

研究报告

2023

5

126

2023

05

25

.....	1
CAR-T	3
CAR-T	3
CAR	4
CAR-T	

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2022 5

“ ”

2012

2020

2022 9

2023 3



T

(Chimeric Antigen Receptor T-Cell Immunotherapy CAR-T)

2012

7

CAR-T

CAR-T



CAR-T

CAR

T

CAR

“

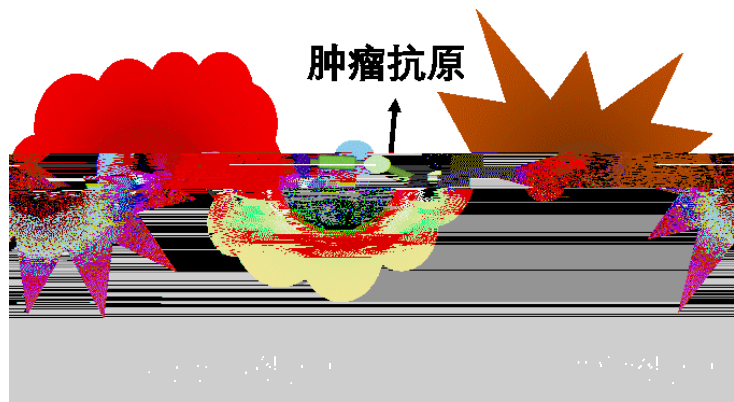
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CAR-T

CAR

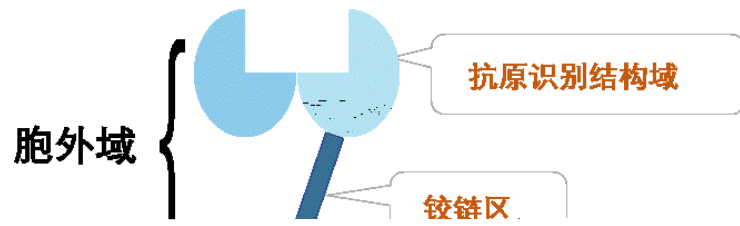


CAR

CAR

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CAR



- CAR T
 scFv CAR
 “ ”

CAR

- CAR
 CAR T
 CD3 CD4 CD8

CD28

- CAR
 T

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4-1BB

CD27

CAR-T

CAR-T

30

CAR-T

T

- **CAR** **scFv**



T

- CAR CD28

4-1BB T “ ”

CAR T

CAR-T CD28

T 4-1BB

CAR-T

CAR-T

CAR-T

- CAR

CD28 4-1BB CD28 OX40

T CAR-T

CAR-

T CAR-T

- CAR

T TRUCK T

T IL-12

NK

- CAR-T CAR-T UCAR-T

T

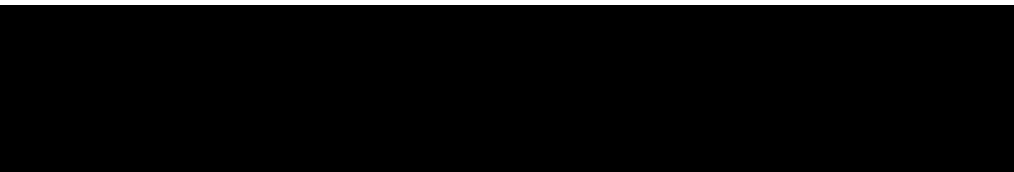
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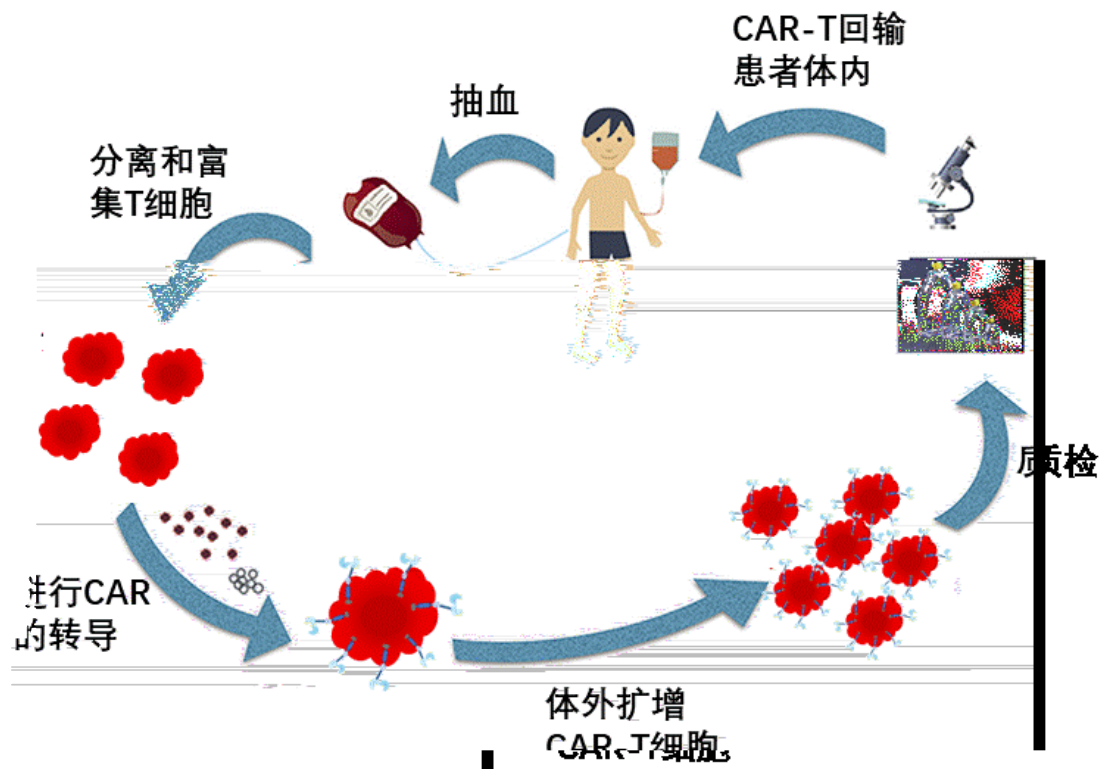


T

CAR-T

	CD3 ζ T	T T
	CD28 4-1BB	CAR-T CAR-T
	CD28 4-1BB CD28 OX40	
	IL-12	
	T CAR-T CAR-T UCAR-	T
T		





2 CAR-T

CAR-T

PBMC

T

T

CAR

CAR-T

CAR-T

10-25

Kymriah

22

Yescarta

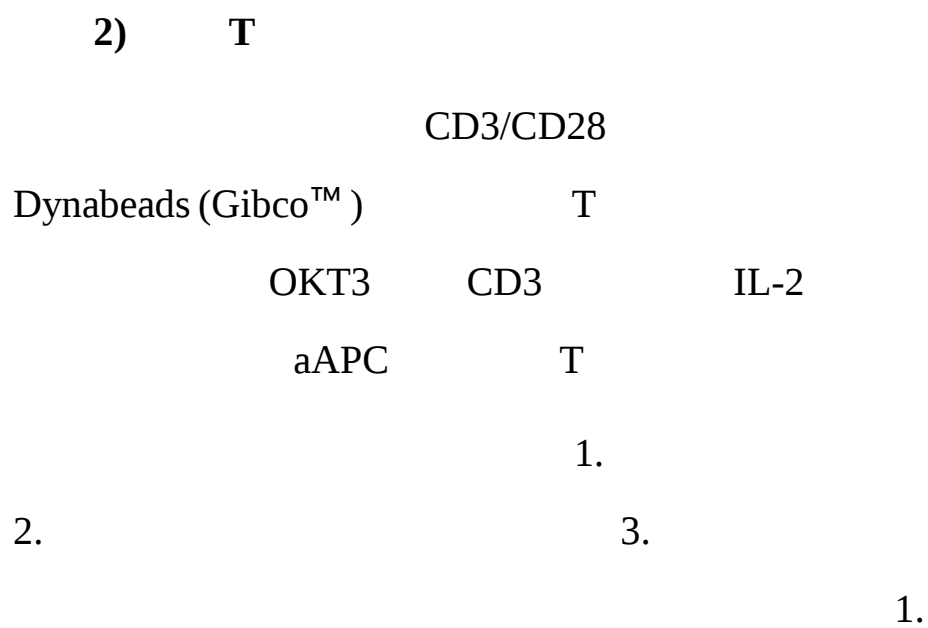
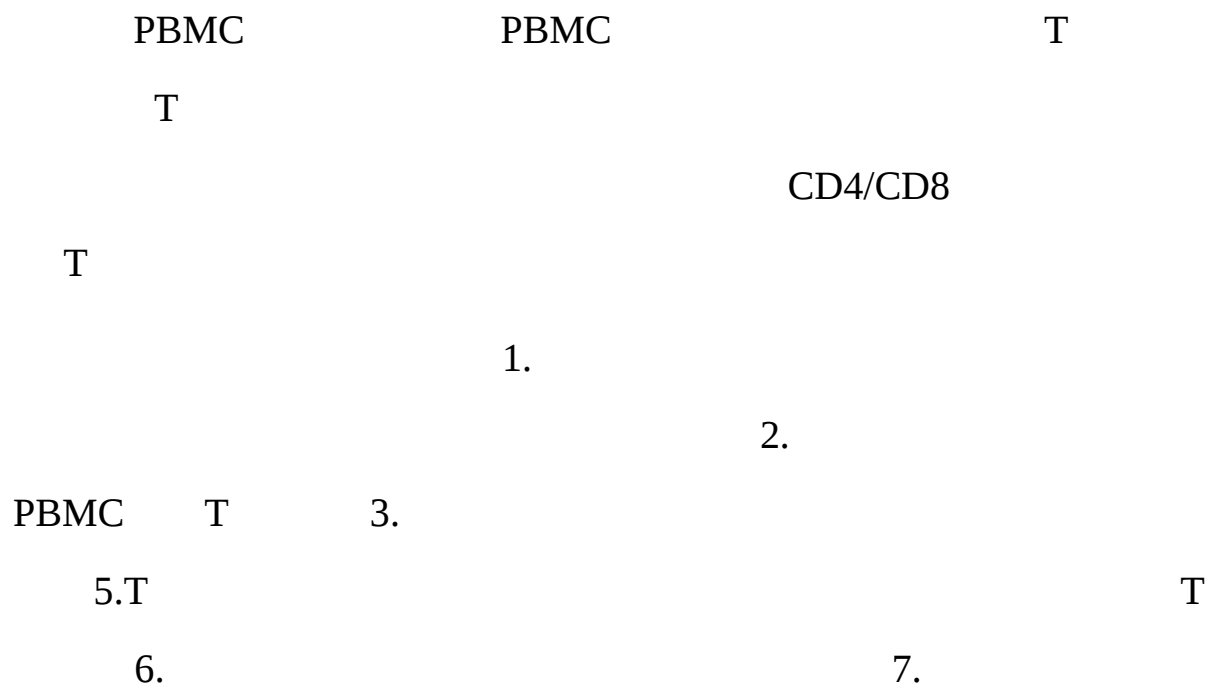
17

1)

PBMC

T

CAR-T





CD3

CD28

IL-2

T

T

3) CAR

CAR

T

CAR-T

CAR

T

-

T

95%

GMP

DNA

CAR-T

CAR

1.

T

2.

T

3.

CAR

T

```

graph TD
    T1[T] --> CAR_T1[CAR-T]
    T1 --> T2[T]
    CAR_T1 --> CliniMACS_Prodigy_1[CliniMACS Prodigy]
    T2 --> CliniMACS_Prodigy_2[CliniMACS Prodigy]
    CliniMACS_Prodigy_1 --> CAR_T2[CAR-T]
    CliniMACS_Prodigy_2 --> T3[T]
    CAR_T2 --> Wave[Wave]
    T3 --> 5L[5L]
    Wave --> G_Rex[G-Rex]
    5L --> 1_CO2[1.CO2]
    G_Rex --> 2[2.]
    1_CO2 --> 3[3.]
    2 --> 4[4.]
    3 --> 5[5.]
    4 --> T4[T]
    5 --> T4
  
```

5)

CAR-T

CAR-T

1.

2.

3.

4.

5.

CAR-T

3 CAR-T

FDA

CAR-T

IND

GMP

CAR-T

CAR-T

CAR-T

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CAR-T

CAR-T

	GMP
CAR-T	

CAR-T

QC

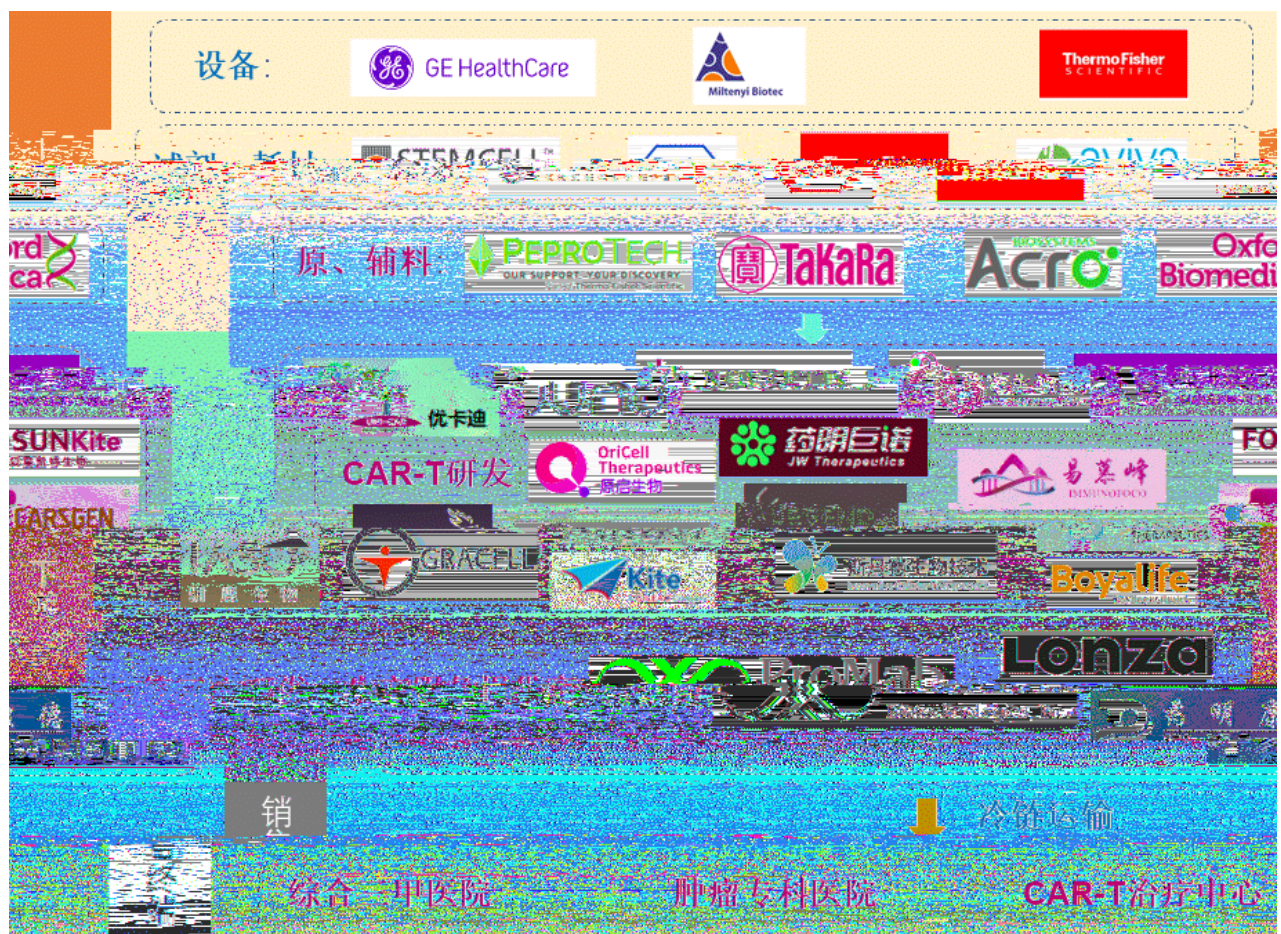
QC

CAR-T

CAR-T

T

CAR-T



• CAR-T

CAR-T



T

GE

Clinic MACS Prodigy

Lonza Co-coon

CAR-T

- **CAR-T**

CDMO

CAR-T

CMO/CDMO

CAR-T

- **CAR-T**

CAR-T

CAR-T

CAR-T

301

CAR-T

CAR-T

2022

30

56%

CAR-T



CAR-T

8

CAR-T

2

B

B

WHO

2021

1975.8

90%

130.5

10%

CAR-T

CAR-T

CAR-T

CAR-T

2017

CAR-T

CAR-T

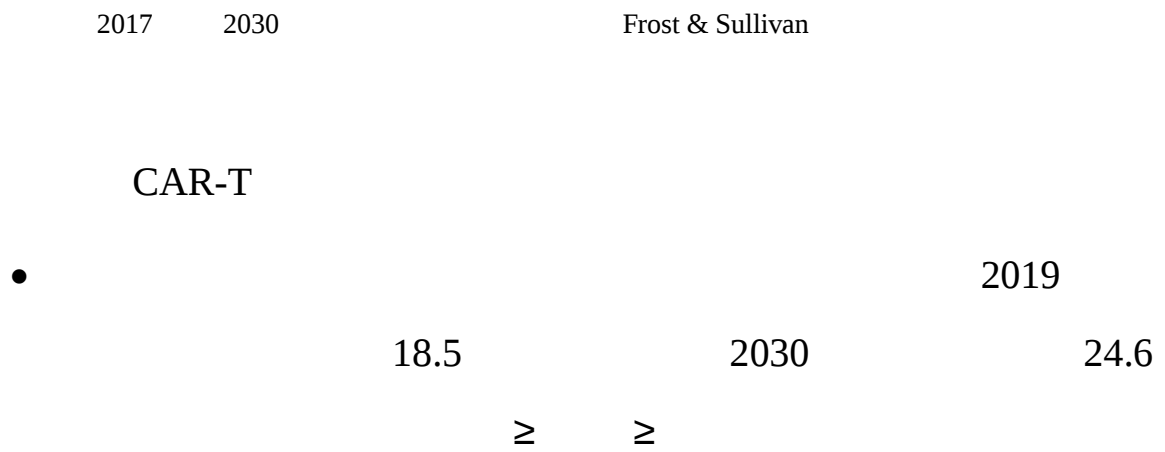
Kymriah

Yescarta

CAR-T

CAR-T

22.1%





CAR-T

-

2019 4.4

2030 5.8

CAR-T

-

CAR-T

“ + ”

2017

CAR-T

-

2009

CAR-T

-



CAR-T

CAR-

T

CAR-T

2009	✓ NK T
2015	✓ ()
2015	✓ “ ” “ ”
2016	✓ “ ”
2016	✓ “ ”
2017	✓ ()
2018	✓ CAR-T CAR-T
2021	✓

2022 CAR-T

Kymriah		CD19	B /	47.5 /		2017.08
Yescarta	/	CD19	B 12 B	37.3 /		2017.10
Tecartus	/	CD19	/ B	37.3 /		2020.07
Breyanzi	BMS	CD19	B	41.03 /		2021.02
Abecma	BMS/ bluebird bio	BCMA		43.79 /		2021.03
Yescarta		CD19	B			2021.06

B

3

CAR-T

CTL019

FDA

ALL

CAR-T

2018

B

5

FL

4-2

✓

ELIANA

✓

B

✓

ORR

80

6

60

CR

✓

CRS

77

NT

40

✓

JULIET

✓

18

B



✓	ORR	52	40%	CR	3
	CR		CR	12	80%
✓		Kymriah 8	3/4	CRS	22% 15%
		2 CRS	3%	3 CRS	50%
		CRS			
✓	ELARA				
✓			2	/	
✓	ORR	86%	CR	68%	
✓				>20%	CRS

	Kymriah		CAR	
	CD19		FMC63	
	Kymriah		CAR-T	
			4-1BB	
	Kymriah		47.5	
	37.3	/	2020	Kymriah
	68%		Kymriah	
			Kymriah	
	2022		Kymriah	
2022	Kymriah	5.36	9%	2022
			CAR-T	
B			CAR-T	
Yescarta	Breyanzi		Kymriah	
			Kymriah	



		Kymriah		37.3	/
Yescarta	Breyanzi	37.3	/	41.03	/

		ORR	CR	CRS	NT	
--	--	-----	----	-----	----	--

2 Yescarta

CAR-T

Yescarta axicabtagene ciloleucel KTE-C19 FKC876

/Kite Pharma

CD19

CAR-T

2017

FDA

B

DLBCL

2021 3

Yescarta

2

FL

2022

4

Yescarta

12

B

LBCL

4-4

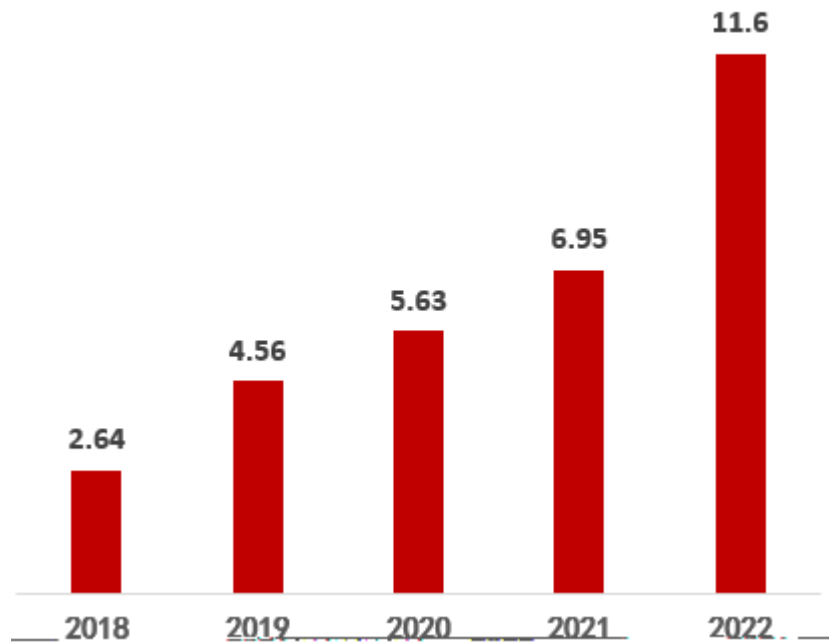
1									
✓	ZUMA-1								
✓	101	/	B						
✓	ORR	72%	CR	51%	OS				
	6								
✓	13%				CRS	31%	NT		
2									
FL									
✓	ZUMA-5								
✓	146								
✓	ORR	91%	CR	60%					
✓	8%				CRS	21%	NT		
3									
✓	ZUMA-7								



✓	359	Yescarta			
✓		Yescarta	6.3	8.3	vs 2.0
		Yescarta			
		2.5	55%		
		Yescarta			
✓	168	Yescarta		7%	25%
		CRS	NT		

	Yescarta	-	CAR
	CD19	FMC63	
CD28	Kymriah	CAR-T	CD28
	Yescarta	37.3	/
Kymriah	DLBCL	2022	Yescarta
11.6	67%	Kymriah	5
	Yescarta		

Yescarta 全球销售额（单位：亿美元）



Yescarta 2017 1 Kite
 Pharma Yescarta
 2020 2 NMPA
 Yescarta DLBCL 2021 6
 NMPA

CAR-T

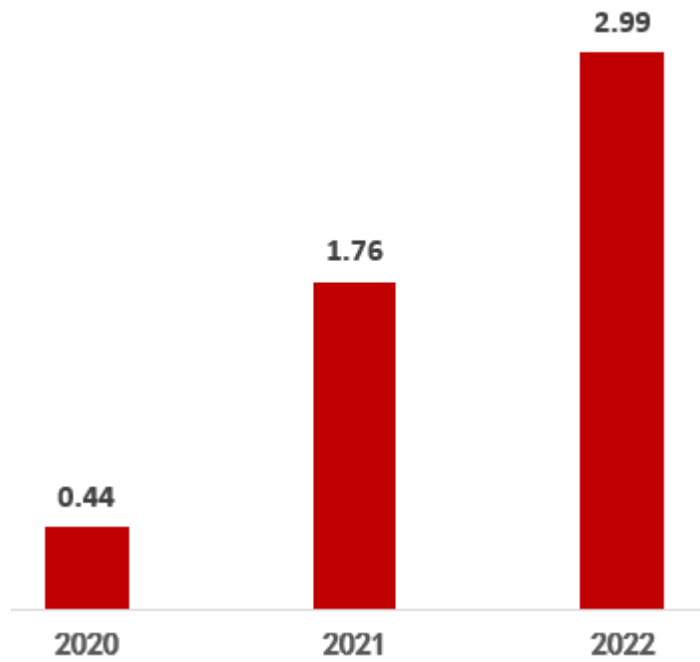
3 Tecartus

CAR-T

Tecartus brexucabtagene autoleucel KTE-X19

/Kite Pharma CD19 CAR-T 2020 7
 FDA Tecartus MCL
 Tecartus MCL CAR-T 2021
 10 Tecartus FDA B

Tecartus 全球销售额（单位：亿美元）



4 Breyanzi CD19 CAR-T

Breyanzi lisocabtagene maraleucel JCAR017 BMS
 CD19 CAR-T 2021 2 FDA Breyanzi
 B DLBCL
 4-6

✓	TRANSCEND NHL 001								
✓	268	r/r LBCL			B				
	B	3B							
✓	256	ORR		73%	CR	53%			
✓	46	CRS		4	CRS		35		
NT	12	NT							

Breyanzi

CAR



CD19 FMC63 CD28
Kymriah CAR-T 4-1BB
Breyanzi 41.03 / 2022
1.82

5 Abecma

BCMA CAR-T

Abecma idecabtagene vicleucel bb2121 BMS Bluebird
B BCMA
CAR-T 2021 3 Abecma FDA
3
CD38 / r/r MM
Abecma BCMA CAR-T
4-7

✓	KarMMa								
✓	127								
✓			ORR	72%	CR	28%			
✓	85	CRS		CRS		9	28%		
	NT	NT	4						

Abecma CAR
CD8 CD8 Abecma CAR-T
4-1BB CD3
Abecma 41.95 / 2022
3.88 Abecma 6.29



Abercma MM 5
/ BCMA CAR-T
BCMA CAR-T

6 CAR-T

Yescarta

Axi-Cel

Kite

Yescarta 2021 6 NMPA

CAR-T

120 /

B

ORR

79.2% ZUMA-1

7 CAR-T

relma-cel

JWCAR029

Juno

Breyanzi

CD19 CAR-T 2021

9 NMPA

B

r/r LBCL 2022 10

NMPA

r/r FL

4-8

CAR

4-1BB

CAR-T

129 /

8

BCMA CAR-

T

CARVYKTI

Cilta-

cel

BCMA CAR-T

Abecma

BCMA CAR-T

r/r MM

4-9





✓	2021	12	ASH			Ib/II	CARTITUDE-1	
		18	97			ORR	97.9%	80.4%
		sCR	2022	2	28	FDA	sCR	78.4%
✓		CRS	7					

CAR

4-1BB

CAR-T

46.50

/

Abecma

41.95

/

BCMA

CAR-T

FDA

ORR

CR

Abecma

mPFS

8.8

mPFS

mOS

20

	Kymrian	CD19	FMC63 CD8 CD3 CAR-T	CAR CD19 4-1BB	

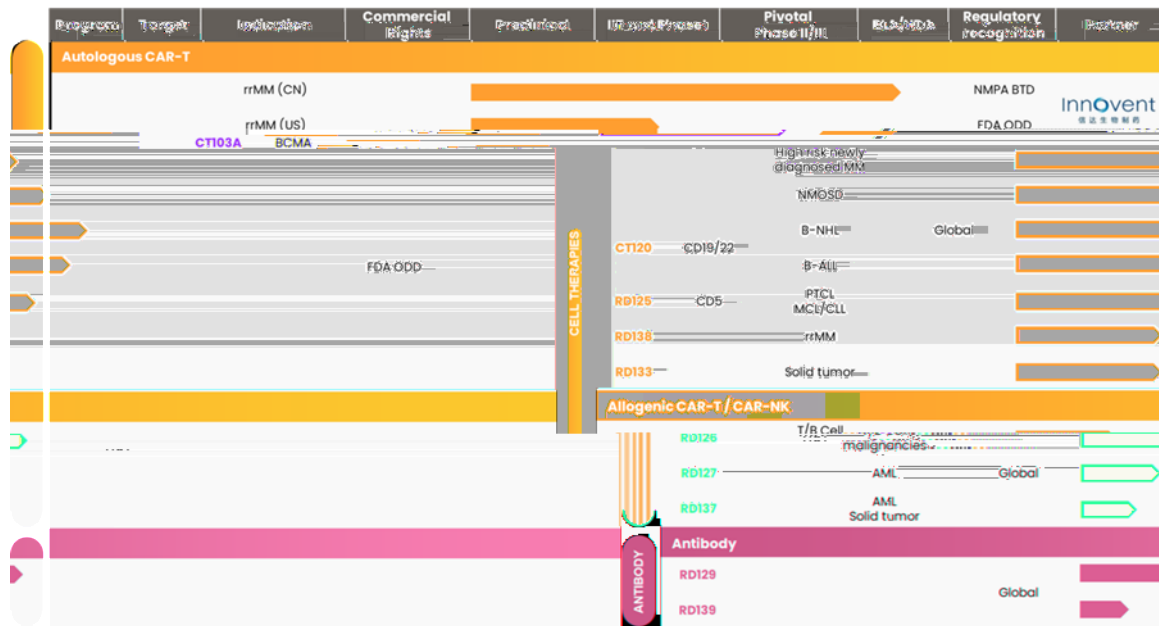
/Kite Pharma	Yescarta	CD19	- CAR CD19 FMC63 CD28 CD28 CD3 CAR-T	Kite Pharma 2017
/Kite Pharma	Tecartus	CD19	Tecartus Yescarta CAR Tecartus XLP™ 15 96%	Kite Pharma NIH
BMS	Breyanzi	CD19	CAR CD19 FMC63 CD28 4-1BB CD3 CAR-T	
BMS / Bluebird	Abecma	BCMA	CD8 CD8 4- 1BB CD3 CAR-T	BMS Bluebird Bio
		CD19	Yescarta	Kite Yescarta
		CD19	Breyanzi CD4 CD8 T 1:1	

			CD4	
			CD8 T	
		BCMA	CAR sdAbs CD3 ζ 4-1BB CAR-T	

CAR-T

全球					美国					中国				
I期	II期	III期	临床前		I期	II期	III期	临床前		I期	II期	III期	临床前	
多发性骨髓瘤 (BCMA)[†] 同种异体	胃癌[†] (CLAUDIN 18.2) 自体	复发或难治性多发性骨髓瘤 (BCMA) LEGEND-2 [†] 自体 NCT03090659	复发或难治性多发性骨髓瘤 (BCMA)[*] CARTIFAN-1 自体 NCT03758417	复发或难治性多发性骨髓瘤 (BCMA)[*] 1-3 前线治疗 CARTITUDE-4 自体 NCT04181827										
非小细胞肺癌 (GPC3) 自体	小细胞肺癌 (DLL3) 自体	胃癌[†] (CLAUDIN 18.2) 自体 NCT04467853	复发或难治性多发性骨髓瘤 (BCMA)[*] CARTITUDE-1 自体 NCT03954520	新诊断多发性骨髓瘤 (BCMA)[*] 没有移植倾向 CARTITUDE-5 自体 NCT04923333										
胰腺癌 CLAUDIN 18.2) 自体		肝细胞癌[†] (GPC3) 自体 NCT05352542	多发性骨髓瘤 (BCMA)[*] CARTITUDE-2 自体 NCT04133636											

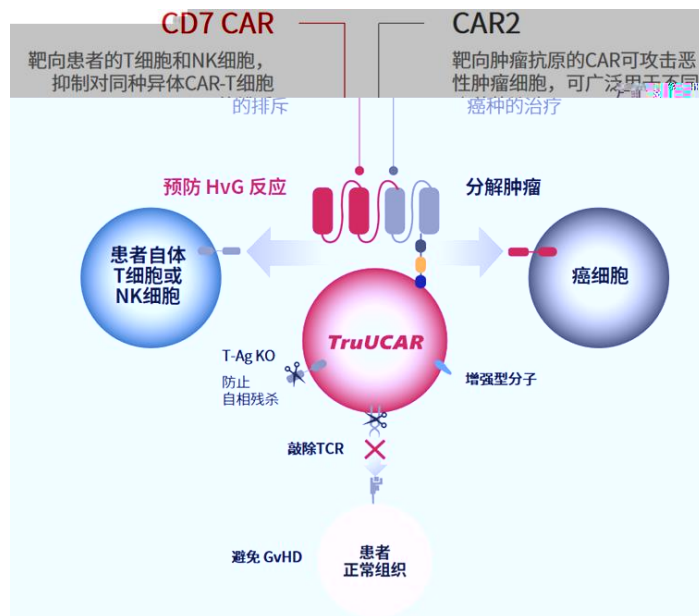
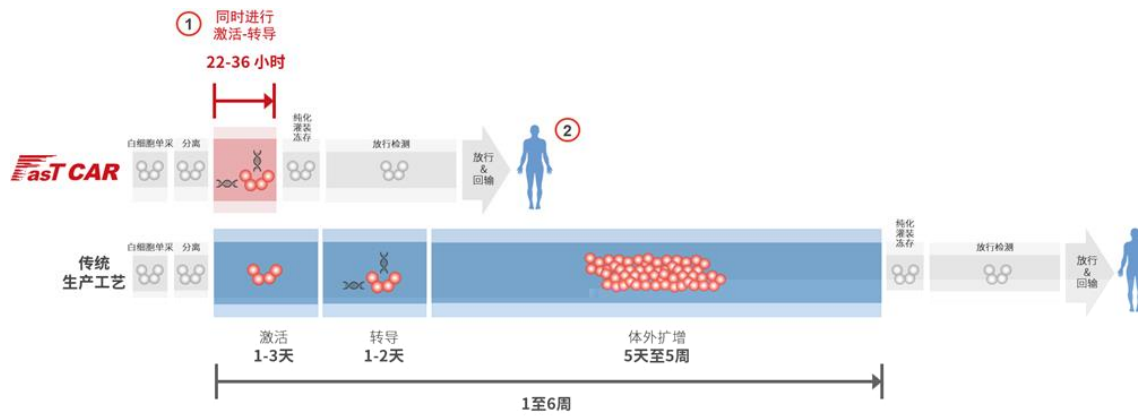
CAR-T细胞疗法							
候选产品 ¹	技术	靶点	适应症	临床前	I期	II期/III期 ²	BLA/NDA
泽沃基奥仑赛注射液 Zevor-cel(CT053) ³	常规技术	BCMA	多发性骨髓瘤	LUMMIGAR 1 (中国)			
			多发性骨髓瘤	LUMMIGAR 2 (美国, 加拿大)			
			多发性骨髓瘤	IIT (中国)			
CT041	常规技术	Claudin18.2	胃癌	ST-01 (中国)			
			胃癌、胰腺癌	ST-02 (美国, 加拿大)			
			胃癌、胰腺癌等	IIT (中国)			
CT011	常规技术	GPC3	肝细胞癌	(中国)			
CT0180	sFv-ε	GPC3	肝细胞癌	IIT (中国)			
CT0181	sFv-ε	GPC3	肝细胞癌	IIT (中国)			
CT0590	THANK-uCAR [®]	BCMA	多发性骨髓瘤	IIT (中国)			
CT048	CycloCAR [®]	Claudin18.2	胃癌、胰腺癌	IIT (中国)			
CT071	未披露	GPC5D	多发性骨髓瘤				
KJ-C2113	CycloCAR [®]	间皮素	实体瘤				
KJ-C2114	THANK-uCAR [®]	未披露	实体瘤				
KJ-C2320	未披露	未披露	急性髓系白血病				





1. 若2期临床研究为注册性试验，则未必要开展3期临床试验。

2. * IIT (研究者发起的临床试验) 为可选而非强制，可作为独立项目安全性和潜在有效性的早期证据。恒嘉生物计划将中国IIT研究中的数据用于向FDA和NMPA提交IND申报；此章并不保证FDA和/或NMPA会接受这些数据。



ID#	靶点	适应症	特点/优劣	里程碑	研发阶段
PA3-17	CD7	复发/难治性T淋巴瘤细胞白血病/淋巴瘤	First and best-in-class potential	2021.08: 中国获批IND 2021.11: 获得FDA孤儿药认定 2022.12: 获得欧委会孤儿药认定	注册临床试验
TAA06	B7-H3	神经母细胞瘤	First and best-in-class potential	2022.03: 获得FDA孤儿药认定 2023.03: 获得FDA儿科罕见病认定 2022.07: 中国获批IND	注册临床试验
UTAA06-γδT	未披露	急性髓系白血病、实体瘤	First-in-class potential	完成中试工艺和体内研究	IIIT
UTAA07-γδT	未披露	复发/难治性T淋巴瘤细胞白血病/淋巴瘤	First-in-class potential	体内研究	临床前
UTAA05-γδT	未披露	急性髓系白血病	First-in-class potential	体内研究	临床前
UTAA13-γδT	未披露	外周T淋巴瘤、NKT淋巴瘤、间变大细胞淋巴瘤	First-in-class potential	体外研究	临床前
UTAA09/17-γδT	未披露	自身免疫病	First-in-class potential	体外研究	临床前
TAA08-mRNA	未披露	衰老相关慢性病	First-in-class potential (in vivo mRNA)	体内研究	临床前
TAA16/13-BsAb	未披露	外周T淋巴瘤、NKT淋巴瘤、间变大细胞淋巴瘤	Best-in-class	体外研究	临床前
LV-based GD	未披露	恶性肿瘤、慢性病	First-in-class potential	体外研究	临床前
UTCR-γδT	未披露	实体瘤	First-in-class potential	体外研究	临床前

平台技术	候选产品	靶点	适应症		专利	临床前	IIT	IND	I期	II期/NDA
SMART	U01	CD19		B淋巴细胞白血病 中枢神经系统白血病	√					
	U51	BCMA		多发性骨髓瘤	√					
MADDS	U16	未披露	血液瘤	非霍奇金淋巴瘤	√					
	U30	未披露		急性髓细胞白血病	√					
SMART MADDS	U87	未披露	实体瘤	自体型 胰腺癌、肺癌、三阴 乳腺癌	√					
	U90	未披露		通用型 肝癌、肺癌	√					

管线进度更新于2021.12.31。

“ ”

	3A	✓ Juno
B	IPO	

	3 IPO	✓ BCMA
		✓ Kite Pharma Yescarta Kite Pharma
	7 A B B+ Pre-C C C+ IPO	✓ CLDN18.2 CAR-T HCC GPC3 CAR-T
	6 A B C C+	✓
	6 A B C IPO	✓ FasTCAR TruUCAR
	4 A B	✓ CD7 T / CD7 CAR-T
	4 A B B+ C	✓ ssCART-19 CAR-T & IL-6 IL-6

CAR-T

CAR-T

CAR-T



-1 PD-L1

CAR-T

TME

CAR-T

CAR-T

1

CAR-T

Claudin18.2

MSLN

3 GPC3

Claudin18.2 CLDN18.2		Claudin18.2 CAR -T CT041 ORR 48.6% ORR 57.1% ORR 61.1% ≥ 3 CRS
MSLN		- MSLN CAR-T 23 OS 17.7 ≥ 2 CRS

		GPC3	CAR-T	Ori-
		CAR-001	/	
3	GPC3	HCC		9
			ORR	44%

2 CAR

CAR-T

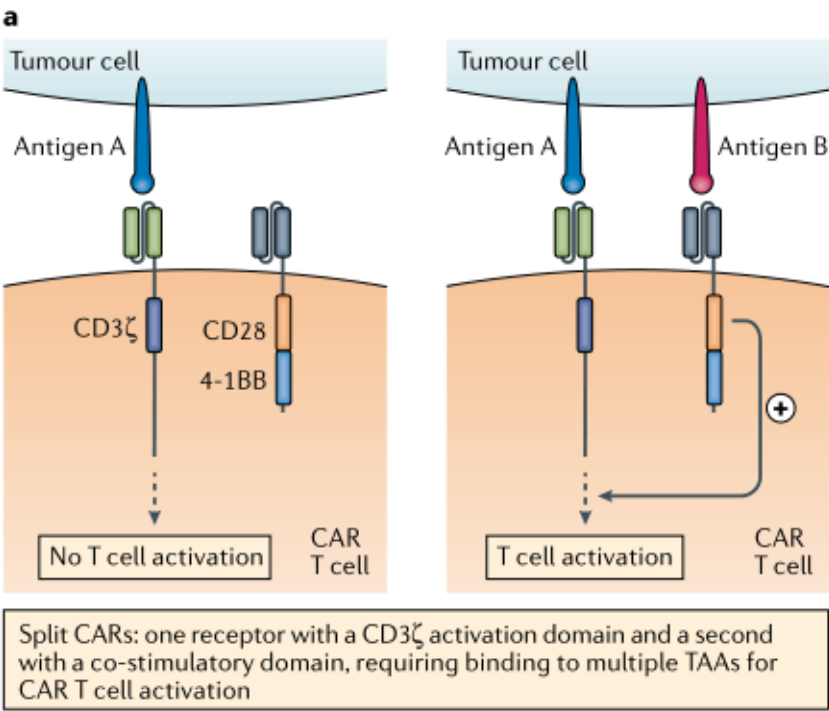
CAR

TAA scFv

CAR-T

TAA

CAR-T



synNotch-CAR T

CAR-T

synNotch

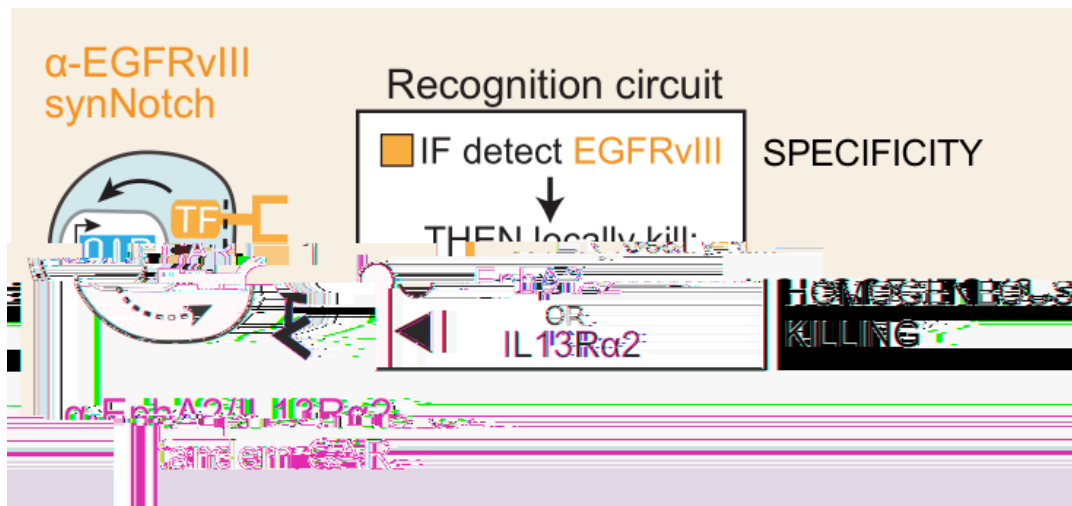
CAR-

T

CAR-T

“

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3

TME

PD-L1

T

PD-

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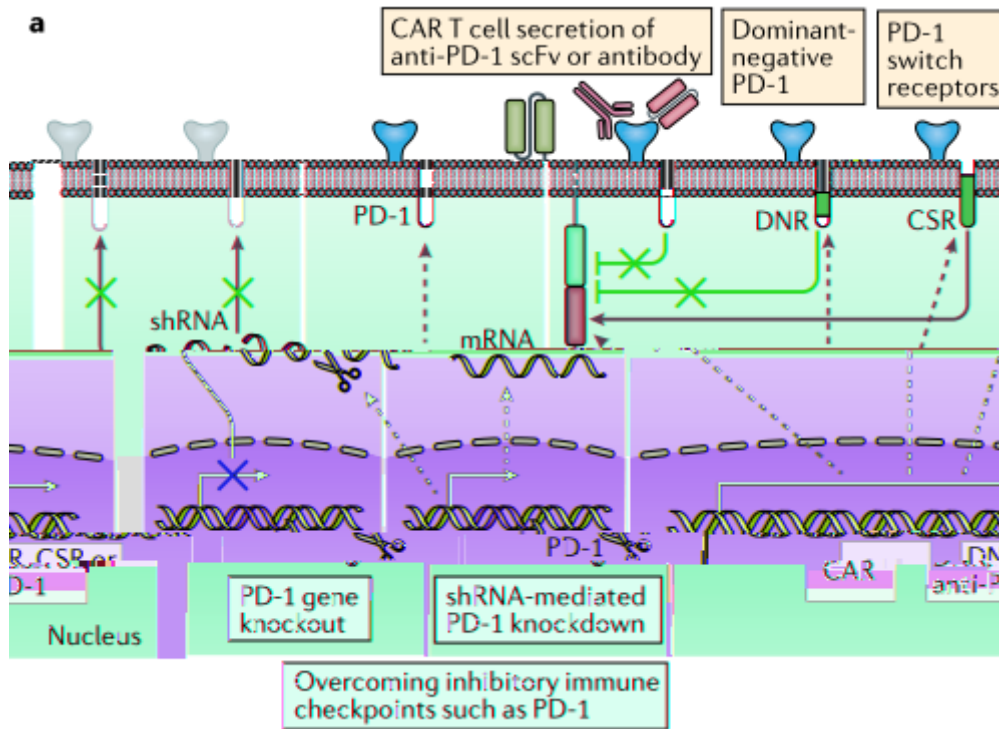
PD-1 DNR

PD-L1

PD-1/PD-L1

PD-1/PD-L1

CAR-T



2021

PD-1

MSLN CAR-T

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IL-12

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IL-

12

CAR-T

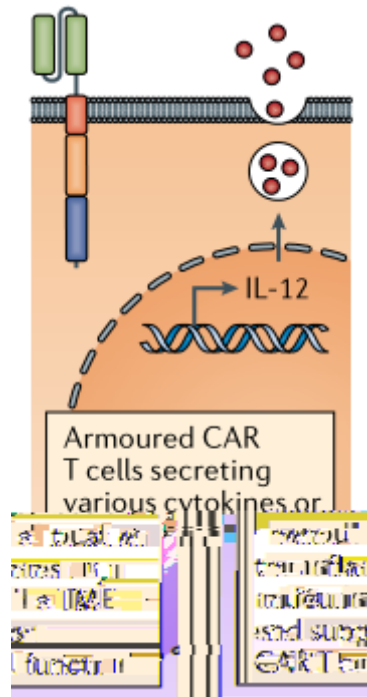
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GPC3 CAR-T

IL-12

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GPC3



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CAR-T

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CAR-T

CXCR5

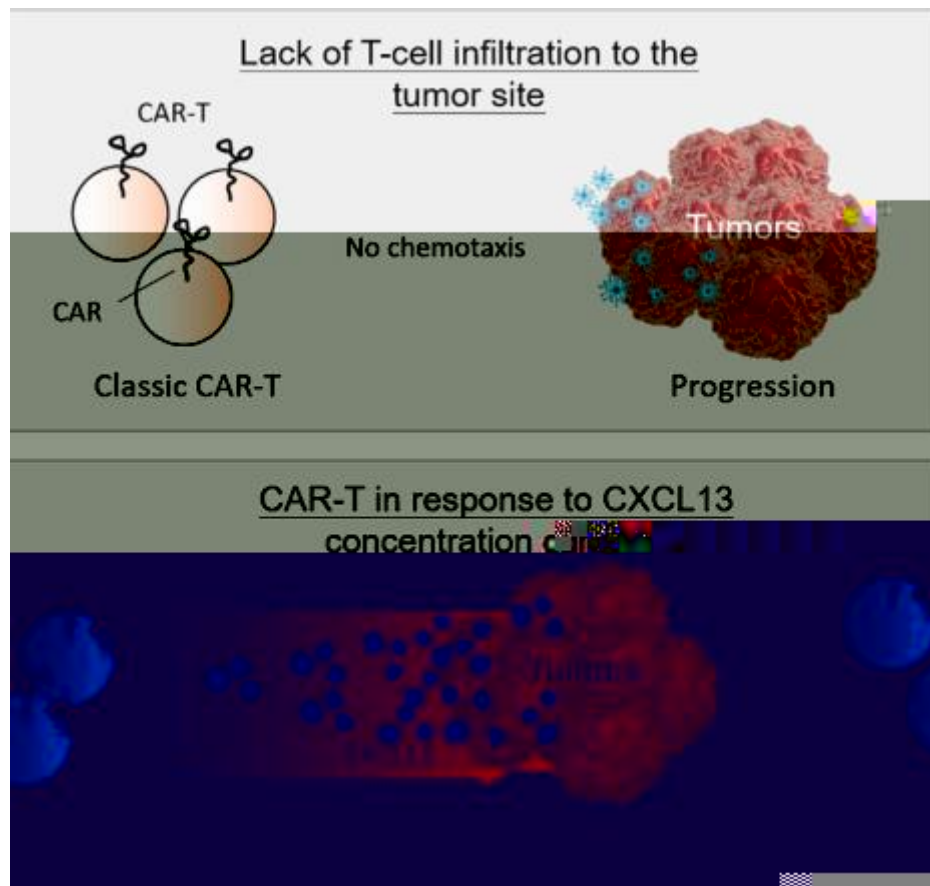
EGFR

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CLDN18.2

CLDN18.2

CAR-T

CT041

CT041



				ORR	48.6%			ORR
57.1%	CT041			CAR-T				
				HCC				
GPC3				CAR-T	CT011	2019	7	
13				HCC	CT011			ORR
20%	3	1	6			10.5%		42%
50.3%				OS	278			
5	CRS	7.7%	1/13	≥ 3	NT			

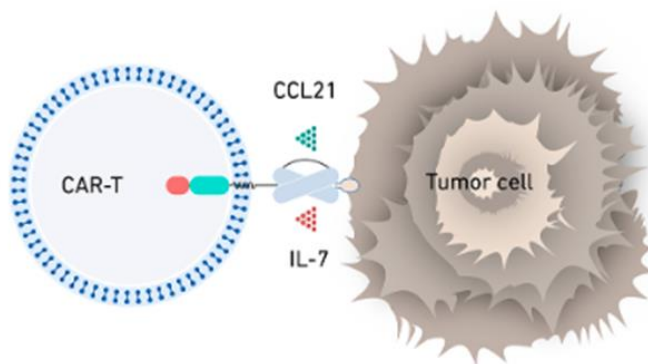
CycloCAR® (Cytokine and Chemokine Loaded CAR)

CycloCAR T CAR

IL-7

CCL21 IL-7 CAR-T

CCL21 CAR-T





Combo-CAR

CAR-T

CAR-T

CT011 GPC3 CAR-T

CT011

CAR-T

CAR-T

CAR-T

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2015

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CAR-T产品管线

原启生物所属权开发管线 原启生物对外合作开发

Cell Therapy Programs	Indication	POC	IND-enabling	IND	Phase I	Phase II/III	IP
CD19-CAR	HBB					Global	
CD19-CAR	Myeloma					Global	
CD19-CAR	Myeloma					Global	
CD19-CAR	Solid Tumor					Global	
CD19-CAR	Solid Tumor					Global	
CD19-CAR	Solid Tumor					Global	
CD19-CAR	Solid Tumor					Global	

Ori®CAR

CAR-T 2022 9 GPC3

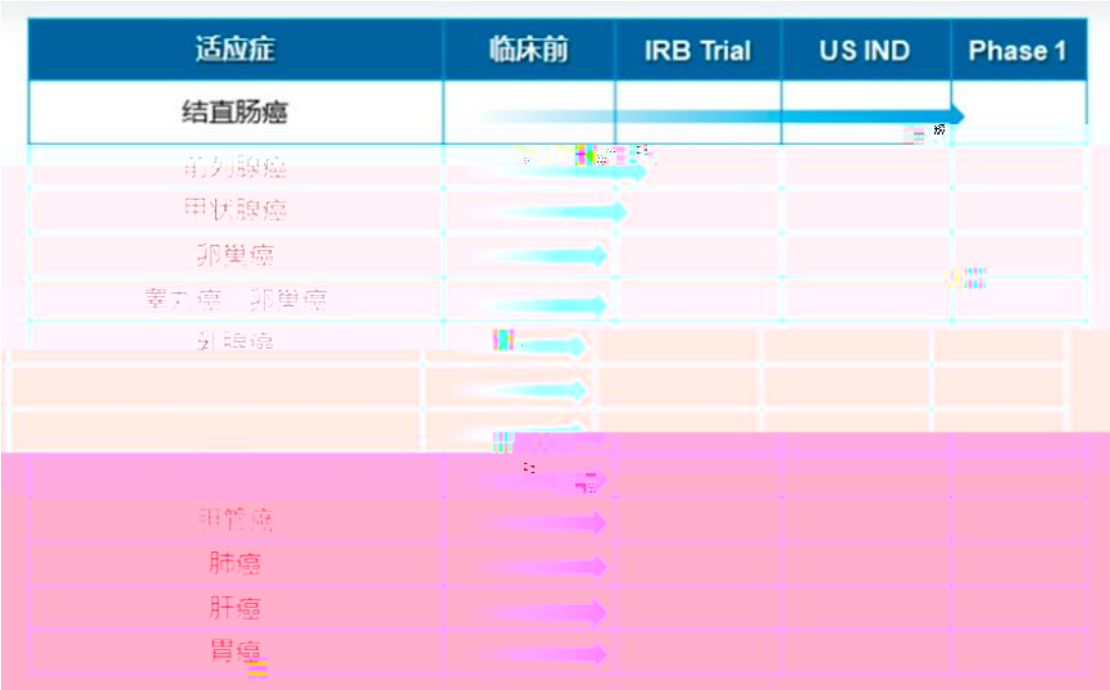
CAR-T -C101

3

ICT

CoupledCAR®

CAR-T



GCC19CART

CoupledCAR®

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GCC19CART

CAR-T

4

2022

4

B7-H3

CAR-T

TAA06

FDA

2022

ESMO

TAA06

TAA06

5

2016

CAR-T

CAR-T

CAR-

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CAR-T

产品	适应症	IIT/II	临床前	临床I期	临床II期	NDA
pCAR-19B	急性淋巴细胞白血病 (3-21岁) 急性淋巴细胞白血病 (22-70岁)					
C-4-29	多发性骨髓瘤 肾细胞癌					
C-13-60	实体瘤					
C-13-90	实体瘤					
D-2-27	急性淋巴细胞白血病/非霍奇金淋巴瘤					
UCAR-T	急性淋巴细胞白血病/非霍奇金淋巴瘤					
UCAR-NK	急性髓系白血病					



2022

12

CEA

CAR-T

-13-60

CEA CAR-T

6

2013

2023

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CAR-T

anti-PD1 MSLN-CAR-T

IND

CAR-T

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KD-

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CAR-T




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Booster

2023

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IMC002

CLDN18.2

CAR-T

IND

FDA

CLDN18.2

	7 A B B+ Pre-C C C+ IPO	✓ CLDN18.2 CAR-T HCC GPC3 CAR-T
	4 Pre-A A B B+	✓ Ori®CAR CAR T TME

	3 A B C	✓ CoupledCAR® CAR-T ✓ GCC19CART CAR-T
	4 A B	✓ B7-H3 CAR-T TAA06
		✓ CEA CAR-T
	7 A B C D	✓ IND CAR- T
	4 A A+	✓ NKG2DL CAR-T
	6 Pre-A A A+	✓ Peri Cruiser®

CAR-T

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				STAR-T
				YTS104
	STAR-T			/
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				IND
	CAR-T			CAR-T
	PD-1			
	CAR-T			

	BCMA CD123 CD19 CD20 CAR-T CEA CAR-T			C-4-29 CAR-T CEA CAR-T
	CD19 CAR-T CD19-BBz 86			CD19 CAR-T
	CRISPR/Cas9 CAR-T PD1-19bbz			CRISPR/Cas9 PD1 CAR-T PD1 CAR-T
	CD7 CAR-T RD13-01			CD7 ORR 82% CR 64%

	OX40 CAR-T	4.55%		B 20BBZ-OX40 CAR-T ORR 100% CR 40% PR 60%
	TCR T CAR-T T			
	“ CAR (Recyclable CAR) ”			CAR-T CAR-T
	CAR-T			CAR CAR- T

	CAR			
	NSG CDX CCR2b CAR T			CAR-T CAR T
	FITC CAR-T CAR-T			CAR-T “ - ”
	CD19/20 CAR T CD19/20 TanCAR-T / B			2020 1 74 ORR 84% CR 74% 10% ≥ 3 CRS 3

	“ ”			CAR-T
	CAR DAP1 NKG2D			CAR-T
	CD276 CAR-T		8000	
	CD19 CD33 CD19-CAR-T CD33-CAR-T		5800	
	HIV-1 CD4 T CAR-T VC-CAR-T			HIV-1 CAR-T 2020 7 30



on-target off-tumor

CAR-T

Intra-tumor heterogeneity, ITH

TAA

tumor microenvironment, TME

immunologic tolerance

cytokine release syndrome CRS

neurotoxicity NT



CAR-T

Orphan Drug Designation, ODD

FDA

ODD

7

NDA/BLA

25%



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