



康宁杰瑞

ALPHAMAB ONCOLOGY

2021 NDR Presentation



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Agenda

- 1 2021 Overview
- 2 Clinical Progress
- 3 R&D Progress
- 4 Operation Progress
- 5 Financial Overview
- 6 Q&A

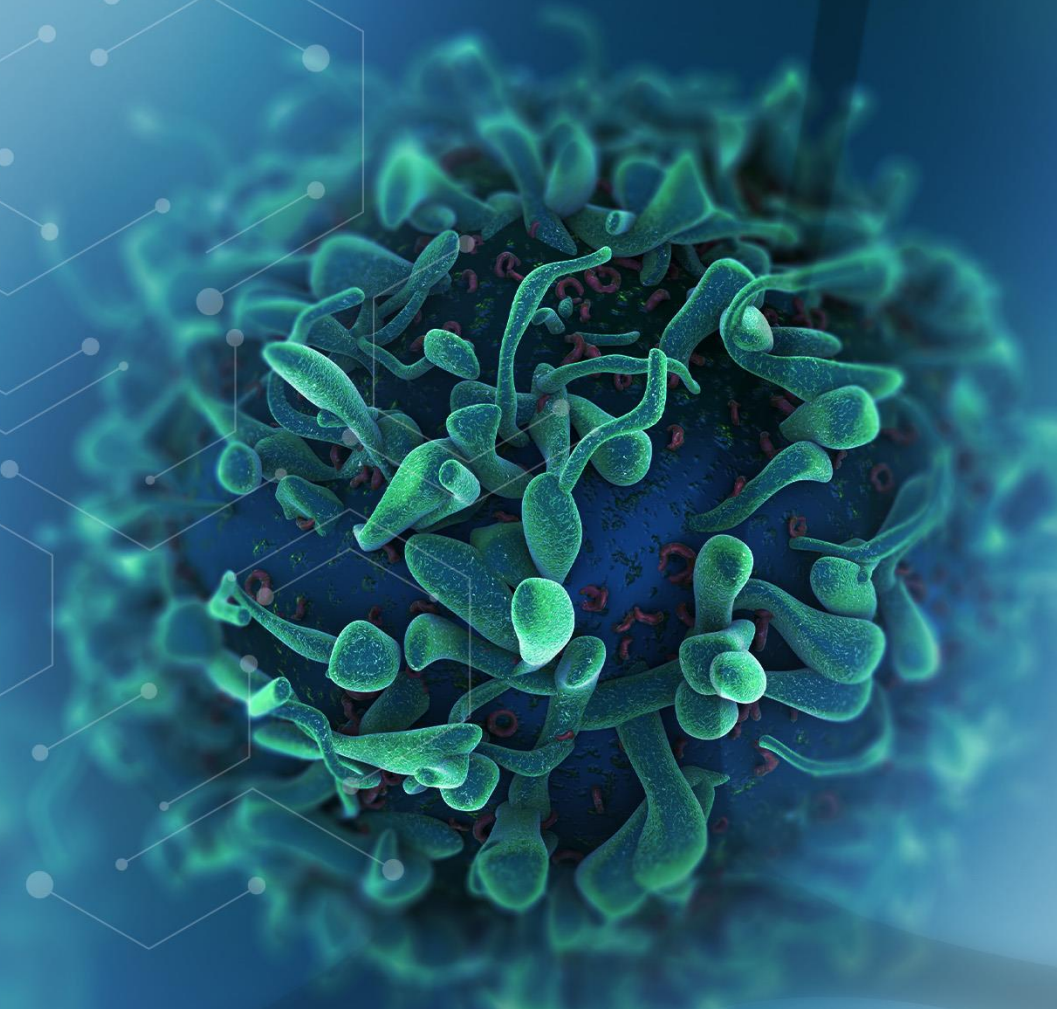


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ALPHAMAB ONCOLOGY

01

2021 Overview





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ALPHAMAB ONCOLOGY

We are a leading clinical-stage biopharmaceutical company in China with a **fully-integrated** proprietary biologics platform in bispecifics and protein engineering, delivering **world-class innovative therapeutic biologics** to cancer patients **globally**



Clinical Pipeline overview

Stage	Drug candidates	Target(s)	Platform	Rights	Key Indications	Pre-clinical	Dose escalation	Proof of concept	Pivotal	NDA
Post-clinical	KN046	PD-L1/CTLA-4 bispecific	sdAb/mAb	Global	NSCLC, Thymic, Pancreatic, HCC, ESCC, TNBC					
	KN026	HER2/HER2 bispecific	CRIB	Global	HER2-positive BC, GC/GEJ					
	KN026 +KN046	Target therapy +IO combo	Biomarker driven	Global	HER2-positive solid tumors					
	KN019	B7	Fusion protein	Global	RA, lupus, renal transplant, GvHD					
Launched	KN035	subQ PD-L1	sdAb/mAb	Global Co-development	MSI-H, BTC, Sarcoma, TMB-H, MSS endometrial					
Pre-IND	JSKN-003	HER2 ADC	BADC	Global	HER2 solid tumors					
	KN052	PD-L1/OX40 bispecific	CRIB	Global	Solid tumors					
	KN062	None RBD conformation bispecific	CRIB	Global	COVID-19					

02

Clinical Progress

Clinical Progress

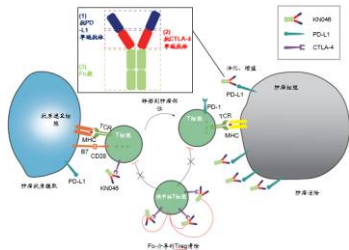
KN046

Dual blockade of PD-L1 and CTLA-4

- More efficacy and safety

Clinical Positioning

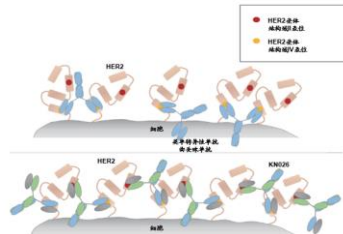
- Large Indications
- PD-(L)1 refractory
- PD-(L)1 Inadequate response



KN026

Dual blockade of HER2 domain II and IV

- Potential for all settings of HER2 aberration
- Synergy with KN046 through immune modulation



KN035

Subcutaneous PD-L1

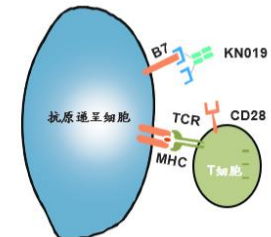
- The world's leading PD-L1 that can be used for subcutaneous injection



KN019

A safe option for autoimmune diseases

- Supplement to immunotherapies for AE management



Clinical Progress-KN046

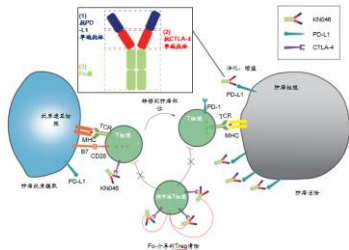
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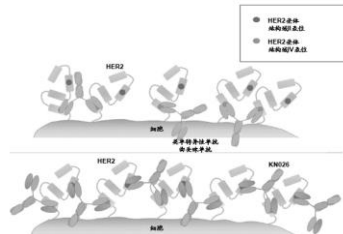
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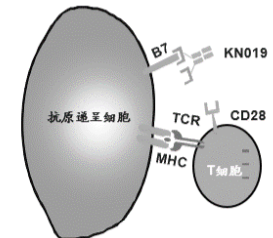
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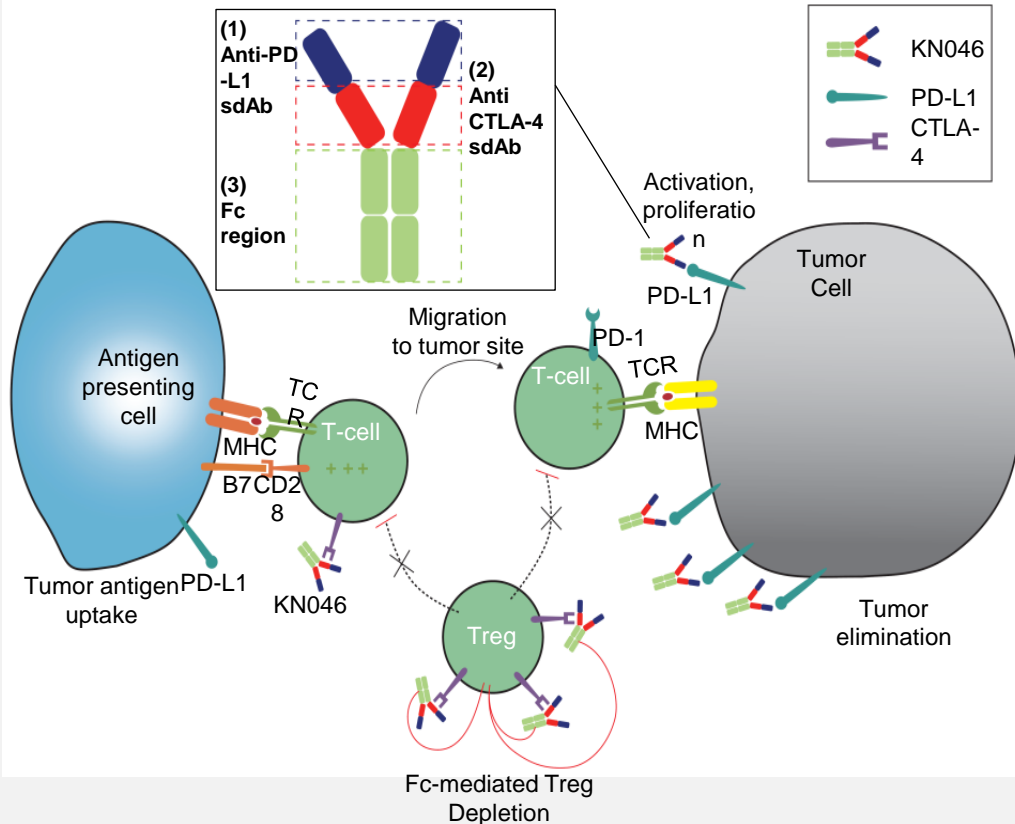
- Supplement to immunotherapies for AE management



KN046: PD-L1/CTLA-4 BsAb



Mechanism of Action



Highlights

1) Targeted drug delivery

- Engineered to enable the anti-PD-L1 sdAb to dominate drug distribution
- Targeted drug delivery to enrich KN046 in tumor-related micro-environment and limit exposure to non-tumor tissues

2) Different CTLA-4 binding epitope











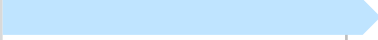
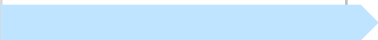
- Our anti-CTLA-4 sdAb mainly binds outside the interface and blocks the CTLA-4/B7 with steric hindrance
- Lead to a potentially improved safety profile

3) Preservation of Fc-mediated effector functions

- Preserves the full Fc functions for Treg Depletion

4) Strong Scientific base to support targeting CTLA-4 and PD-L1 with Bispecifics

KN046 Major Clinical Trials

Key strategies	Indication	Mono/ Combo	Proof of concept	Pivotal	NDA
Large indications	1L NSCLC, sq	+chemo			
PD-(L)1 refractory patients	PD-(L)1 refractory NSCLC	+Lenvatinib			
PD-(L)1 Inadequate response	≥2L Thymic carcinoma	Mono			
	1L Pancreatic Cancer	+chemo			
	1L HCC	+Lenvatinib			
	1L TNBC	+nab-paclitaxel			
	1L ESCC	+chemo			

KN046 – Erfonrilimab - Preliminary Results in a Nutshell

Indication Efficacy & Safety	KN046(Over 1,000 patients have been enrolled in clinical studies)						
	NSCLC, sq 1L	PD-(L)1 refractory NSCLC	PDAC 1L	HCC 1L	Thymic carcinoma ≥2L	TNBC 1L	ESCC 1L
Mono/Combo	+chemo	mono	+chemo	+Lenvatinib	mono	+chemo	+chemo
OS	74.9% (12 month same with 15 month)	20.2 months (mOS)	--	--	--	77.1% (15 months)	--
mPFS	5.5 months	2.8 months	--	--	--	13.8 months	--
ORR	57.6%	8.3%	50%	57%	75%	40%	58.3%
DCR	84.8%	50%	95.5%	95%	100%	96%	91.6%
TRAE≥Grade3	25.3%	--	27.6%	8%	33.3%	48.1%	13.3%
Trial Status	Recruitment of Phase III finished (N=482)	Phase II/III has been initiated	To initiate pivotal trial	To complete the US FDA EoP2 Communication	To complete the Chinese enrollment	--	--

Unique Features of KN046 So Far

Over **1,000** patients already treated with KN046 in company sponsored trials and ISTs

Efficacy



- Relevantly high RR across indications, remarkably as ICI even as single agent
- Activity in ICI naïve and pretreated patients
- Significant preliminary OS prolongation – to be confirmed

Safety



- Typical safety profile of a PDx inhibitor with
- Virtually no peripheral CTLA4 toxicities
- Infusion Reactions pronouncedly happening at later infusions but overall number and grade similar to other IgG1 mAbs

What's the differentiation?



- World class innovative Bifunctional with differentiated structural and functional properties
- **1** China-local and **2** Global pivotal studies successfully launched, **1** IND of Phase III has been approved and **1** further Phase III in IND approval phase
- **2** further indications from Tier 1 with strong data waiting for resource to pursue
- High potential for additional Tier **2** indications to explore

I. KN046 in large indication: NSCLC

KN046 Pivotal Trial: 1L NSCLC (ENREACH-LUNG-01) Recruitment Completed-1/3

Inclusion criteria

- 1) Stage IIIb/c not amenable to curative CRT or stage IV squamous NSCLC
- 2) Systemic treatment naïve
- 3) No known EGFR mutation
- 4) Baseline measurable disease

RANDOMIZED
1:1

4 cycles: KN046 5 mg/kg Q3W +
Carbo/paclitaxel Q3W
Maintenance: KN046 5 mg/kg Q2W
(n = 241)

placebo 5 mg/kg Q3W +
Carbo/paclitaxel Q3W
(n = 241)

PD

Survival follow up

IRC confirmed
PD

KN046 5 mg/kg
Q2W

Nivolumab 240 mg
Q2W

1:1

Stratification

- PD-L1 expression level (PD-L1 $\geq 1\%$ vs PD-L1 $< 1\%$)
- Tumor Staging (Stage III vs IV)


Primary endpoint


- PFS
- OS

Key secondary endpoints

- ORR
- DCR
- DOR etc.

KN046-202 1L NSCLC (2021ASCO)-2/3

 **Patient Status:** Enrolled 87 patients with stage IV NSCLC who have not received systemic treatment, including 51 non-sq and 36 sq NSCLC patients
Median treatment time is 21 weeks

 **Efficacy:** For sq NSCLC patients, ORR was **57.6%**, DCR was **84.8%**, mPFS was **5.5 months**, 12-month OS rate was **69.6%**; mPFS of PD-L1 \geq 1% sq-NSCLC patients was **10.8 months** (n=16)
For non-sq NSCLC patients, ORR was 45.8%, DCR was 89.6%, mPFS was **6.9 months**, 12-month OS rate was **76.1%**

Comparable trials:	KN046-202		Checkmate 9LA		Keynote 407
Drugs	KN046+chemo		Nivo+Ipi+chemo		Pembro+chemo
PD-L1+ percentage	PD-L1 \geq 1%: 55%		-		PD-L1 \geq 1%: 64%
Type	sq	Non-sq	sq	Non-sq	sq
n	36	51	115	246	278
12-month OS rate	74.9% (same for 15-month OS rate)		64%	63%	64.7%
ORR	57.6%	45.8%	38.2%		62.6%
DCR	84.8%	89.6%	83.7%		86.0%

Notes:

1. The trial is ongoing and the data is as of January 19, 2021

KN046-202 1L NSCLC (2021ASCO) -3/3

Subgroup analysis by PD-L1 expression level:

- Similar survival curves were observed in patients **with PD-L1 $\geq 1\%$** and **PD-L1 $< 1\%$**
- mPFS of **PD-L1 $\geq 1\%$** sq-NSCLC patients was **10.8 months** (n=16), which is consistent with the PFS benefit in KN046-201 trial for 2L sq-NSCLC patients (7.3 months)

Comparable trials	KN046-202		Checkmate 9LA	
Drug	KN046+chemo	KN046+chemo	Nivo+Ipi+chemo	Nivo+Ipi+chemo
PD-L1 expression	PD-L1 $\geq 1\%$	PD-L1 $< 1\%$	PD-L1 $\geq 1\%$	PD-L1 $< 1\%$
n	46	37	-	-
12-month OS rate	75.2%	73.0%	66%	63%




Safety:


- Grade 3 and above TRAE related to KN046 is **25.3%** (n=87)
- Grade 3 and above irAE is **8.0%**


Notes:

1. The trial is ongoing and the data is as of January 19, 2021


KN046-202: 1L advanced NSCLC harboring resistant oncogenic driver alterations (2021 ESMO)

 **Patient Status:** 12 pts (EGFR exon 20 insertion mutation, n=8; HER2 exon 20 insertion mutation, n=1; EGFR amplification, n=2; RET fusion, n=1) were enrolled. The median treatment duration of KN046 was 21 weeks

 **Trial Design:** KN046, 5mg/kg Q3W + 4 cycles' pemetrexed (500 mg/m², for non-squamous NSCLC) or paclitaxel (175 mg/m², for squamous NSCLC) and carboplatin (area under the curve 5 mg/m²) until progressive disease, unacceptable toxicity, withdrawal of informed consent or death

 **Efficacy:** **ORR 50%, DCR 91.7%, mPFS 8.7months**, Median OS was not reached, and **OS rate was 100% at 6 months** Out of 21 evaluable patients

Comparable Trials:	KN046-202	ZENITH20	CHRYSALIS
Drugs	KN046+Chemo	poziotinib	amivantamab-vmjw
N	12	22	81
mPFS	8.7months	7.2months	NA
ORR	50%	27.8%	40%
DCR	91.7%	86.1%	NA

 **Safety:** 9 pts occurred at least 1 Grade ≥ 3 TEAEs, the most common were neutrophil count decreased (n=4, 33.3%), alanine aminotransferase increased (n=3, 25.0%), anaemia (n=2, 16.7%), white blood cell count decreased (n=2, 16.7%), aspartate aminotransferase increased (n=2, 16.7%). 5 (41.7%) pts experienced irAEs, all were of Grade 1 or 2

II. KN046 in PD-(L)1 refractory patients: NSCLC

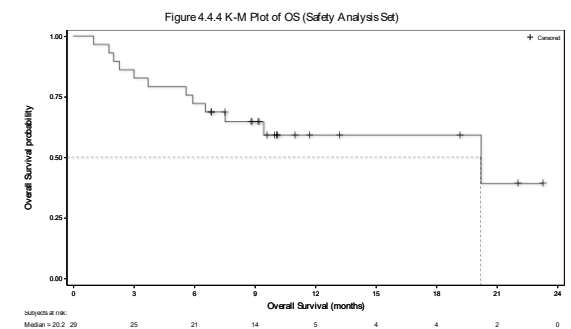
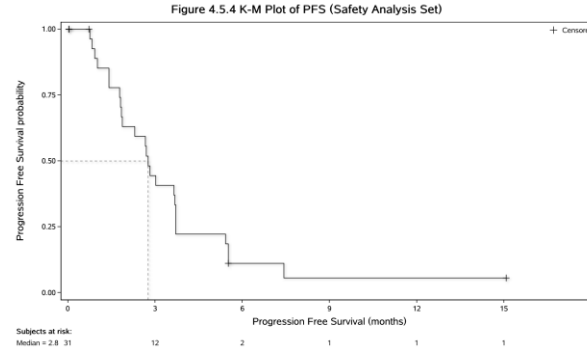
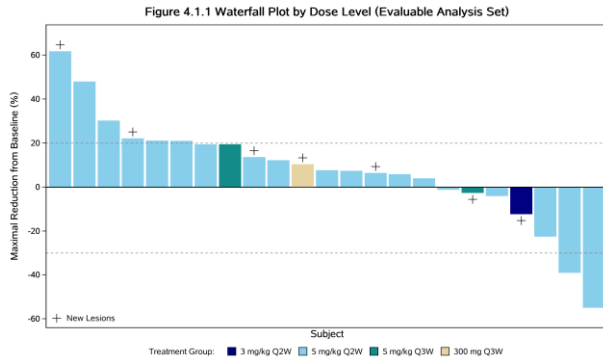
KN046-CHN-001 and KN046-201 in ICI Refractory Patients

1 Preliminary efficacy of KN046 monotherapy in anti-PD1 refractory NSCLC

Waterfall plot (DCR 50%)

Progression-free survival (2.8 months)

Overall survival (20.2 month)



2 Comparable trials in NSCLC

Comparable trials	KN046-CHN-001 & KN046-201	Yuki Katayama 2019	Fujita 2019	ENCOR-601
Drug	KN046 monotherapy	Anti-PD-1 I-O	Atezolizumab	Entinostat+ Pembrolizumab
Patients #	29	35	18	72
ORR	8.3% (DCR 50%)	5.9% (DCR 42.9%)	0 (DCR 38.9%)	10% (DCR 60%)
mPFS	2.8 months	2.7 months	1.7 months	2.8 months
mOS	20.2 months	7.4 months	NA	11.7

Notes:

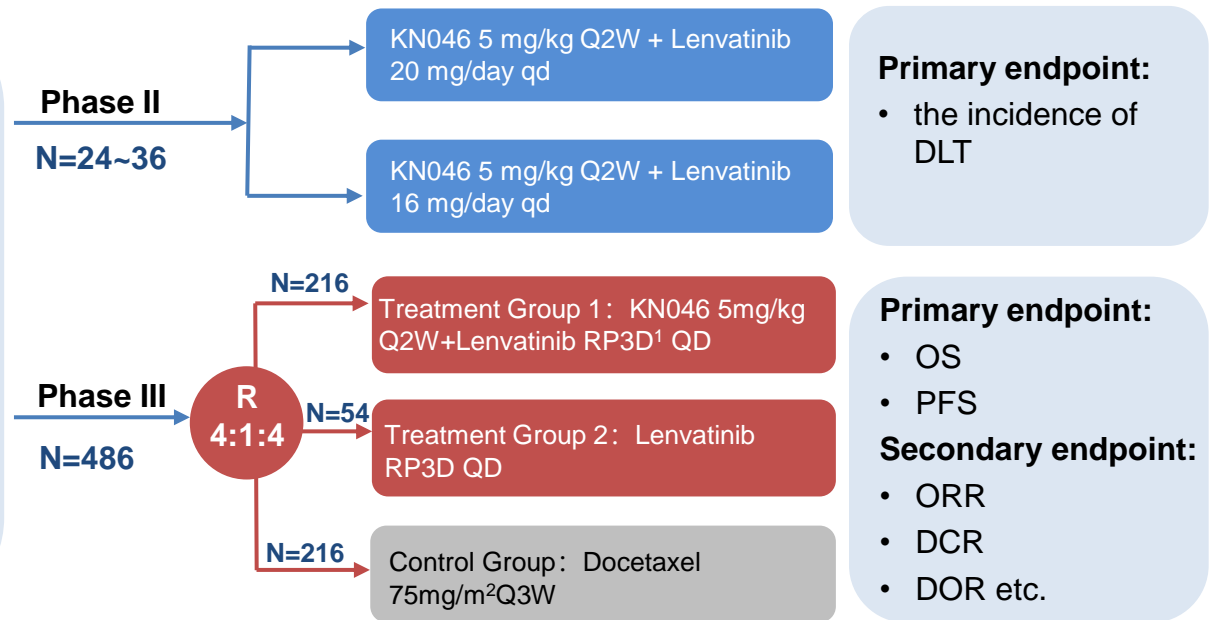
1. The median OS of PD-(L)1 in 2L lung cancer is 9-12 months

KN046 in PD-(L)1 Refractory Patients with NSCLC (ENREACH-LUNG-02)

Inclusion criteria

- IIIB or IIIC, or IV (AJCC 8th edition), not suitable for radical treatment, or recurrence after radical radiotherapy or surgical resection
- Patients with advanced NSCLC who have **previously received 1L or 2L PD-(L)1 and platinum-containing dual-drug chemotherapy**, or
- Patients who have previously received **1L or 2L PD-(L)1 monotherapy** and not have received platinum-containing dual-drug chemotherapy

Trial Design



- This study was conducted in patients with advanced NSCLC who had previously received PD-(L)1 treatment and their disease progressed. This study includes two stages, phase II and phase III.

Note1: RP3D: recommended phase III dose

III. KN046 in indications with inadequate response to PD-(L)1:

- Pancreatic ductal adenocarcinoma
- HCC
- Rare thoracic tumors
- TNBC
- ESCC

KN046-IST-04: 1L Pancreatic Ductal Adenocarcinoma (2021 CSCO)



Patient Status: 29 patients were enrolled, median age (range) 57 (36-75) years, 58.6% of subjects had distant metastases; the median exposure time of KN046 was 14.1 weeks



Trial design: KN046 (5mg/kg, q2w) combined with nab-paclitaxel and gemcitabine for 4~6 cycles, then KN046 (5mg/kg, q2w) for maintenance treatment



Efficacy: Among the 22 patients who underwent at least one tumor assessment, 1 patient achieved complete response, ORR was 50.0% and DCR was 95.5% , the six-month PFS rate was 62.3%

Drugs:	KN046+chemo	Nivo+chemo	Pembro+chemo	Durva+Treme+ chemo
Stage	II	I	Ib/II	II
N	22	50	11	119
ORR	50.0%	18%	27%	30%
DCR	95.5%	64%	100%	71%



Safety: The TRAE related to KN046 at grade 3 and above is 27.6%

The incidence of SAEs related to KN046 was 3.4%, the incidence of AEs related to KN046 leading to treatment termination was 6.9%, and no AEs that caused death occurred

Notes:

1. The trial is ongoing, and the data is as of May 26, 2020

KN046-IST-05: 1L HCC(2021 ESMO)



Patient Status: 25 patients with Barcelona Clinic Liver Cancer (BCLC) stage B or C were enrolled



Trial design: Lenvatinib 12 mg/day (bodyweight [BW] \geq 60 kg) or 8 mg/day (BW <60 kg) orally and KN046 5 mg IV on Day 1 of a 21-day cycle until disease progression or intolerable toxicity or 2 years



Efficacy: RECIST v1.1: ORR was **57%** and DCR was **95%** (n=21)

mRECIST: ORR was **76.2%**, DCR was **95%** (n=21)

Comparable Trials:	KN046+IST-05	KN524	Imbrave 150	Orient32
Drugs	KN046+Lenvatinib	pembrolizumab+Lenvatinib	Atezolizumab+Bevacizumab	Sinti+ Bevacizumab
N	21	100	501	571
ORR (RECIST v1.1)	57%	36%	30%	21%
DCR (RECIST v1.1)	95%	88%	74%	72%



Safety: The TRAE related to KN046 was 60% (n=15), 8% of which was \geq grade 3. The \geq grade 3 TRAE related to KN046 were pneumonitis (n=1, 4.0%) and platelet count decreased (n=1, 4.0%)

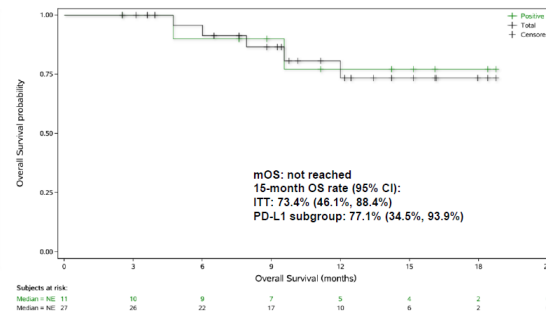
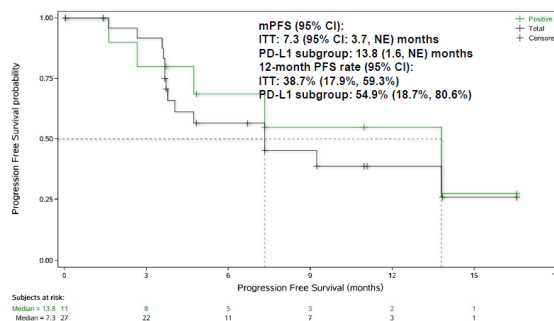
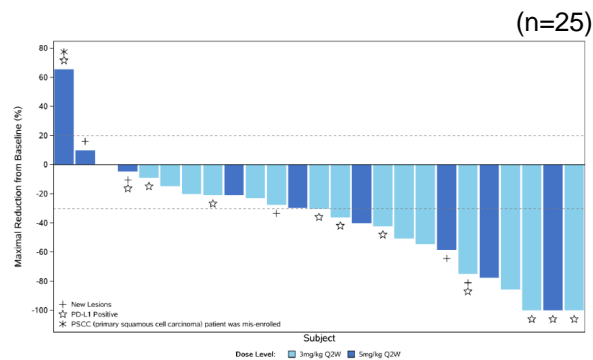
KN046-203 1L TNBC (2021 AACR)

1 Preliminary efficacy of KN046 plus nab-paclitaxel in 1L TNBC

Waterfall plot (DCR 96%)

PFS (13.8 months in PD-L1 positive group)

OS (15 months OS rate 77.1%)




2 Comparable trials in 1L TNBC

Comparable trials	KN046-203	KEYNOTE-355	IMpassion130
Drug	KN046+chemo (nab-paclitaxel)	Keytruda+chemo VS chemo (nab-paclitaxel, paclitaxel, or orencitabine plus carboplatin)	Tecentriq+chemo VS chemo (nab-paclitaxel)
Patients #	11 (PD-L1 positive)	425 VS 211 (PD-L1 positive)	185 VS 184 (PD-L1 positive)
mPFS	13.8 months	7.6 months VS 5.6 months	7.5 months VS 5.0 months
mDOR	13.7 months	not reached yet	8.5 months VS 5.5 months
mOS	not reached yet; 15 months OS rate 77.1%	not reached yet	25.0 months VS 15.5 months; 15 months OS rate 67.0%

Notes:

1. Data cut-off date Mar 8, 2021; trial ongoing
2. KN046-203 use patients in IC PD-L1 \geq 1% subgroup, KEYNOTE-355 use patients in CPS \geq 1 subgroup, IMpassion130 use patients in TPS \geq 1% subgroup

KN046-204: 1L ESCC (2021 ASCO)

 **Patient Status:** 15 patients were enrolled without prior systemic treatment, all were male, 52.3% ≥ 60 years old, 64% ECOG PS score was 1, 80% had distant metastasis at baseline

12 of them could be evaluated for efficacy analysis

The median exposure time of KN046 is 11.4 weeks, and the average treatment period is 2.4 cycles



Trial design: KN046 (5mg/kg, q3w) combined with paclitaxel and cisplatin for 4~6 cycles, then KN046 (5mg/kg, q3w) for maintenance treatment



Efficacy: ORR was **58.3%** and DCR was **91.6%**(n=12)

7 PR (including 1 CR of target lesions); 4 SD (3 of which with major tumor burden reduction > 20%)

Comparable trials	KN046-204	KEYNOTE 590	RATIONALE 205
Drug	KN046+chemo	Pembro+chemo VS chemo	Tislelizumab+chemo
n	12	548	15
ORR	58.3%	45% VS 29.3%	46.7%



Safety: The TRAE related to KN046 at grade 3 and above is only **13.3%**, which were nausea (n=1, 6.7%) and rash (n=1, 6.7%); no KN046 related SAE, and no grade 4 or 5 AE.

The incidence of infusion reactions was 7.8%, mostly of grade 1-2

Notes:

1. The trial is ongoing and the data is as of January 14, 2021
2. The KEYNOTE 590 trial contains data on esophageal squamous cell carcinoma and esophageal adenocarcinoma. The ORR is not reported separately and is data for the entire population (n=749)

Clinical Progress-KN026

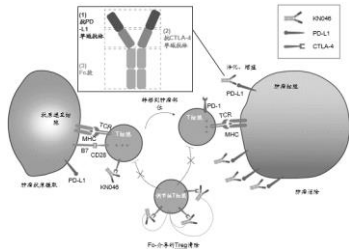
KN046

Dual blockade of PD-L1 and CTLA-4

- More efficacy and safety

Clinical Positioning

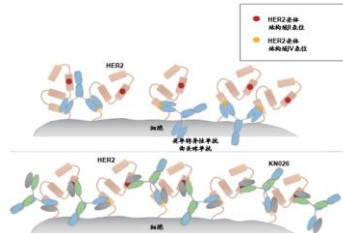
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Dual blockade of HER2 domain II and IV

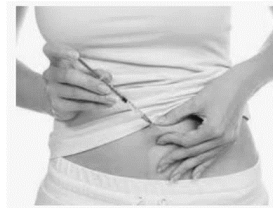
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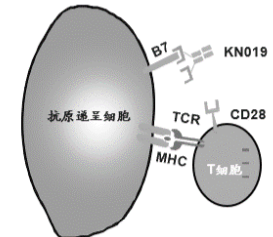
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A safe option for autoimmune diseases

- Supplement to immunotherapies for AE management

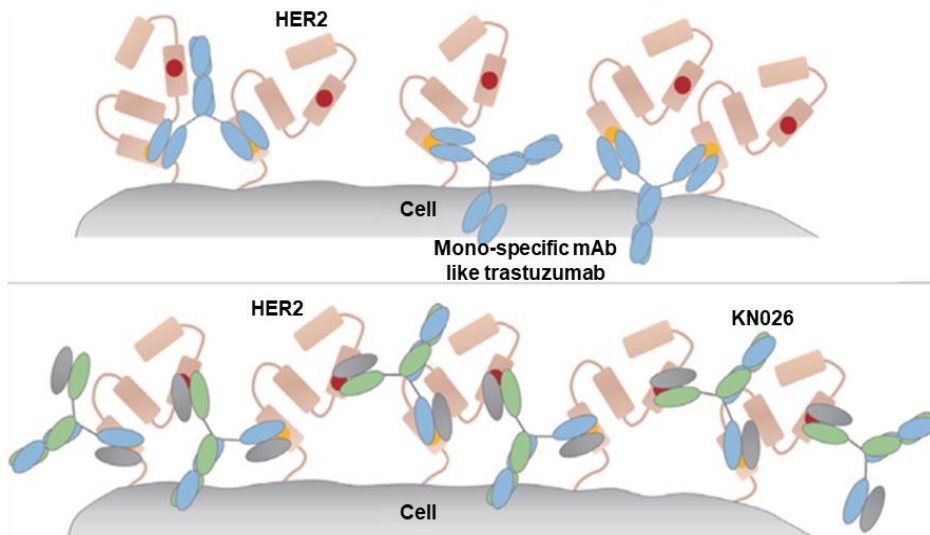


KN026 : HER2/HER2 BsAb



Mechanism of action

- Epitope on domain II of HER2 receptor
- Epitope on domain IV of HER2 receptor



Highlights

- Dual blockade of parallel HER2-related signaling pathways
- Enhanced multiple HER2 receptor binding and internalization
- Fc-based BsAb with full effector functions

Collaboration with CSPC in relation to the Development and Commercialization of KN026 in Mainland China



Agreement Amount (up to RMB1 billion)

Upfront Payment

RMB
150
million

Development Milestone Payment

RMB
450
million

Sales Milestone Payment

RMB
400
million

a double-digit tiered sales commission

Agreement Points

- **Indication:** Breast Cancer and gastric cancer
- **Authority:** the development and commercialization in mainland China (excluding Hong Kong, Macau or Taiwan)
- **Clinical development responsibilities:** The joint development committee will be responsible for the development plan and the design of the clinical trial protocol. CSPC is responsible for the clinical development and registration application, and costs and expenses of all clinical development activities

KN026 Major Clinical Trials

Tumor Type	Combo/Mono	Line NO.	Proof of concept	Pivotal	NDA
HER2+BC	+ KN046	≥ 2L		★	
	+ docetaxel	1L		★	
	+ docetaxel	Neoadjuvant therapy		★	
	+ palbociclib	≥ 2L			
HER2+GC/GEJ	+ chemo	≥ 2L		★	
	+KN046	1L		★	
	mono	≥ 2L			
HER2+ solid tumors	+ KN046	Late line		★	

★ Pivotal Trial

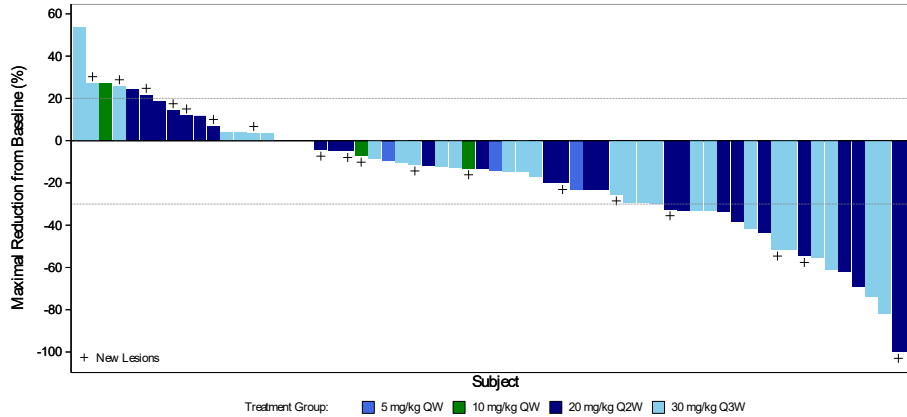
Notes:

1. FPI – first patient in

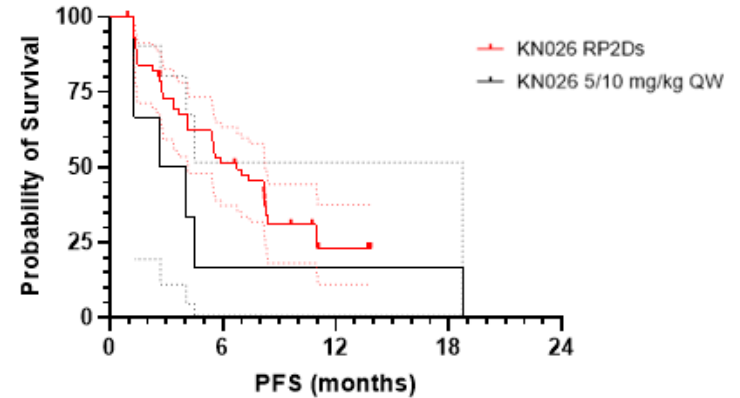
KN026-CHN-001

KN026 is well tolerated and has demonstrated encouraging anti-tumor activity in HER2-positive breast cancer patients who have failed standard anti-HER2 therapies.

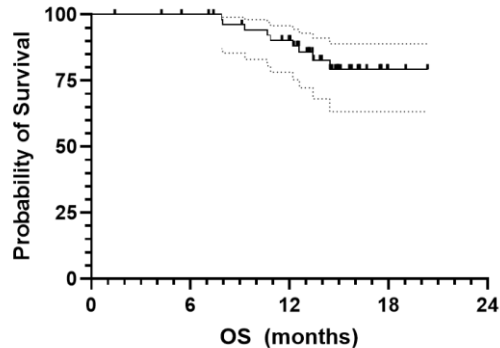
Waterfall plot



Progression-free survival (6.8 months at RP2Ds)



Overall survival (1-year OS rate at RP2Ds 90.3%)



- Median age: 54 (range: 31~69)
- Median prior lines of HER2 target therapies: 2 (range: 1~12)
- **mPFS 6.8 months at RP2Ds**
 - 5.5 months at 20 mg/kg Q2W
 - 7.4 months at 30 mg/kg Q3W
- **1-year OS rate at RP2Ds 90.3%**

Notes:

1. Data cut-off 21-Dec-2020

KN026-202: ≥2L HER2-positive GC/GEJ (2021 ASCO)

KN026+KN046 for the treatment of GC/GEJ has been granted orphan drug desiregistration trial in 2021H2gination by the US FDA and Plan to initiate ≥2L GC/GEJ



Patient Status: 31 patients were enrolled, including 20 HER2 high expression patients with a median treatment time of ~20 weeks and 11 HER2 medium and low expression patients with a median treatment time of ~6 weeks



Trial design: single-arm, open label, multi-center phase II study

Two cohorts: 1) HER2 high expression (IHC3+ or IHC 2+ ISH+), 2) HER2 medium and low expression (IHC 1+/2+ ISH- or IHC 0/1+ISH+)



Efficacy: for 18 evaluable HER2 high expression patients, ORR **55.6%**, DCR **72.2%**, 9-month PFS rate **60.4%**, mPFS and mOS have not yet been reached

for 9 patients who had received prior trastuzumab treatment, ORR **44.4%**, DCR **66.7%**, mPFS **5.6 months**, mOS **11 months**

Comparable trials	KN026-202		ZW25-101
Drug	KN026	KN026	ZW25
Subgroup	All with HER2 high expression	Prior Trastuzumab treated with HER2 high expression	All with HER2 high expression
n	18	9	33
ORR	55.6%	44.4%	33%
DCR	72.2%	66.7%	61%





Safety: Low rate of Grade 3/4 KN026 related TRAE (**9.7%**), no KN026 related death was reported


Notes:

- The trial is ongoing and the data is as of December 25, 2020


KN046-IST-02: HER2+ Gastrointestinal Tumors (2021 ESMO)

 **Patients Status:** 44 patients were enrolled, median age (range) was 56 (29-74) years, 39 patients were ECOG PS 1, 34 patients were HER2 positive, and 24 patients were HER2-positive GC/GEJ, 10 patients had received trastuzumab


 **Trial Design:** KN026 + KN046 at three doses (dose 1: KN026 at 20 mg/kg Q2W and KN046 at 3mg/kg Q2W; dose 2: KN026 at 20 mg/kg Q2W with loading on day 1, 8 of cycle 1, and KN046 at 5mg/kg Q3W; dose 3: KN026 at 30 mg/kg Q3W with loading on day 1, 8 of cycle 1 and KN046 at 5mg/kg Q3W)


 **Efficacy:** For 36 evaluable patients the **ORR** was **38.9%** with **mDOR 11.2 months**. In 27 HER2-positive patients, the **ORR** was **51.9%** with **mDOR 11.2 months**; Among those 27 patients 21 were GC/GEJ, 7 treatment naïve patients had **ORR** of **71.4%**, 14 late line patients had **ORR** of **42.9%**. In 24 GC/GEJ patients, 7 treatment naïve patients had a **6-month OS rate** of **100%**, the 12-month overall survival rate was not reached, 17 late line patients had a **6-month OS rate** of **93.3 %**, **12-month OS rate** of **62.2%**

1LGC Comparable Trials	KN046-IST-02	KEYNOTE-811	ToGA	JACOB
Drugs	KN026+KN046	pembrolizumab + trastuzumab + chemo	trastuzumab+Capecitabine/Fluorouracil+Cisplatin	trastuzumab+Capecitabine/Fluorouracil+Cisplatin
N	7	264	294	389
ORR	71.4%	74.4%	47%	48.3%


 **Safety:** 18.2% of patients encountered at least one grade ≥3 TRAE and the most common was anemia (4.5%)

KN026-203: KN046+KN026 HER2+Breast Cancer(2021 SABCS)

 **Patients Status:** Enrolled **36** patients with the median age of 53.0 years(range: 33,67), 30 of 36 patients(83.3%) received >2 lines of HER2-targetd combinational therapies in the metastatic setting.

 **Trial Design:** Receive KN026(30 mg/kg Q3W) plus KN046 (5 mg/kg Q3W) until progression, unacceptable toxicities or patient withdrawal

 **Efficaty:** for **33** evaluable patients, **ORR 48.5%**, **one patient achieved CR, DCR 78.8%**.

 **Safety:** for **36** evaluable patients, **5 patients (13.9%)** experienced \geq grade 3 TRAEs. The most common TRAEs were infusion related reaction (41.7%)、 pruritus (22.2%)

Comparable Trials	KN026-203 ¹	EMILIA	DESTINY-Breast 03	PHENIX
Drugs	KN026+KN046	T-DM1	DS8201 ²	Pyrotinib+capecitabine
N	33	495	261	185 ³
Enrolled patients	> 50%patients received \geq 3L treatment	Received the treatment of trastuzumab and taxanes	Received the treatment of trastuzumab and taxanes	Received the treatment of trastuzumab and taxanes
ORR	48.5%	43.6%	79.7%	68.6%

Note: 1. the trial is ongoing and the data is as of 10/8/2021

2. The safety of DS8201: 99.6% experienced TEAE, 52.1% experienced \geq grade 3 TEAEs., 19.1% experienced the severe TEAE. And 10.5% experienced ILD, among them 0.8% incurred grade 3 ILD

3. among them, 68(36.8%) patients were not received previous treatment, 70(37.8%) were previously received 1L treatment and 47(25.4%) were previously received 2L treatment

Clinical Progress-KN035

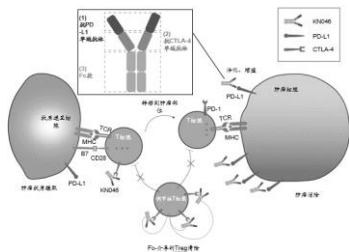
KN046

Dual blockade of PD-L1 and CTLA-4

- More efficacy and safety

Clinical Positioning

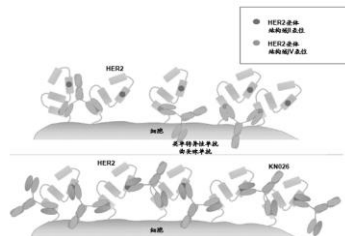
- Large Indications
- PD-(L)1 refractory
- PD-(L)1 Inadequate response



KN026

Dual blockade of HER2 domain II and IV

- Potential for all settings of HER2 aberration
- Synergy with KN046 through immune modulation



KN035

Subcutaneous PD-L1

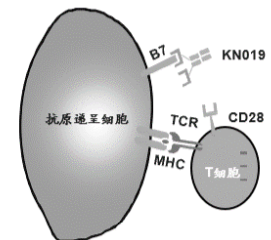
- The world's leading PD-L1 that can be used for subcutaneous injection



KN019



A safe option for autoimmune diseases



- Supplement to immunotherapies for AE management




KN035: The First-global SubQ PD-L1 with BLA Launched in China

VS Intravenous infusion vs. subcutaneous Injection



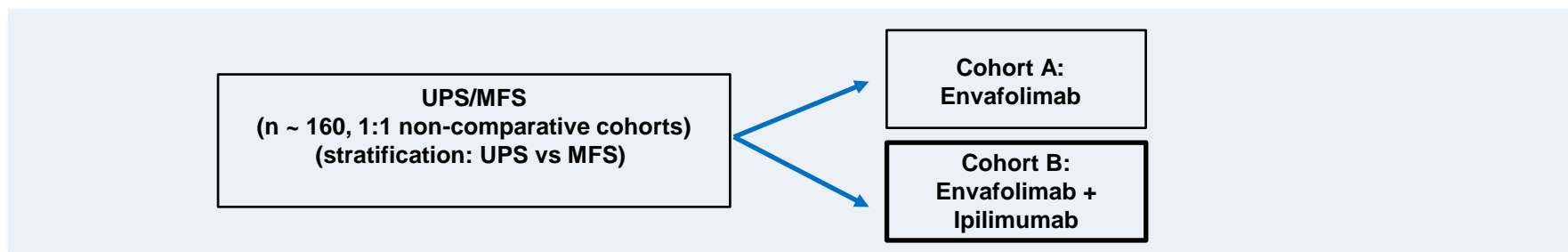
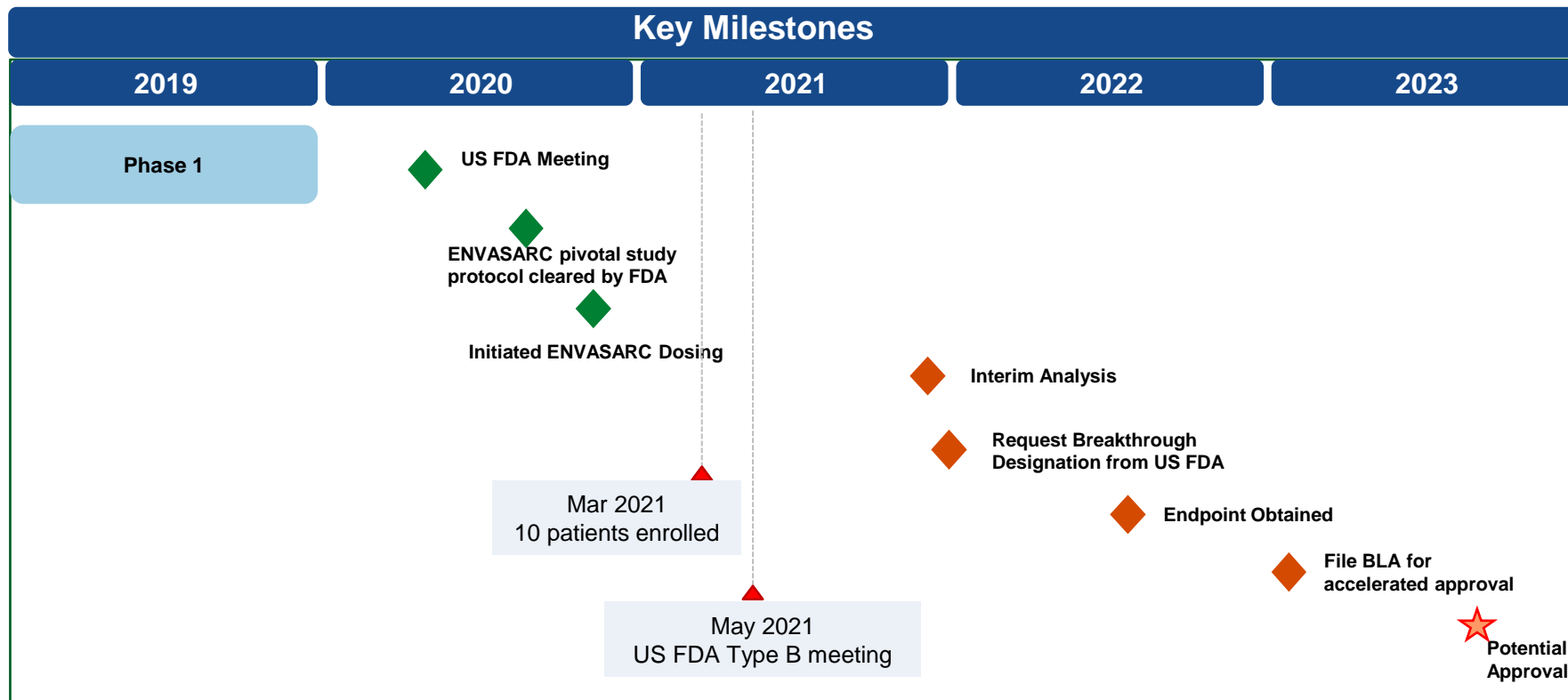
Intravenous Infusion  subcutaneous Injection 

 **Advantages**

- Easier administration
- Better safety profile
- More efficient utilization of medical resources
- More convenient for maintenance usage
- Preferred for patients with limited vein access and infusion related reactions

- On November 25, 2021, KN035 was launched in China in the treatment of MSI-H/dMMR advanced solid tumors
- On December 8, 2021, the first batch of prescriptions was fully implemented

KN035: Clinical Development Summary – Collaboration with Tracoon in UPS/MFS in US



Clinical Progress-KN019

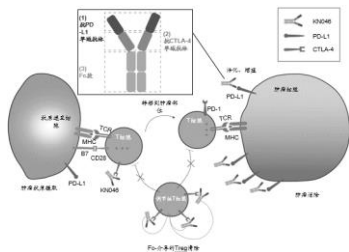
KN046

Dual blockade of PD-L1 and CTLA-4

- More efficacy and safety

Clinical Positioning

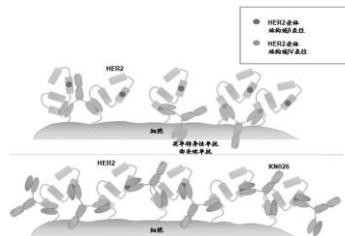
- Large Indications
- PD-(L)1 refractory
- PD-(L)1 Inadequate response



KN026

Dual blockade of HER2 domain II and IV

- Potential for all settings of HER2 aberration
- Synergy with KN046 through immune modulation



KN035

Subcutaneous PD-L1

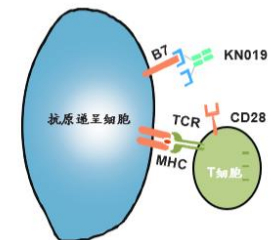
- The world's leading PD-L1 that can be used for subcutaneous injection



KN019

A safe option for autoimmune diseases

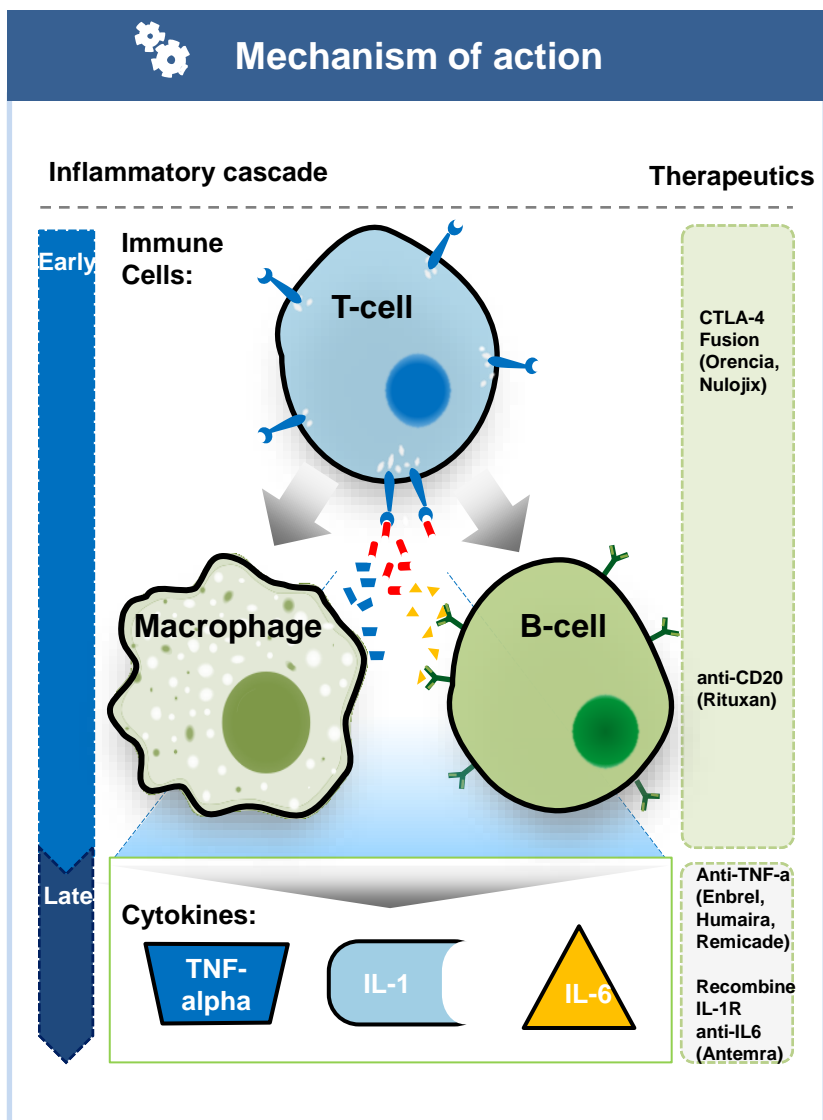
- Supplement to immunotherapies for AE management



KN019: CTLA-4 Fusion Protein - Immunosuppressant Drug



Mechanism of action



Clinical development progress

- Phase II Chinese Rheumatoid Arthritis Trial: Complete patient enrollment (N~140)
- Plans to initiate a clinical study of bioavailability in 2021 to switch from intravenous infusion to subcutaneous administration
- Plans to start Phase III registered clinical trials in the second half of 2022

03

R&D Progress

Cutting-edge R&D Platforms Continuously Advance R&D Pipeline



sdAb



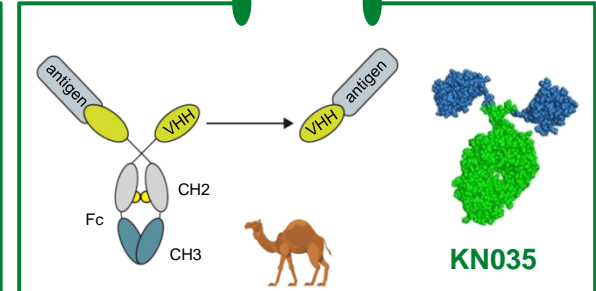
Smaller and more stable with a compact structure



Ideal building blocks for multifunctional biologics



Proof-of-concept: KN035¹, KN046², KN052



CRIB



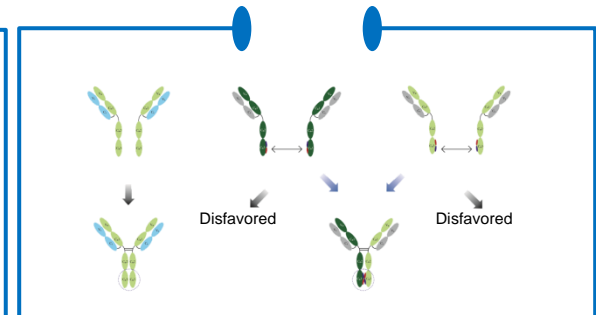
Maintain full-length antibody properties



Optimized for commercial-scale manufacturing



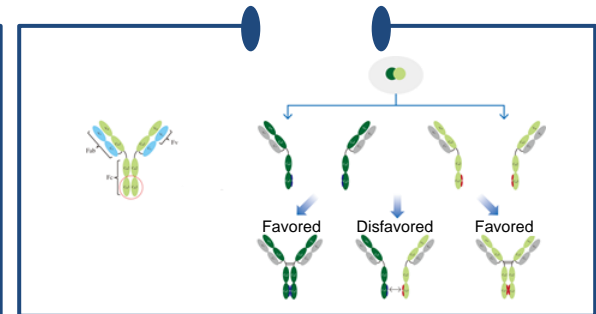
Proof-of-concept: KN026³



CRAM



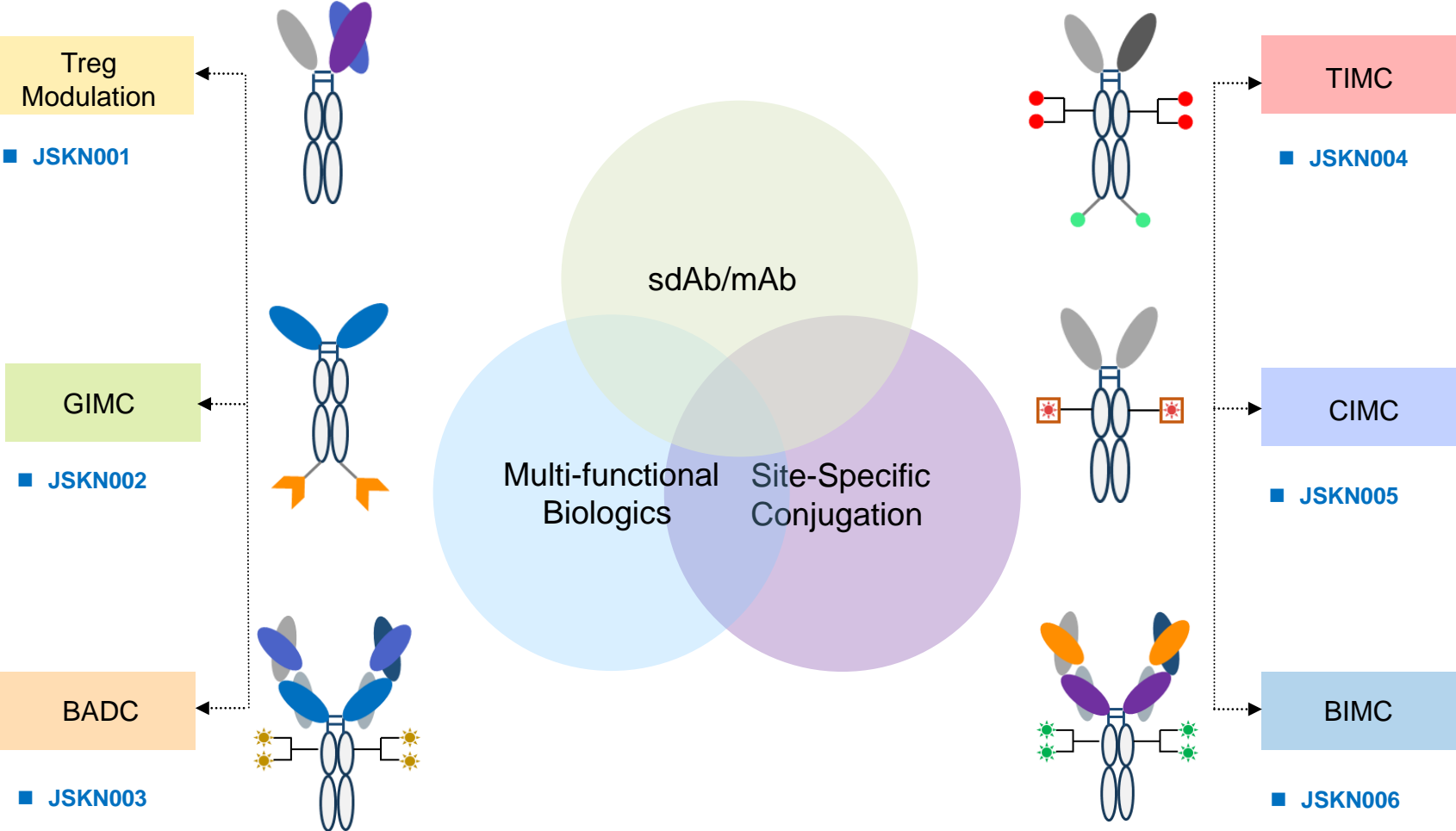
A single streamlined process to produce multiple mAbs with adjustable pre-determined ratio



Notes:

1. Launched in November 25, 2021
2. Pivotal trial stage
3. Pivotal trial stage

Expanded Multi-Functional Platforms Transform Next Generation R&D Portfolio

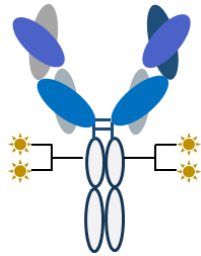


Pre-IND product overview

JSKN-003

Anti-HER2 Paratopes Bispecific ADC

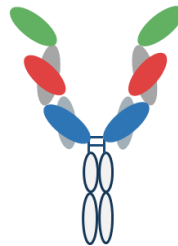
- Shows strong anti-tumor activity in CDX model
- Shows Superior Serum Stability



KN052

Anti-PD-L1/OX40 Bispecific Antibody

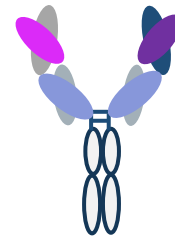
- Shows synergistic antitumor activity in MC38 tumor model



KN062

Bispecific COVID-19 Neutralization Antibody

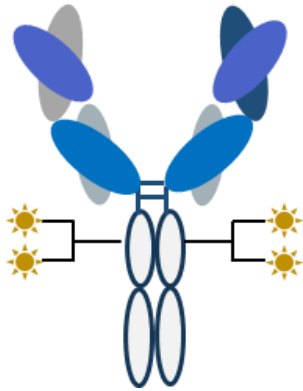
- 3c1+2H2 combination show stronger neutralization activity than mono paratope treatment



JSKN003: Anti-HER2 Paratopes Bispecific ADC



Product Structure



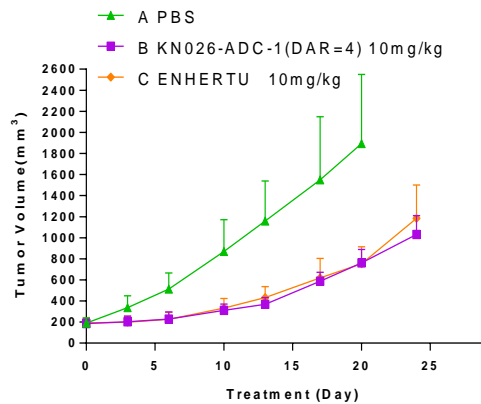
Highlights

- Targeting two different paratopes of HER2 (KN026)
- Site specific conjugation, DAR 3-4
- Better serum stability for better safety potential
- Strong activity in HER2 high and low expression cells in CDX Model

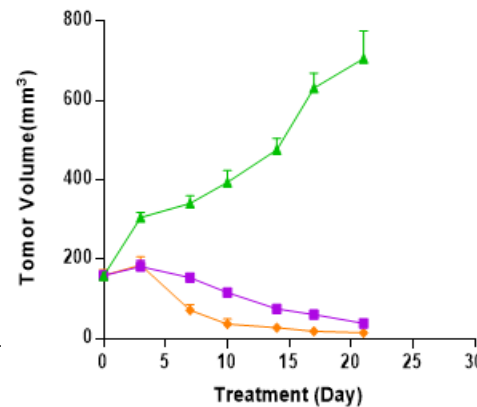
JSKN003 shows strong anti-tumor activity in CDX model

Shows Superior Serum Stability

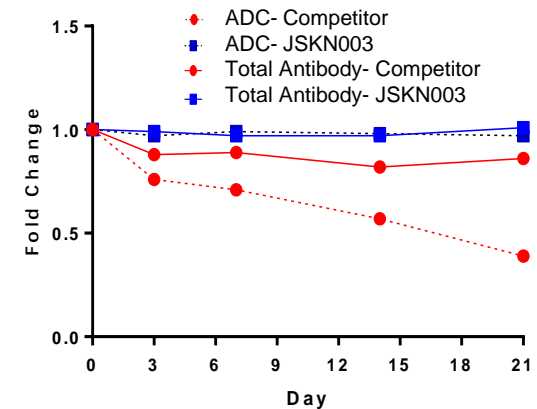
BxPC-3 CDX Model (HER2 low)



N87 CDX Model (HER2 high)



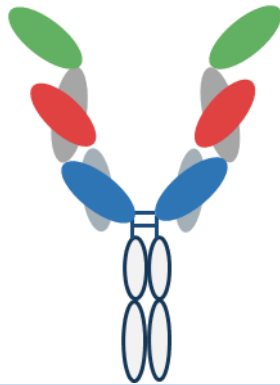
Human Serum



KN052: Anti-PD-L1/OX40 Bispecific Antibody



Product Structure



Humanized VHH to PD-L1, Antagonist

Human Fab to OX40, Agonist

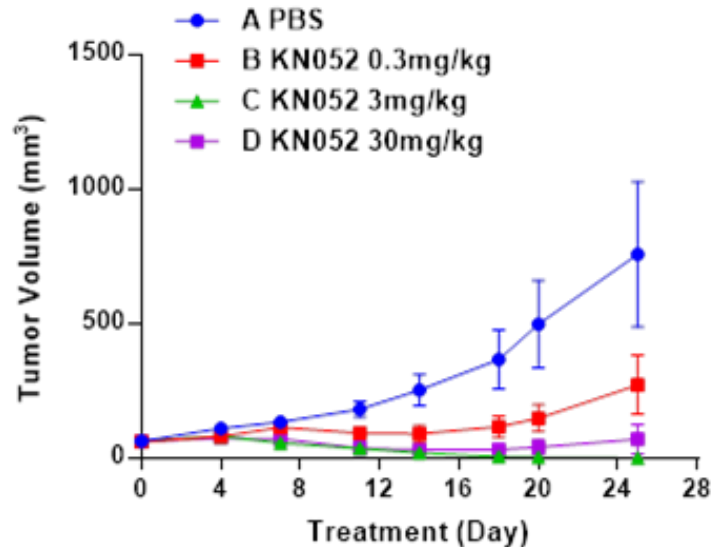
Wildtype IgG1Fc



Highlights

- PD-L1 antagonist and OX40 agonist activity in one molecule
- Tandem structure for antigen binding domain arrangement to attenuate anti-OX40 toxicity
- Wildtype IgG1 Fc with full Fc function

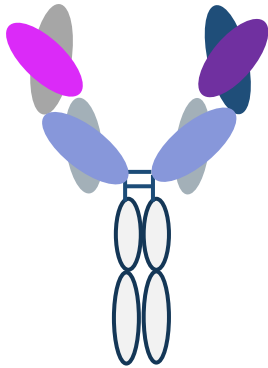
KN052 shows synergistic antitumor activity in MC38 tumor model



KN062: Bispecific COVID-19 Neutralization Antibody



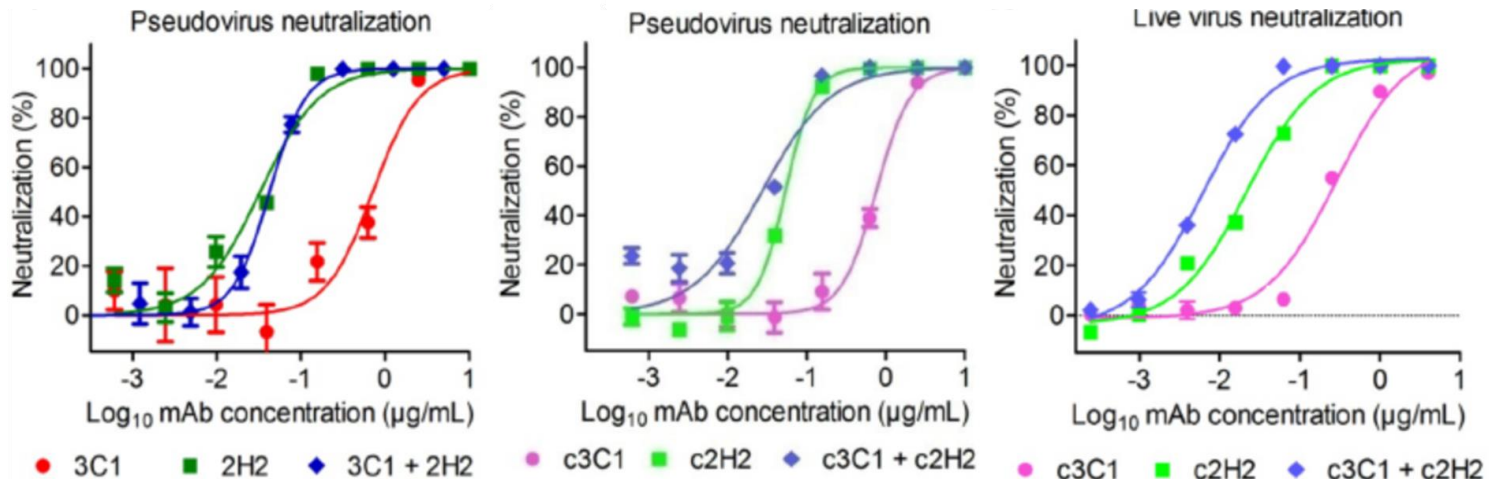
Product Structure



Highlights and Strategy

- Combination of two antibodies targeting different paratopes outside of escaping mutant
- Potential to combo with approved COVID-19 antibodies
- Progress has been made, and the future development strategies depend on the development of COVID-19

3c1+2H2 combination show stronger neutralization activity than mono paratope treatment

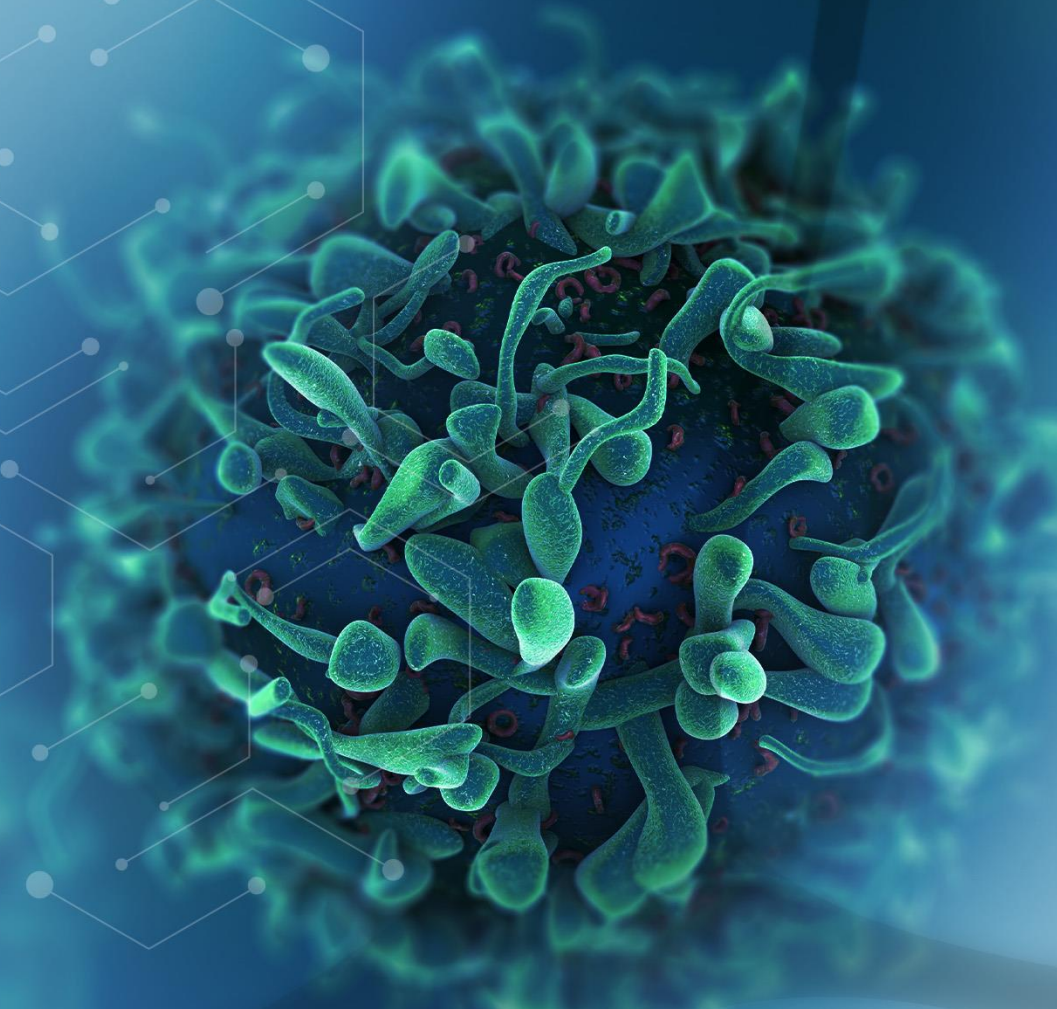


Pre-clinical Pipeline overview

Drug candidates	Target(s)	Platform	Rights	Key Indications
JSKN-001	Undisclosed	CRIB	Global	Solid tumors
JSKN-002	Undisclosed	GIMC	Global	Solid tumors
JSKN-004	Undisclosed	TIMC	Global	Solid tumors
JSKN-005	Undisclosed	CIMC	Global	Solid tumors
JSKN-006	Undisclosed	BIMC	Global	Solid tumors
KN053	Undisclosed bispecific	sdAb/ mAb	Global	Solid tumors
KN055	Undisclosed bispecific	sdAb/mAb, fusion protein	Global	Solid tumors
KN058	Undisclosed bispecific	sdAb/mAb, fusion protein	Global	Solid tumors
KN138	None-blocking CTLA-4	sdAb/mAb	Global	Solid tumors

04

Operation Progress



Business Development: Comprehensive Combo Strategy

..to unlock KN046 and KN026's full potential

Partner	Product	Status
辉瑞 Pfizer	KN046+Inlyta® (axitinib)	IND of Phase II clinical trial
泽璟制药 Zelgen	KN046+Donafenib Tosylate	Phase II clinical trial
广东东阳光 Sunshine Lake	KN046+Ningetinib Toluenesulfonate	Phase II clinical trial
开拓药业 Kintor Pharmaceutical	KN046+ALK-1 (Activin Receptor- Like Kinase-1)	Phase I/II clinical trial
辉瑞 Pfizer	KN026+Ibrance® (palbociclib)	Phase II Clinical trial
赛诺菲 Sanofi	KN026+Taxotere® ⁽³⁾ (Docetaxel)	Completed the enrollment of Phase II clinical patients

Note:

1. Sanofi has the exclusive right to choose KN026 strategic cooperation, and can give priority to advance clinical research for KN026

Strong Manufacturing Capabilities

- The Phase I (2x2,000L) production lines of our new manufacturing facilities has obtained **Drug Production License** by Jiangsu Provincial Drug Administration in June, 2020
- The KN035 production line has passed **the GMP on-site inspection**



Capacity planning

Current capacity: **6,000L** (2x2,000L, 2x1,000L)

Capacity under construction: **6,000L** (3*2,000L)

Re-plan the production capacity: **30,000L** (6*5,000)

Total capacity

 **42,000L**

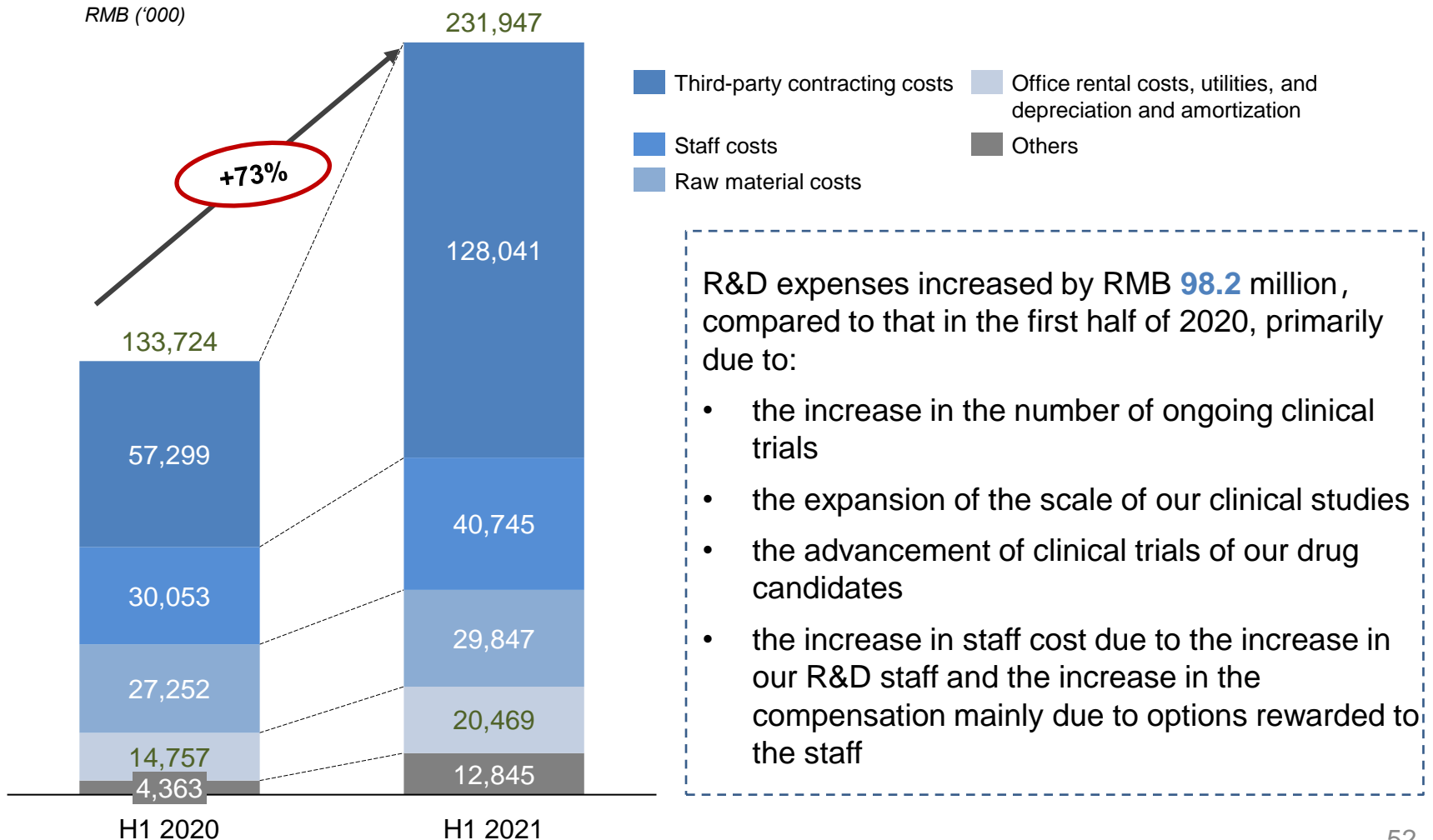
05

Financial Highlight



Increased R&D Expense Due to Expansion and Advancement of Clinical Trials

Comparison of R&D expenses between H1 2020 and H1 2021



Consolidated Statement of Comprehensive Income

<i>(RMB'000)</i>	Six months ended June 30	
	2021(unaudited)	2020(unaudited)
Other income	22,503	44,341
Other gains and losses	(13,552)	33,666
R&D expenses	(231,947)	133,724
Administrative expenses	(38,131)	(40,579)
Finance costs	(6,237)	(6,804)
Loss before taxation	(267,364)	(103,100)
Income taxation	-	-
Loss for the period	((267,364))	(103,100)

Balance Sheet

<i>(RMB'000)</i>	June 30, 2021 (unaudited)	December 31, 2020 (audited)
Non-current assets		
Property, plant and equipment	381,544	361,030
Right-of-use assets	35,252	31,991
Deposits paid for acquisition of property, plant and equipment	24,736	12,797
Other receivables and deposits	33,914	34,476
	475,446	440,294
Current assets		
Inventories	51,002	44,321
Other receivables, deposits and prepayments	53,126	84,795
Financial assets at fair value through profit or loss ("FVTPL")	55,010	43,530
Derivative financial instruments	3,717	5,863
Time deposits with original maturity over three months	1,159,836	1,835,398
Cash and cash equivalents	702,018	185,321
	2,024,709	2,199,228
Current liabilities		
Trade and other payables	148,661	121,939
Amount due to a related company	9,994	3,765
Lease liabilities	11,354	10,146
Bank borrowings	209,800	188,000
Contract liabilities	-	469
Deferred income	3,216	5,216
	383,025	329,535
Net current assets	1,641,684	1,869,693
Total assets less current liabilities	2,117,130	2,309,987
Non-current liabilities		
Lease liabilities	5,326	3,309
Bank borrowings	86,712	21,350
Contract liabilities	12,510	12,244
Deferred income	2,000	-
	106,548	36,903
Net assets	2,010,582	2,273,084
Capital and reserves		
Share capital	13	13
Reserves	2,010,569	2,273,071
Total equity	2,010,582	2,273,084

06

Q&A

