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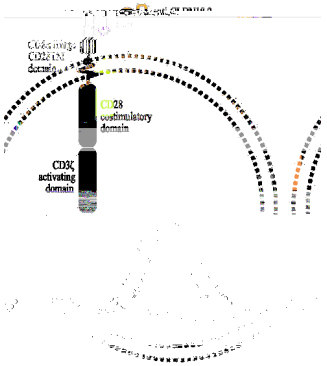
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CT041 : A Humanized Claudin18.2-redirected CAR-T

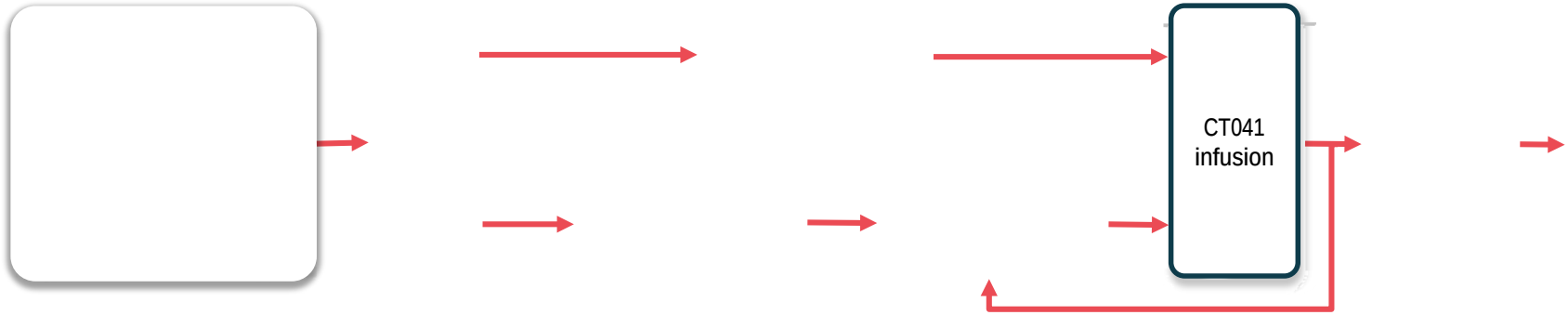
Claudin18.2 (CLDN18.2) a pan-cancer target

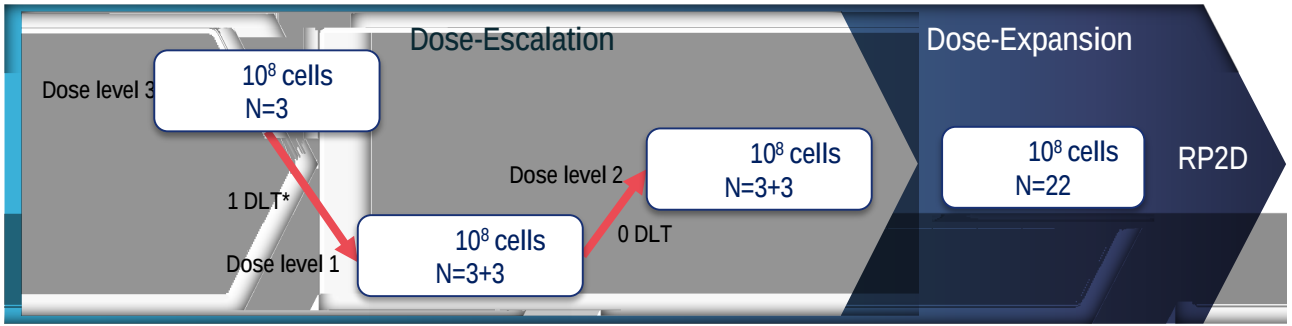
Expressed in a diverse variety of epithelial tumor types[1]

Medium to high expression in ~60



Study Design





Patient Demographics and Baseline Characteristics

Characteristics of all patients	Total (
Median age (range), year	53.0 (25–74)
Disease Type, n(%)	
GC/GEJ	28 (75.7)
PC	5 (13.5)
Other	4 (10.8)
ECOG, n (%)	
0	2 (5.4)
1	35 (94.6)
Bridging therapy, n (%)	28(75.7)
Expression intensity and rate of CLDN 18.2 in tumor tissue, n (%)	
Low expression	5 (13.5)
Medium expression	13 (35.1)
High expression	19 (51.4)

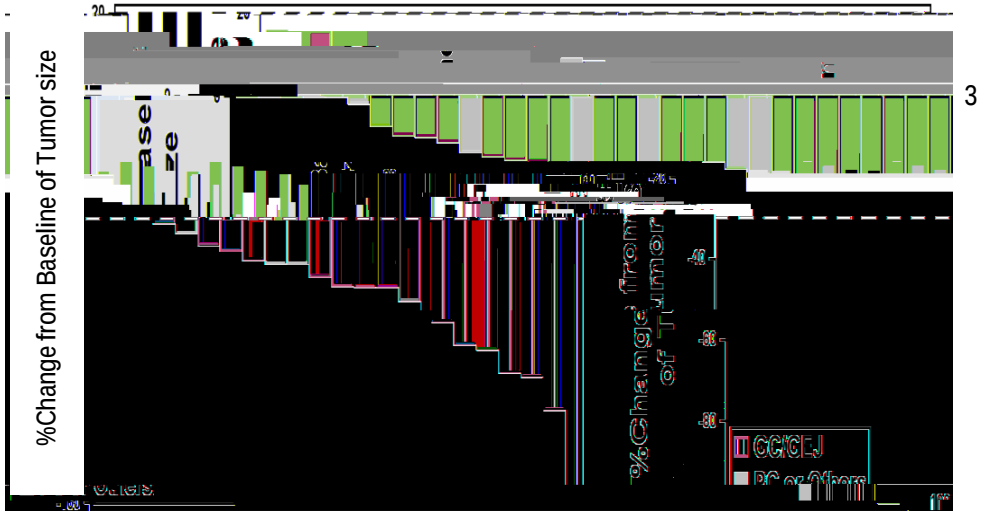
Adverse Event Summary

	Dose Escalation			Dose Expansion	Total
	8 (N=6)	8 (N=6)	8 (N=3)	8 (N=22)	
ALL AEs	6 (100)	6 (100)	3 (100)	22 (100)	37 (100)
DLT	0	0	1 (33.3)	0	1 (2.7)
AE leading to study withdrawal	0	0	0	0	0
AE leading to drug withdrawal	0	0	1 (33.3)	0	1 (2.7)
AE leading to death	0	0	0	0	0

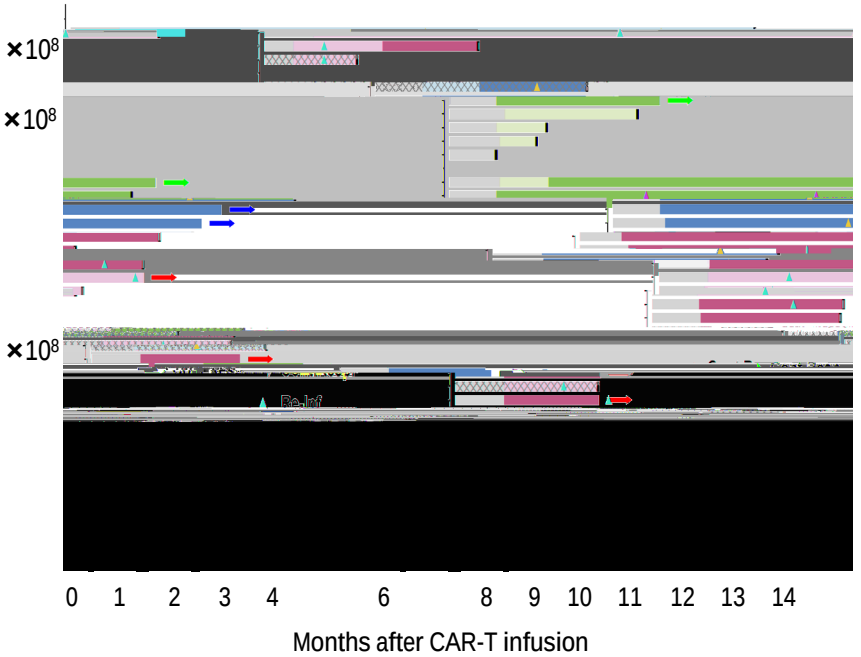
Efficacy : All patients

Thirty-six of the 37 subjects had target lesions. 31 subjects had different degrees of shrinkage of target lesions.

According to RECIST 1.1, ORR and DCR reached 48.6% (18/37) and (27/37) respectively.

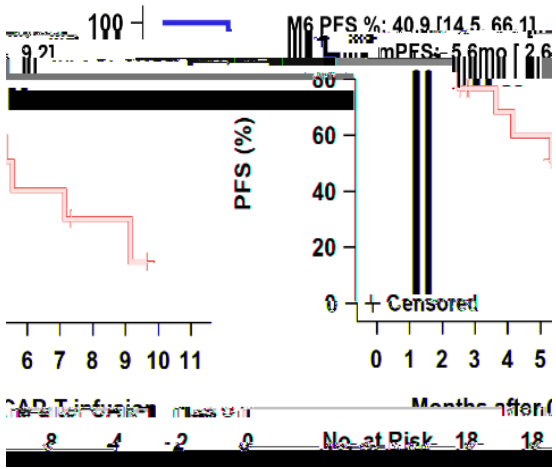


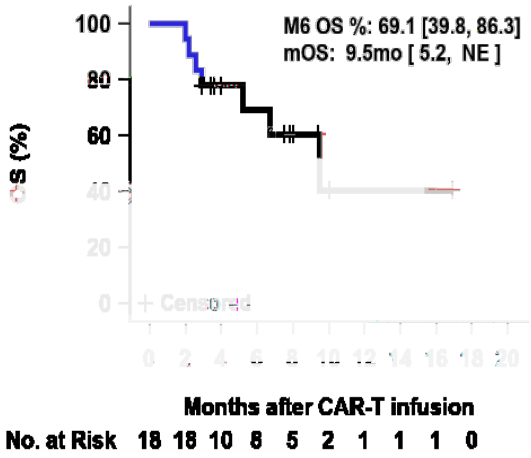
GC/GEJ
PC pancreatic adenocarcinoma



GC/GEJ patients who failed at least 2 prior lines of therapy (especially more than 40% patients ever exposed to an anti-PD-(L)1 antibody) at the dose of 2.5×10^8 CAR T cells achieved an ORR of 61.1%, DCR of 83.3%, mPFS* of .6m, mDOR of 6.4m, mOS* of 9. m with a median follow up duration* of 7.6m (95%CI 5.6, 8.6) .

	×10^8 cells (N=18)	
Best Overall Response		
CR	0	
PR	11 (61.1%)	
	4 (22.2%)	
PD	3 (16.7%)	
ORR	11 (61.1%)	[35.75, 82.70]
DCR		[58.58, 96.42]
*		[2.6, 9.2]
*		[5.2, NE]
mDOR	6.4m	[2.7, NE]





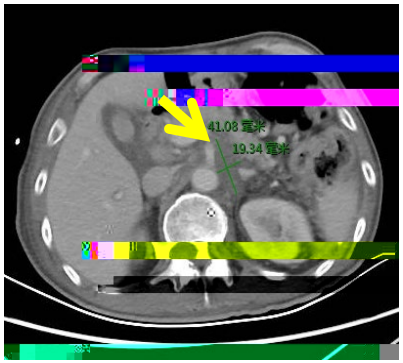
-T infusion date.

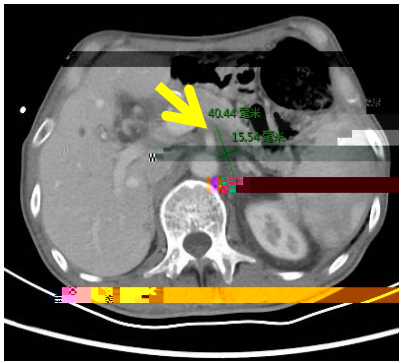
		ORR
CLDN18.2 expression		
High expression (	19	57% (37.2, 75.5)
Medium expression (2+, 40% and <	7	58% (33.5, 79.7)
Low expression (+ or < 40%)	2	50% (1.3, 98.7)
Anti-PD-		
Not used	16	63% (35.4, 84.8)
	12	50% (21.1, 78.9)
Peritoneal Metastasis		
	19	58% (33.5 , 79.7)
No	9	56% (21.2, 86.3)
WH[Classification		
	12	58% (27.7, 84.8)
Others	15	60% (32.3, 83.7)
Lauren Classification		
Intestinal	10	70% (34.8, 93.3)
Diffused / Mixed	16	50% (24.7, 75.3)

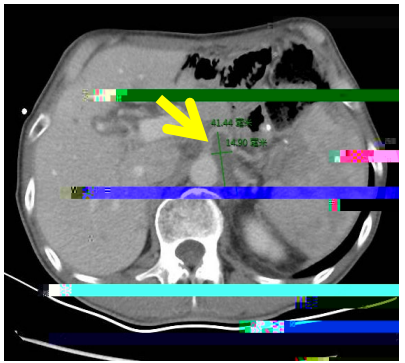
Case Sharing : Rapid and sustained tumor lesion remission

Pt04, 53/M, with liver, lung, bone metastasis and multiple lymph node and peritoneum metastasis, had received 2 prior lines of therapy including PD-1 antibody, achieved PR till 32 weeks, CLDN18.2 3+ 60%.

Retroperitoneal Lymph Node



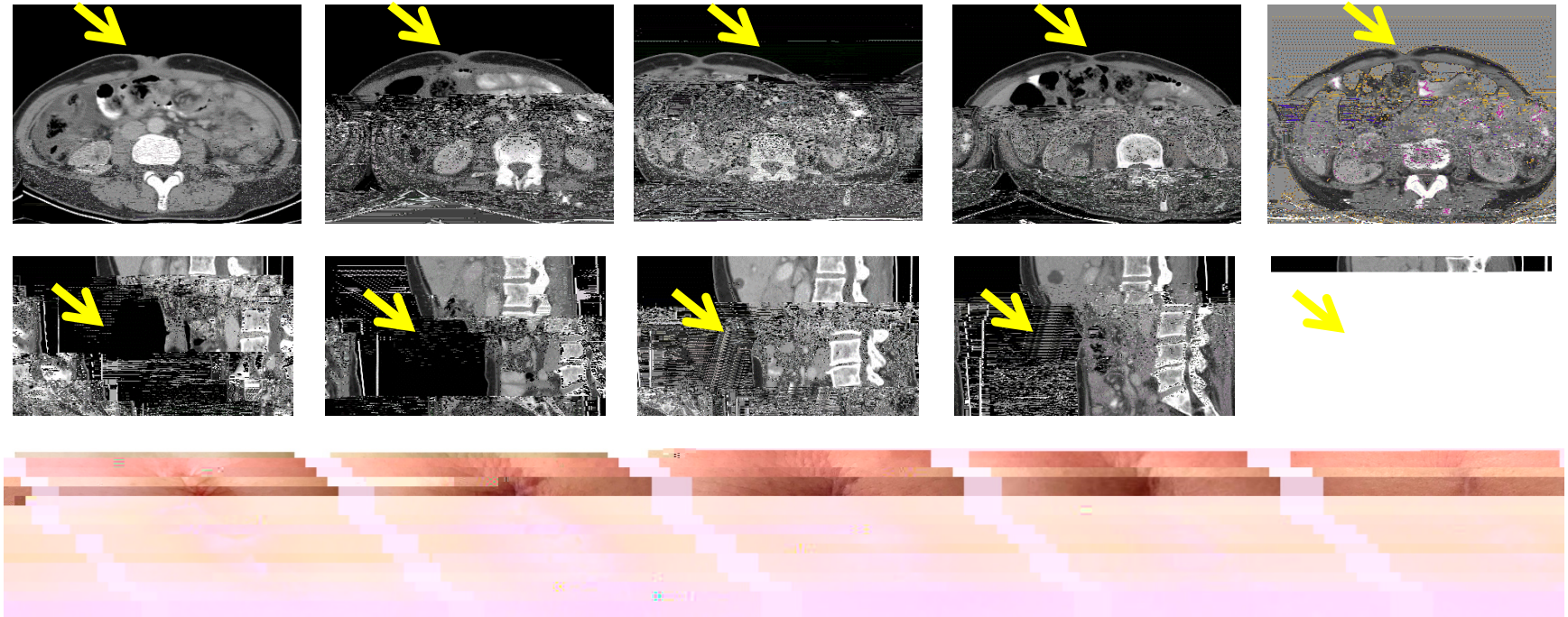




	Pre-infusion	Post-infusion W4	W8	W32
Short Axis	30mm	19mm	16mm	15mm

Case Sharing : Long-term tumor response

Pt08, 57/F, GC with peritoneal metastasis and Sister Mary Joseph nodule, had received 3 prior lines of therapy including PD-1 antibody, achieved



Pre-infusion | Post-infusion W4 | W12 | W24 | W40

CT041 CAR T-cell Expansion and Serum Biomarkers

In average, the CAR copies peaked around Day 7and persisted still Week 4, and CAR copies peak decreased post 2nd - 3rd dose ;
Responders had relative higher CAR copies peak;
The prolonged PFS positively correlated with increased AUC_{last} ;
Patients with Grade 2 CRS had higher ILn.5elritpeakvke panitdose ith r ade1.i

Conclusions

No treatment-related death, DLT occured in 28 days, and immune effector cell-associated neurotoxicity syndrome (ICANS) were reported;

Grade 1 or Grade 2 CRS occurred in 94.6% subjects, no Grade 3 CRS reported.

Efficacy

The ORR for all patients was 48.6%, and DCR reached 73%. The mOS and mDOR have not reached;

GC/GEJ patients who failed at least 2 prior lines of therapy (especially more than 40% patients ever exposed to anti-PD-(L)1 antibody) at a dose of 2.5×10^8 CAR T cells achieved ORR of 61.1%, DCR of 83.3%, mPFS of .6 months (95%CI, 2.6 9.2), mOS of 9. months (95%CI, 5.2, NE);

Pharmacokinetics characteristics

The CAR copies peaked around 7 days, median persistent duration of one month

The CAR copies peak was significantly higher in the responders than in the nonresponders. The prolonged PFS positively correlated with increased AUC_{last} .

CT041 at dose levels of 2.5-5.0×10^8 CAR-T cells was well tolerated in patients with CLDN18.2 positive digestive system cancers and delivers high response rate and sustained remission in the previously treated GC/GEJ patients.

Thanks

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