2025 ASCO® ANNUAL MEETING

Claudin18.2-specific CAR T cells (Satri-cel) versus treatment of physician's choice (TPC) for previously treated advanced gastric or gastroesophageal junction cancer (G/GEJC): Primary Results from a randomized, open-label, phase II trial (CT041-ST-01)

Changsong Qi[1], Chang Liu[1], Zhi Peng[1], Yanqiao Zhang[2], Jia Wei[3], Wensheng Qiu[4], Xiaotian Zhang[1], Hongming Pan[5], Zuoxing Niu[6], Meng Qiu[7], Yanru Qin[8], Weijia Fang[9], Feng Ye[10], Ning Li[11], Tianshu Liu[12], Yumeng Wang[13], Daijing Yuan[13], Zonghai Li[13], Lin Shen[1, *]

[1]Peking University Cancer Hospital, Beijing, China; [2]Harbin Medical University Cancer Hospital, Harbin, China; [3]Nanjing Drum Tower Hospital, Nanjing, China; [4]The Affiliated Hospital of Qingdao University, Qingdao, China; [5]Sir Run Run Shaw Hospital, Zhejiang University School of Medicine, Hangzhou, China; [6]Cancer Hospital of Shandong First Medical University, Jinan, China; [7]West China Hospital, Sichuan University, Chengdu, China; [8]The First Affiliated Hospital of Zhengzhou University, Zhengzhou, China; [9]The First Affiliated Hospital, Zhejiang University School of Medicine, Hangzhou, China; [10]The First Affiliated Hospital of Xiamen University, Xiamen, China; [11]Henan Cancer Hospital, Affiliated Cancer Hospital of Zhengzhou University, Zhengzhou, China; [12]Zhongshan Hospital, Fudan University, Shanghai, China; [13]CARsgen Therapeutics Co., Ltd., Shanghai, China; [*]Corresponding author

Changsong Qi, MD

Key Takeaway Points/Conclusions

- Satricabtagene autoleucel (satri-cel)/CT041 demonstrated significant progression-free survival (PFS) improvement and a clinically meaningful overall survival (OS) benefit in patients with previously treated, advanced G/GEJC.
  - ✓ Globally, this is the first ever randomized controlled trial of a CAR T-cell therapy in solid tumors to achieve superiority.
  - ✓ This trial expanded the the percentage of CLDN18.2 positive patients with G/GEJC.
- Satri-cel showed a manageable safety profile consistent with previous phase I results.
- These results support satri-cel as a new treatment option for advanced G/GEJC.

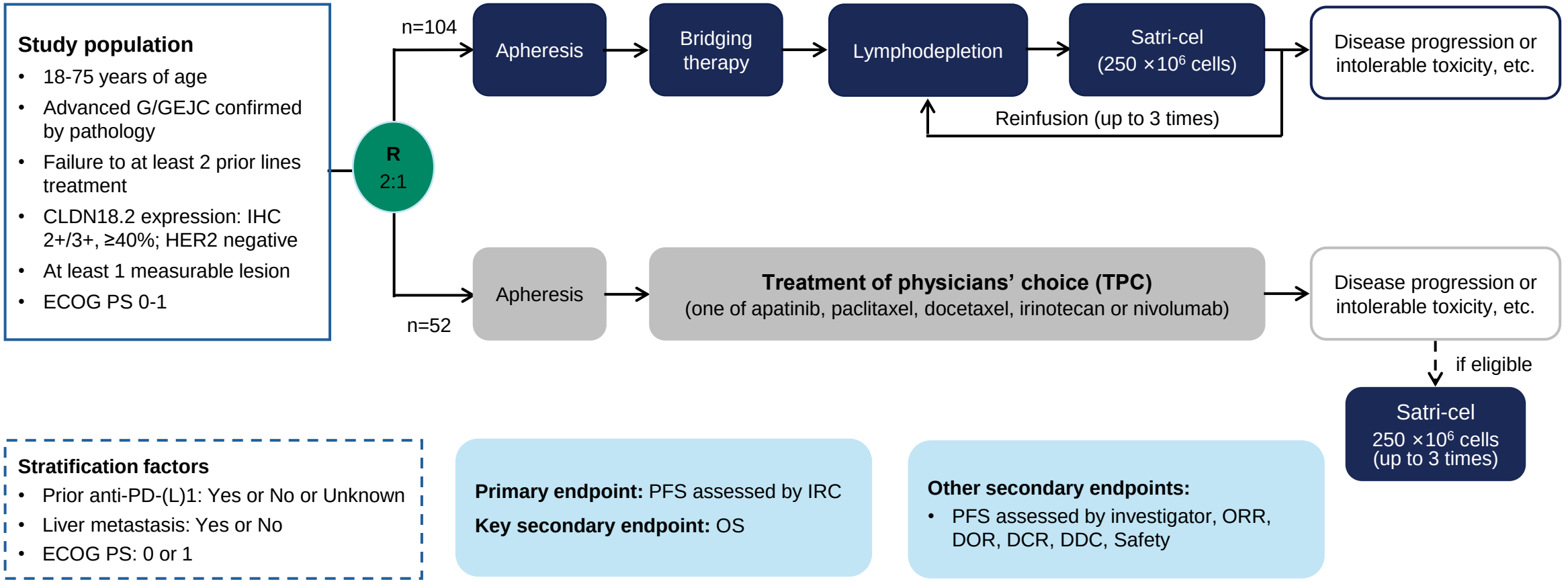
Background

- Claudin18.2 (CLDN18.2) is overexpressed in various gastrointestinal tumours, particularly in G/GEJC, and it has emerged as a promising therapeutic target in G/GEJC[1].
- Satri-cel/CT041, an autologous CLDN18.2-specific CAR T therapy, had showed encouraging efficacy in previously treated patients with advanced G/GEJC in phase I clinical trials[2, 3].
- Here we report the primary results from the phase II randomized controlled trial (CT041-ST-01, NCT04581473).

1. Nakayama I, Qi C, Chen Y, Nakamura Y, Shen L, Shitara K. Claudin 18.2 as a novel therapeutic target. *Nat Rev Clin Oncol* 2024; 21: 1–16.
2. Qi C, Gong J, Li J, et al. Claudin18.2-specific CAR T cells in gastrointestinal cancers: phase 1 trial interim results. Nat Med 2022; 28: 1189–98.
3. Qi C, Liu C, Gong J, et al. Claudin18.2-specific CAR T cells in gastrointestinal cancers: phase 1 trial final results. Nat Med 2024; 30: 1–11.

Trial Design and Procedure schema

An open-label, multicenter, randomized controlled trial conducted in China.



Stratification factors
- Prior anti-PD-(L)1: Yes or No or Unknown
- Liver metastasis: Yes or No
- ECOG PS: 0 or 1

Primary endpoint: PFS assessed by IRC

Key secondary endpoint: OS

Other secondary endpoints:
- PFS assessed by investigator, ORR, DOR, DCR, DDC, Safety

Data cutoff：October 18, 2024

Statistical Considerations

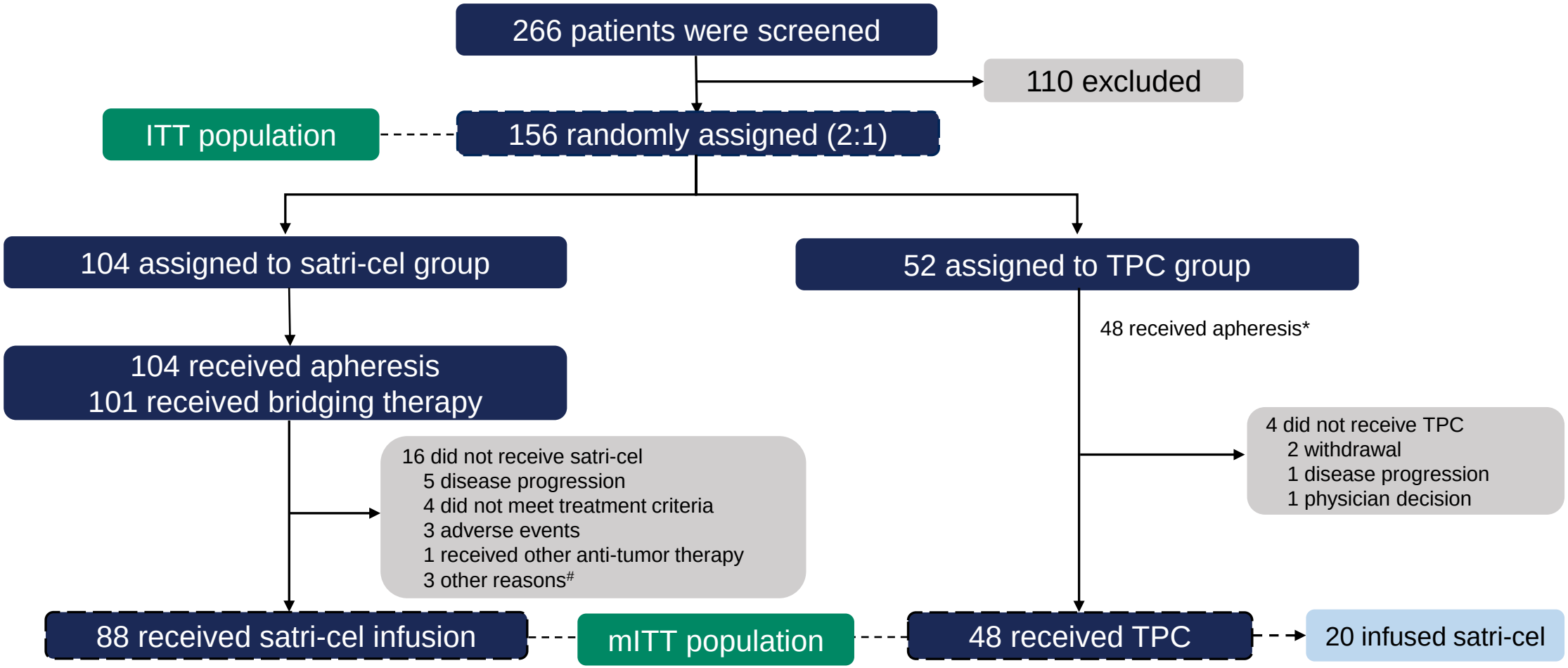
- For **primary endpoint PFS**, a HR of 0.55 (45% risk reduction with satri-cel vs TPC) was hypothesized and median PFS in TPC was 3 months. The event goal for PFS to achieve 84.7% power at 1-sided α of 0.025 was 114. The sample size was 150 based on an estimate of 114 PFS events with a 15% dropout rate.

- For **key secondary endpoint OS**, a HR of 0.56 was hypothesized and median OS in TPC was 6 months. The event goal for OS to achieve 80% power at 1-sided α of 0.025 was 107 if the PFS analysis achieved statistical significance.

- Data cutoff date was October 18, 2024 for PFS and the final OS analysis was conducted at the same time as 105 OS events were reached. The α level of 0.025 was recycled to the final OS analysis as PFS was tested positive.

Data cutoff：October 18, 2024

Patient Disposition



*One was not apheresed per physician's decision and received TPC
#Three patients requested to withdraw from study treatment.

Data cutoff：October 18, 2024

Baseline Characteristics

Characteristics	Satri-cel group (n=104)	TPC group (n=52)
Age, median (IQR), years	53.5 (45.0, 60.0)	50.5 (43.0, 58.0)
Sex, n (%)		
Male	56 (53.8)	31 (59.6)
Female	48 (46.2)	21 (40.4)
Ethnicity, n (%)		
Chinese	104 (100%)	52 (100%)
ECOG, n (%)		
0	17 (16.3)	8 (15.4)
1	87 (83.7)	44 (84.6)
Primary tumor site, n (%)		
Gastric	88 (84.6)	48 (92.3)
Gastroesophageal junction	16 (15.4)	4 (7.7)
Signet ring cell carcinoma*	41 (**39.4**)	27 (**51.9**)
Lauren type, n (%)		
Intestinal type	21 (20.2)	12 (23.1)
Diffuse type	45 (**43.3**)	26 (**50.0**)
Mixed type	29 (**27.9**)	8 (**15.4**)
Unknown	9 (8.7)	6 (11.5)
Previous gastrectomy, n (%)	49 (47.1)	31 (59.6)

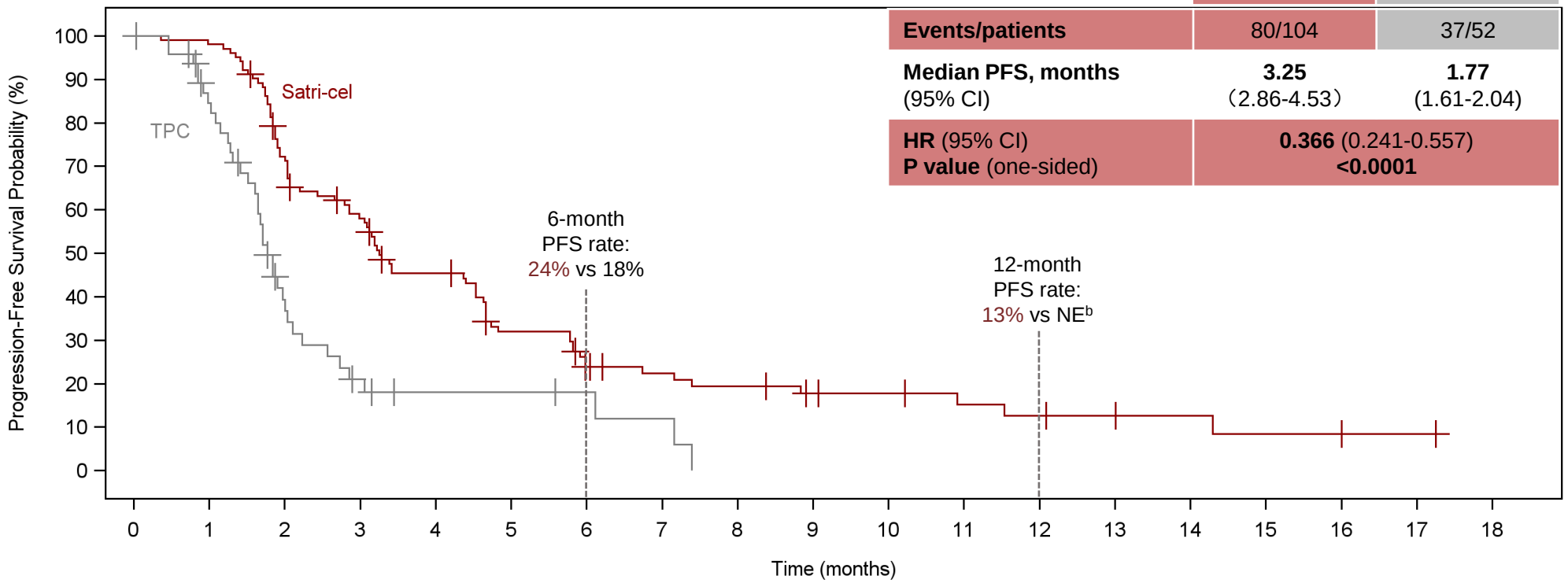
Characteristics	Satri-cel group (n=104)	TPC group (n=52)
CLDN18.2 expression, n (%)†		
Medium expression	24 (23.1)	10 (19.2)
High expression	80 (76.9)	42 (80.8)
Number of prior lines, n (%)‡		
2	76 (73.1)	42 (80.8)
≥3	28 (26.9)	10 (19.2)
Previous systemic therapies, n (%)		
Fluorouracil/analogs and derivativesl	101 (97.1)	52 (100)
Taxanes	96 (92.3)	47 (90.4)
Platinum	103 (99.0)	50 (96.2)
Prior anti-PD-(L)1	81 (77.9)	42 (80.8)
Number of metastatic organs, n (%)		
≤2	53 (51.0)	25 (48.1)
≥3	51 (**49.0**)	27 (**51.9**)
Metastatic organs, n (%)		
Peritoneal	72 (**69.2**)	31 (**59.6**)
Liver	21 (20.2)	10 (19.2)
Lung	9 (8.7)	7 (13.5)
Bone	8 (7.7)	9 (17.3)

* Inclusion of signet ring cell carcinoma components includes those with WHO classification of signet ring cell carcinoma or those accompanied by signet ring cell carcinoma.
† CLDN18.2 expression classification: High expression is defined as the sum of the percentages of tumor cells with 3+ and 2+ CLDN18.2 expression being ≥ 70%; medium expression is defined as the sum being ≥ 40% but < 70%.
‡ Second-line treatment includes all second-line treatments and first-line treatments that concurrently used three chemotherapeutic drugs, namely taxane [or anthracycline], platinum, and fluorouracil.
IQR=interquartile range. ECOG =Eastern Cooperative Oncology Group. CLDN18.2=claudin-18 isoform 2.

Primary Endpoint: PFS (ITT) assessed by IRC[a]

Satri-cel demonstrated statistically significant PFS improvement

	Satri-cel	TPC
Events/patients	80/104	37/52
Median PFS, months (95% CI)	**3.25** （2.86-4.53）	**1.77** (1.61-2.04)
HR (95% CI)	**0.366** (0.241-0.557)	
P value (one-sided)	**<0.0001**	



No. of Risk (events)

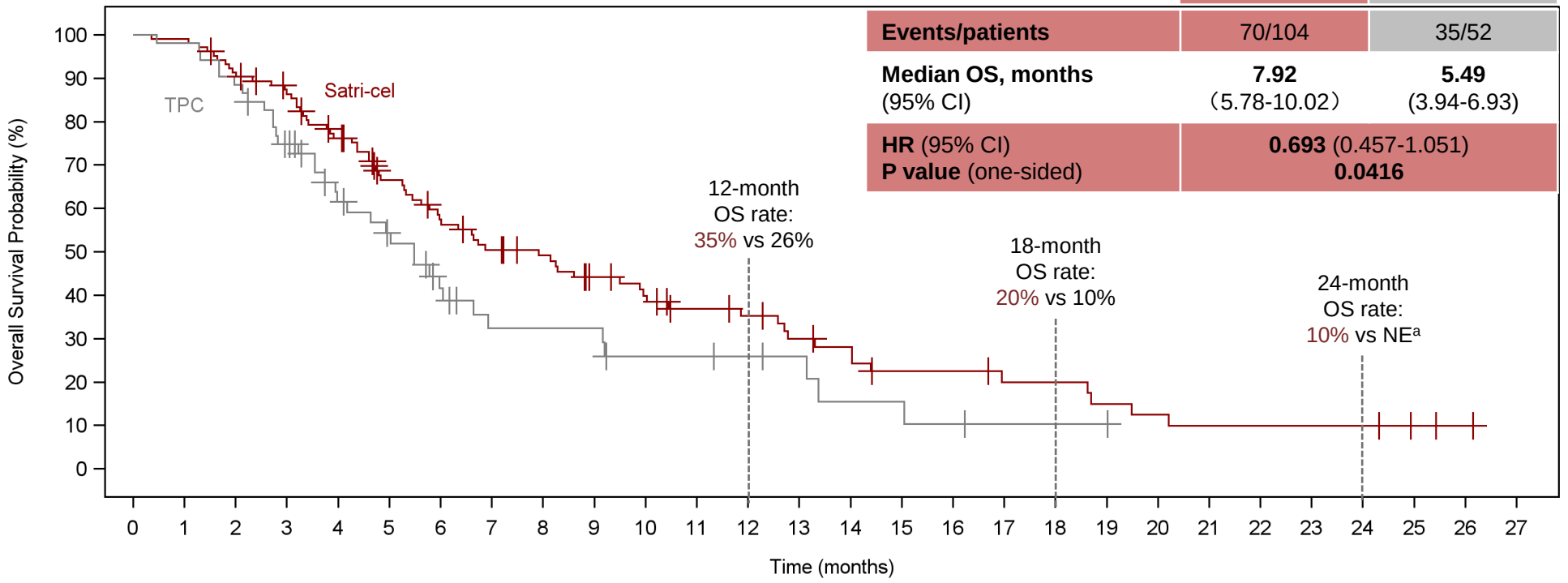
Satri-cel	104 (0)	100 (2)	72 (28)	56 (42)	42 (54)	28 (66)	19 (73)	15 (74)	13 (76)	10 (77)	9 (77)	6 (78)	5 (79)	4 (79)	3 (79)	2 (80)	2 (80)	1 (80)	0 (80)
TPC	52 (0)	37 (7)	15 (26)	7 (33)	4 (34)	4 (34)	3 (34)	2 (35)	0 (37)										

Date cutoff: October 18, 2024.
Median follow-up: 9·07 months (satri-cel group) vs 3·45 months (TPC group).

a: Per RECIST v1.1.
b: 12-month PFS rate could not be estimated in the TPC group.

Key Secondary Endpoint: OS (ITT)

Satri-cel demonstrated clinically meaningful OS benefit



	Satri-cel	TPC
Events/patients	70/104	35/52
Median OS, months (95% CI)	**7.92** (5.78-10.02)	**5.49** (3.94-6.93)
HR (95% CI)	**0.693** (0.457-1.051)	
P value (one-sided)	**0.0416**	

No. of Risk (events)

Satri-cel	104 (0)	103 (1)	94 (9)	86 (14)	74 (24)	59 (33)	50 (41)	43 (47)	39 (48)	32 (52)	28 (55)	23 (57)	21 (58)	17 (61)	15 (62)	11 (65)	11 (65)	8 (66)	8 (66)	6 (68)	5 (69)	4 (70)	4 (70)	4 (70)	4 (70)	2 (70)	1 (70)	0 (70)
TPC	52 (0)	51 (1)	46 (6)	37 (13)	27 (19)	22 (22)	15 (27)	10 (30)	10 (30)	10 (30)	7 (32)	7 (32)	6 (32)	5 (32)	3 (34)	3 (34)	2 (35)	1 (35)	1 (35)	1 (35)	0 (35)							

Date cutoff: October 18, 2024.
Median follow-up: 14·42 months (satri-cel group) vs 11·33 months (TPC group).

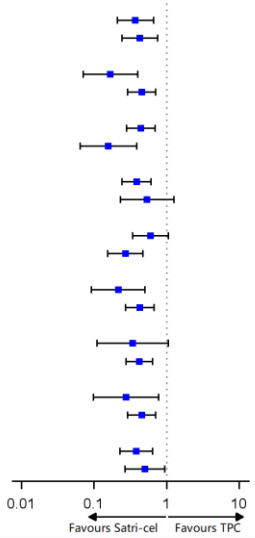
a: 24-month OS rate could not be estimated in the TPC group.

PFS and OS Subgroup Analysis (ITT)

PFS and OS benefit of Satri-cel was observed across the prespecified subgroups

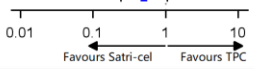
Subgroup analysis of PFS

Subgroup	Satri-cel Events/Patients	TPC Events/Patients	Adjusted HR	P value for interaction
Age				0.4260
≤60	61/81	32/43	0.38 (0.24, 0.59)	
>60	19/23	5/9	0.59 (0.22, 1.59)	
Sex				0.2443
F	35/48	17/21	0.32 (0.18, 0.58)	
M	45/56	20/31	0.51 (0.30, 0.88)	
ECOG (IWRS)				0.3580
0	13/17	5/8	0.63 (0.22, 1.77)	
1	67/87	32/44	0.37 (0.24, 0.58)	
Primary tumor site				0.6865
Gastric	66/88	34/48	0.41 (0.27, 0.63)	
Esophagogastric junction	14/16	3/4	0.32 (0.09, 1.12)	
Previous gastrectomy				0.0448
Yes	37/49	18/31	0.55 (0.31, 0.97)	
No	43/55	19/21	0.24 (0.14, 0.43)	
Lauren classification				0.2662
Intestinal type	19/21	7/12	0.46 (0.19, 1.13)	
Diffuse type	29/45	19/26	0.40 (0.22, 0.71)	
Mixed type	24/29	7/8	0.16 (0.07, 0.38)	
Unknown	8/9	4/6	0.39 (0.12, 1.32)	
WHO classification				0.7425
Signet ring cell carcinoma	29/41	21/27	0.37 (0.21, 0.66)	
None signet ring cell carcinom	51/63	16/25	0.42 (0.24, 0.75)	
CLDN18.2 expression				0.0427
Medium expression	19/24	8/10	0.17 (0.07, 0.40)	
High expression	61/80	29/42	0.45 (0.29, 0.71)	
Number of prior lines				0.0394
2	56/76	30/42	0.44 (0.28, 0.69)	
≥3	24/28	7/10	0.16 (0.06, 0.39)	
Prior anti-PD-(L)1 (IWRS)				0.4867
Yes	61/82	29/41	0.38 (0.24, 0.61)	
No	17/19	8/10	0.54 (0.23, 1.25)	
Number of metastatic organs				0.0452
≤2	43/53	17/25	0.60 (0.34, 1.06)	
≥3	37/51	20/27	0.27 (0.15, 0.47)	
Liver metastasis (IWRS)				0.1625
Yes	19/20	8/9	0.22 (0.09, 0.51)	
No	61/84	29/43	0.42 (0.27, 0.67)	
Lung metastasis				0.7293
Yes	8/9	5/7	0.34 (0.11, 1.06)	
No	72/95	32/45	0.42 (0.27, 0.64)	
Bone metastasis				0.3825
Yes	7/8	8/9	0.28 (0.10, 0.78)	
No	73/96	29/43	0.45 (0.29, 0.70)	
Peritoneal metastasis				0.5055
Yes	52/72	22/31	0.38 (0.23, 0.64)	
No	28/32	15/21	0.50 (0.27, 0.94)	



Subgroup analysis of OS

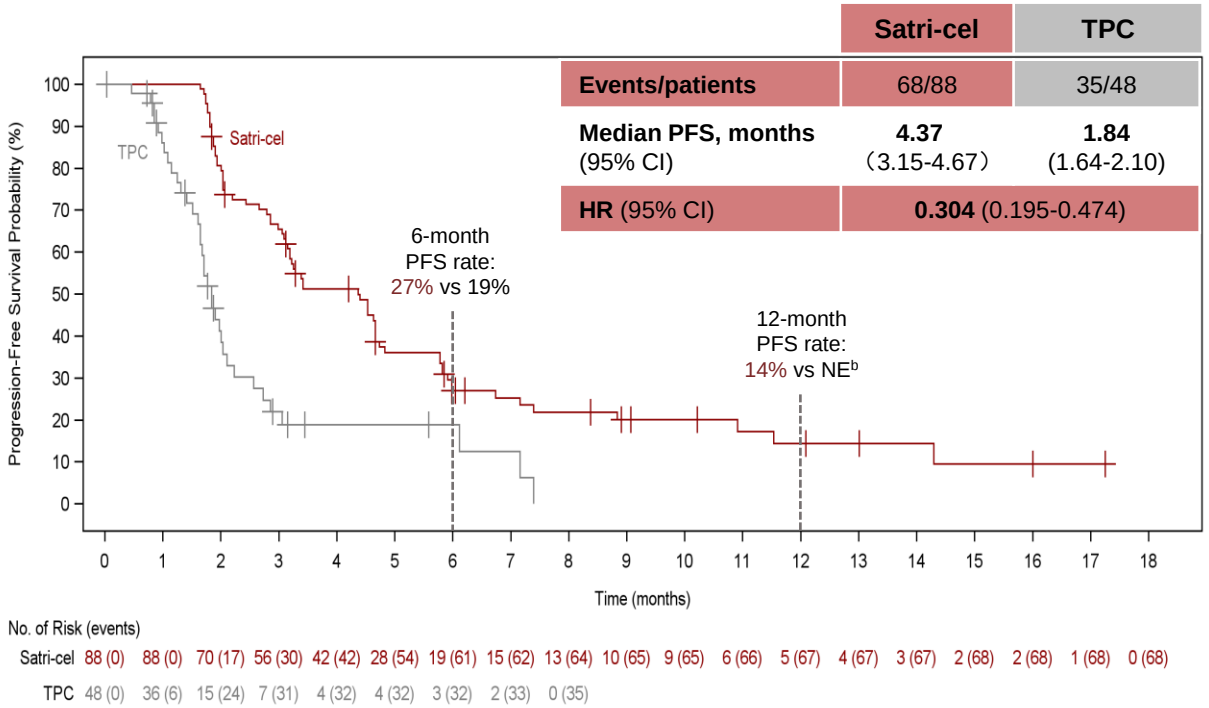
Subgroup	Satri-cel Events/Patients	TPC Events/Patients	Adjusted HR	P value for interaction
Age				0.7211
≤60	55/81	30/43	0.71 (0.46, 1.12)	
>60	15/23	5/9	0.58 (0.21, 1.62)	
Sex				0.1129
F	28/48	17/21	0.48 (0.26, 0.88)	
M	42/56	18/31	0.93 (0.53, 1.63)	
ECOG (IWRS)				0.7951
0	11/17	5/8	0.61 (0.21, 1.75)	
1	59/87	30/44	0.71 (0.45, 1.10)	
Primary tumor site				0.3369
Gastric	59/88	31/48	0.71 (0.46, 1.10)	
Esophagogastric junction	11/16	4/4	0.39 (0.12, 1.23)	
Previous gastrectomy				0.0950
Yes	32/49	17/31	0.86 (0.48, 1.56)	
No	38/55	18/21	0.43 (0.24, 0.76)	
Lauren classification				0.9054
Intestinal type	12/21	7/12	0.61 (0.24, 1.55)	
Diffuse type	30/45	18/26	0.68 (0.38, 1.22)	
Mixed type	22/29	6/8	0.80 (0.32, 1.98)	
Unknown	6/9	4/6	0.45 (0.12, 1.62)	
WHO classification				0.7395
Signet ring cell carcinoma	25/41	20/27	0.65 (0.36, 1.17)	
None signet ring cell carcinom	45/63	15/25	0.74 (0.41, 1.34)	
CLDN18.2 expression				0.9034
Medium expression	18/24	7/10	0.71 (0.29, 1.70)	
High expression	52/80	28/42	0.66 (0.42, 1.06)	
Number of prior lines				0.7204
2	51/76	29/42	0.65 (0.41, 1.04)	
≥3	19/28	6/10	0.79 (0.31, 1.98)	
Prior anti-PD-(L)1 (IWRS)				0.9690
Yes	55/82	28/41	0.71 (0.45, 1.12)	
No	14/19	7/10	0.62 (0.25, 1.55)	
Number of metastatic organs				0.1386
≤2	33/53	12/25	0.98 (0.50, 1.90)	
≥3	37/51	23/27	0.52 (0.30, 0.88)	
Liver metastasis (IWRS)				0.5760
Yes	14/20	6/9	0.52 (0.20, 1.37)	
No	56/84	29/43	0.71 (0.45, 1.12)	
Lung metastasis				0.1227
Yes	4/9	7/7	0.28 (0.08, 0.95)	
No	66/95	28/45	0.77 (0.49, 1.21)	
Bone metastasis				0.8048
Yes	6/8	7/9	0.82 (0.27, 2.44)	
No	64/96	28/43	0.70 (0.45, 1.10)	
Peritoneal metastasis				0.3365
Yes	51/72	23/31	0.78 (0.47, 1.27)	
No	19/32	12/21	0.50 (0.24, 1.05)	



PFS and OS Supplementary Analysis (mITT)

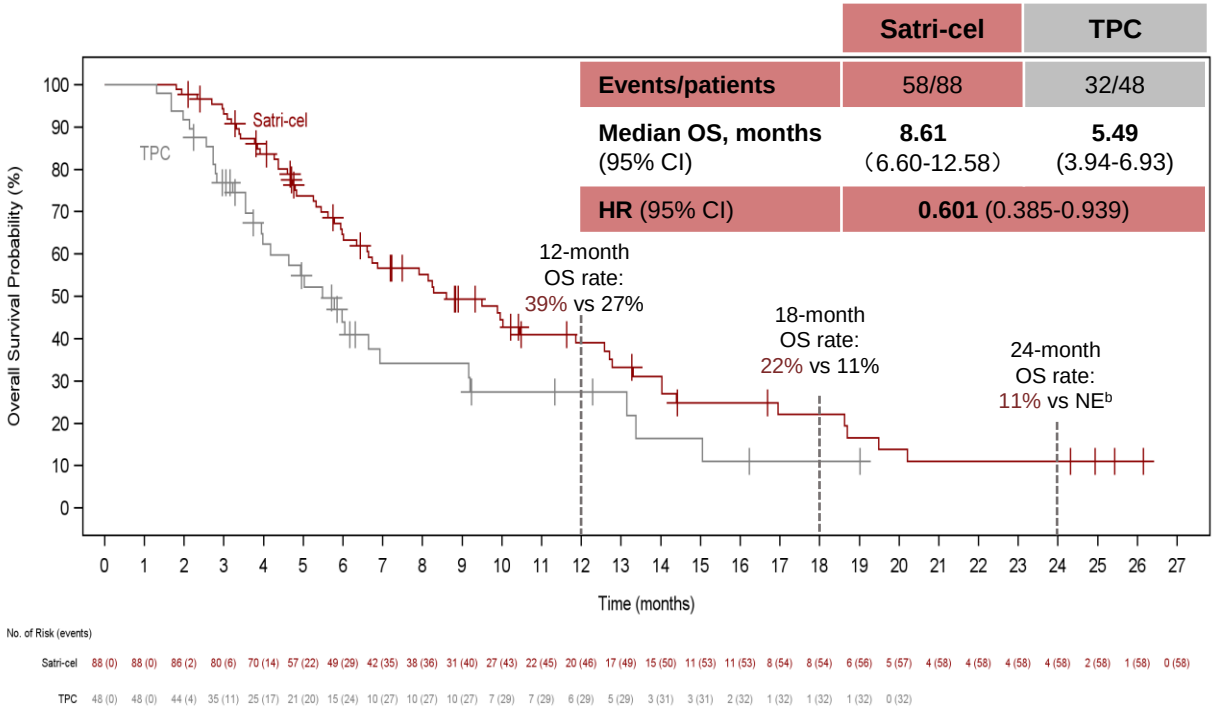
In treated population, PFS per IRC and OS were obviously longer in Satri-cel group vs TPC group

PFS assessed by IRC[a]



	Satri-cel	TPC
Events/patients	68/88	35/48
Median PFS, months (95% CI)	**4.37** （3.15-4.67）	**1.84** (1.64-2.10)
HR (95% CI)	**0.304** (0.195-0.474)	

OS in mITT population



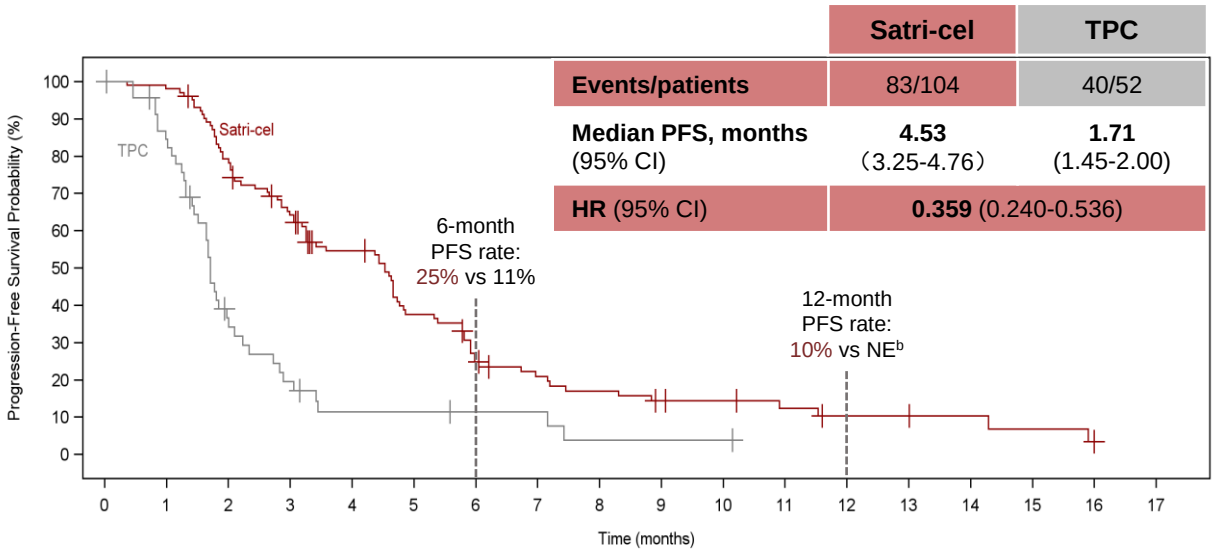
	Satri-cel	TPC
Events/patients	58/88	32/48
Median OS, months (95% CI)	**8.61** （6.60-12.58）	**5.49** (3.94-6.93)
HR (95% CI)	**0.601** (0.385-0.939)	

Date cutoff: October 18, 2024.
a: Per RECIST v1.1. b: the rate could not be estimated in the TPC group.

Secondary Endpoints: PFS assessed by Investigator

PFS was obviously longer in Satri-cel group vs TPC group both in ITT and mITT set

In ITT population[a]

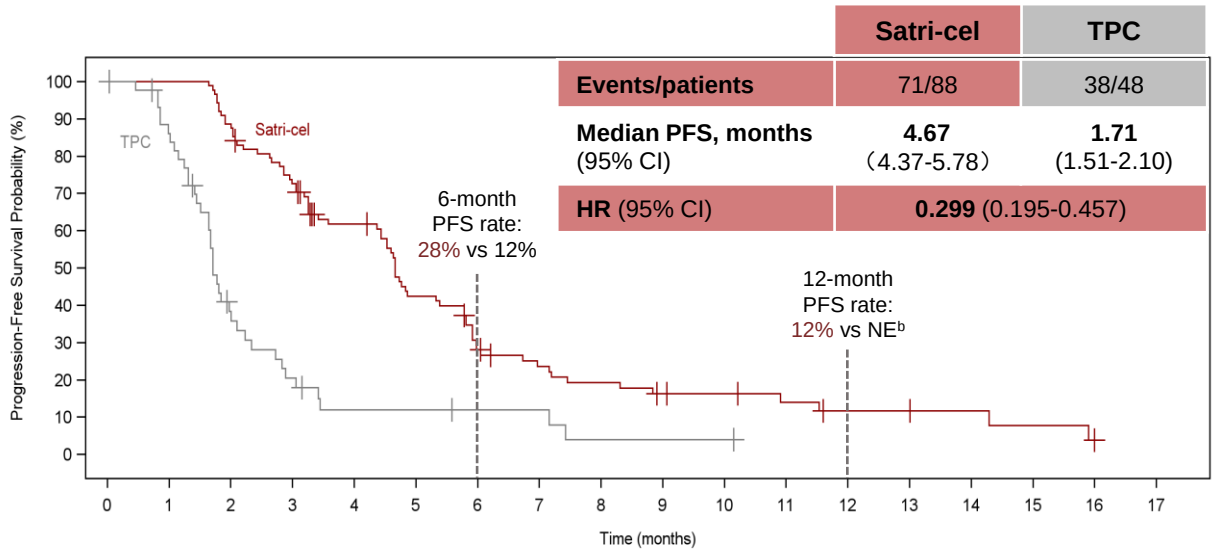


	Satri-cel	TPC
Events/patients	83/104	40/52
Median PFS, months (95% CI)	**4.53** (3.25-4.76)	**1.71** (1.45-2.00)
HR (95% CI)	**0.359** (0.240-0.536)	

No. of Risk (events)

Satri-cel	104 (0)	100 (2)	80 (21)	63 (36)	49 (45)	33 (60)	21 (71)	16 (74)	13 (77)	10 (79)	9 (79)	6 (80)	4 (81)	4 (81)	3 (81)	2 (82)	1 (83)
TPC	52 (0)	38 (7)	15 (28)	8 (35)	4 (38)	4 (38)	3 (38)	3 (38)	1 (40)	1 (40)	1 (40)	0 (40)					

In mITT population[a]



	Satri-cel	TPC
Events/patients	71/88	38/48
Median PFS, months (95% CI)	**4.67** (4.37-5.78)	**1.71** (1.51-2.10)
HR (95% CI)	**0.299** (0.195-0.457)	

No. of Risk (events)

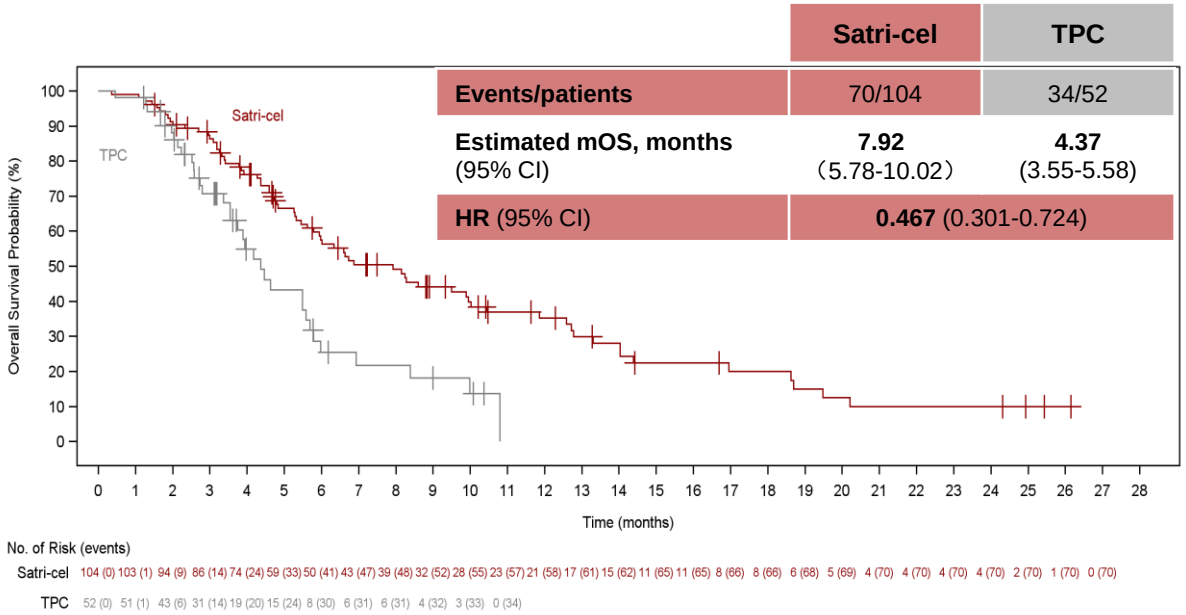
Satri-cel	88 (0)	88 (0)	78 (10)	63 (24)	49 (33)	33 (48)	21 (59)	16 (62)	13 (65)	10 (67)	9 (67)	6 (68)	4 (69)	4 (69)	3 (69)	2 (70)	1 (71)
TPC	48 (0)	37 (6)	15 (26)	8 (33)	4 (36)	4 (36)	3 (36)	3 (36)	1 (38)	1 (38)	1 (38)	0 (38)					

Date cutoff: October 18, 2024.
a: Per RECIST v1.1. b: the rate could not be estimated in the TPC group.

Adjusting for treatment switching: OS analyzed by RPSFT[a] model

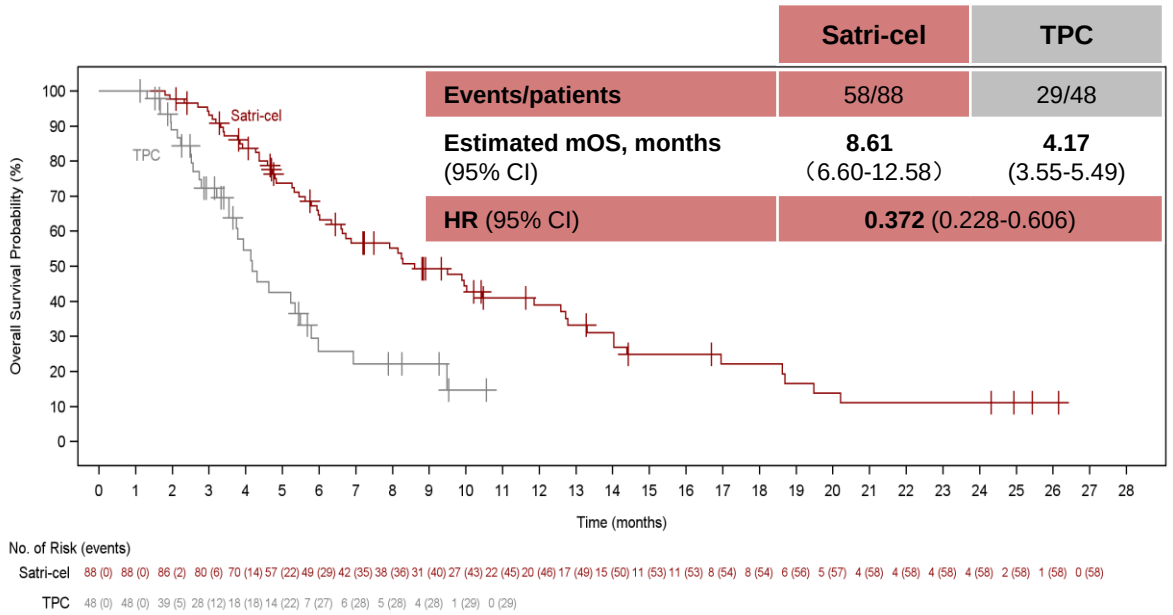
The estimated mOS was 1.81-2.06 fold longer with satri-cel vs TPC, providing a 53% and 63% reduction in risk of mortality in the ITT and mITT populations, respectively.

OS (ITT) analyzed by RPSFT model



	Satri-cel	TPC
Events/patients	70/104	34/52
Estimated mOS, months (95% CI)	**7.92** (5.78-10.02)	**4.37** (3.55-5.58)
HR (95% CI)	**0.467** (0.301-0.724)	

OS (mITT) analyzed by RPSFT model



	Satri-cel	TPC
Events/patients	58/88	29/48
Estimated mOS, months (95% CI)	**8.61** (6.60-12.58)	**4.17** (3.55-5.49)
HR (95% CI)	**0.372** (0.228-0.606)	

- 42% (20/48) of patients in the TPC group subsequently received satri-cel infusion.
- Among all 108 patients (88 in satri-cel group, 20 in TPC group) treated with satri-cel, **mOS reached 9.17 months** (95% CI 6·64–12·58).

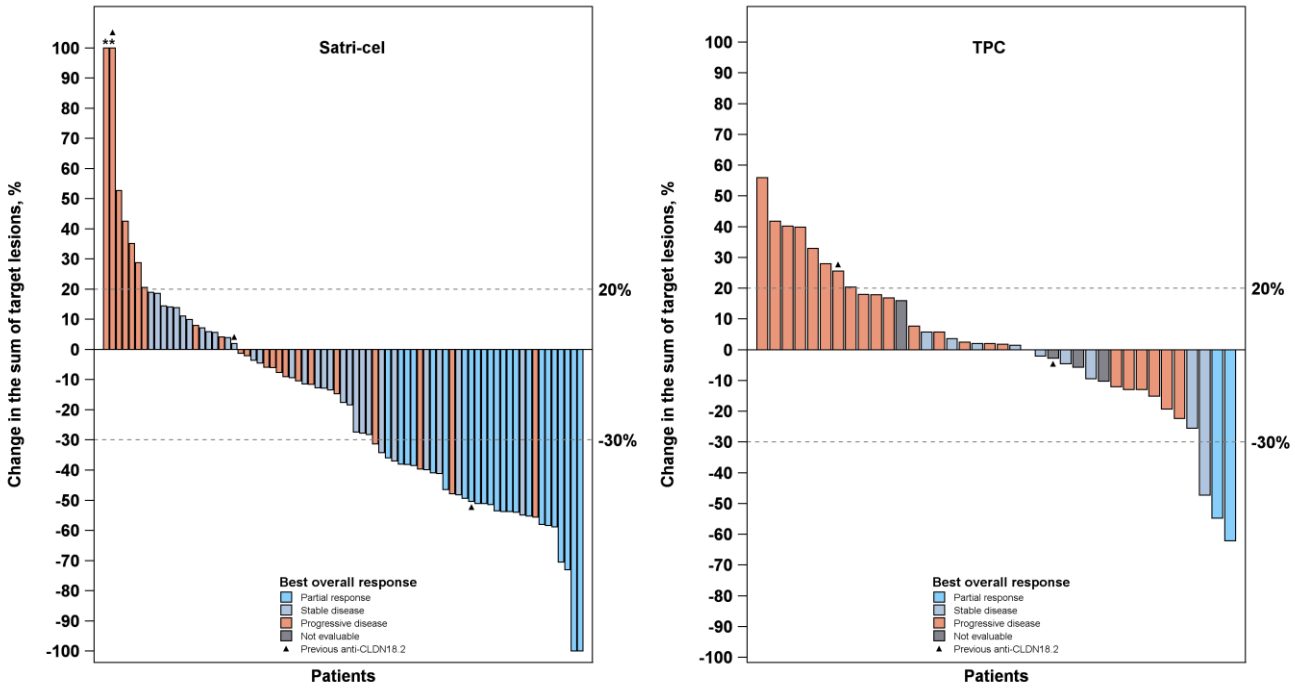
Date cutoff: October 18, 2024.
a: RPSFT: Rank Preserving Structural Failure Time. RPSFT model applied to adjust survival time for TPC patients who received satri-cel.

Tumor Response assessed by IRC[a]

ORR and DCR were obviously improved in patients treated with satri-cel

	Satri-cel group (n=76[b])	TPC group (n=45[b])
Best overall response		
CR, n (%)	0	0
PR, n (%)	23 (30)	2 (4)
SD, n (%)	30 (40)	9 (20)
PD, n (%)	22 (29)	24 (53)
NE, n (%)	1 (1)	10 (22)
ORR, n (%) [95% CI]	23 (30) [20 - 42]	2 (4) [1 - 15]
DCR, n (%) [95% CI]	53 (70) [58 - 80]	11 (24) [13 - 40]

Changes in target lesions



a. Tumor response was confirmed by independent review committee according to RECIST v1.1.
b. Patients with measurable disease in mITT as assessed by IRC.

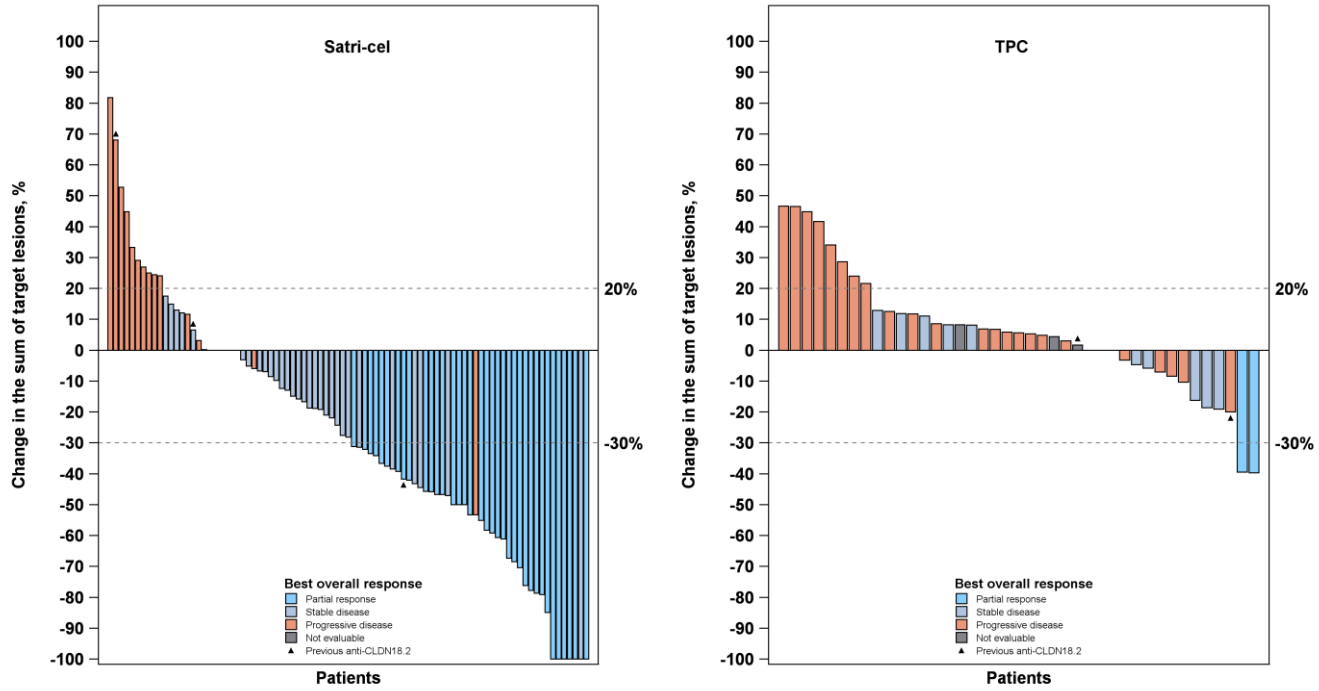
Tumor Response assessed by Investigator[a]

ORR and DCR were obviously improved in patients treated with satri-cel

	Satri-cel group (n=88)	TPC group (n=48)
Best overall response		
CR, n (%)	0	0
PR, n (%)	36 (41)	2 (4)
SD, n (%)	35 (40)	11 (23)
PD, n (%)	16 (18)	25 (52)
NE, n (%)	1 (1)	10 (21)
ORR, n (%) [95% CI]	36 (41) [31 - 52]	2 (4) [1 - 14]
DCR, n (%) [95% CI]	71 (81) [71 - 88]	13 (27) [15 - 42]

a. Tumor response was confirmed by investigator according to RECIST v1.1 in mITT.

Changes in target lesions

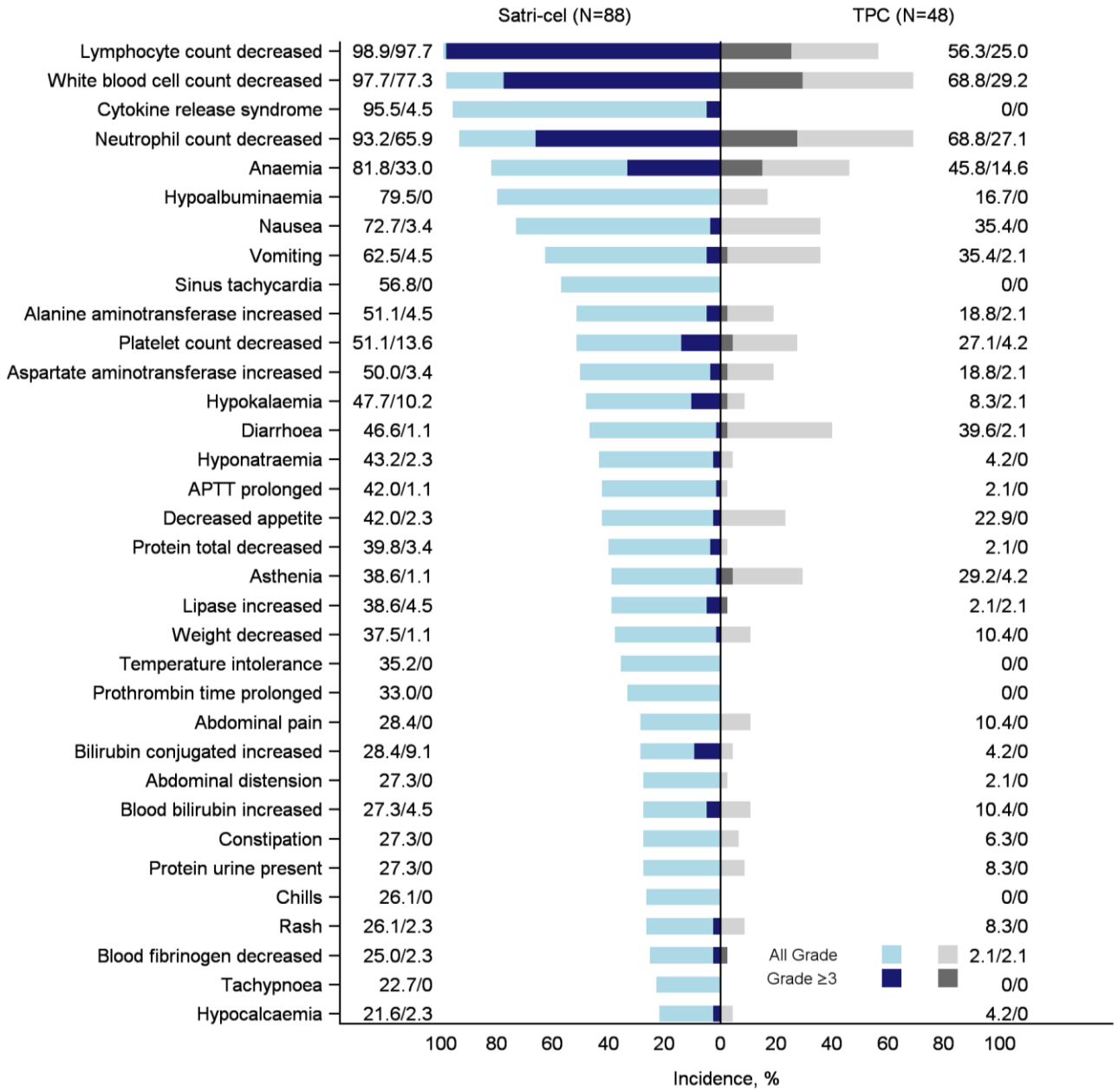


Safety: Adverse events in the safety set

Safety, n (%)	Satri-cel group (n=88)		TPC group (n=48)	
	All grade	Grade ≥3	All grade	Grade ≥3
All treatment-emergent adverse events (TEAEs)	88 (100%)	87 (98.9%)	44 (91.7%)	30 (62.5%)
TEAEs related to treatment (TRAEs)	88 (100%)	87 (98.9%)	44 (91.7%)	27 (56.3%)
TRAEs leading to discontinuation	0	0	2 (4.2%)	1 (2.1%)
TRAEs leading to death	1 (1.1%) [1]	1 (1.1%)	1 (2.1%) [2]	1 (2.1%)
Cytokine release syndrome (CRS)	84 (95.5%)	4 (4.5%) [3]	0	0
Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)	0	0	0	0

Treatment was defined as bridging therapy, lymphodepletion and Satri-cel infusion in Satri-cel group and treatment of physician's choice in TPC group.
[1] disseminated intravascular coagulation; [2] coagulopathy; [3] all grade 3.

Safety: TRAEs[#]



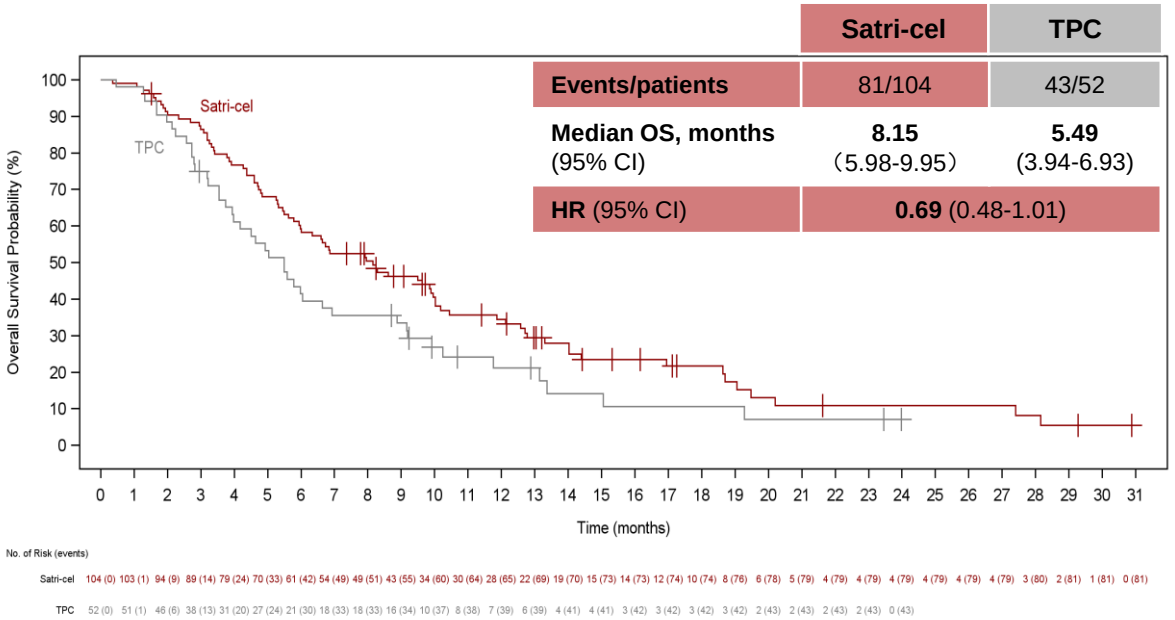
[#]Including All TRAEs with an incidence of ≥ 20% or Grade ≥ 3 with incidence of ≥ 5%.
*TRAEs: treatment-emergent adverse events (TEAEs) related to treatment.
Treatment was defined as bridging therapy, lymphodepletion and Satri-cel infusion in Satri-cel group and treatment of physician's choice in TPC group.

Adhoc analysis: OS

Updated analysis with 5 months additional follow-up after primary analysis

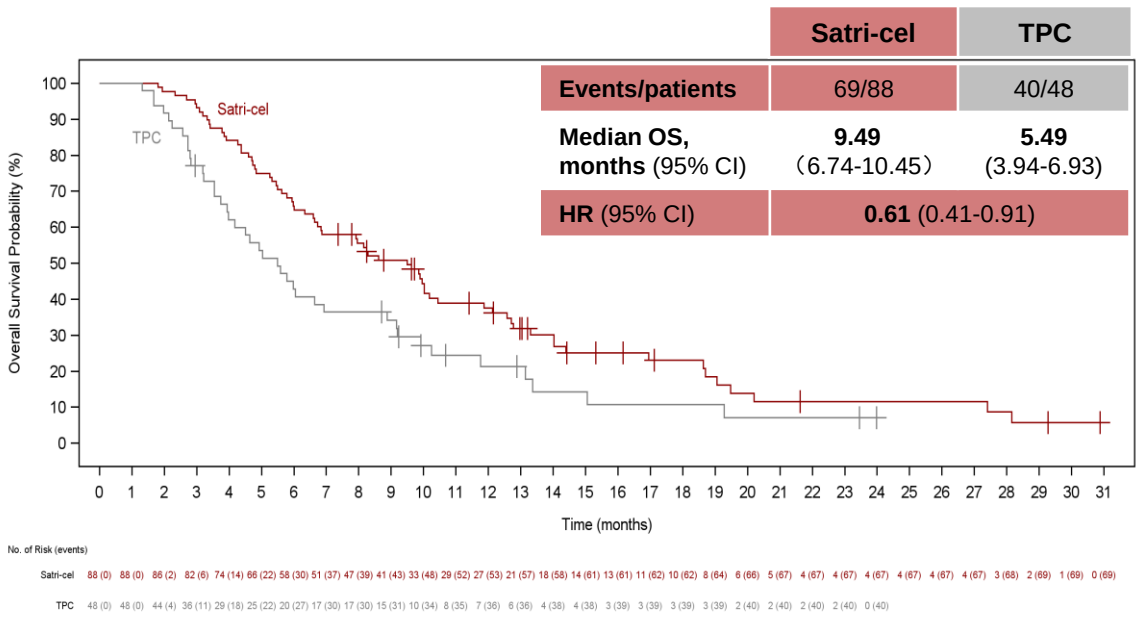
OS improvement are more obvious in the satri-cel group with longer follow-up

OS (ITT)



	Satri-cel	TPC
Events/patients	81/104	43/52
Median OS, months (95% CI)	**8.15** （5.98-9.95）	**5.49** (3.94-6.93)
HR (95% CI)	**0.69** (0.48-1.01)	

OS (mITT)



	Satri-cel	TPC
Events/patients	69/88	40/48
Median OS, months (95% CI)	**9.49** （6.74-10.45）	**5.49** (3.94-6.93)
HR (95% CI)	**0.61** (0.41-0.91)	

Date cutoff: March 18, 2025.
Median follow-up: : 17·12 months (satri-cel group) vs 23.46 months (TPC group).

Limitations

- The sample size in this study was powered for primary endpoint and therefore, may not be adequate to yield definitive conclusions from the subgroup analyses.
- There were 16 patients whose CAR T-cells could not be infused after apheresis in the satri-cel group mostly due to rapid tumour progression, which led to patients no longer meeting the eligibility criteria for CAR T-cell treatment.
- Future improvements may involve speeding up CAR T-cell manufacturing or performing early apheresis in clinically stable frontline patients.

Conclusions / Key Takeaways

- Satri-cel/CT041 demonstrated **statistically significant PFS improvement and clinically meaningful overall survival benefit** in G/GEJC patients compared to standard of care.
  - In ITT population, mPFS assessed by IRC: HR 0.366 (95% CI: 0.241, 0.557; p<0.0001); mOS: HR 0.693 (95% CI: 0.457, 1.051; one-sided p=0.0416)
  - In mITT population (treated patients), mPFS assessed by IRC: HR 0.304 (95% CI: 0.195, 0.474); mOS: HR 0.601 (95% CI: 0.385, 0.939)
- This trial expanded the the percentage of CLDN18.2 positive patients with G/GEJC.
- We observed a manageable safety profile alongside long-term benefit in many patients.
- These data suggest that satri-cel could become a new treatment option and provide a strong rationale for continued investigation of satri-cel in earlier lines of treatment for patients with advanced G/GEJC.

Full Publication- *The Lancet*

Claudin-18 isoform 2-specific CAR T-cell therapy (satri-cel) versus treatment of physician's choice for previously treated advanced gastric or gastro-oesophageal junction cancer (CT041-ST-01): a randomised, open-label, phase 2 trial

Changsong Qi, Chang Liu*, Zhi Peng*, Yanqiao Zhang*, Jia Wei*, Wensheng Qiu*, Xiaotian Zhang, Hongming Pan, Zuoxing Niu, Meng Qiu, Yanru Qin, Weijia Fang, Feng Ye, Ning Li, Tianshu Liu, Anwen Liu, Xizhi Zhang, Changlu Hu, Jun Zhang, Jiuwei Cui, Xiaoyan Lin, Shubin Wang, Jian Zhang, Tongyu Lin, Xiujuan Qu, Xianglin Yuan, Jifang Gong, Jian Li, Wanwan Gao, Lun Gai, Yumeng Wang, Daijing Yuan, Zonghai Li, Lin Shen*

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- This study was sponsored by CARsgen Therapeutics Co., Ltd. We thank Shumin Wang and Weimeng Feng for medical writing support, as well as Xiang Zhang and Zijing Zhang for statistical analysis.

Lay Summary

- Globally, this is the first ever study of CAR T-cell therapy compared with the current available standard of care, it aims to show whether CAR T-therapy can achieve a better efficacy in late-stage gastric cancer.
- In this study, late-stage gastric cancer patients with a tumor biomarker positive, namely CLDN18.2, was included. When compared with the standard treatment, the CAR T-therapy product, namely satri-cel or CT041, showed a significantly longer survival without disease progression or death. Meanwhile, satri-cel also demonstrated a much longer overall survival time and higher tumor reduction rate. The unintended adverse reactions can be managed by physicians.
- These data suggest that satri-cel could become a new treatment option for this patient population. Continued investigation of satri-cel in earlier lines of treatment for gastric cancer patients could be expected.