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CSTONE
PHARMACEUTICALS

CStone Business Update

December 20th, 2023

Stock Code: 2616. HK

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Agenda

1. ROR1 ADC Updates
2. PD-L1 ex-China Progress
3. Commercialization Strategy
4. Expected Catalysts

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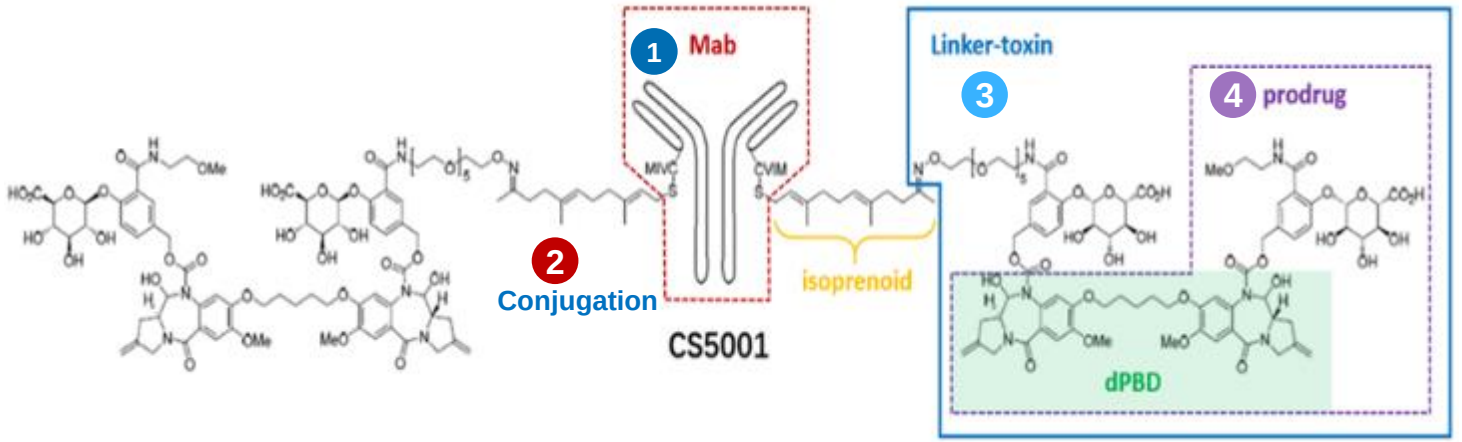
4. Expected Catalysts

CS5001 (ROR1 ADC) is a potential FIC/BIC ROR1 ADC globally with Ph1 study ongoing in US, Australia and China

An ADC target for both hematological malignancies and solid tumors

- Largely absent in normal blood lymphocytes and adult tissues [1~3]
- Embryotic protein over-expressed by various hematological malignancies, particularly B-cell lymphomas [4, 5]
- Widely expressed in solid tumors such as TNBC, ovarian cancer, and adeno-NSCLC [2,6~13]
- First-in-class molecule acquired by Merck for US$2.75Bn in Nov 2020 at Ph1

4 key differentiators support best-in-class potential:



Potentially less immunogenicity

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

Controlled quality and production

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

Potentially wider therapeutic window

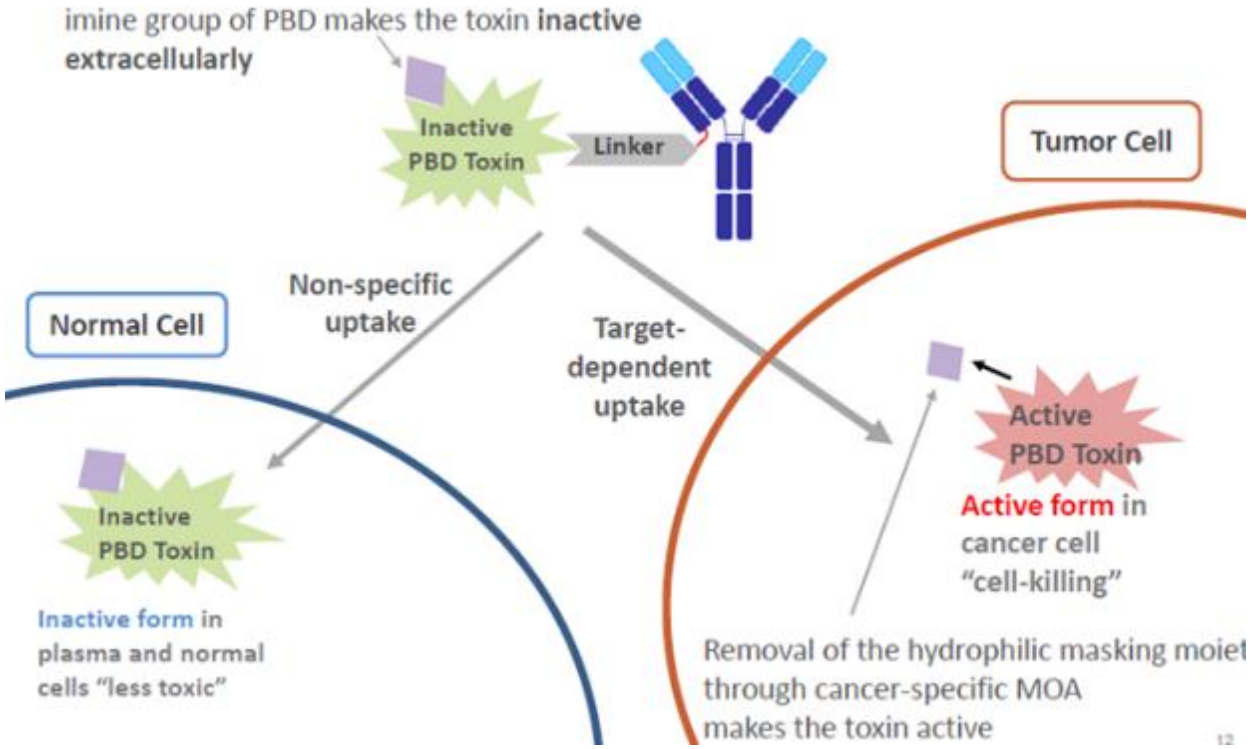
3 Proprietary **tumor-selective cleavable linker** (cleaved by β-glucuronidase), shows exceptional stability in serum

4 Proprietary **tumor-activated PBD dimer toxin prodrug** (released by β-glucuronidase)

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

Novel prodrug technology minimize 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

Inactive

Tumor selective activation

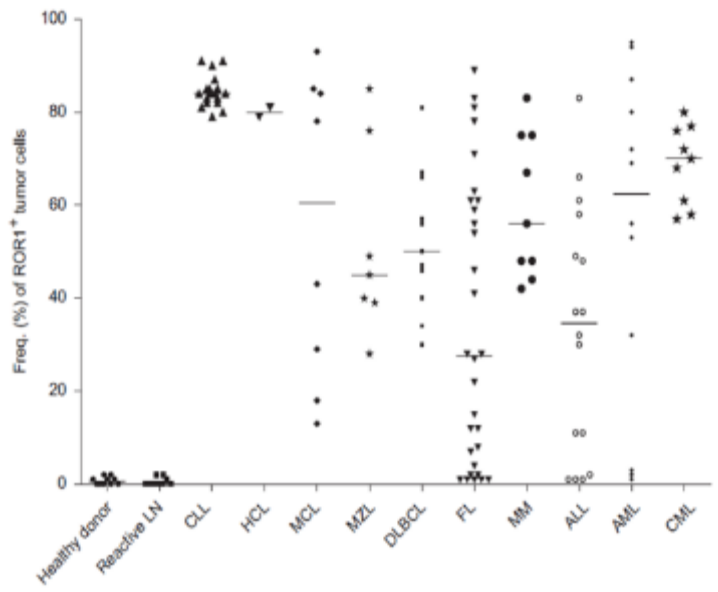
ADCs tested	IC_{50} (nM) Tumor cell line 144h
Naked PBD-ADC	0.23
PBD prodrug-ADC	0.19

Active

ROR1 is a promising target for the treatment of multiple tumor types

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

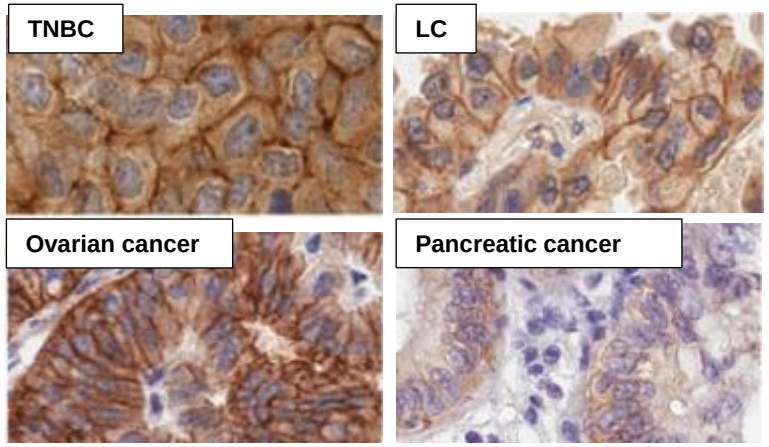
ROR1 expression in different hematological malignancies



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

ROR1 expression in different solid tumor types

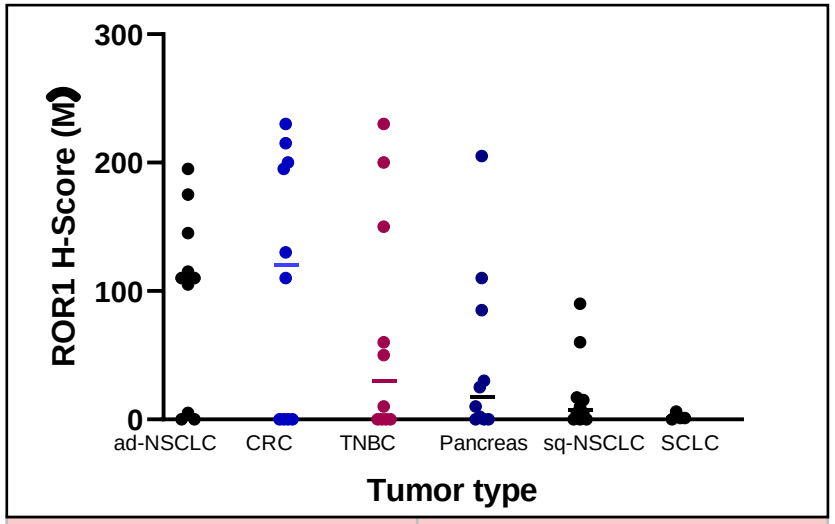
Tumor type	Positive rate
TNBC	56% (n=56)
Lung cancer	42% (n=137)
Ovarian cancer	50% (n=159)
Pancreatic cancer	15% (n=38)



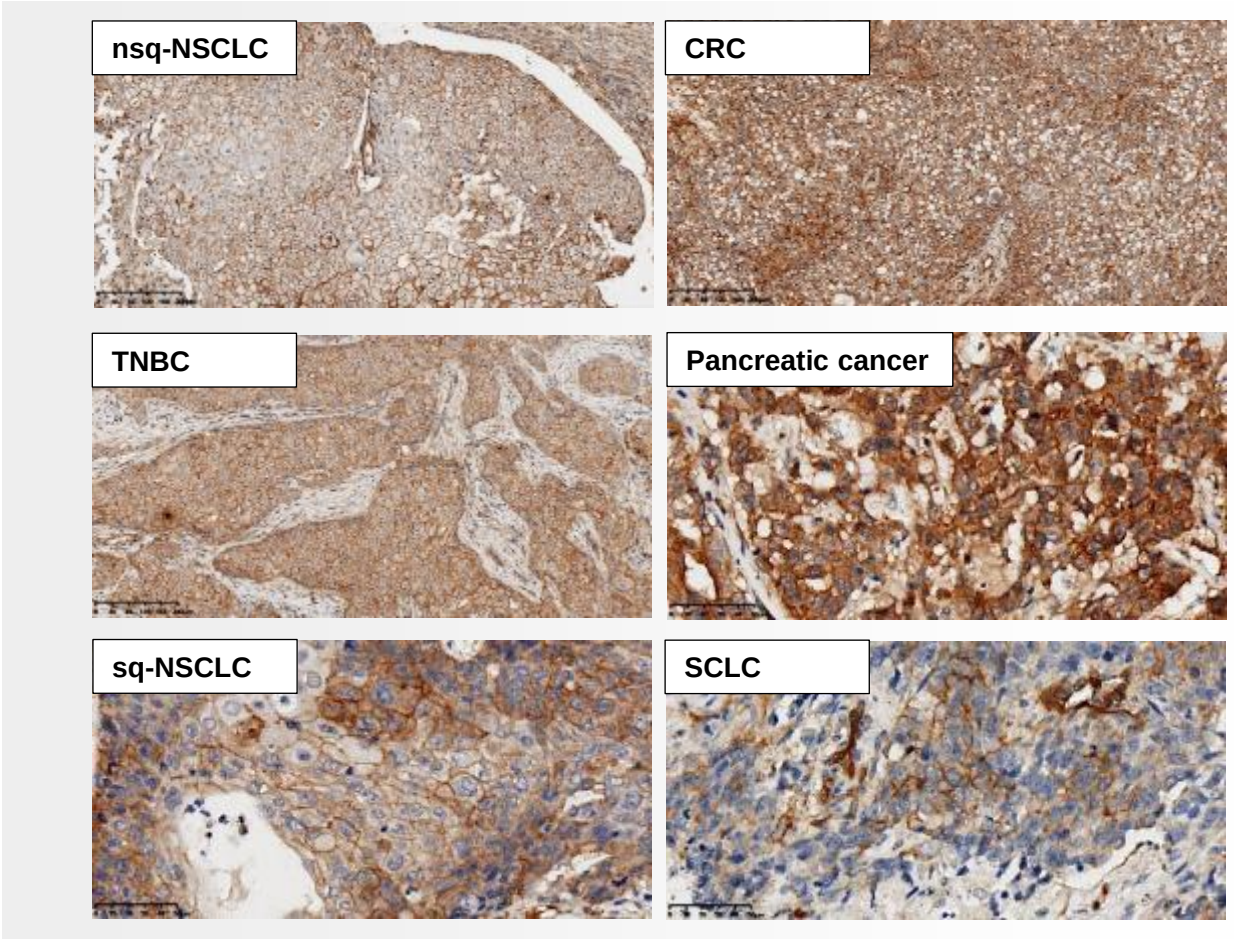
ROR1 expression is homogeneous,
defined as definite membranous staining of over 50% of tumor cells

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

ROR1 expression in solid tumor has been validated by CStone proprietary mAb



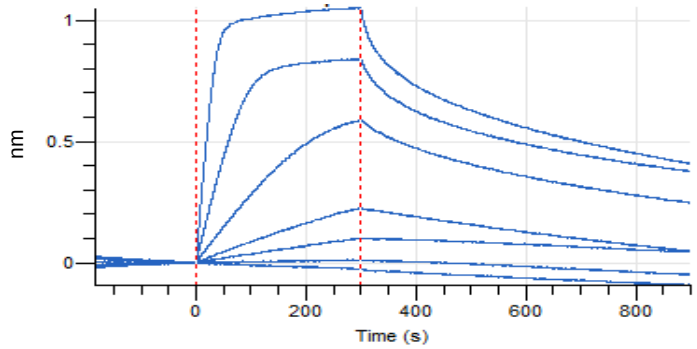
Tumor type	H-Score≥50
Nsq-NSCLC	70%
CRC	60%
TNBC	50%
Pancreatic cancer	30%
Sq-NSCLC	20%
SCLC	0



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

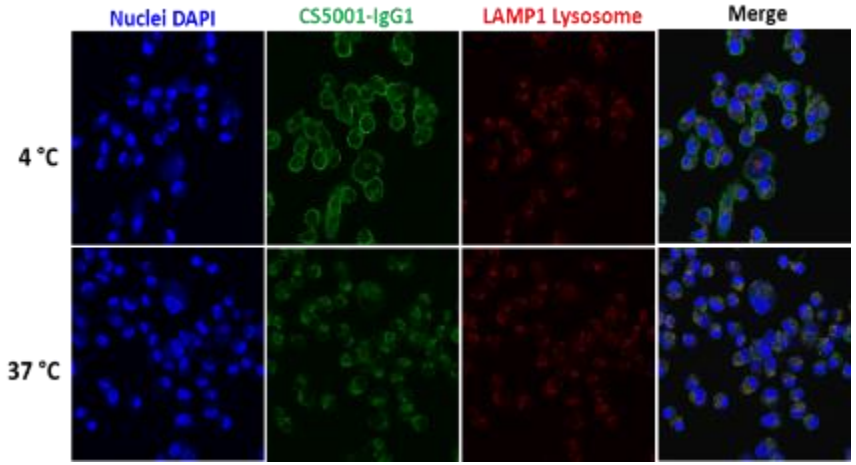
CS5001 selectively bound to human ROR1 with high affinity and triggered rapid and high internalization

CS5001 showed high affinity to human ROR1

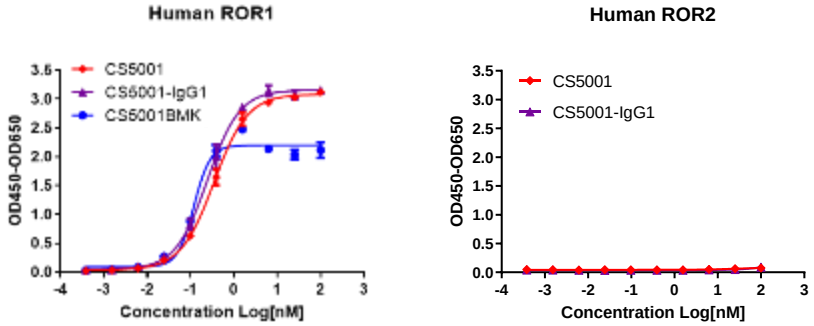


Sample	ka (1/Ms)	kd (1/s)	KD (M)
CS5001	1.59E+06	2.19E-03	1.38E-09

Internalization and intracellular trafficking of CS5001-IgG1

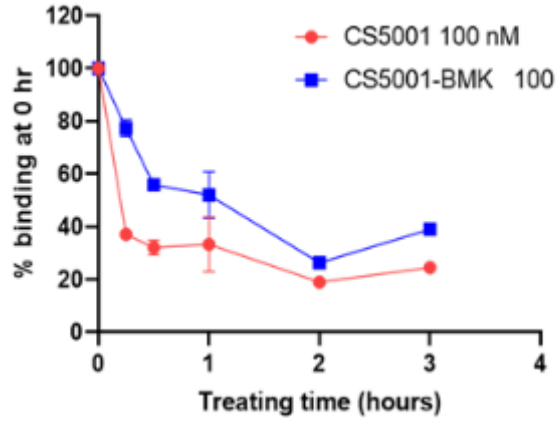


CS5001 was highly selectively binding to human ROR1



	Human ROR1	Human ROR2
CS5001 (EC_{50}, nM)	0.347	No binding
CS5001-IgG1 (EC_{50}, nM)	0.245	No binding
CS5001BMK (EC_{50}, nM)	0.119	-

Rapid internalization of CS5001(37° C)



MDA-MB-231 cells were treated with ROR1 mAb or ADC at 4° C or 37° C and were examined using confocal microscope or flowcytometry

Note: CS5001-IgG1: mAb of CS5001. CS5001BMK: benchmark, an MMAE-based ROR1 ADC (same sequence, linker & toxin as VLS-101)

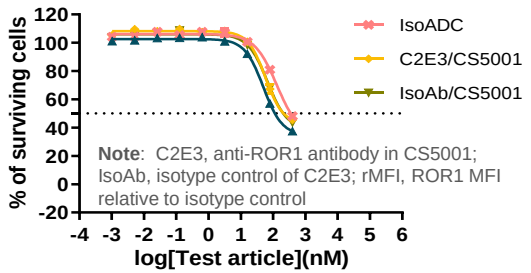
CS5001 demonstrated highly potent ROR1-dependent cytotoxicity in solid tumor and hematological malignancy cell lines

CS5001 killed tumor cells with potency and ROR1- dependency

ROR1 negative

MCF7

rMFI 0.93

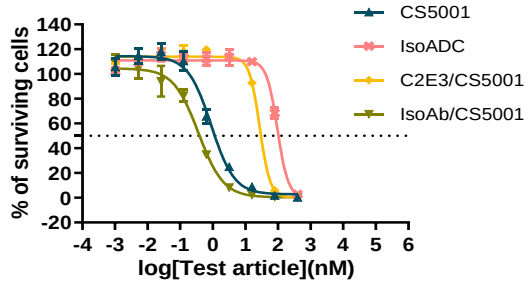


	CS5001	IsoADC	C2E3/CS5001	IsoAb/CS5001
IC_{50} (nM)	113.41	354.32	212.56	206.14
IC_{50} fold change	Ref.	3	1.9	1.8

ROR1 expressing

JeKo-1

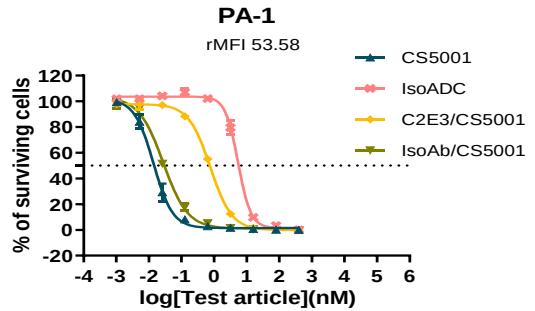
rMFI 15.48



	CS5001	IsoADC	C2E3/CS5001	IsoAb/CS5001
IC_{50} (nM)	1.15	103.36	30.04	0.39
IC_{50} fold change	Ref.	90	26	0.4

PA-1

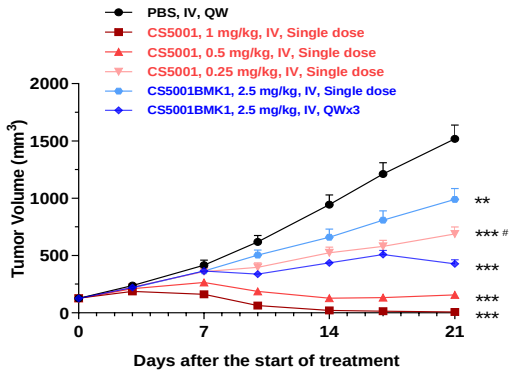
rMFI 53.58



	CS5001	IsoADC	C2E3/CS5001	IsoAb/CS5001
IC_{50} (nM)	0.02	5.68	0.74	0.03
IC_{50} fold change	Ref.	284	37	1.5

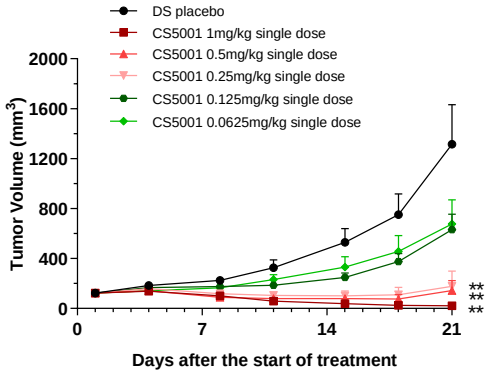
CS5001 remarkably killed tumor cells in CDX models

Jeko1 (Mantle cell lymphoma)



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

PA-1 (Ovarian cancer)



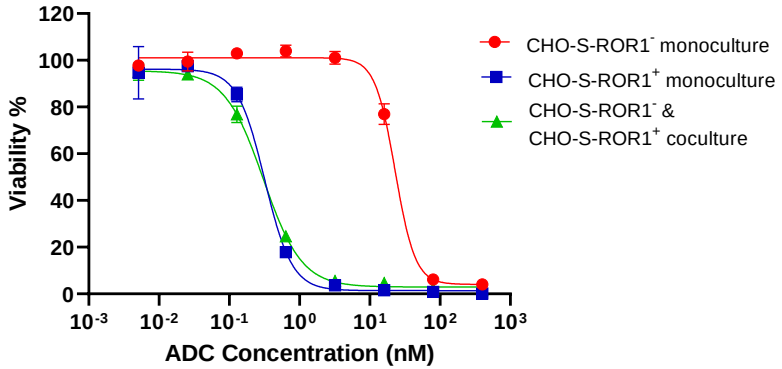
Treatment	TGI %	CR
CS5001, 1 mg/kg, Single dose	108	2/8
CS5001, 0.5 mg/kg, Single dose	98	1/8
CS5001, 0.25 mg/kg, Single dose	95	0/8
CS5001, 0.125 mg/kg, Single dose	57	0/8
CS5001, 0.0625 mg/kg, Single dose	53	0/8

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

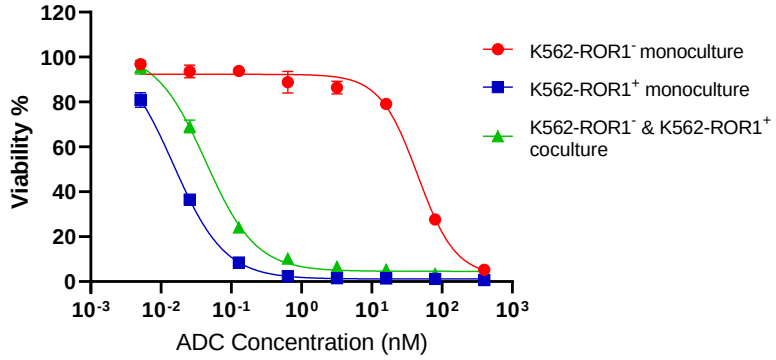
CS5001 demonstrated robust bystander killing effect in co-culturing assays with ROR1+/- cells

ROR1- tumor cells co-cultured with the same cells but transfected with ROR1

CHO-S & CHO-S-ROR1 coculture

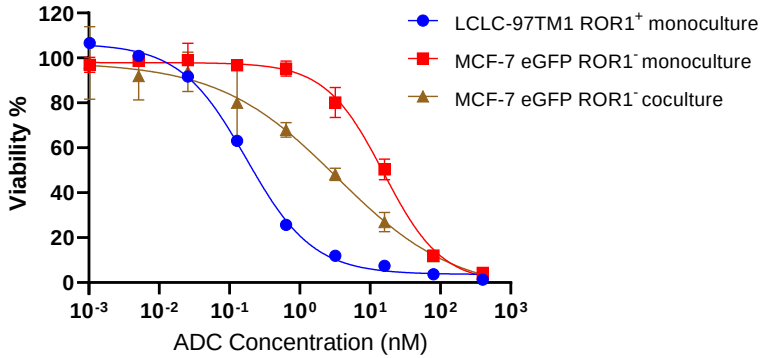


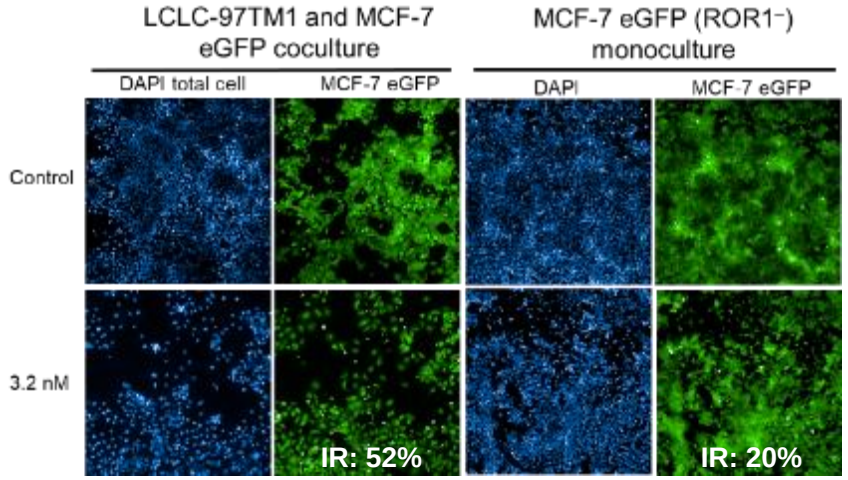
K562 & K562-ROR1 coculture



ROR1- tumor cells co-cultured with tumor cells endogenously expressing ROR1

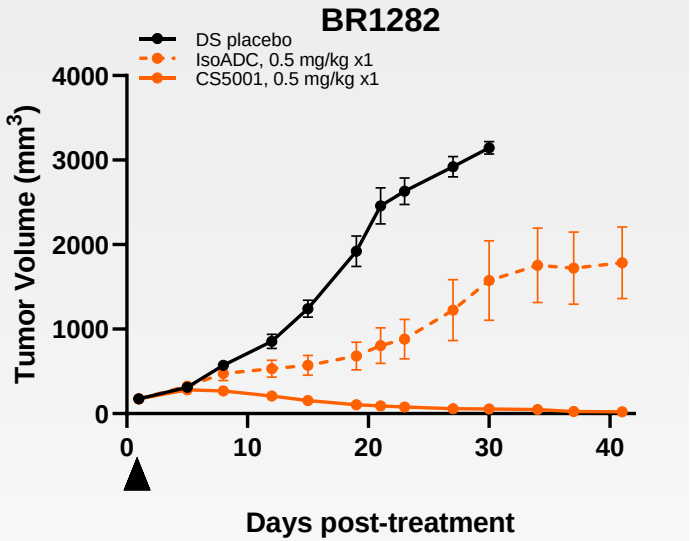
LCLC-97TM1 & MCF-eGFP coculture



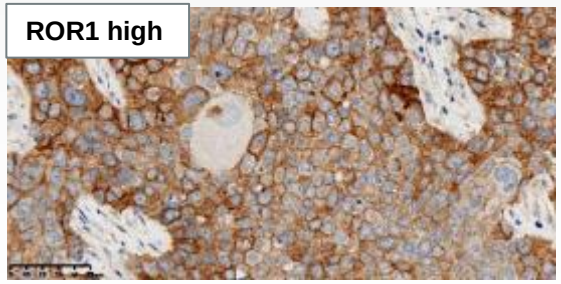


IR: inhibition rate

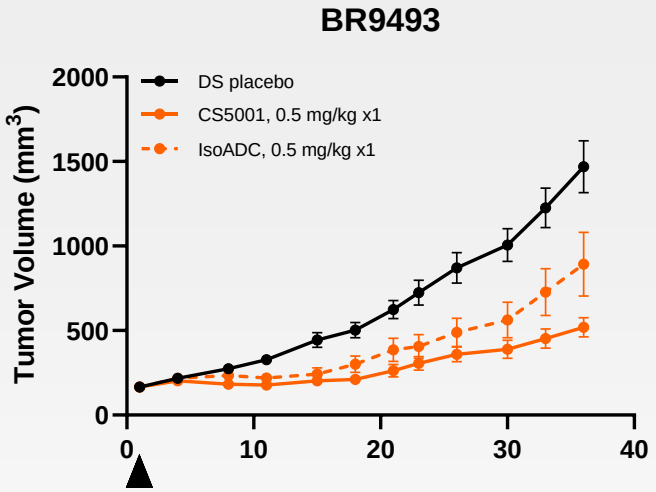
ROR1-dependent anti-tumor activity was demonstrated in solid tumor PDX models



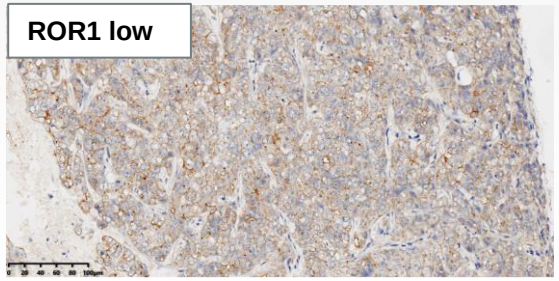
ROR1 high



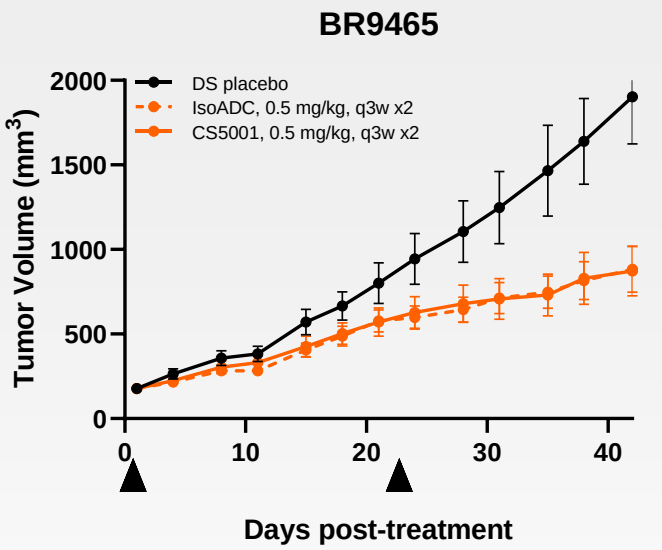
Group	TGI(D30)
IsoADC	53%
CS5001	104%



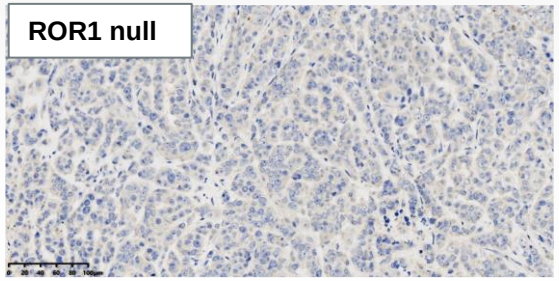
ROR1 low



Group	TGI (D30)
IsoADC	53%
CS5001	73%



ROR1 null



Group	TGI (D30)
IsoADC	50%
CS5001	50%

Phase 1 Study Design: CS5001-101

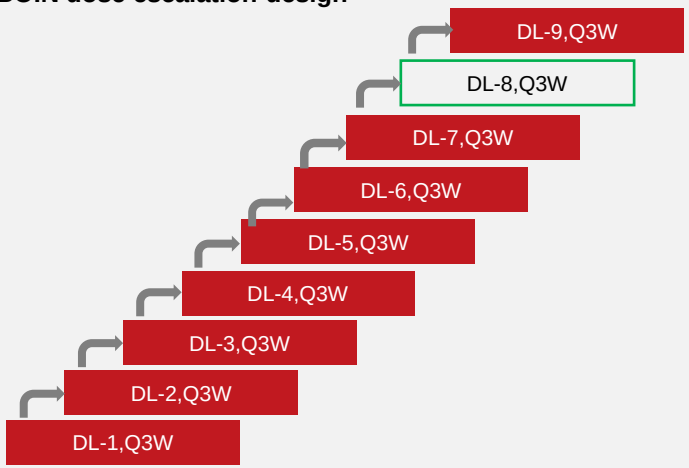
A Phase 1, Dose-Escalation and Dose-Expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Antitumor Activities of CS5001, an Anti-ROR1 Antibody Drug Conjugate, in Patients with Advanced Solid Tumors and Lymphomas

Phase 1a Dose Escalation (BOIN Design) + Backfill

Key eligibility criteria

- Age 18 years or older
- Solid tumor: pathologically confirmed, unresectable advanced solid tumor (>=2L)
- Lymphoma: pathologically confirmed B-cell lymphoma (>=3L)
- r/r CHL must have received brentuximab vedotin and checkpoint inhibitor.
- r/r CLL/SLL must have received BTKi
- >=1 evaluable lesion
- Adequate organ function
- Available tumor samples for biomarker analysis

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



Tentative RP2D

Phase 1b Dose Expansion/pivotal Extension

A. **B cell lymphma 1 (>=3L); N = up to 80**

B. **B cell lymphoma 2 (>=3L); N = up to 124**

C. **Solid tumor 1 (>=2L); N = up to 82**

D. **ROR1-positive solid tumors (including TNBC, endometrial cancer, ovarian cancer, NSCLC, gastric cancer and pancreatic cancer) (≥ 3L); N = up to 30**

Primary objective:
- Characterize CS5001 safety and tolerability, and determine MTD/tentative RP2D

Secondary objective:
- PK profile of CS5001 (ADC), total antibody, prodrug and the free cytotoxin SG2057
- Preliminary anti-tumor activity of CS5001

Exploratory objective:
- The predictive value of ROR1 expression on treatment response to CS5001

Primary objective:
- To evaluate the efficacy of CS5001 in patients with selected advanced malignancies

Secondary objective:
- To further evaluate the efficacy of CS5001 in patients with selected advanced malignancies
- To further assess the safety and tolerability of CS5001 in patients with selected advanced malignancies
- To further characterize the PK profile of CS5001 (ADC), total antibody, prodrug and the free cytotoxin SG2057

Exploratory objective:
- The predictive value of ROR1 expression on treatment response to CS5001

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

CS5001 is a well tolerated and stable ADC and has demonstrated preliminary anti-tumor activities

A Escalated to Dose Level 8 (DL8) with no DLT events

- DLT evaluation completed at prior 7 dose levels, DL8 currently under evaluation
- DLT not observed, suggesting the drug being safe and well-tolerated
- Adverse events observed to date mostly Grade 1 or 2

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

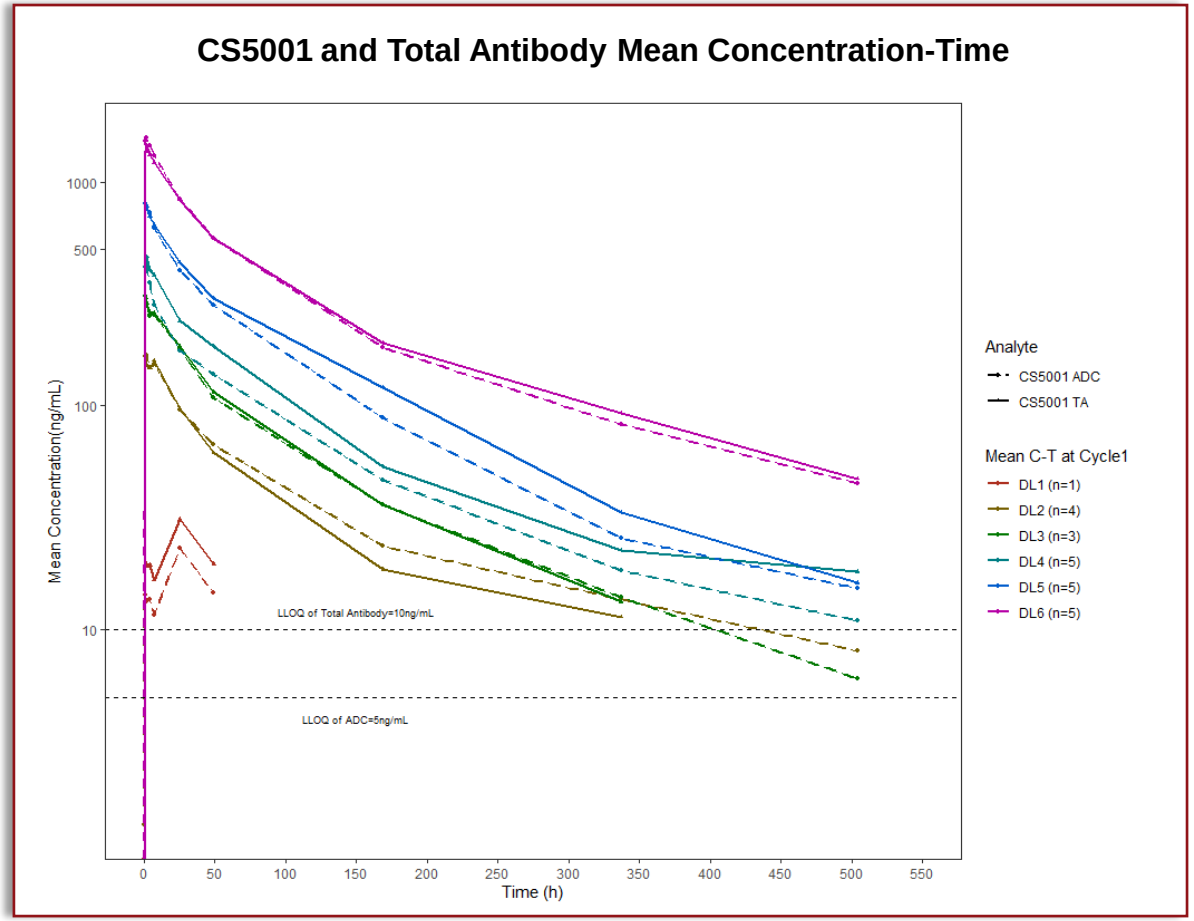
- Two PRs out of the five Hodgkin Lymphoma patients from DL3, DL5 and DL6
- One PR out of the two pancreatic adenocarcinoma patients from DL2 and DL7
- Efficacy at higher dose levels being evaluated

C Clinical pharmacokinetics profile as expected

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

Human pharmacokinetics profile as expected

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



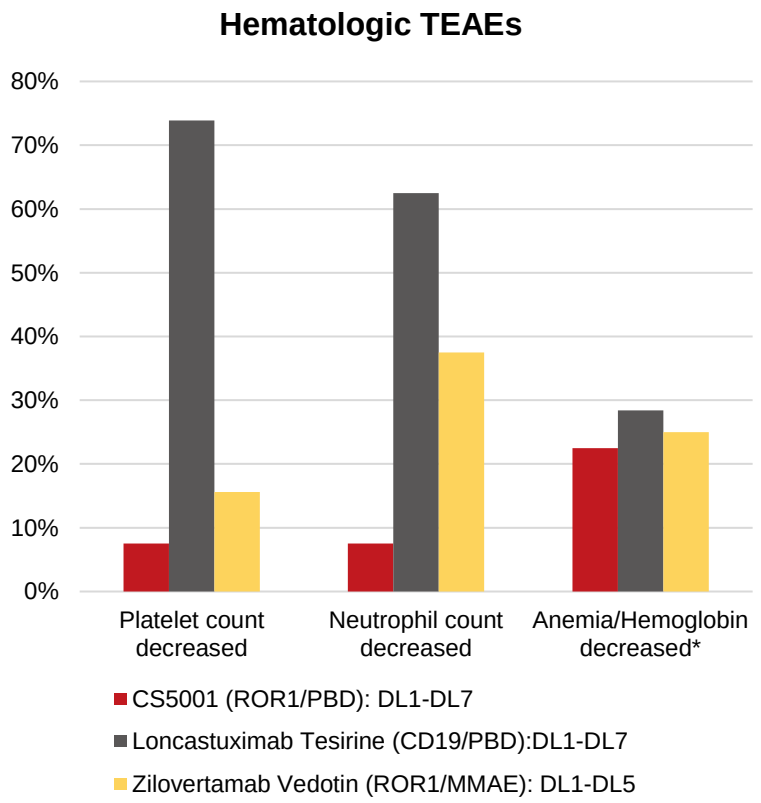
Background information of three relevant ADCs for safety comparisons

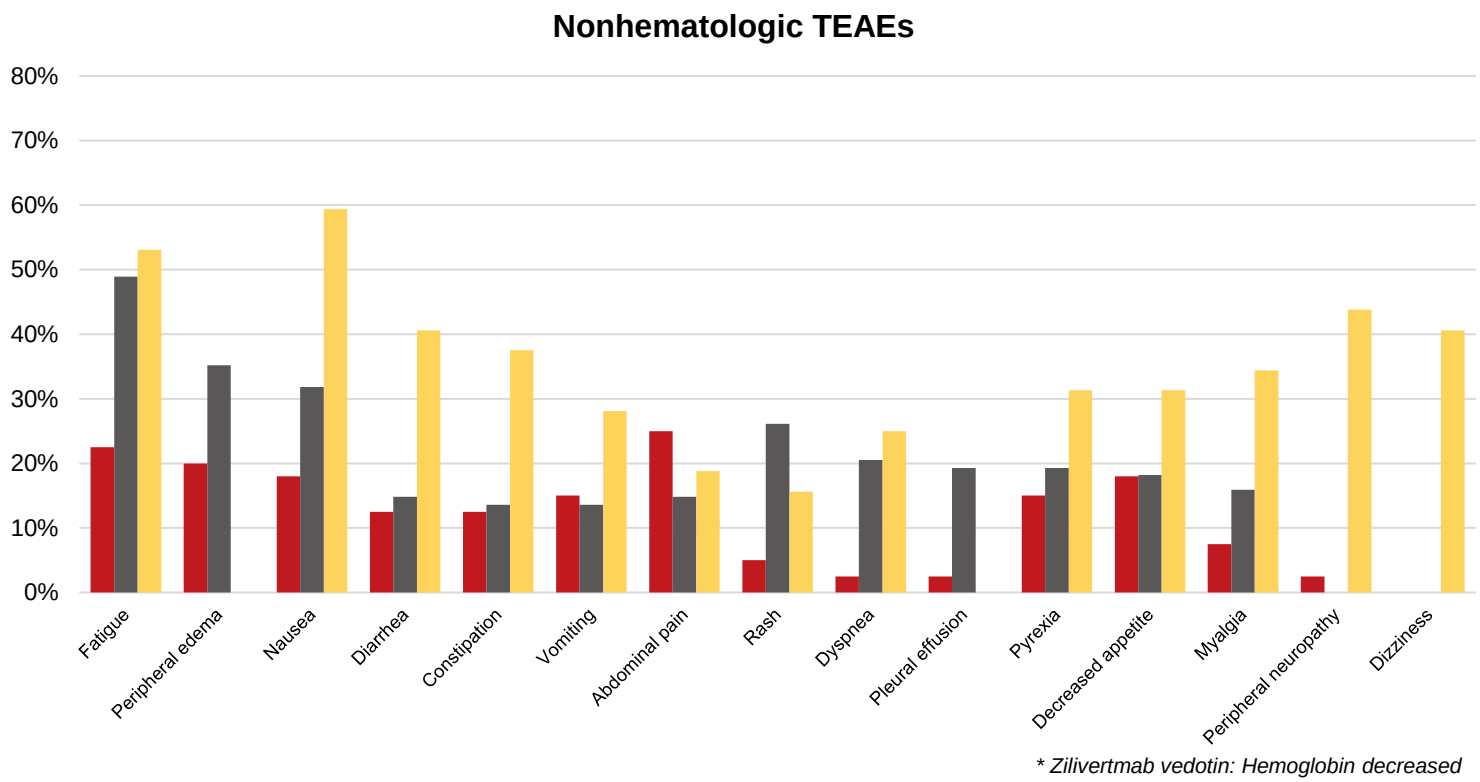
		CS5001 (ROR1/PBD prodrug)	Zilovertamab Vedotin (ROR1/MMAE)	Loncastuximab Tesirine (CD19/naked PBD)
Molecule property	Antibody	Fully human ROR1 mAb	Humanized ROR1 mAb	Humanized CD19 mAb
	Linker	Isoprenoid-β-glucuronide	Mc-vc-PAB	cathepsin-cleavable valine-alanine
	Payload	Prodrug of PBD dimer	MMAE	Naked PBD dimer
	Cleavage mechanism of linker	Cleavable by β-glucuronidase (tumor selective)	Cleavable by proteases	Cleavable by proteases
	Conjugation	Site specific and homogeneous	Randomized	Randomized
	DAR	2	Avg. 4 (0-8)	2.3 (0-6)
Clinical	**Indications**	Both heme & solid tumor (Ph I)	Heme (Ph I) ; Solid tumor (Ph II); DLBCL (Ph II and Ph II/III combo)	Heme DLBCL (Launched)
	Regions	Ongoing trial in US, AUS, CN	Ongoing trial in US, CN	Marketed in US, EU
	PK $T_{1/2}$	~5 days	3.8 days	7.2-12.5 days

Note: mc-vc-PAB linker: maleimidocaproyl-valine-citrulline-para-aminobenzoate; Gly5-EDA (Glycine)5-ethylene diamine

Favorable phase 1 safety profile of CS5001 vs. two other relevant ADCs

Lower frequency of hematologic and nonhematologic AEs observed for CS5001 up to Dose Level 7





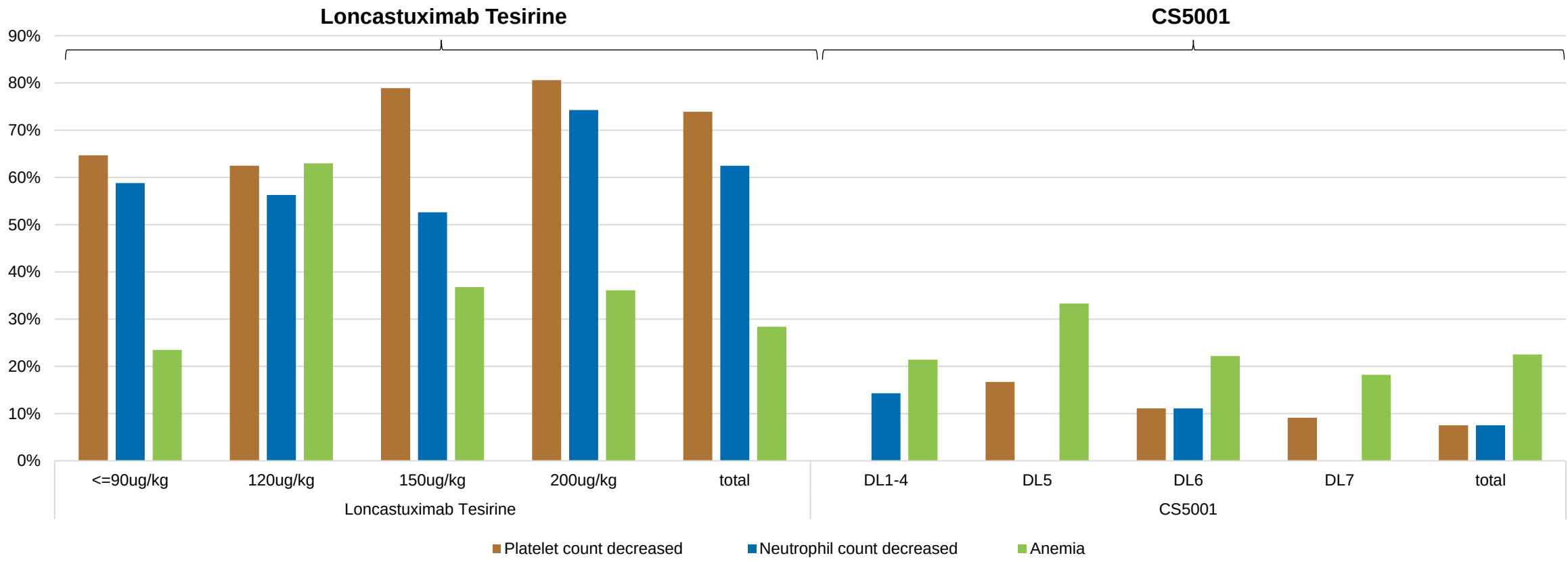
** Zilivertmab vedotin: Hemoglobin decreased*

TEAE>=25%

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.

Comparing to other PBD-based ADC, CS5001 exhibited lower hematologic toxicity across different dose levels

Hematologic TEAEs by Dose Levels-Loncastuximab Tesirine vs. CS5001

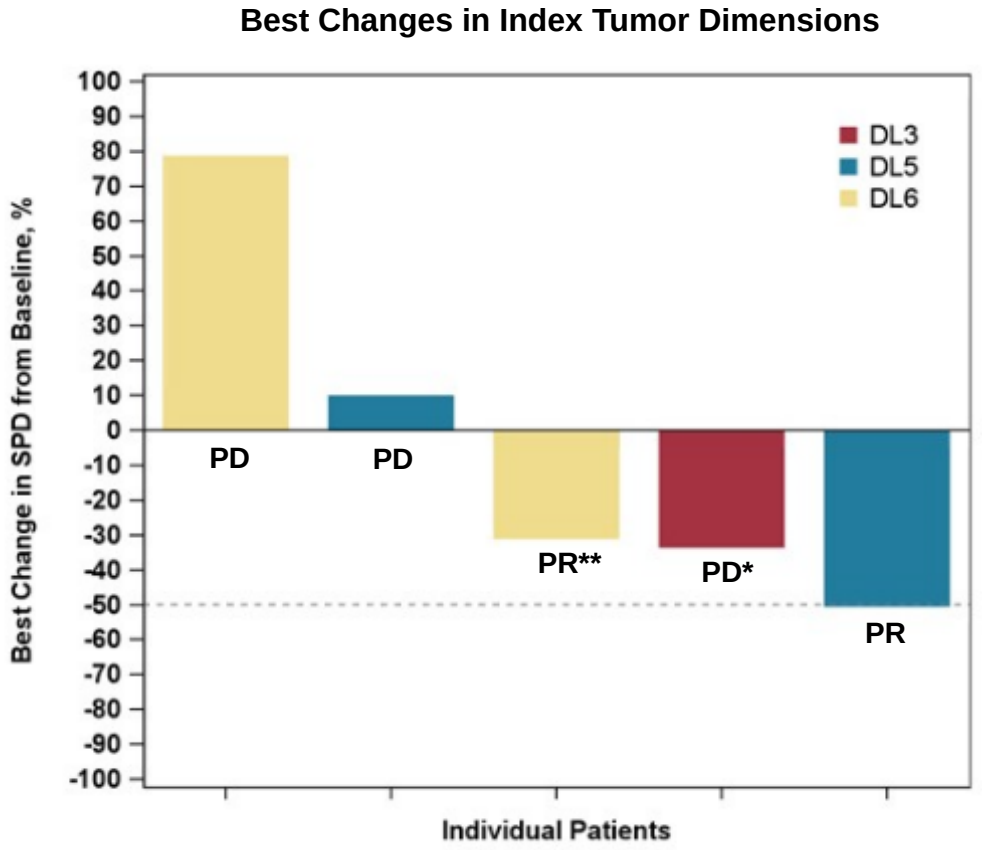


Wang ML, et al.NEJM Evidence. DOI: 10.1056/EVIDoa2100001; Brad S Kahl 1, Clin Cancer Res. doi: 10.1158/1078-0432.CCR-19-0711.

Preliminary efficacy observed in Hodgkin Lymphoma during dose escalation

Two partial responses and one mixed response observed in Hodgkin Lymphoma patients

- **Five Hodgkin Lymphoma patients from DL3, DL5 and DL6 had at least one post-baseline tumor assessment**
  - ➢ Male/female: 3/2
  - ➢ Median age: 36 (33-54) years
  - ➢ Four (80%) patients received ≥3 prior lines of anti-tumor treatment
- **Two PRs per Lugano 2014 and one mixed response* observed among the five Hodgkin Lymphoma patients**

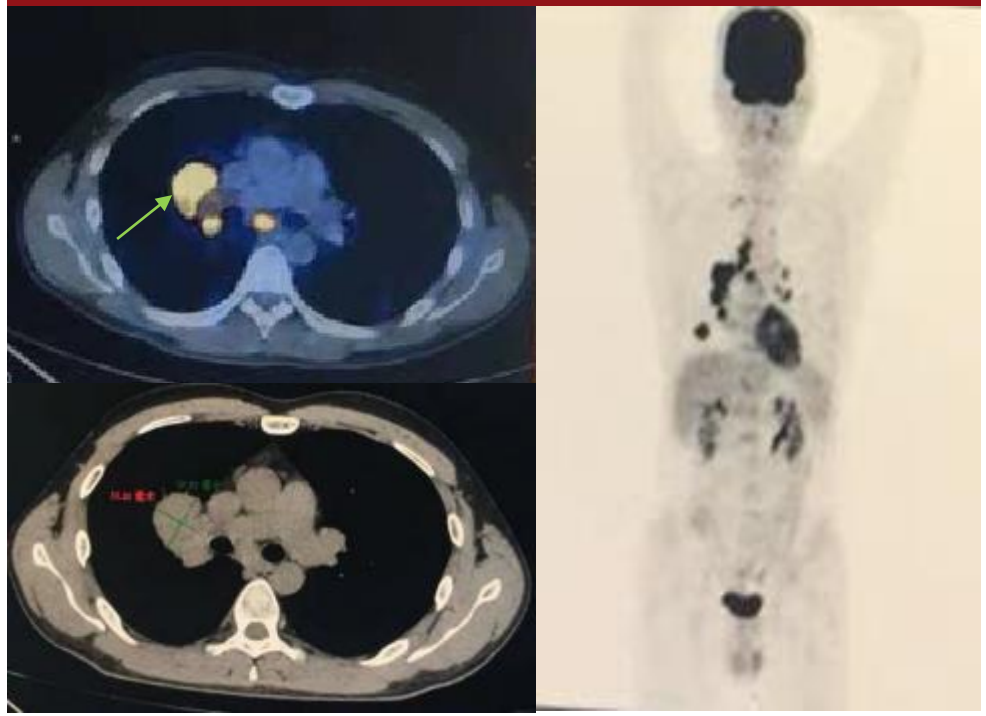


** Mixed response(coexistence of responding and non-responding lesions) was observed for this patient in the first tumor assessment. The patient continued to received CS5001 after disease progression as a potential clinical benefit was derived. This patient had two intra-subject dose escalation with DL6 as the highest dose.*
*** The reduction of SPD based CT didn't reach 50%, however, PET based response was PMR for this patient, resulting in the overall response of PR*

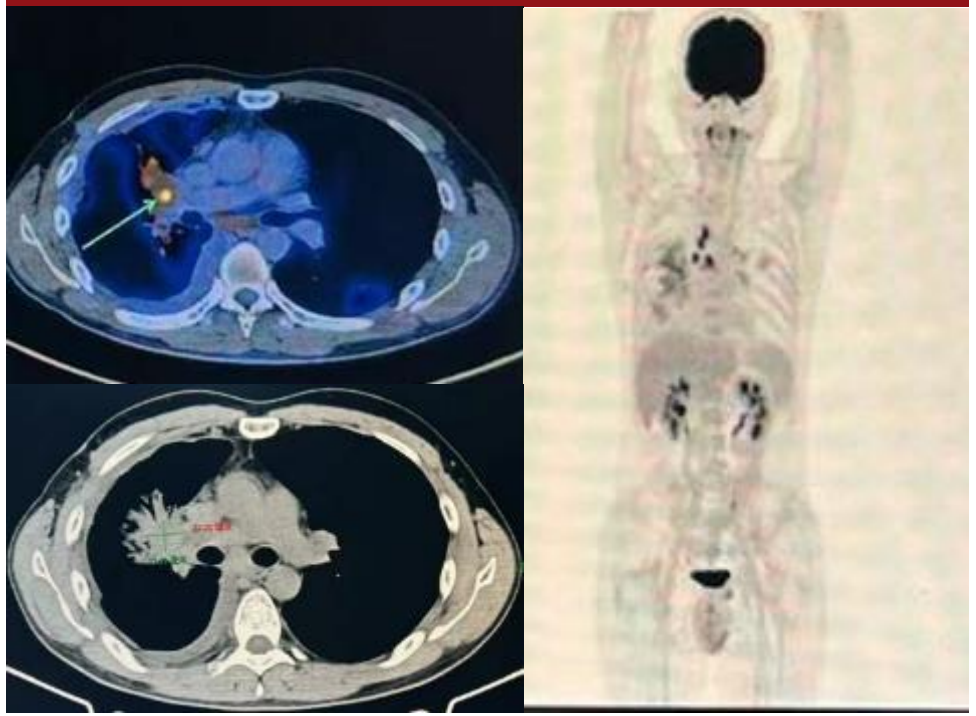
Patient 0104003: 33-year-old (y/o) male, Stage IV Hodgkin Lymphoma

- ✓ The patient's disease relapsed following two prior lines of chemotherapies, which included ABVD and RCHOP.
- ✓ After receiving 4 cycles of CS5001 treatment, a **partial response** was observed per Lugano 2014.

Baseline



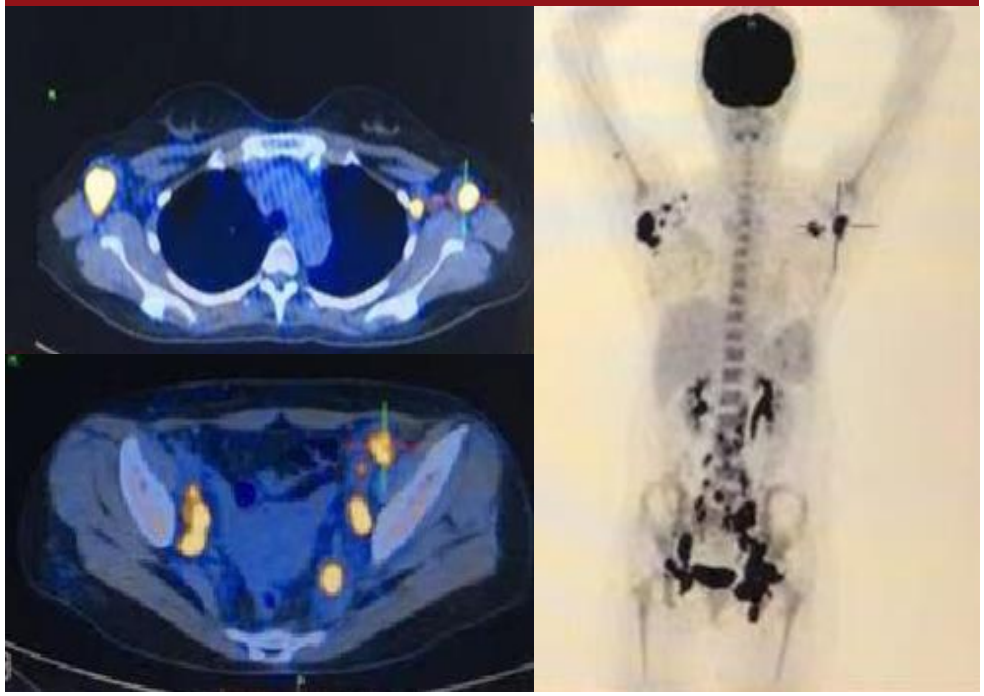
After 4 cycles treatment of CS5001



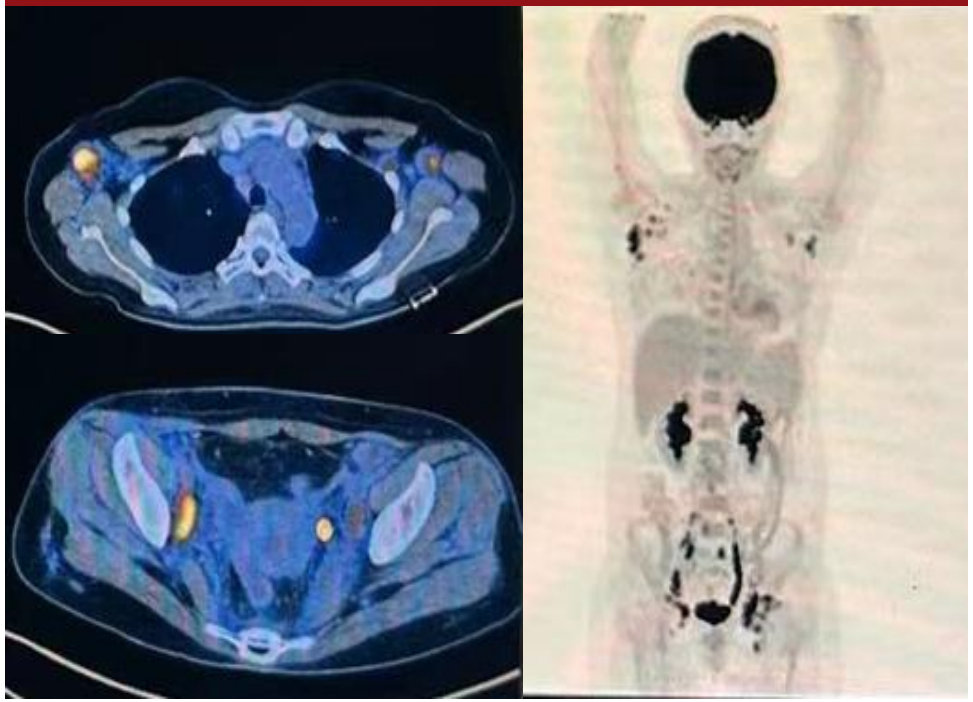
Patient 0104002: 34 y/o female, Stage IV Hodgkin Lymphoma

- ✓ The patient had a refractory disease following five prior lines of therapies, which included ABVD, GVD, Sintilimab+Decitabine, ICE+Sintilimab, and IBI-322.
- ✓ Following 4 cycles of CS5001 treatment, a **partial response** was observed per Lugano 2014

Baseline



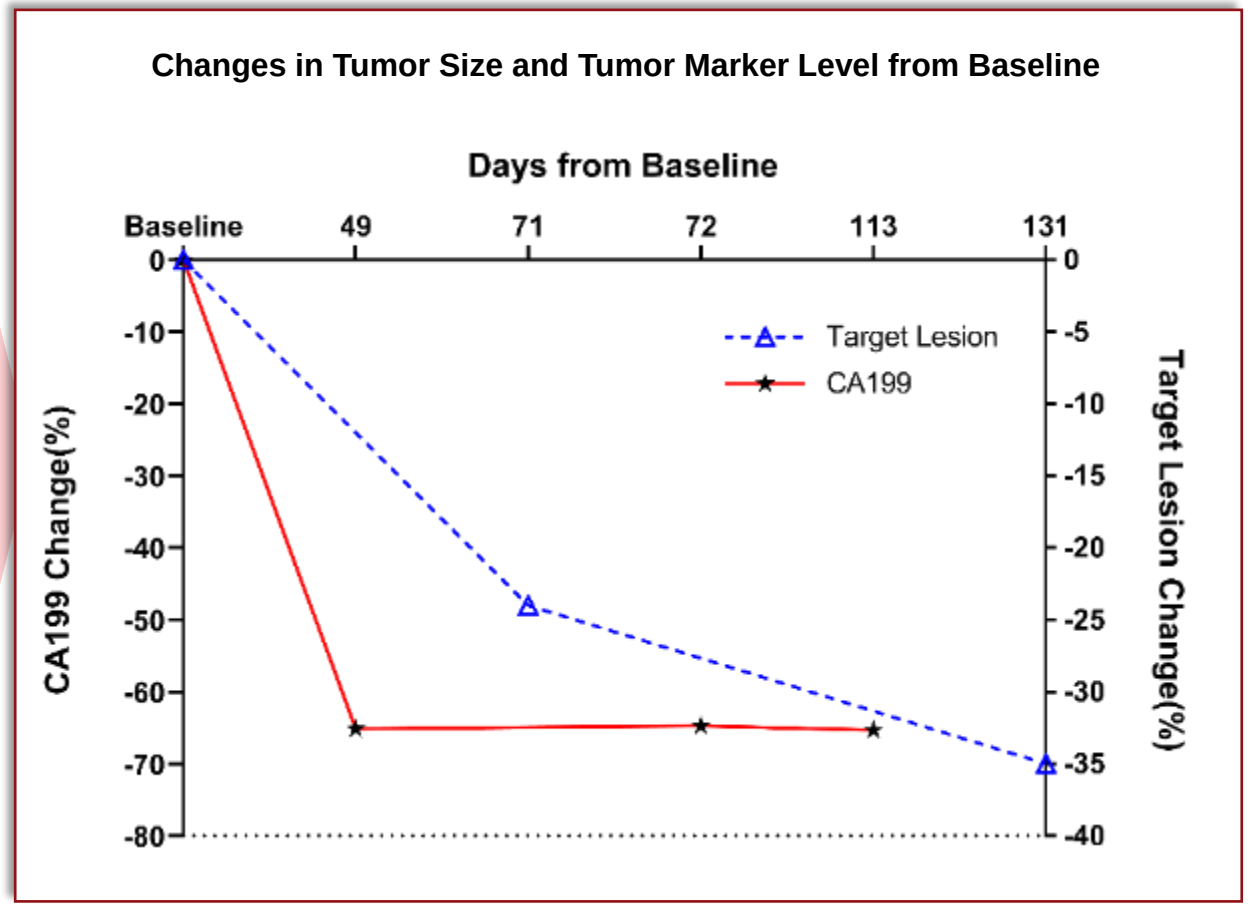
After 4 cycles treatment of CS5001



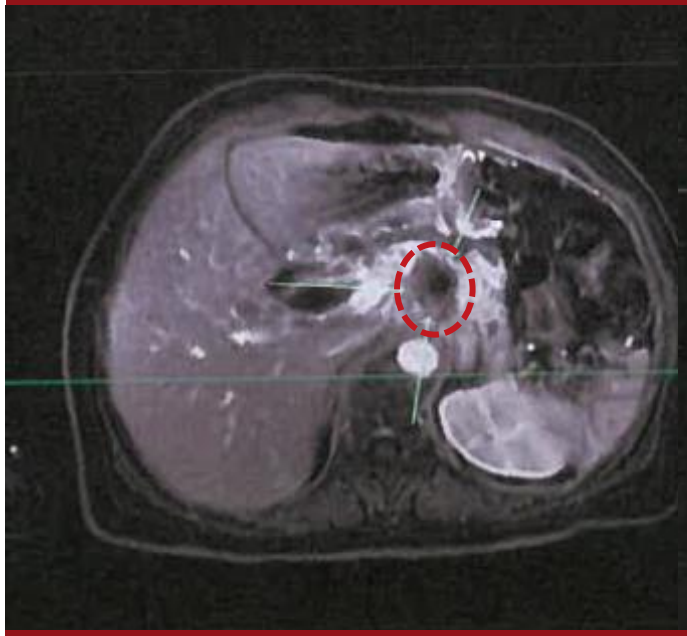
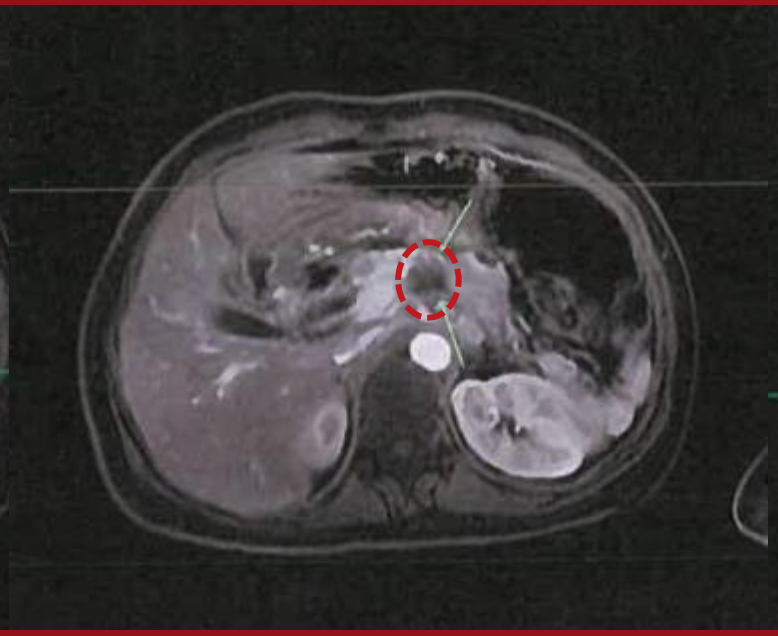
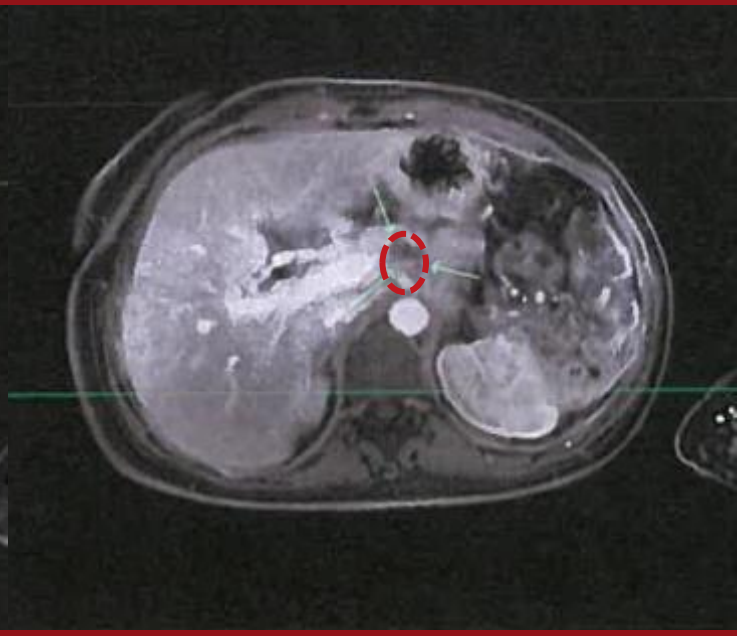
Preliminary efficacy observed in Pancreatic Adenocarcinoma during dose escalation

One partial response observed in pancreatic adenocarcinoma

- 52 y/o Jordanian female with advanced pancreas adenocarcinoma treated at Scientia Clinical Research, Australia
- **Prior Therapies:** Two NTRK inhibitors with the best response being stable disease
- **Tumor Biomarker**: At Week 6, tumor biomarker CA199 decreased by 65%, and maintained at a low level thereafter.
- **Treatment Response:** At Week 18, a partial response was observed per RECIST v1.1



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

Screening	After 9 weeks of CS5001 treatment	After 18 weeks of CS5001 treatment
		
37 mm	28 mm (SD -24%)	24 mm (PR -35%)

- ✓ 52 y/o female with advanced pancreatic adenocarcinoma
- ✓ Baseline MRI: target lesion pancreatic surgical bed soft tissue mass with a longest diameter of 37 mm
- ✓ After 9 weeks of CS5001 treatment, the longest diameter of target lesion reduced to 28 mm (24% reduction), the overall response is SD
- ✓ After 18 weeks of CS5001 treatment, the longest diameter of target lesion reduced to 24 mm (35% reduction), the overall response is PR

Summary

1. **CS5001, a novel ROR1–directed PBD-ADC, appears well tolerated and safe in the first-in-human phase 1 study**
   - *No DLT was observed and MTD was not reached*
   - *Lower toxicities were observed comparing to other relevant ADCs*
2. **CS5001 demonstrated preliminary antitumor activities in both solid tumor and lymphoma**
3. **PK data suggested a dose-proportional exposure and excellent stability of the linker**
4. **Enrolment in the dose escalation portion is ongoing, with continued evaluation of tolerability and efficacy in both solid tumors and lymphomas**

Agenda

1. ROR1 ADC Updates
2. **PD-L1 ex-China Progress**
3. Commercialization Strategy
4. Expected Catalysts

Sugemalimab – Ex-China Progress

EU/UK MAA regulatory review proceeding as expected; positive feedback from FDA type B consultation

2023 Aug 8

Transition from EQRx completed

As of today

EU/UK MAA review ongoing according to schedule

EMA MAA:

- **D120 LoQ received in Jun. with all the questions addressed and response submitted in Oct.**
- **D180 LoOI received from EMA on Dec 14, confirmed that previous questions were well addressed in first round response, no red flags**
- **Official GCP inspection notification received from EMA in July**
  - One study center inspection completed in Nov 23 with no critical findings
  - Another study center and CRO inspection expected in late Jan/early Feb 24

MHRA MAA:

- **Final D80 RFI received from UK MHRA in Oct without un-addressable questions**
- **Response to D80 RFI submitted in Nov**

EU and UK regulatory decision expected in 2024 Q2/Q3

R/R ENKTL FDA type B consultation with positive feedback

FDA agreed with CStone in Dec 2023 on enabling ENKTL BLA filing based on the data from GEMSTONE-201 study and a mini bridging study

Re-partnering process on-going

Agenda

1. ROR1 ADC Updates
2. PD-L1 ex-China Progress
3. **Commercialization Strategy**
4. Expected Catalysts

Commercialization Strategy

Leverage the strength of partners in commercialization to maximize the value of commercial / late-stage pipeline

Nov. 1st, 2023

Partner with: 三生制药 3SBIO INC.

Strategic partnership and exclusive licensing

Nofazinlimab

Anti-PD-1 antibody

- *RMB60 million upfront*
- *Regulatory and sales-based milestones and tiered sales royalties*
- *CStone retains the rights to nofazinlimab outside mainland China and is actively looking for partners*

Nov. 8th, 2023

Partner with: 艾力斯

Exclusive commercial promotion right

Pralsetinib

RET inhibitor

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

Benefits for CStone

1. **The right partner with commercial synergy and efficiency**
2. **Improved profit margin with commercial cost savings from 2024**
3. **Replenish cash position to fuel further R&D**

Internally-developed multiple pipeline assets for future growth

Tri-specific antibody

CS2009

(PD-1 x VEGF x another IO target)

Expect IND in 2024

- ✓ **Potential FIC next-generation IO backbone to replace current PD-(L)1 based SOC**
- ✓ Target **3 critical immune-suppressive pathways** in the tumor microenvironment
- ✓ May **deepen response** of a PD(L)1-based therapy in large tumor types including NSCLC and HCC

ADCs

CS5005

Expect IND in 2024/25

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

CS5006

Expect IND in 2024/25

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

Other programs

Under exploration

Bi/tri-specific antibodies and bi-specific ADCs

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

Agenda

1. ROR1 ADC Updates
2. PD-L1 ex-China Progress
3. Commercialization Strategy
4. **Expected Catalysts**

Expected Catalysts for the Next 12 Months

Assets		Catalysts	Date
Sugemalimab (PD-L1)	Marketed	Regulatory decision for 1L stage IV NSCLC in EU and ex-China partnership exploration	1H 2024
		Regulatory decision for 1L stage IV NSCLC in UK	2H 2024
		NDA approval for 1L GC/GEJ in mainland China	Q1 2024
Lorlatinib (ROS1)	In pivotal trial	Topline readout and supplemental NDA filing for ROS1-positive NSCLC in mainland China	2024
Nofazinlimab (PD-1)	In pivotal trial	Topline readout in 1L HCC (in combination with lenvatinib) and ex-China partnership exploration	Q1 2024
CS5001(ROR1 ADC)	In Ph1 trial	Update on clinical safety and efficacy	By the end of 2023
		Conference presentation on Ph1 data and partnership exploration	1H 2024
		Initiation of Ph1b/2 trial with registration potential	2024

Other potential catalysts

Ex-China partnerships for other assets with global rights

IND of pre-clinical assets with BIC / FIC potential

Key value driver

Abbr.: 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

Thanks

Q&A

END