data of WaveLINE-007, ASH 2024)

	ZV 1.75mg/kg N=15	ZV 2.0mg/kg N=15	ZV 2.25mg/kg N=6	Total N=36
Objective Response <sup>a</sup> , % (95% CI)	15 100% (78.2 – 100.0)	14 <sup>b</sup> 93.3% (68.1 – 99.8)	6 100% (54.1 – 100.0)	35 97.2% (85.5 – 99.9)
Partial Response	0	0	0	0
<b>Complete Response</b>	<b>15 (100%)</b>	<b>14 (93.3%)</b>	<b>6 (100%)</b>	<b>35 (97.2%)</b>
Median DOR (range), months	NR (2.4+-20.2+)	NR (1.3+-19.7+)	NR (13.8+-16.9+)	NR (1.3+-20.2+)
12-month DOR rate	91.7%	92.3%	100%	93.5%

Data cutoff: August 6 2024; <sup>a</sup>Per Lugano criteria by investigator; <sup>b</sup>One patient receiving ZV 2.0mg/kg was not evaluable for efficacy since they discontinued treatment; NR, not reached; R-CHP, cyclophosphamide, doxorubicin, and prednisone plus rituximab

# CS5001 clinical development targeting lymphoma and solid tumors: across first-line, frontline, monotherapy and combination therapies

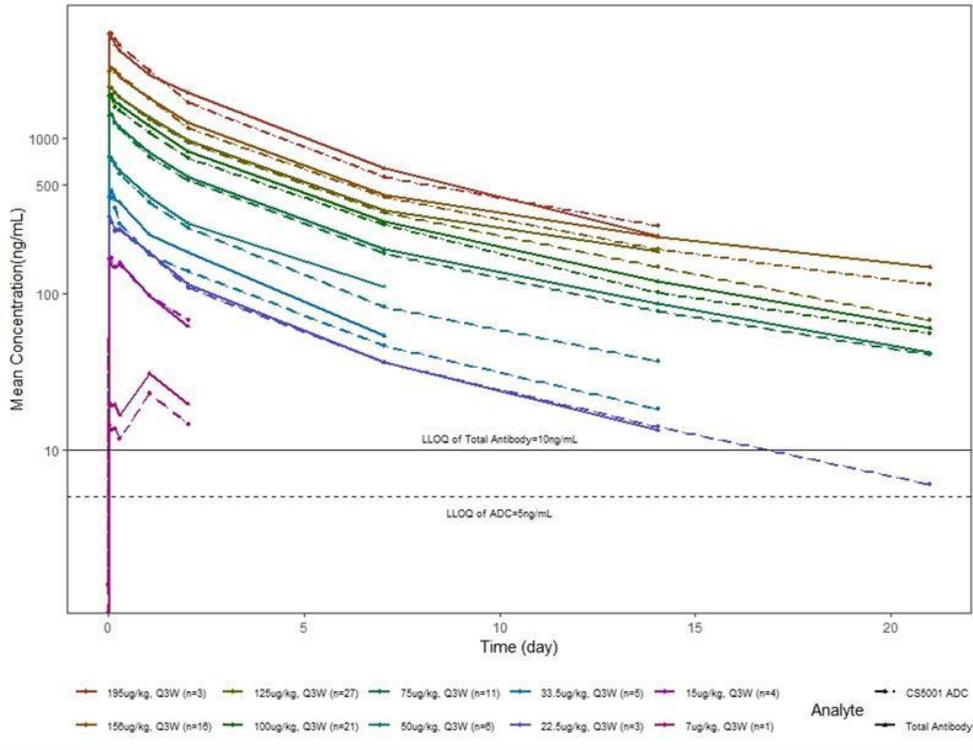
Phase Ib dose expansion ongoing, actively pursuing fast-to-market regulatory pathway



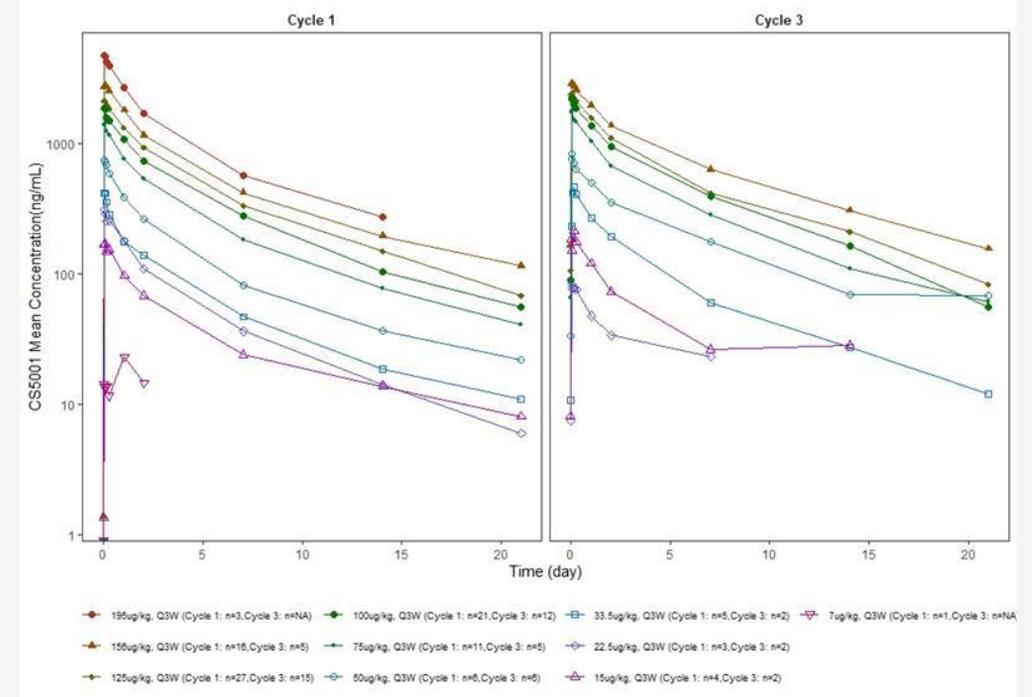
DL, dose level; SoC, standard-of-care; RP2D, recommended phase II dose; r/r, relapsed and refractory; DLBCL, diffuse large B cell lymphoma; MCL, mantle cell lymphoma; MZL, marginal zone lymphoma; FL, follicular lymphoma; CLL, chronic lymphocytic leukemia; SLL, small lymphocytic lymphoma

# CS5001 PK profile: excellent linker stability with potentially reduced systemic toxicity

**CS5001 exhibits similar PK profile to total antibody, indicating high ADC stability in circulation**



**CS5001 demonstrates no significant accumulation after multi-cycle dosing**



- CS5001 exhibits overall dose-proportional drug exposure with an apparent half-life ( $t_{1/2}$ ) of ~5 days
- 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 Summary

A potentially BIC with better efficacy and broader indications covering aggressive and indolent lymphoma, and solid tumors

- 1 **CS5001 is well tolerated in heavily pre-treated patients with advanced B-cell lymphoma and solid tumor across doses from 7 to 195 µg/kg.**
  - Dose escalation completed and **no DLT** reported up to DL10
  - Tentative RP2D determined for NHL at DL8 (125 µg/kg)
- 2 **Encouraging anti-tumor activity with high ORR observed in both aggressive and indolent lymphoma starting from the effective dose regardless of ROR1 expression**
  - Hodgkin lymphoma: ORR **60%**; non-Hodgkin lymphoma: ORR **56.3%**
  - In addition to DLBCL, objective responses also observed in MCL, MZL, FL, and high-grade B-cell lymphoma.
- 3 **Potent efficacy observed at the preliminary RP2D (DL8, 125 µg/kg) for lymphoma**
  - Among all evaluable B-cell lymphoma at DL8: ORR: **77%**
- 4 **The first ROR1-ADC that reported anti-tumor activities in solid tumors (NSCLC, pancreatic cancer, etc.)**
- 5 **Phase Ib ongoing for:**
  - Dose optimization for monotherapy in late-line DLBCL with potential single-arm registration
  - Combo with SOCs in 1L and 2L DLBCL
  - Evaluation of mono- and combo-therapy with IO in ROR1+ solid tumors
  - Evaluation of mono- and combo-therapy in other B-cell malignancies (FL, MCL, CLL/SLL, etc.)

**02**

*Pipeline Updates*

***Key Clinical Programs:***

***CS2009***

***(PD-1/VEGF/CTLA-4 trispecific mAb)***

# Pipeline 2.0: an innovative portfolio with global rights

CS2009: leading position globally to target PD-1, VEGFA and CTLA-4

Drug candidate	Right	Indication	Discovery	Preclinical Development	IND-Enabling	FIH	POC
CS5001 <sup>1</sup> (ROR1 ADC)		Solid tumors hematologic malignancies					
CS2009 (PD-1/VEGF/CTLA-4 trispecific antibody)		Solid tumors					
CS2011 (EGFR/HER3 bispecific antibody)		Solid tumors					
CS5007 (EGFR/HER3 bispecific ADC)		Solid tumors					
CS5005 (SSTR2 ADC)		Solid tumors					
CS5008 (SSTR2/DLL3 bispecific ADC)		Solid tumors					
CS5005-R (SSTR2 RDC)		Solid tumors					
CS5006 (ITGB4 ADC)		Solid tumors					
CS5009 (B7H3/PD-L1 bispecific ADC)		Solid tumors					
CS2013 (Bispecific antibody, undisclosed targets)		<b>Autoimmune</b>					
CS2015 (Bispecific antibody, undisclosed targets)		<b>Autoimmune</b>					

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 from LigaChem Biosciences, Inc. (LCB) to lead development and commercialization of LCB71/CS5001 outside the Republic of Korea

Antibody ADC RDC Global Rights

# CS2009, a potential FIC/BIC PD-1/VEGF/CTLA-4 trispecific antibody

With greater potential than PD-1/VEGF bsAbs to become the next-generation IO backbone to replace anti-PD-(L)1 antibodies in current SOC

## A potential FIC/BIC trispecific antibody targeting large indications

### Molecular design

- A trispecific molecule combining three validated clinical targets
- **Synergistic activities** between PD-1 and CTLA-4 arms, and between PD-1/CTLA-4 arms and VEGF arm, leading to higher activity in TME with reduced systemic toxicity
- Preferentially invigorates exhausted TILs
- HNSTD/NOAEL in Cyno: **100 mg/kg**
- Single cell clone yield: **7 g/L**

### Target indication

- Tackling broader patient populations including NSCLC, OC, RCC, cervical cancer, HCC, GC, SCLC, etc.

### Competitive landscape

- Potentially first-in-class/best-in-class

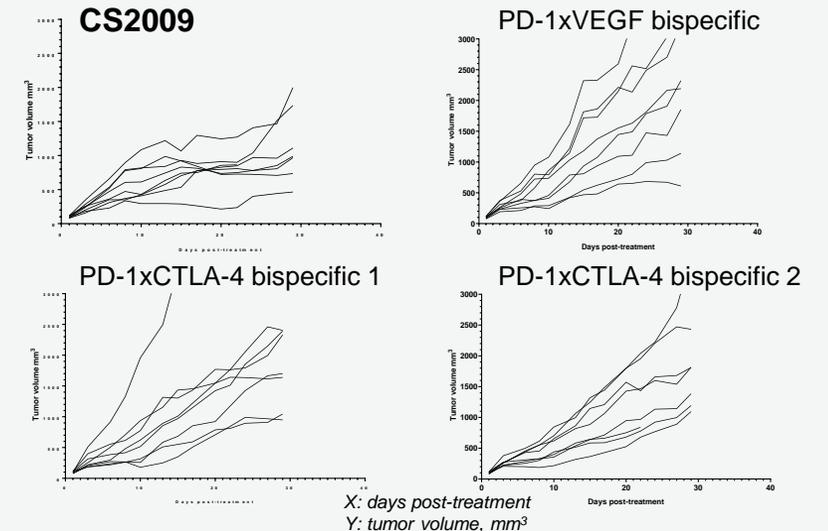
## Differentiated molecular design



\* Representative molecular configuration

## Preclinical data

In the *in vivo* efficacy study on MC38-hPD-L1 in the hPD-1/PD-L1/CTLA-4 triple transgenic mice (immune-competent) model, CS2009 exhibited **more potent antitumor activities versus competitors**



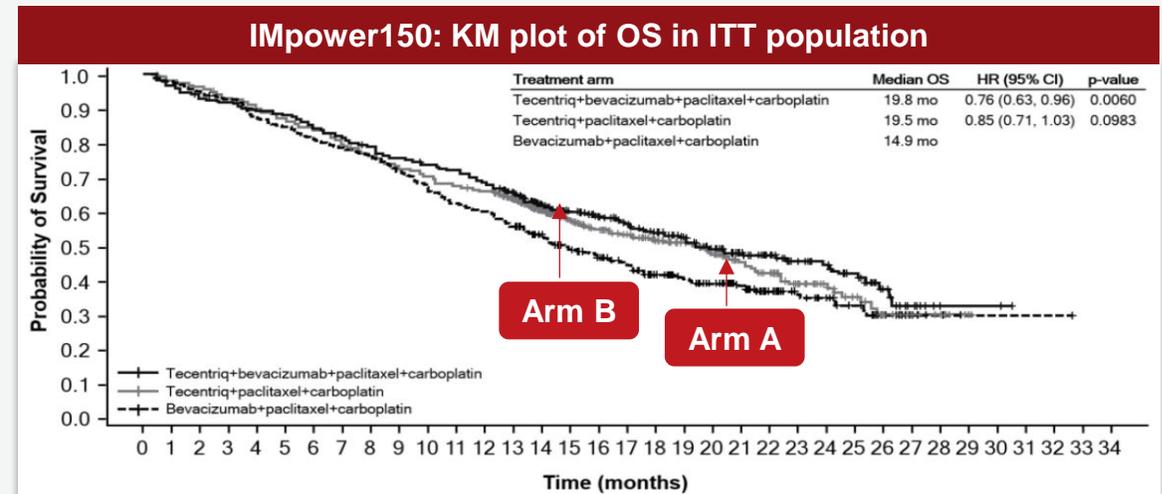
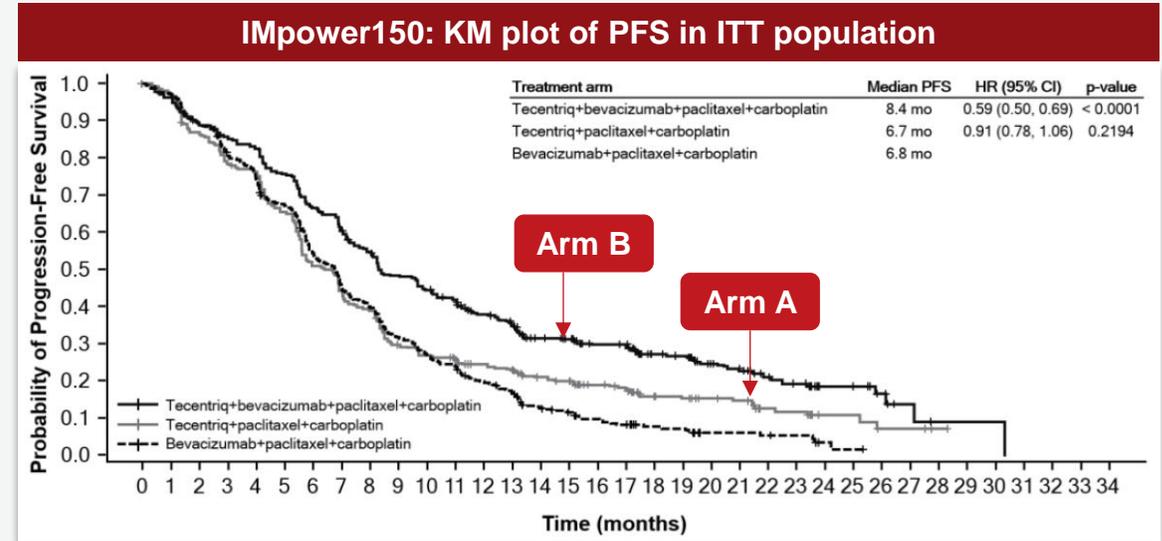
## Preliminary clinical development plan

- **A global, first-in-human trial initiated with first patient dosed in Australia in Mar. 2025; China IND submitted in Feb. 2025.**
- **Fast-to-market trial: single-arm phase II trial for later-line NSCLC, RCC, cervical cancer, HCC, GC, etc.**
- **Global phase III trials: 1L NSCLC, OC, RCC, cervical cancer, HCC, GC, SCLC, etc.**

# Maximizing survival benefit with PD-1/VEGF/CTLA-4 triple-targeting approach (1/2)

"PD-1/L1 + VEGF" combination compared to PD-(L)1 monotherapy: unclear overall survival (OS) benefits

Efficacy endpoint	Arm A (Atezolizumab + Paclitaxel + Carboplatin)	Arm B (Atezolizumab + Bevacizumab + Paclitaxel + Carboplatin)
<i>Investigator-assessed PFS (RECIST v1.1)*</i>	n = 402	n = 400
No. of events (%)	330 (82.1%)	291 (72.8%)
Median duration of PFS (months)	6.7	8.4
95% CI	(5.7, 6.9)	(8.0, 9.9)
Stratified hazard ratio <sup>‡^</sup> (95% CI)	0.67 (0.57, 0.79)	
p-value <sup>1,2</sup>	< 0.0001	
<i>OS interim analysis*</i>	n = 402	n = 400
No. of deaths (%)	206 (51.2%)	192 (48.0%)
Median time to events (months)	19.5	19.8
95% CI	(16.3, 21.3)	(17.4, 24.2)
Stratified hazard ratio <sup>‡^</sup> (95% CI)	0.90 (0.74, 1.10)	
p-value <sup>1,2</sup>	0.3000	

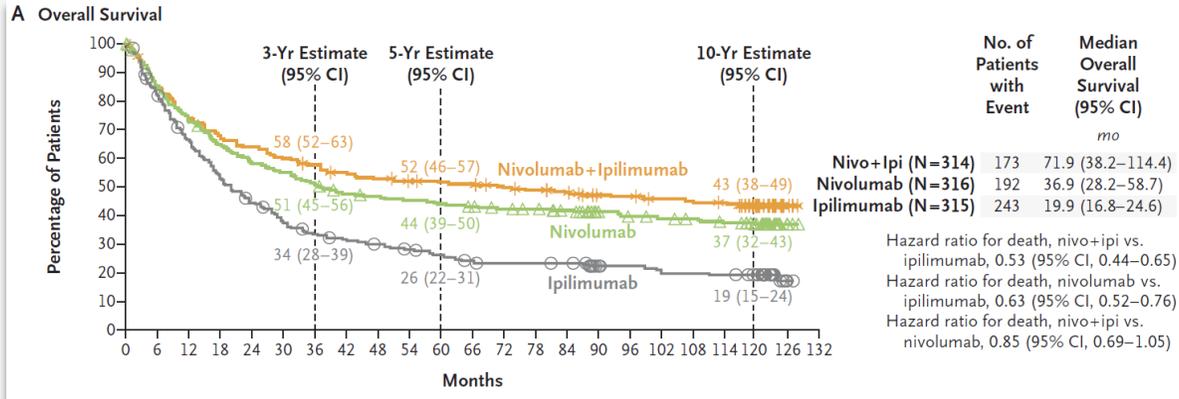


- "PD-1/L1 + VEGF" combination significantly improved PFS in NSCLC patients compared to PD-1/L1 monotherapy but showed no clear OS benefit, especially in PD-L1 low-expression subgroups.
- IMpower150 results showed that Arm B (**PD-L1 + VEGF** + chemo) improved PFS but not for OS, compared to Arm A (**PD-L1 + chemo**). Additionally, Arm B (**PD-L1 + VEGF** + chemo) failed to demonstrate OS benefits in the subgroup with <1% PD-L1 expression compared to the control arm.

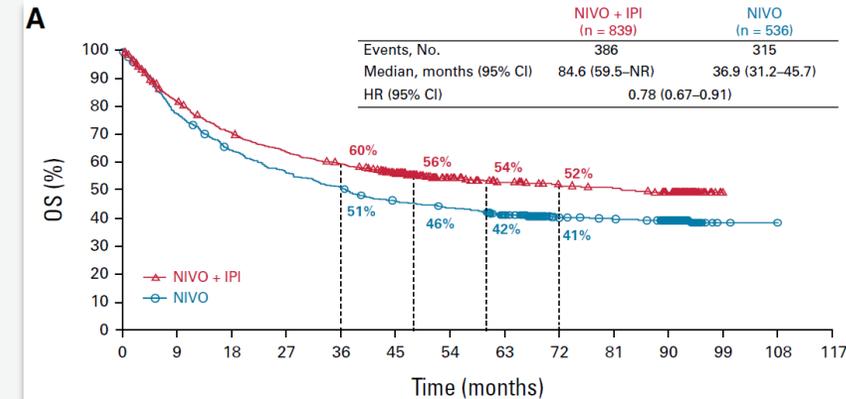
# Maximizing survival benefit with PD-1/VEGF/CTLA-4 triple-targeting approach (2/2)

"PD-1/L1 + CTLA-4" combination shows significant PFS and OS benefits, particularly long-term OS improvement

## "PD-1/L1 + CTLA-4" combo shows significant PFS and OS benefits, particularly long-term OS improvement, e.g., Nivolumab (PD-1) + Ipilimumab (CTLA-4) in advanced melanoma

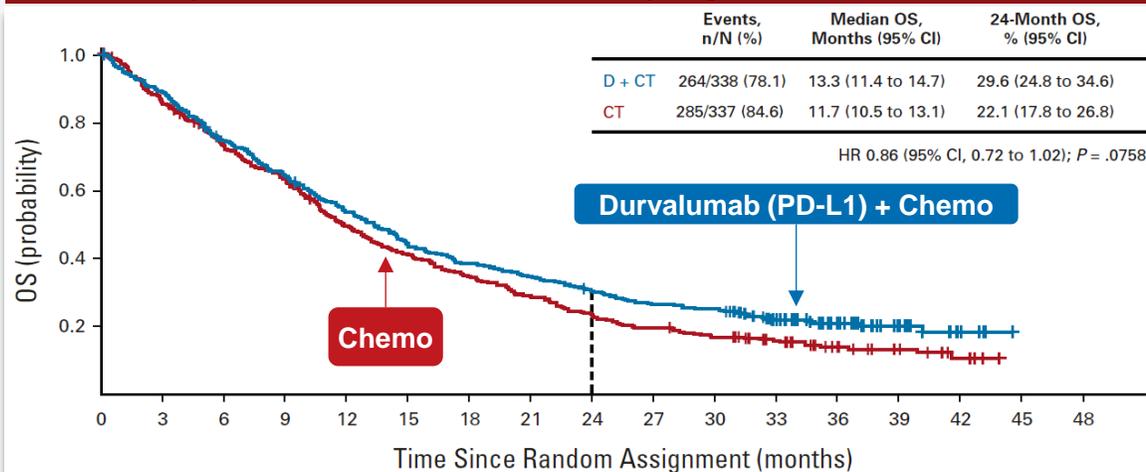


Source: **CheckMate067**, 10-Year Outcomes with Nivolumab plus Ipilimumab in Advanced Melanoma, NEJM



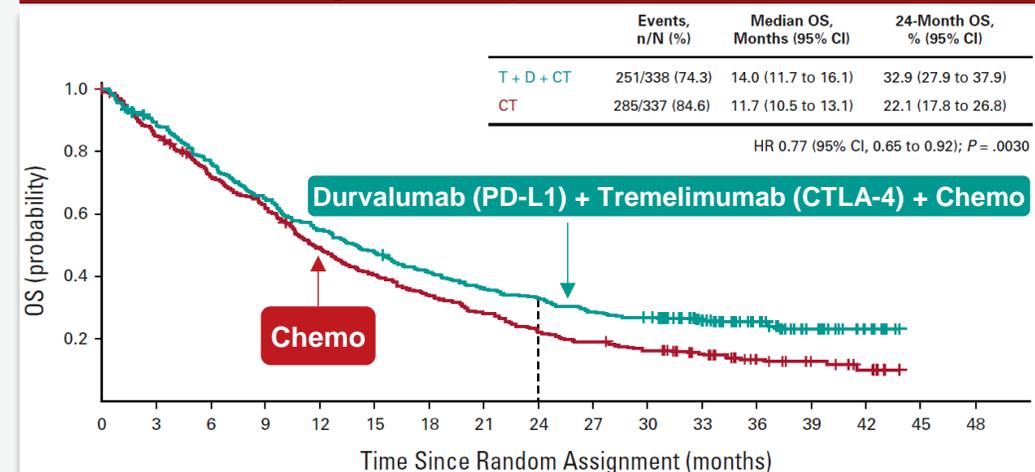
Source: Pooled Long-Term Outcomes With Nivolumab Plus Ipilimumab or Nivolumab Alone in Patients With Advanced Melanoma, JCO

## In NSCLC, Durvalumab (PD-L1) + Chemo vs. Chemo Alone: Improved PFS but No Statistically Significant OS Benefit



Source: POSEIDON Study

## Durvalumab (PD-L1) + Tremelimumab (CTLA-4) + Chemo vs. Chemo Alone: Significant Improvement in Both PFS and OS



Source: POSEIDON Study

# PD-1/VEGF/CTLA-4 trispecific mAb holds great clinical and commercial value

Greater potential than PD-1/VEGF bsAbs to become the next-generation IO backbone to replace anti-PD-(L)1 antibodies in current SOC

## Approved indications for 3 targets

- Lung cancer→
- Hepatocellular carcinoma→
- Renal cell carcinoma→
- Colorectal cancer→

## Approved indications for PD-(L)1 & VEGF

- Cervical cancer→

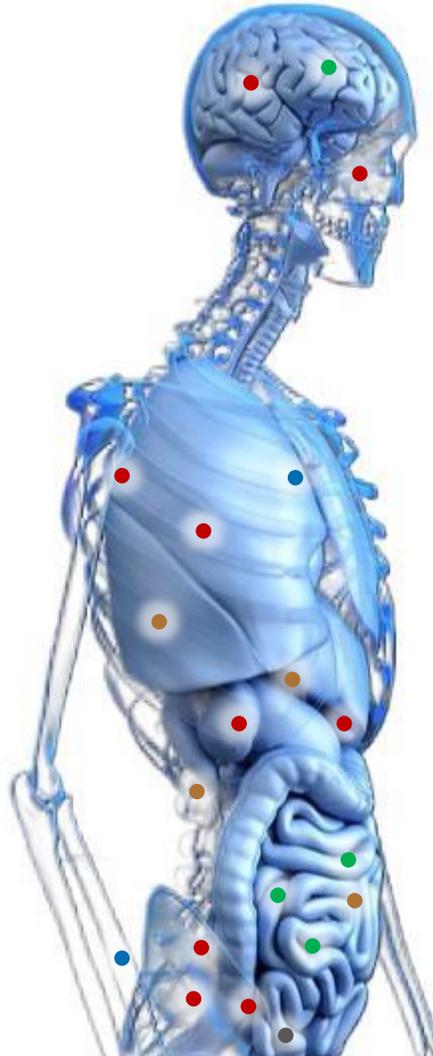
## Approved indications for PD-(L)1 & CTLA-4

- Esophageal cancer→
- Melanoma→

## Approved indications for VEGF

- Glioblastoma→
- Peritoneal cancer→
- Ovarian cancer→
- Fallopian tube carcinoma→

... ..



## Approved indications for PD-(L)1

- ←Head and neck squamous cell carcinoma
- ←Nasopharyngeal carcinoma
- ←Hodgkin lymphoma
- ←Triple negative breast cancer
- ←Biliary tract cancer
- ←Gastric cancer
- ←Urothelial carcinoma
- ←Bladder cancer
- ←Endometrial cancer

... ..

**Broad indications with huge clinical potential**

**60+**

Approved indications targeting PD-(L)1, VEGF, CTLA-4 (mono or multi targeting)

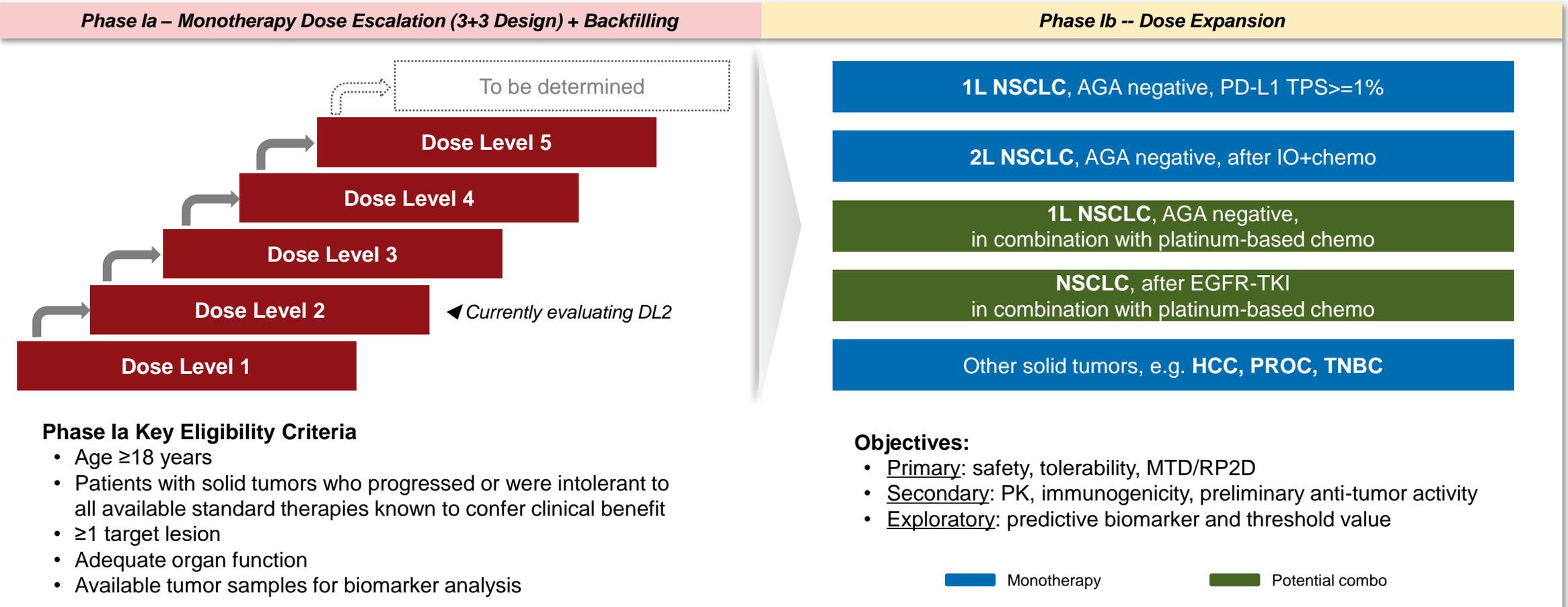
**Remarkable commercial value to exceed current market potential for bsAbs**

**\$90bn**

Current projection from Summit for the market potential of PD-1/VEGF bsAb

# CS2009 global phase I trial ongoing in Australia, to be expanded to the US and China

A phase I, dose-escalation and dose-expansion study to evaluate the safety, tolerability, pharmacokinetics and antitumor activities of CS2009 in patients with advanced solid tumors

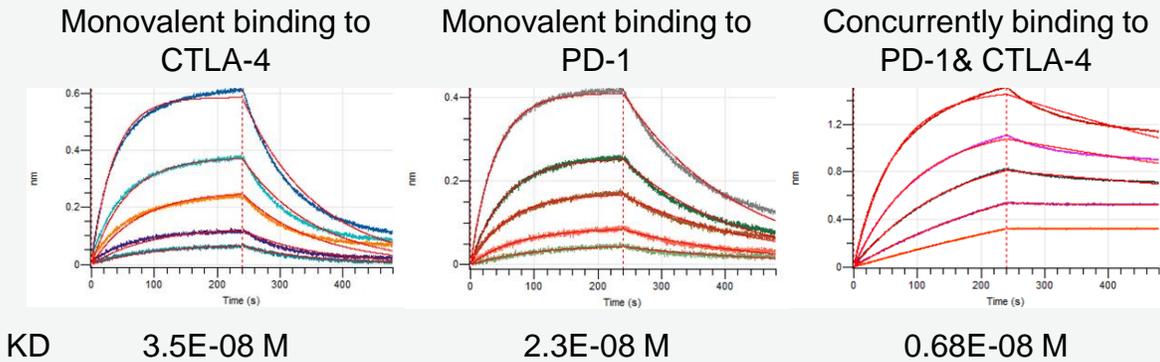


## Milestones & near-term catalysts

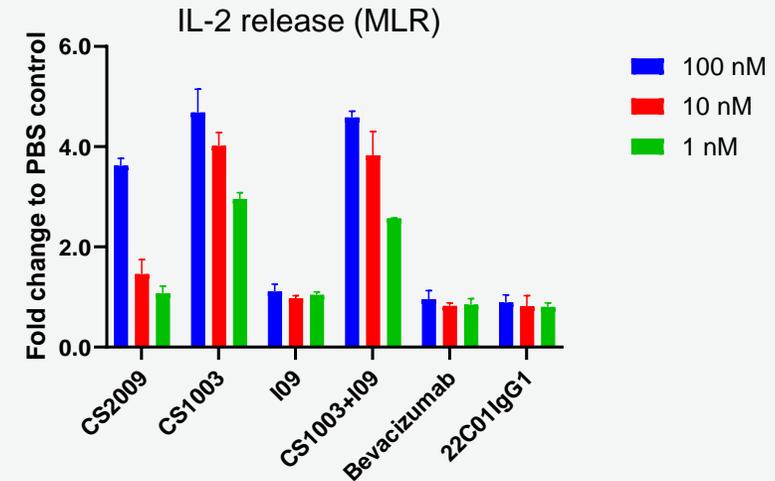


# CS2009 has a balanced affinity ratio between PD-1 and CTLA-4, confirmed multi-target engagement with synergy, and potent checkpoint inhibitor (CPI) function

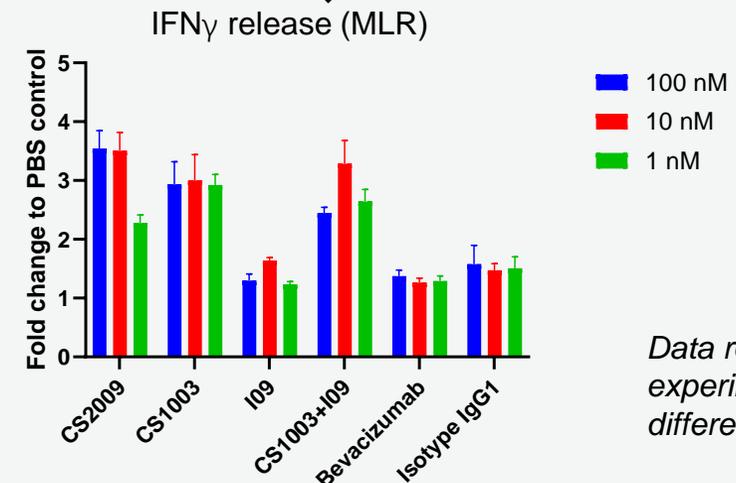
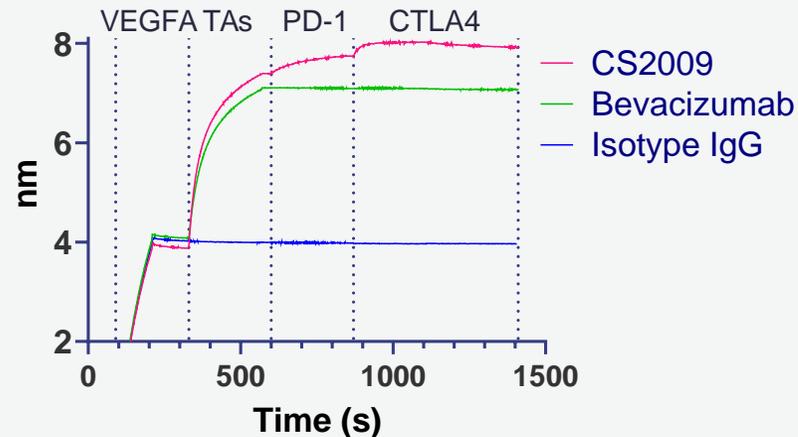
Balanced binding affinity to PD-1 or CTLA-4, enhanced affinity when engaged two targets together (synergy)



IL2 & IFN-γ release assays using PBMCs confirmed CS2009 as a potent CPI molecule.



Confirmed multi-target engagement by Octet

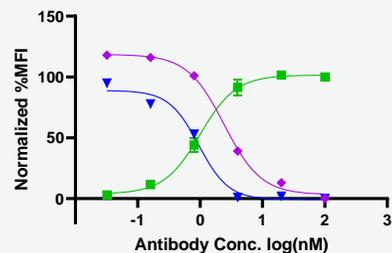


Data represents one of three experiments performed with different donor pairs.

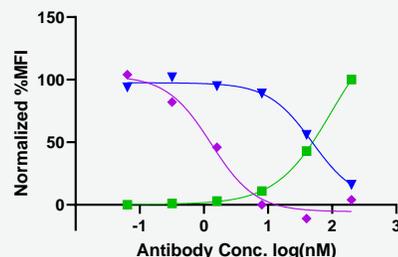
Notes: CS2009 data were comparable to the published preclinical results of AK112 (Zhong TT, et al, 2025)  
 1. CS1003 is anti-PD-1 molecule; 2. I09 is anti-CTLA-4 molecule with non-function Fc; 3. Bevacizumab is an anti-VEGF molecule.

# CS2009 preferentially and effectively blocks PD-1 and CTLA-4 on double-positive TILs, while sparing CTLA-4 on single-positive T cells to reduce systemic toxicity

## CHOs-PD-1/CTLA-4



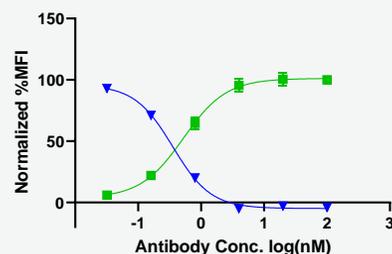
▲ unbound CTLA4  
▲ unbound PD1  
■ CS1003+CS1002



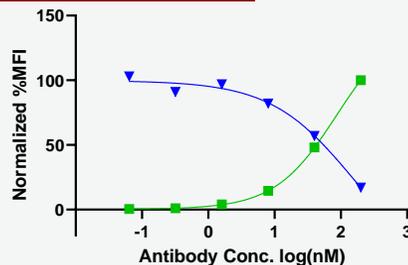
▲ unbound CTLA4  
▲ unbound PD1  
■ CS2009

- PD-1/CTLA-4  $\approx$  40:1, similar to the ratio on TILs
- Blocked CD80/CTLA-4 and PD-1/PD-L1 as effectively as the combo regimen

## NK92-PD-1



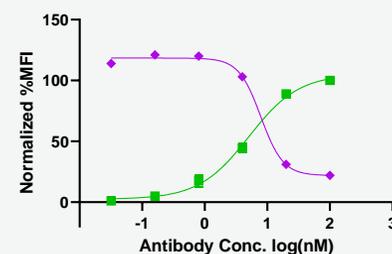
▲ unbound PD1  
■ CS1003+CS1002



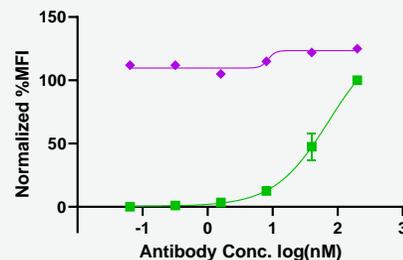
▲ unbound PD1  
■ CS2009

- PD-1 single positive
- Monovalent anti-PD-1 arm of CS2009 retains function.

## CHOK1-CTLA-4



▲ unbound CTLA4  
■ CS1003+CS1002



▲ unbound CTLA4  
■ CS2009

- CTLA-4 single positive
- Monovalent anti-CTLA-4 arm of CS2009 couldn't block the interaction between CD80 and CTLA-4 dimer

Combo

CS2009

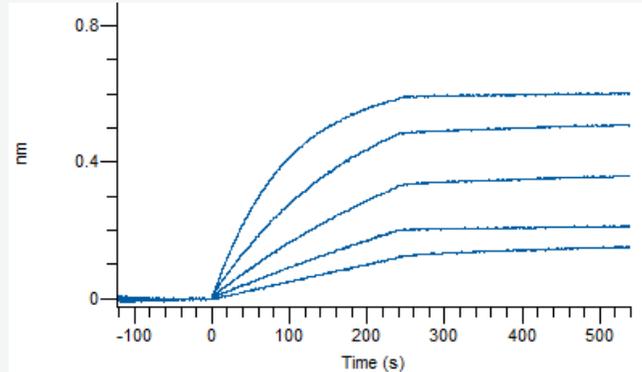
**Note:** Unbound PD-1 or CTLA-4 on cell membrane were measured with fluorescence labeled PD-L1 or CD80 respectively in flow cytometry.

PD-L1 binds to PD-1 with micromolar affinity. Cheng X, et al. JBC 2013.

AK112 20mpk q2w Cmin-ss is  $\sim$ 700nM\*, CS2009 with similar PK profile will be able to fully block PD-1 & CTLA-4 on double-positive TILs and PD-1 single-positive T cells.\*Sophia F, et.

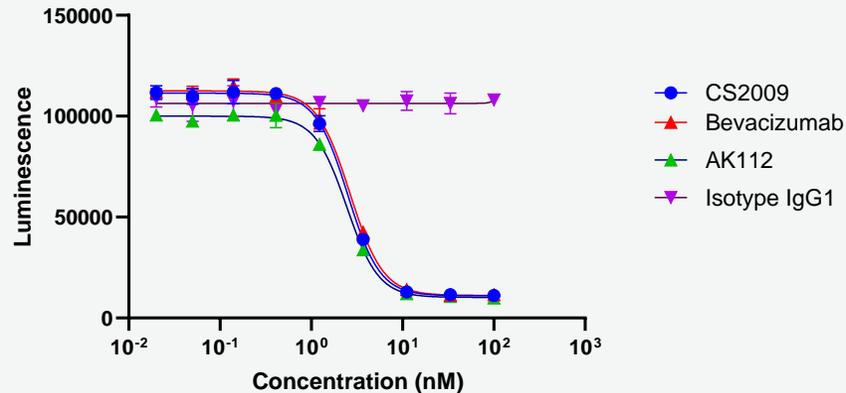
# CS2009 demonstrates equivalent VEGF-inhibitory activity as bevacizumab

## Octet

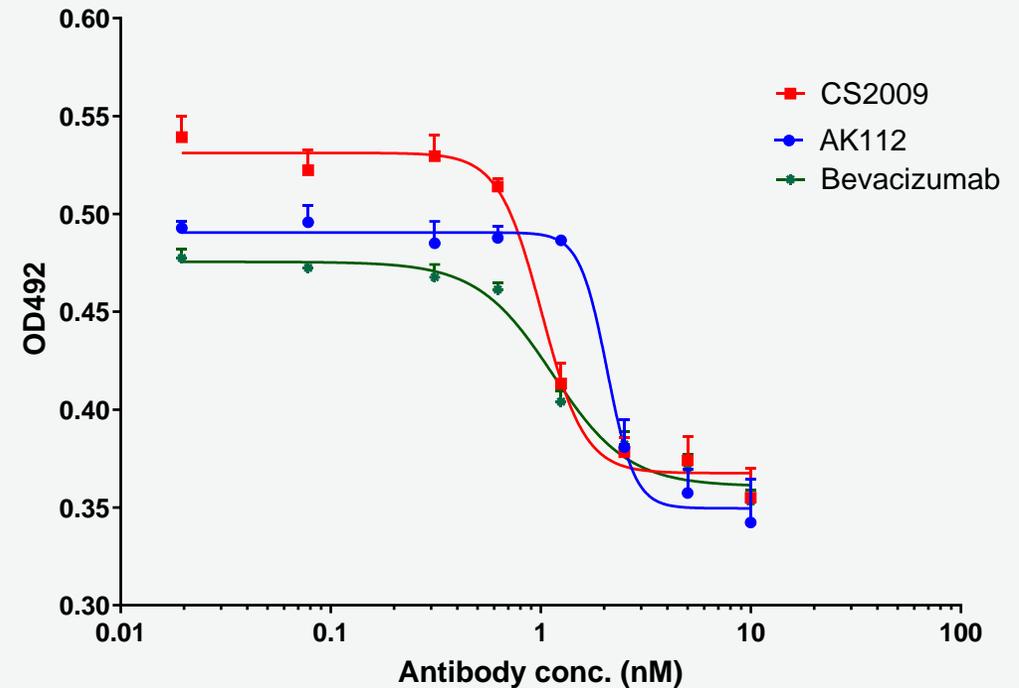


No attenuation on binding affinity to VEGFA (KD: approx.  $1e-12$  M), comparable to bevacizumab (KD:  $2e-12$  M in house data)

## HEK293-VEGFR2-NFAT-Luc cells In the presence of 0.5 nM VEGFA



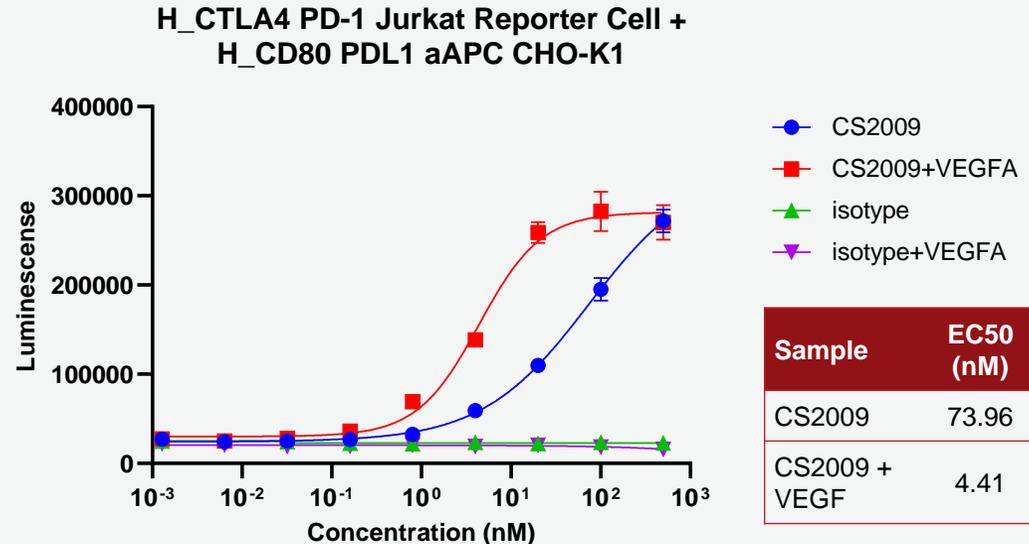
## HUVEC proliferation inhibition assay In the presence of 1.0 nM VEGFA



HUVEC proliferation inhibition assay demonstrated that the potency of anti-angiogenesis (IC50 1nM) is comparable to bevacizumab (IC50 1nM) and AK112 (IC50 2nM).

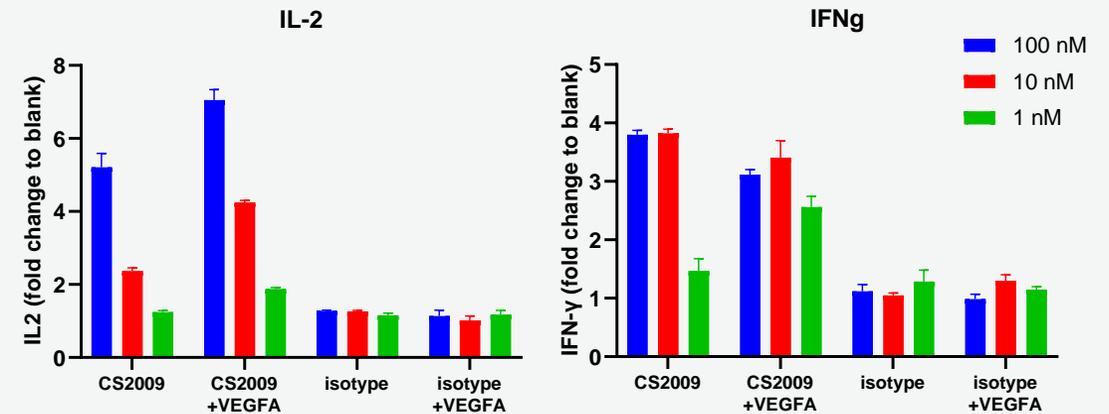
# Synergy between CPI and VEGF arms: CS2009's CPI activity is enhanced by crosslinking with VEGFA dimers

## PD-1/CTLA-4 Dual-reporter Assay



- Co-incubation with saturated VEGF dimer triggers crosslinking between VEGF and CS2009.
- The crosslinking enhances CS2009's binding avidity to PD-1/CTLA-4 double-positive cells, resulting in approximately **20-fold increase** in CPI activity.

## Mixed Lymphocytes Reaction (MLR) Assay



- The crosslinking enhances T-cell activity, leading to increased IL-2 secretion at all tested dose levels.
- The crosslinking also enhances T-cell activity by increasing IFN $\gamma$  secretion at low dose (1 nM); no clear difference at higher doses (10 nM and 100 nM) potentially due to IFN $\gamma$  levels plateau.

The observed synergistic effect likely translates into enhanced therapeutic effect of CS2009, given the well-known elevated level of VEGF in the tumor microenvironment (TME) under hypoxic conditions

# CS2009 Summary

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- 1 CS2009 is designed with confirmed IO function by in vitro / in vivo studies and full VEGF inhibitory activity as bevacizumab. **Synergy** between PD-1 arm and CTLA-4 arm; and synergy between CPI arms and VEGF arm potentially enhance activities in TME and **reduce systemic toxicities**
- 2 CS2009 exhibits **superior in vivo efficacy** versus its major competitors
- 3 CS2009 has demonstrated **promising PK/Tox profile**
- 4 Cell line development is expected to achieve **high yield** (approx. 7 g/L), the same level as monoclonal antibodies
- 5 **100 mg/kg as HNSTD/NOAEL** was determined in GLP-compliant repeat-dose toxicity study
- 6 **Patent** filed in Q3 2024
- 7 A global, first-in-human trial initiated with **first patient dosed** in Australia in Mar. 2025; **China IND submitted** in Feb. 2025
- 8 Targeting indications of NSCLC, OC, RCC, CC, HCC, GC, etc., **aiming to replace PD-1/L1 in current SOC**s

# 02

## *Pipeline Updates*

# ***Innovative Early Programs :***

# Pipeline 2.0: an innovative portfolio with global rights

Drug candidate	Right	Indication	Discovery	Preclinical Development	IND-Enabling	FIH	POC	
CS5001 <sup>1</sup> (ROR1 ADC)		Solid tumors hematologic malignancies						
CS2009 (PD-1/VEGF/CTLA-4 trispecific antibody)		Solid tumors						
CS2011 (EGFR/HER3 bispecific antibody)		Solid tumors						
CS5007 (EGFR/HER3 bispecific ADC)		Solid tumors						
CS5005 (SSTR2 ADC)		Solid tumors						
CS5008 (SSTR2/DLL3 bispecific ADC)		Solid tumors						
CS5005-R (SSTR2 RDC)		Solid tumors						
CS5006 (ITGB4 ADC)		Solid tumors						
CS5009 (B7H3/PD-L1 bispecific ADC)		Solid tumors						
CS2013 (Bispecific antibody, undisclosed targets)		<b>Autoimmune</b>						
CS2015 (Bispecific antibody, undisclosed targets)		<b>Autoimmune</b>						

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 from LigaChem Biosciences, Inc. (LCB) to lead development and commercialization of LCB71/CS5001 outside the Republic of Korea

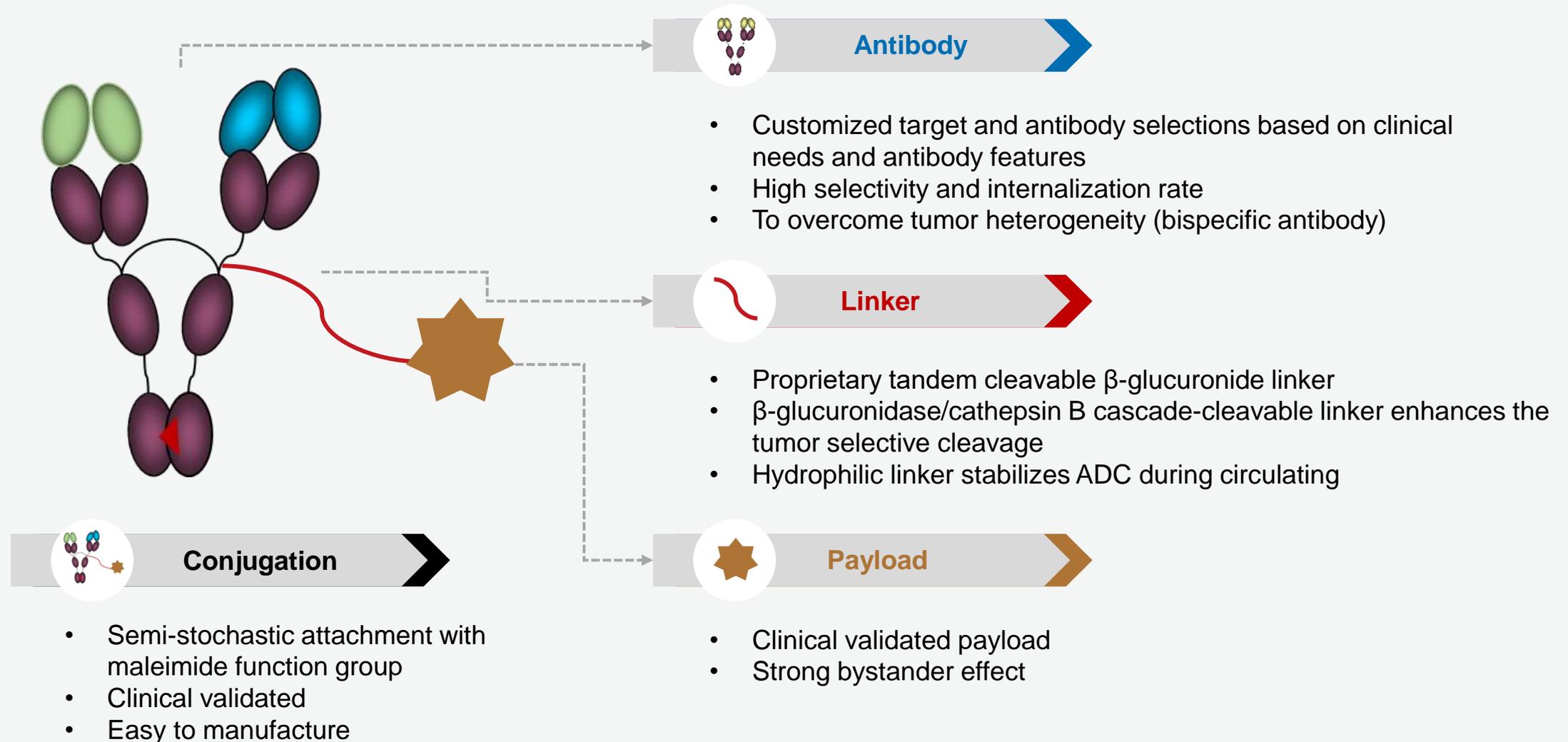
Antibody ADC RDC Global Rights

# 02

*Pipeline Updates*

***Innovative Early Programs :  
ADC platform and related assets  
(EGFR/HER3, SSTR2, ITGB4)***

# CStone has built a modular proprietary antibody drug conjugate (ADC) platform, enabling customized molecular design and screening



# CS5007, a potentially best-in-class EGFR/HER3 bispecific ADC & its antibody backbone, CS2011

## Potential best-in-class

### Molecular design

- **Synergistic blocking** of EGFR and HER3 signaling for enhanced therapeutic effects, while **minimizing off-target toxicity** in normal tissues.
- Better developability and **PK profile** compared to leading competitors
- CStone's **proprietary linker** (CSL20) & **payload** (highly potent topoisomerase I Inhibitor – exatecan)

### Target indication

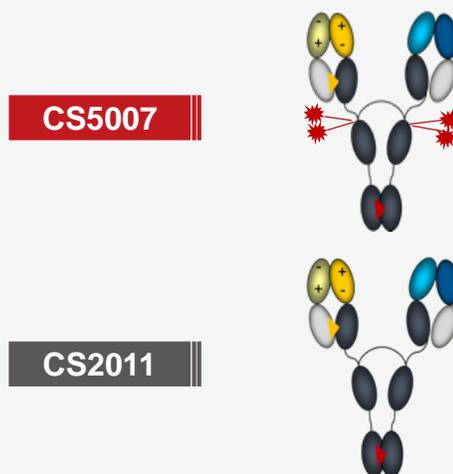
- Solid tumors including NSCLC, SCCHN, CRC, etc.

### Competitive landscape

- Two potential competitors, one in phase III trial and the other in IND-enabling.

## Differentiated Molecular Design

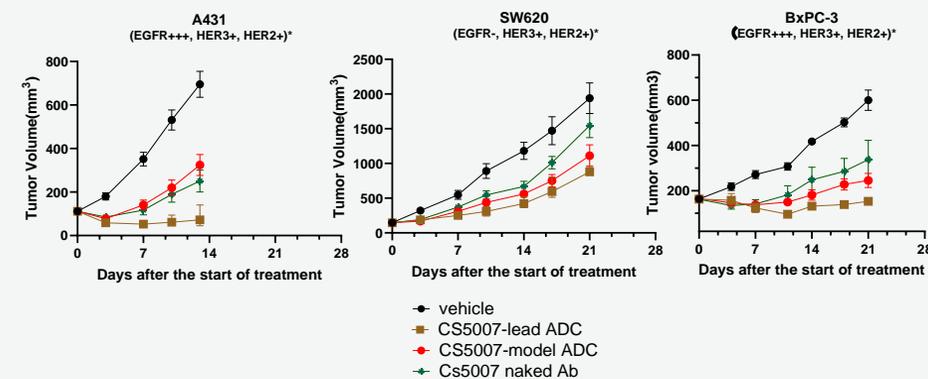
\* Representative molecular configurations



*Note: CS2011 is the bispecific antibody backbone of CS5007 ADC*

## Preclinical Data

CS5007 lead ADC demonstrated **more potent** tumor growth inhibition vs. model ADC and naked bsAb on xenografted tumors with different levels of EGFR and HER3 expression, e.g. SW620 (EGFR-/HER3+), A431 (EGFR+++ /HER3-), and BxPC3 (EGFR++ /HER3+)



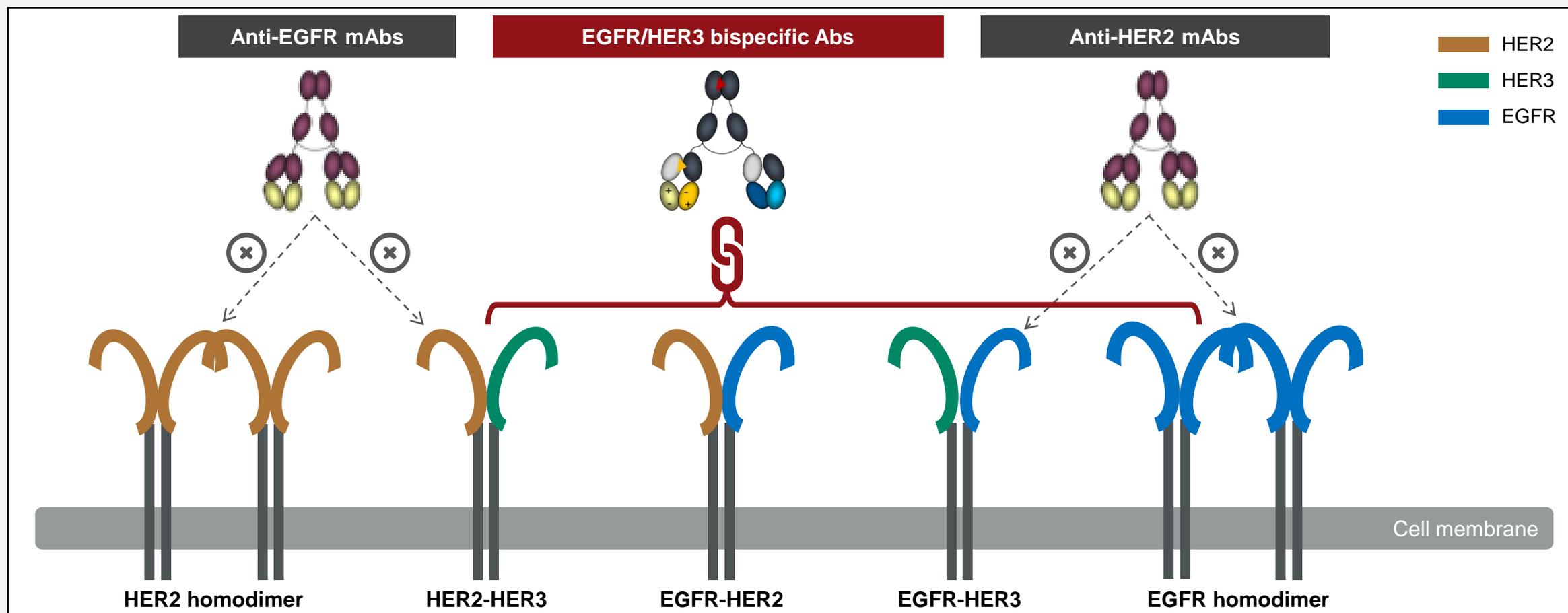
## Preliminary Development plan

1. **IND expected in 2H 2025 (CS2011) and 1H 2026 (CS5007)**
2. *Fast-to-market: targeting later-line NSCLC & SCCHN*
3. *Global phase III trial: targeting 1L NSCLC, SCCHN, and CRC, versus current SoC*

# CS2011/CS5007 designed to overcome tumor heterogeneity

Simultaneously targeting EGFR homodimer, EGFR/HER3 heterodimer, EGFR/HER2 heterodimer, HER2/HER3 heterodimer

- EGFR/HER3 bispecific antibodies (e.g. CS2011) can tackle almost all HER-family receptors except HER2 homodimers (including EGFR, HER3, AKT, ERK, etc.)
- HER3 dimerizes with EGFR, HER2 & HER4 which belong to the same HER family and are involved in tumor cell survival and proliferation through signaling cascade. (\*referring to Daiichi's U3-1402 introduction)



# CS5005, a first-in-class SSTR2-ADC based on CStone's proprietary ADC platform

A novel ADC on validated cancer target with FIC potential

## Molecular Design

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

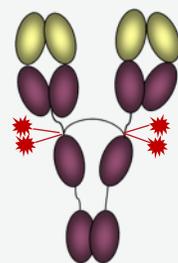
## Target Indication

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

## Competitive Landscape

- First-in-class

## Differentiated Molecular Design

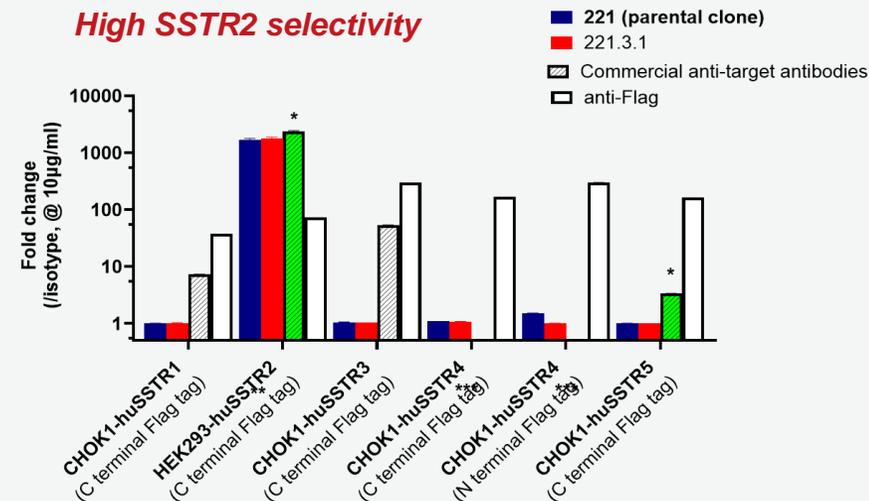


FIC SSTR2 ADC  
(DAR4 or 8)

## Preliminary Clinical Development Plan

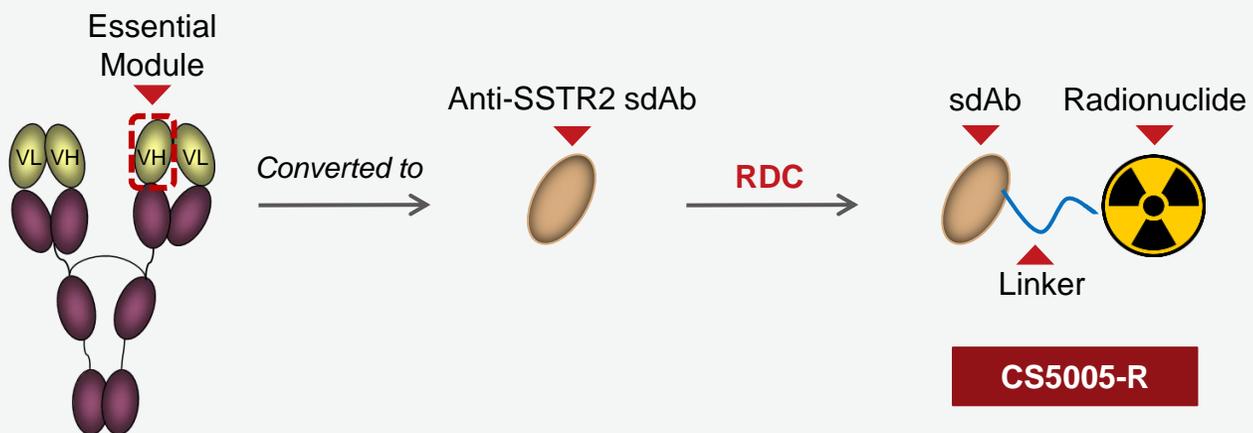
- **IND expected in 2025/2026**
- *Fast-to-market trial: single-arm phase II trial for later-line SCLC, 3L NEC, Gr3 NET, etc.*
- *Global phase III trials: 1L SCLC, 2L NET, etc.*

## Preclinical Data



Exploring other modalities targeting SSTR2, e.g. RDC, SSTR2xDLL3 bispecific ADC, etc.

# CS5005-RDC, a 2<sup>nd</sup>-generation RDC by leveraging our proprietary anti-SSTR2 mAb



### Advantages of anti-SSTR2 sdAb:

- Delivers better tissue distribution than antibodies
- Better selectivity than peptides.
- Derived from CStone's own proprietary anti-SSTR2 antibody
- High affinity and selectivity

### Target Indications:

- Aiming to address **neuroendocrine neoplasms** and SSTR2-expressing tumors, including **SCLC**.

### Development milestones:

- Potentially first-in-class
- IND expected in 2026

# CS5008, a first-in-class SSTR2xDLL3 bispecific ADC based on CStone's proprietary ADC platform

## FIC and potential BIC

### Molecular Design

- Constructed to target two clinically validated solid tumor **targets with similar expression profile in NET/NEC/SCLC**
- CStone's **proprietary anti-SSTR2/DLL3 clones** with high affinity and tumor-selectivity
- mAb-like developability and PK profile
- CStone's **proprietary linker & payload**

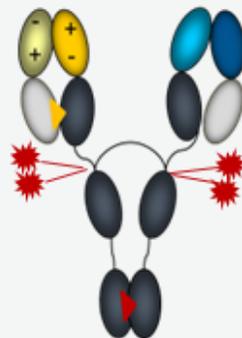
### Target Indication

- SCLC, NECs, NETs etc.

### Competitive Landscape

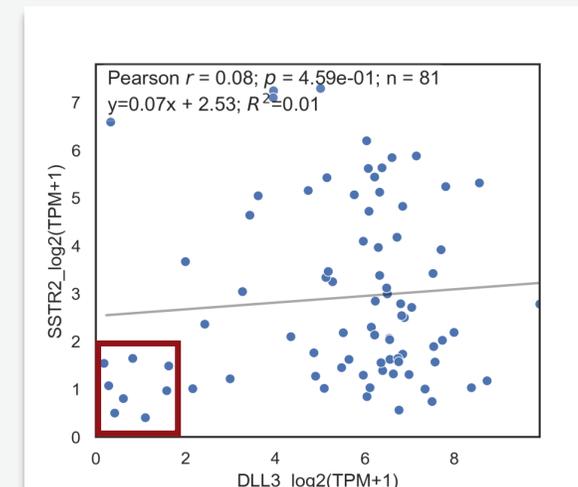
- First-in-class

## Differentiated Molecular Design



## Preclinical Data

- *Dual targeting SSTR2 and DLL3 overcomes intra/inter tumor heterogeneity.*
- *Only ~10% of patients don't express either SSTR2 or DLL3.*



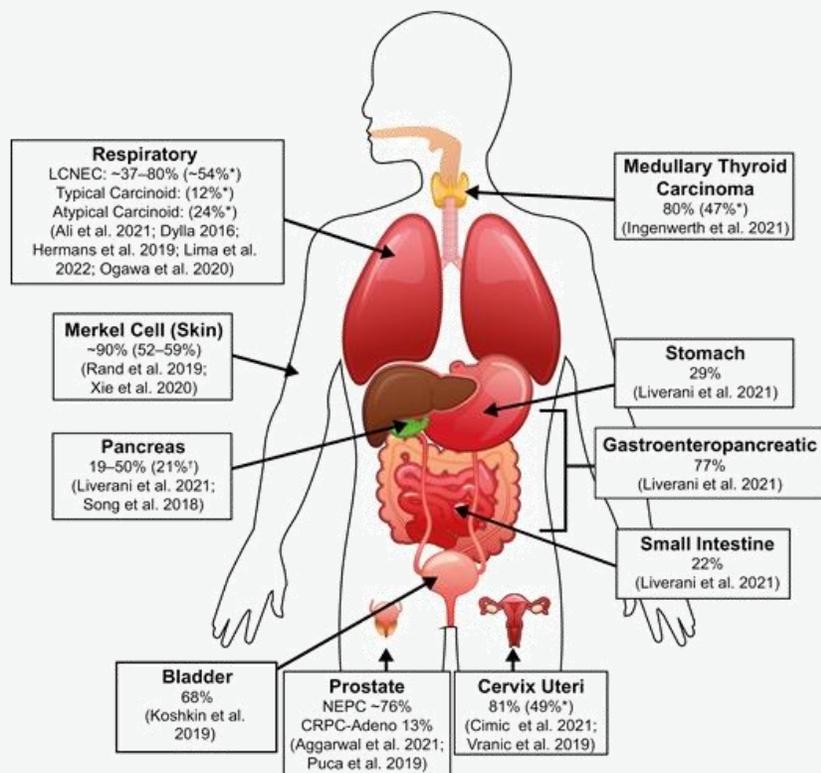
## Preliminary Development Plan

- **IND expected in 2026**
- *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.*

# Rationale for simultaneous targeting DLL3 and SSTR2: both were highly overexpressed in SCLCs and neuroendocrine tumors/cancers (NETs/NECs)

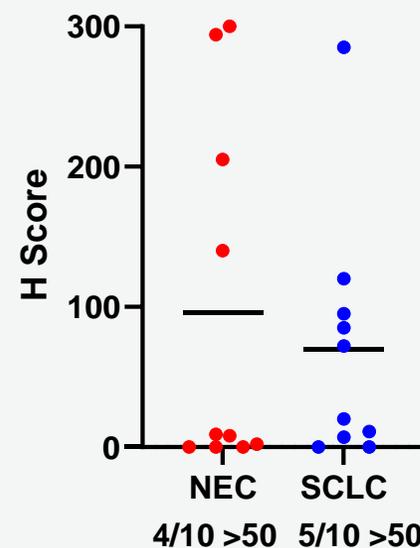
DLL3 is a clinically validated target for SCLCs with well-documented overexpression in NETs/NECs.

SSTR2 is a clinically validated target for NETs/NECs with overexpression in SCLC & NETs/NECs well-documented and confirmed by in-house IHC.

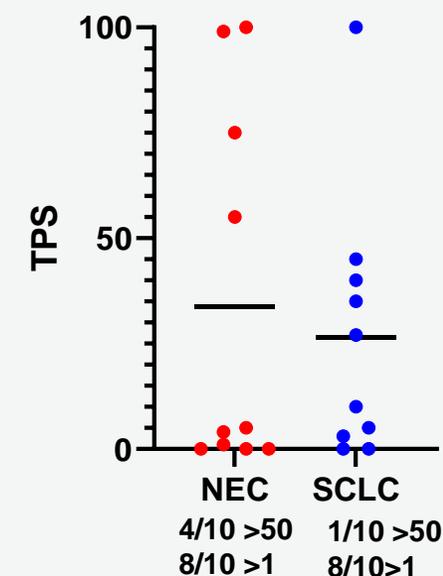


Representative DLL3 prevalence (i.e., >1% DLL3-expressing cells) by immunohistochemistry in NETs.<sup>1</sup>

## IHC score



## TPS



Consistent with the published data<sup>2</sup> that 35% of tumor samples from SCLC patients show IHC H-score  $\geq 50$ , classified as positive.

# CS5006, a first-in-class ITGB4-ADC based on CStone's proprietary ADC platform

## An ADC targeting ITGB4, an integrin protein

### Molecular Design

- Target identified to be overexpressed in multiple solid tumors by CStone's **bioinformatic algorithm**
- CStone's **proprietary antibody** with high affinity and selectivity
- CStone's **proprietary linker & payload**

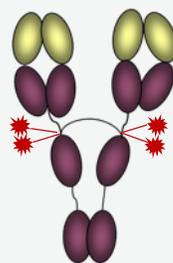
### Target Indication

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

### Competitive Landscape

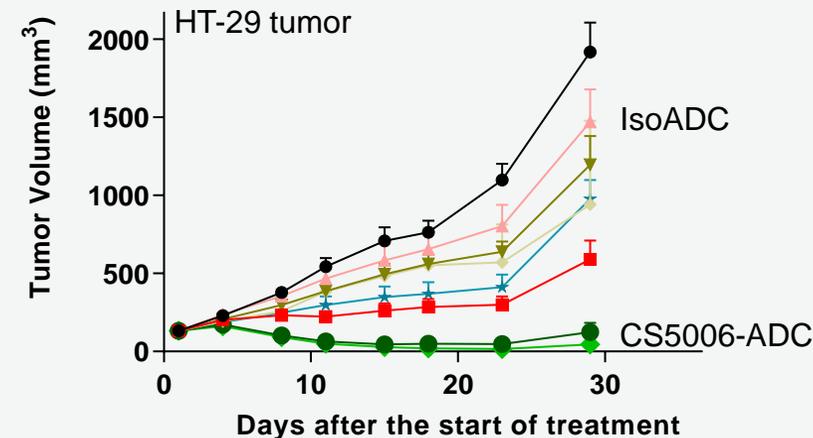
- First-in-class

### Differentiated Molecular Design



FIC ITGB4 ADC  
(DAR4)

### Preclinical Data



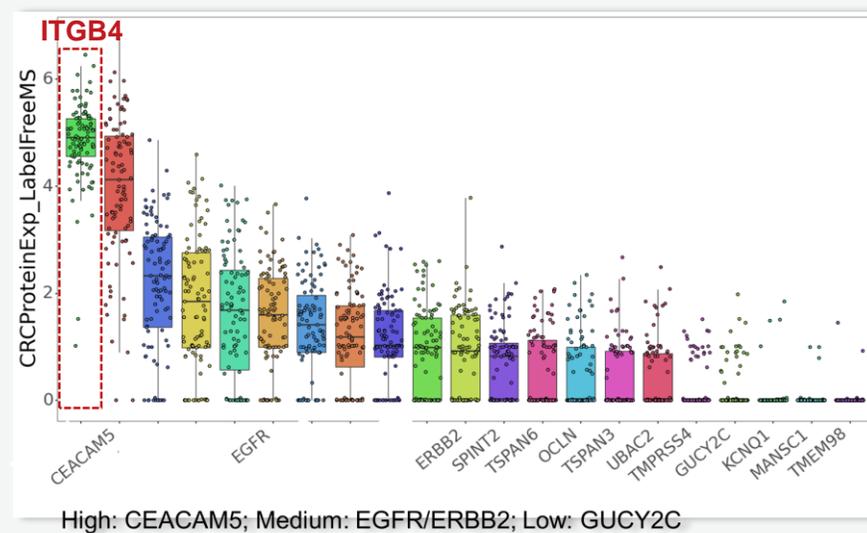
### Preliminary Clinical Development Plan

- **IND expected in 2025/2026**
- *Fast-to-market trial: single-arm phase II trial for later-line SCCHN, ESCC, etc.*
- *Global phase III trials: 1L NSCLC, SCCNH, ESCC, etc.*

# ITGB4 identified by AI-based ADC target discovery algorithm

## Key selection criteria for indication specific novel TAAs

- 1 Absolute protein over-expression in tumor tissues
- 2 Minimal/no expression in normal tissues or critical normal organs (e.g. heart, kidney, etc.)
- 3 High expression in tumor cells in TME
- 4 Low off-target cytotoxicity in in vitro KO/KD models
- 5 High internalization rate



## AI-driven target prioritization workflow

Genome-wide machine learning ranking

Top 100 indication specific TAAs

Computational & quantitative proteomics

Absolute high protein expression

Proprietary bioinformatic algorithm

(PCT/CN2022/074991)  
Tumor vs normal  
Tumor vs TME

Rapid validation of targets

Top 3 TAAs

**02**

*Pipeline Updates*

***Innovative Early Programs :  
Autoimmune***

# CS2013, a potential best-in-class bispecific antibody to target autoimmune diseases

## First-in-class/Best-in-class

### Molecular Design

- B-cell directed therapeutics
- Constructed for blocking two important ligands for B cell development and survival
- Well-designed to trigger synergistic effect
- Better developability and much longer half-life
- Designed to be suitable for s.c. injection and long dosing interval

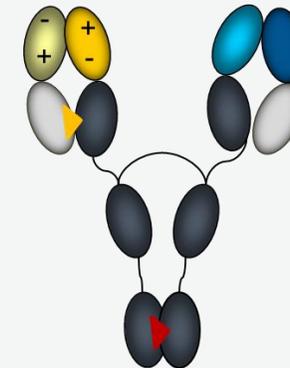
### Target Indication

- B cell related autoimmune disease including **SLE, RA, IgAN**, etc.

### Competitive Landscape

- First-in-class/Best-in-class

## Differentiated Molecular Design



## Preliminary Development Plan

1. **PCC expected in Q1 2025; IND expected in 2026**
2. *Fast-to-market: targeting severe lupus nephritis*
3. *Global phase III trial: TBD*

# CS2015, a potential best-in-class bispecific antibody to target type 2 inflammatory diseases

## First-in-class/Best-in-class

### Molecular Design

- Th2 directed therapies
- Constructed for blocking two important ligands for Th2 immune response
- Well-designed to trigger synergistic effect
- Better developability and much longer half-life
- Designed to be suitable for s.c. injection and long dosing interval

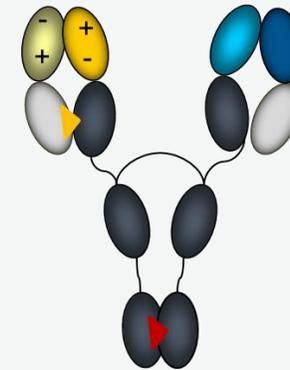
### Target Indication

- Type 2 inflammation including **atopic dermatitis (AD), asthma**, etc.

### Competitive Landscape

- First-in-class/Best-in-class

## Differentiated Molecular Design



## Preliminary Development Plan

1. **PCC expected in 2025; IND expected in 2026**
2. *Fast-to-market: targeting dupilumab non-responders bearing severe AD*
3. *Global phase III trial: type 2 inflammation*

# CStone's mature and innovative portfolio covers a broad of indications with rapidly growing commercial value

~200K  
China annual incidence<sup>[1]</sup>

2,000K+  
Global annual incidence<sup>[2]</sup>

5,000K+  
Global annual incidence<sup>[3]</sup>

## Precision Medicine

- **Pralsetinib** (commercial)  
*FIC RET inhibitor*
- **Avapritinib** (commercial)  
*FIC KIT/PDGFR inhibitor*

## 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)  
*CTLA-4, co-dev with Hengrui, received IND approval for 1L late-stage nsq-NSCLC; initiated phase III clinical trial for 1L late-stage HCC*

## 🌿 Pipeline 2.0 🌿

- **CS5001** (clinical) *ROR1-ADC in leading position worldwide*
- **CS2009** (clinical) *PD-1/VEGF/CTLA-4 trispecific antibody*
- **CS2011** (pre-clinical) *EGFR/HER3 bispecific antibody*
- **CS5007** (pre-clinical) *EGFR/HER3 bispecific ADC*
- **CS5005** (pre-clinical) *SSTR2 ADC*
- **CS5005-R** (pre-clinical) *SSTR2 RDC*
- **CS5008** (pre-clinical) *SSTR2/DLL3 bispecific ADC*
- **CS5006** (pre-clinical) *ITGB4 ADC*
- **CS5009** (pre-clinical) *B7H3/PD-L1 bispecific ADC*
- **CS2013** (pre-clinical) *undisclosed autoimmune bispecific antibody*
- **CS2015** (pre-clinical) *undisclosed autoimmune bispecific antibody*
- ... ..and other exploratory programs

**03**

# ***Financial Highlights***

# FY2024 financial results

Significantly lower operating loss on stringent cost control and business model transition

Mn RMB	FY 2024	FY 2023	Change
<b>GROUP REVENUES</b>	<b>407.2</b>	<b>463.8</b>	<b>-12%</b>
Sales of Pharmaceutical Products	175.1	336.7	-48%
License Fee Income	204.0	95.7	113%
Royalty Income	28.1	31.4	-11%
<b>OPERATING EXPENSES</b> (Non-IFRS <sup>[1]</sup> Measures)	<b>(349.1)</b>	<b>(872.8)</b>	<b>-60%</b>
Research and development expenses (Non-IFRS <sup>[1]</sup> Measures)	(124.7)	(534.7)	-77%
Selling, marketing and admin expenses (Non-IFRS <sup>[1]</sup> Measures)	(224.4)	(338.1)	-34%
<b>OTHER INCOMES/ OTHER GAINS AND LOSSES</b>	<b>30.1</b>	<b>250.1</b>	<b>-88%</b>
Other incomes	27.1	50.6	-46%
Other gains and losses	3.0	199.5	-98%
<b>LOSS FOR THE YEAR</b> (Non-IFRS <sup>[1]</sup> Measures)	<b>(94.0)</b>	<b>(330.2)</b>	<b>-72%</b>

## Total Group Revenues of RMB 407.2Mn

- 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 ivosedinib in Dec 2023 which created a total deal value of USD 50 Mn

## Loss for the year down 72% to RMB 94.0Mn

- 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	31 <sup>st</sup> December 2024	31 <sup>st</sup> December 2023	Change
<b>CASH BALANCE</b> <sup>[2]</sup>	<b>672.9</b>	<b>1,026.7</b>	<b>(353.8)</b>

## Cash Balance of RMB 672.9Mn

- Reduced operating cash burn by RMB 245.6 Mn (FY 2024 : RMB 343.2Mn vs. FY 2023 : RMB 588.8Mn)

[1] 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; [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		2025			
		Q1	Q2	Q3	Q4
Exploring global BD partnerships for CS5001, CS2009, CS2011, CS5007, CS5005/CS5008 and CS5006					
Key clinical programs	CS5001 (ROR1 ADC)				Data presentation at 2025 ASH
	CS2009 (PD-1/VEGF/CTLA-4 tsAb)	Phase Ia study initiation	Periodic safety, PK, antitumor activity evaluations		Phase I clinical data disclosure
Pipeline 2.0	CS2011 (EGFR/HER3 bsAb)		Preclinical data disclosure at 2025 AACR		IND and FIH trial →
	CS5007 (EGFR/HER3 bispecific ADC)				IND and FIH trial →
	CS5005 (SSTR2 ADC)/ CS5008 (SSTR2/DLL3 bispecific ADC)				IND and FIH trial →
	CS5006 (ITGB4 ADC)				IND and FIH trial →
Commercial / late-stage programs	Sugemalimab (PD-L1)	More ex-China commercial partnerships and commercial launch			
	Pralsetinib (RET)	Approval of ANDA for manufacturing localization			
	Avapritinib (KIT/PDGFR $\alpha$ )	Launch domestic supply*			
	Nofazinlimab (PD-1)		Pre-planned OS final analysis readout Ex-China partnership exploration		

\*Domestic supply launched in Feb 2025  
Abbr.: tsAb, trispecific antibody; bsAb, bispecific antibody

C1



基石药业  
KINGSTONE  
PHARMACEUTICALS



*Thanks*





# *Appendix*



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

## – Pipeline 2.0

Drug candidate	Right	Indication	Discovery	Preclinical Development	IND-Enabling	FIH	POC
CS5001 <sup>1</sup> (ROR1 ADC)		Solid tumors hematologic malignancies					
CS2009 (PD-1/VEGF/CTLA-4 trispecific antibody)		Solid tumors					
CS2011 (EGFR/HER3 bispecific antibody)		Solid tumors					
CS5007 (EGFR/HER3 bispecific ADC)		Solid tumors					
CS5005 (SSTR2 ADC)		Solid tumors					
CS5008 (SSTR2/DLL3 bispecific ADC)		Solid tumors					
CS5005-R (SSTR2 RDC)		Solid tumors					
CS5006 (ITGB4 ADC)		Solid tumors					
CS5009 (B7H3/PD-L1 bispecific ADC)		Solid tumors					
CS2013 (Bispecific antibody, undisclosed targets)		<b>Autoimmune</b>					
CS2015 (Bispecific antibody, undisclosed targets)		<b>Autoimmune</b>					

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

Antibody ADC RDC Global Rights

# 60% ORR among 10 evaluable **Hodgkin lymphoma** at dose levels 5 to 9; 100% ORR (2 CRs & 1 PR) observed in dose level 8 cohort (125 µg/kg)

## Best overall response (BOR) in evaluable patients with Hodgkin lymphoma

BOR, n(%)	DL4 33.5 µg/kg (n=1)	DL5 50 µg/kg (n=2)	DL6 75 µg/kg (n=2)	DL7 100 µg/kg (n=3)	DL8 125 µg/kg (n=3)	DL9 156 µg/kg (n=0)	All DLs (N=11)
CR	0	0	0	1 (33%)	2 (66.7%)	0	3 (27.3%)
PR	0	1 (50%)	1 (50%)	0	1 (33%)	0	3 (27.3%)
SD	0	0	0	0	0	0	0
PD	1 (100%)	1 (50%)	1 (50%)	2 (66.7%)	0	0	5 (45.5%)
ORR	0	1 (50%)	1 (50%)	1 (33%)	3 (100%)	0	6 (54.5%)

### ▶ Hodgkin Lymphoma

- Objective responses observed from **DL5 (50 µg/kg) and above**, including 3 CRs and 3 PRs among 10 evaluable patients at DLs 5-9 (**ORR: 60.0%**).
- 2 CRs and 1 PR** observed at **DL8 (125 µg/kg)** among 3 evaluable patients.

Source: 2024 ASH Poster

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

# 56% ORR among 16 evaluable **non-Hodgkin lymphoma** at dose levels 7 to 9; 70% ORR in dose level 8 cohort (125 µg/kg)

## Best overall response (BOR) in evaluable patients with non-Hodgkin lymphoma

BOR, n(%)	DL4 33.5 µg/kg (n=1)	DL5 50 µg/kg (n=0)	DL6 75 µg/kg (n=3)	DL7 100 µg/kg (n=5)	DL8 125 µg/kg (n=10)	DL9 156 µg/kg (n=1)	All DLs (N=20)
CR	0	0	0	1 (20%)	2 (20%)	0	3 (15%)
PR	0	0	0	0	5 (50%)	1 (100%)	6 (30%)
SD	0	0	0	0	1 (10%)	0	1 (5%)
PD	1 (100%)	0	3 (100%)	4 (80%)	2 (20%)	0	10 (50%)
ORR	0	0	0	1 (20%)	7 (70%)	1 (100%)	9 (45%)

### ▶ Non-Hodgkin Lymphoma

- Objective responses observed from **DL7 (100 µg/kg) and above**, including **3 CRs (2 DLBCL and 1 mantle cell lymphoma)** and **6 PRs (3 DLBCL, 1 marginal zone lymphoma, 1 high-grade B-cell lymphoma and 1 follicular lymphoma)** among 16 evaluable patients at DLs 7-9 (**ORR: 56.3%**).
- A notably higher **ORR of 70.0%** observed at **DL8 (125 µg/kg)** among 10 evaluable patients.

Source: 2024 ASH Poster

DL – dose level; ORR – objective response rate; CR – complete response; PR – partial response; SD – stable disease; PD – progressive disease; DLBCL – diffuse large B-cell lymphoma

# CS5001 demonstrates anti-tumor activities in solid tumors (NSCLC, pancreatic cancer, etc.) in addition to lymphomas

## 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%)

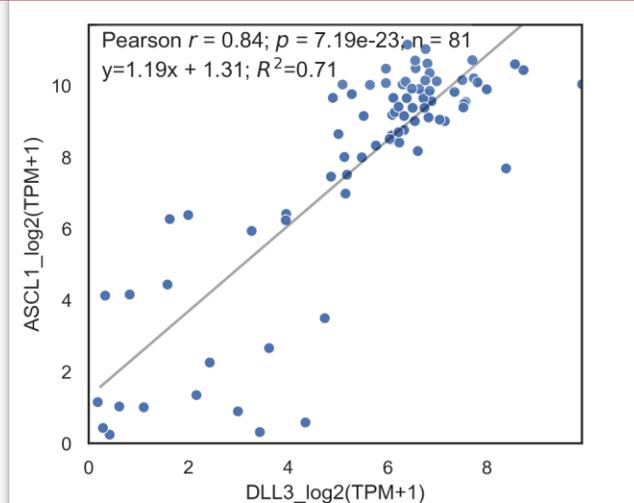
- ▶ PRs and SDs with reduced tumor burden emerging in various types of solid tumors at higher doses
- ▶ Notably in non-small cell lung cancer (NSCLC) (**1 PR and 3 SDs**), triple-negative breast cancer (TNBC) (**1 SD**), pancreatic cancer (**1 PR**), and ovarian cancer (**1 SD**)
- ▶ Most of these patients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

Source: 2024 ASCO Poster

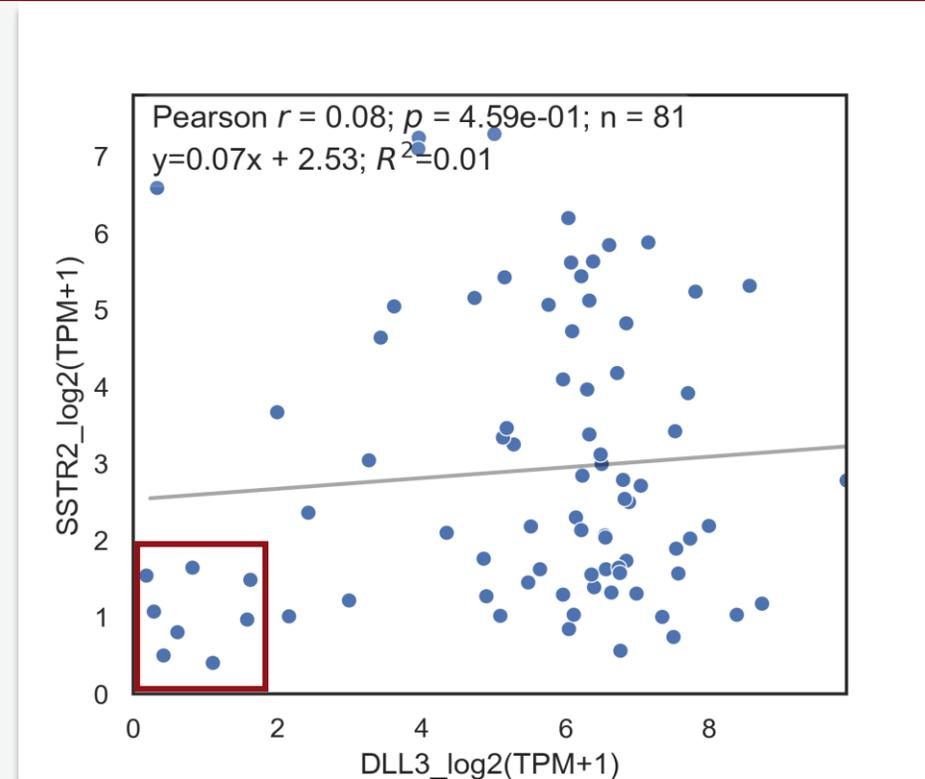
DL – dose level; CR – complete response; PR – partial response; SD – stable disease; PD – progressive disease

# Bioinformatics analysis on SCLC samples supports DLL3/SSTR2 dual-targeting to overcome tumor heterogeneity

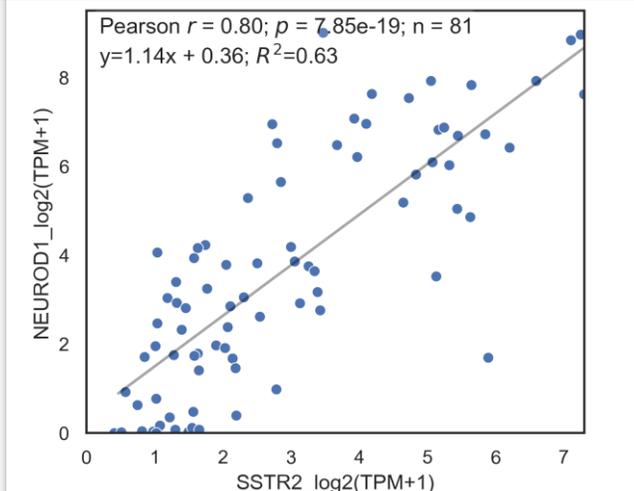
## DLL3 expression is driven by ASCL1



## Dual targeting SSTR2 and DLL3 overcomes tumor heterogeneity and expands target population



## SSTR2 expression is driven by NEUROD1



- Coexpression suggests targeting both SSTR2 and DLL3 will be able to overcome intra/inter SCLC tumor heterogeneity.
- Only ~10% of patients don't express either SSTR2 or DLL3.



**END**