



康宁杰瑞

ALPHAMAB ONCOLOGY

2020 Annual Result  
Investor Presentation

March 24 2021

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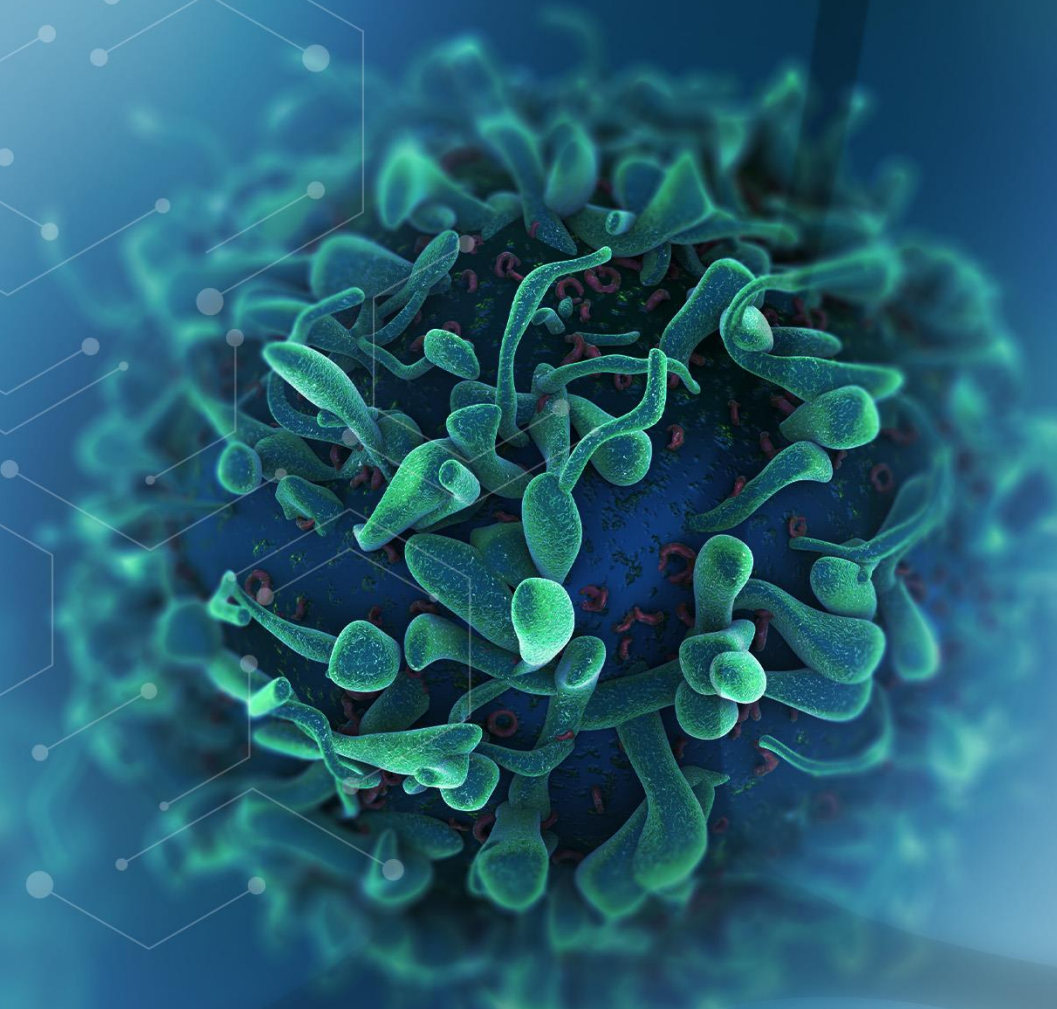
# Agenda

	<u>Presenter</u>
<b>1</b> 2020 Overview	Dr. Ting Xu, Founder, Chairman & CEO
<b>2</b> R&D Progress	Dr. Ting Xu, Founder, Chairman & CEO
<b>3</b> Clinical Progress	Dr. Johannes Nippgen, CMO
<b>4</b> Operation Progress	Ms. Yang Liu, VP, Corporate Operations
<b>5</b> 2021 Catalyst	Dr. Ting Xu, Founder, Chairman & CEO
<b>6</b> Financial Overview	Dr. Ting Xu, Founder, Chairman & CEO
<b>7</b> Q&A	Management team



# 01

## 2020 Overview





# 康宁杰瑞

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**.

## Track Record

- Founded by a visionary scientist who has made contributions to over **100** patents and patent applications since 2011
- Strong in-house R&D contributed to the CMC processes of many biosimilar candidates including **4** out of **11** biosimilar BLAs filed in China from 2017 to 2019

## Global Rights

- All in-house developed candidates
- Global rights (IP, Commercial)
- **>30** ongoing global or China clinical trials

## Innovation

- All in-house developed proprietary platforms including sdAb/mAb, CRIB, CRAM, BADC, BIMC, TIMC, GIMC and CIMC
- Robust first-in-class global next-generation product pipeline: **16** products, with **1** BLA submitted, **3** in late clinical stage, and **3** IND enabling

## Integrated Platform

- Fully-integrated platform consisting of drug discovery, development, manufacturing and near-term commercialization

# Pipeline overview

Stage	Drug candidates	Target(s)	Platform	Rights	Key Indications	Pre-clinical	Dose escalation	Proof of concept	Pivotal	NDA
Late-stage	KN046	PD-L1/CTLA-4 bispecific	sdAb/mAb	Global	NSCLC, Thymic, HCC, Pancreatic, 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	▶				
	KN035	subQ PD-L1	sdAb/mAb	Global Co-development	MSI-H, BTC, Sarcoma, TMB-H, MSS endometrial	▶ NDA submitted in 2020Q4				
Clinical/IND	KN019	B7	Fusion protein	Global	RA, lupus, renal transplant, GvHD	▶ Phase II ongoing				
	KN052	PD-L1/OX40 bispecific	CRIB	Global	Solid tumors	▶				
	KN062	None RBD conformation bispecific	CRIB	Global	COVID-19	▶				
	JSKN-003	HER2 ADC	BADC	Global	HER2-positive/low solid tumors	▶				
Pre-clinical	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	▶				

# Major progresses



## Program Progress

- ✓ **1 BLA under Priority Review by NMPA:** Envafohimab(KN035) MSI-H/dMMR advanced solid tumors
- ✓ **4 pivotal trials kicked off:**
  - KN046 NSCLC
  - KN046 thymic carcinoma
  - KN046+KN026 HER2+ solid tumors
  - KN035 soft tissue sarcoma in US by Tracon
- ✓ **3 Orphan Drug Designation granted by US FDA :**
  - KN035 BTC
  - KN046 thymic epithelial tumor
  - KN026+KN046 gastric cancer
- ✓ **9 IND approved:**
  - 6 in China: KN046 late stage GI (combo Donafenib), KN046 solid tumors and blood tumors including HCC (combo Ningetinib), KN046+KN026 HER2-positive or low solid tumors, KN026 HER2-positive or low mBC (mono or combo docetaxel), KN026 HER2-positive mBC (combo palbociclib or palbociclib+fulvestrant)
  - 3 in US: KN046 thymic carcinoma, KN046 PD-(L)1 refractory NSCLC, KN035 soft tissue sarcoma
- ✓ **8 clinical data presentations** at ASCO, AACR, SITC and WCLC

# Major progresses



## Operation Progress

- ✓ **10 partnerships :**
  - KN026 : **Sanofi, Pfizer**
  - KN046 : Zelgen (泽璟), Sunny Lake (东阳光), Kintor (开拓), Sinovent (信诺维), InxMed (应世)
  - KN035 : Simcere (先声), Tracon
  - KN062 : Institut Pasteur Shanghai (中科院上海巴斯德)
- ✓ **Drug production license :** The 2x2,000L production lines of the new manufacturing facilities obtained Drug Production License
- ✓ **Further expansion of management team :**
  - CMO, Dr. Johannes Nippgen, Ph.D.
  - VP Clinical Operations, Ms. Han Fu
  - VP Biometrics, Dr. Yi Xia, Ph.D.
  - VP Registration Affairs, Dr. Li Wan, Ph.D., RAC
  - VP Quality, Mr. Weidong Ma
- ✓ **Establishing operation center in Shanghai**



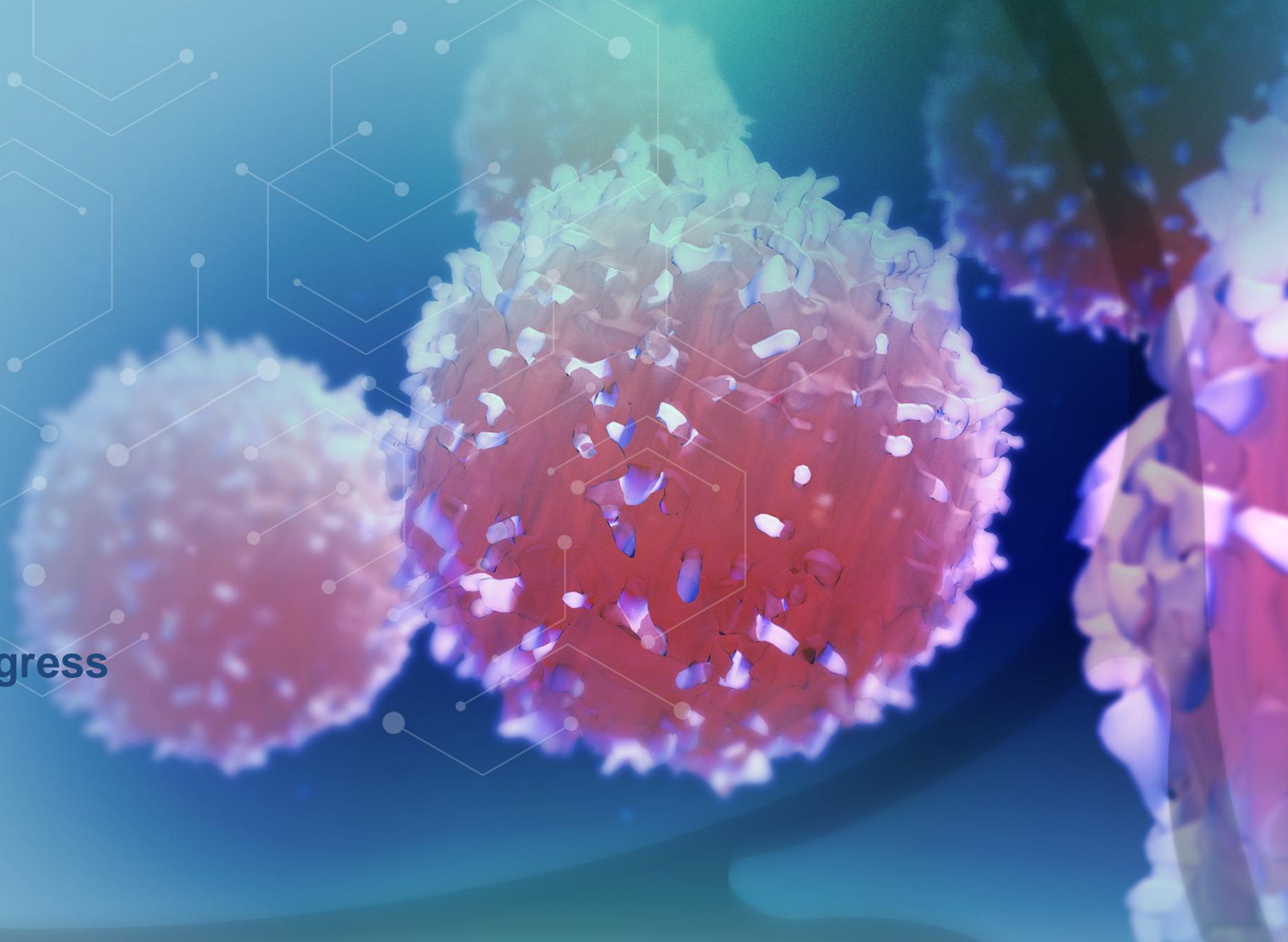
## Finance and capital market

- ✓ **Increased R&D expenses :** increased from RMB166.7 million for FY2019 to RMB331.2 million for FY2020, primarily due to expansion and advancement of clinical trials
- ✓ **Healthy cash reserve :** cash balance of RMB2,021 million as of December 31, 2020
- ✓ **Inclusion to the Hang Seng Composite Index, Hang Seng Healthcare Index, Southbound Stock Connect**



# 02

## R&D Progress



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



sdAb



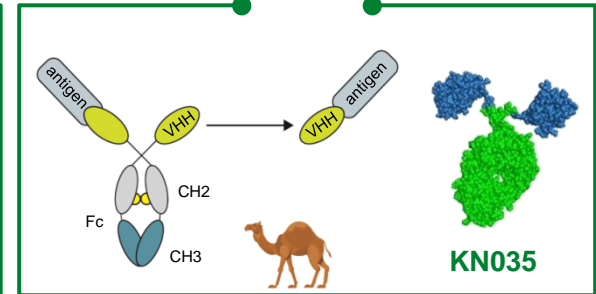
Smaller and more stable with a compact structure



Ideal building blocks for multifunctional biologics



Proof-of-concept: KN035<sup>1</sup>, KN046<sup>2</sup>, KN052



CRIB



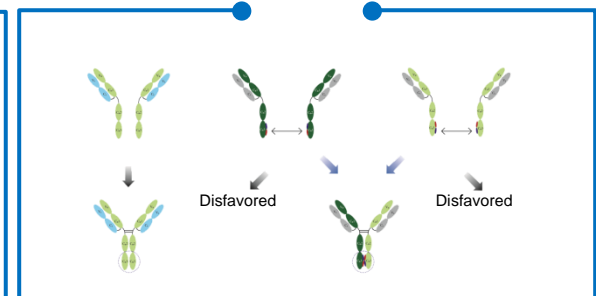
Maintain full-length antibody properties



Optimized for commercial-scale manufacturing



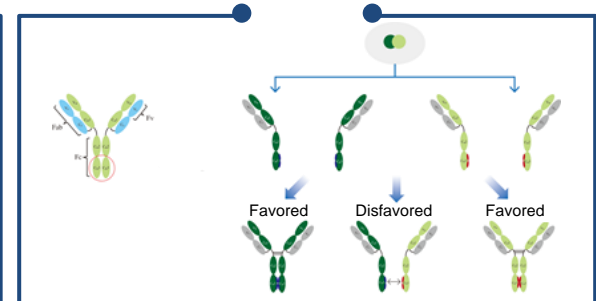
Proof-of-concept: KN026<sup>3</sup>



CRAM



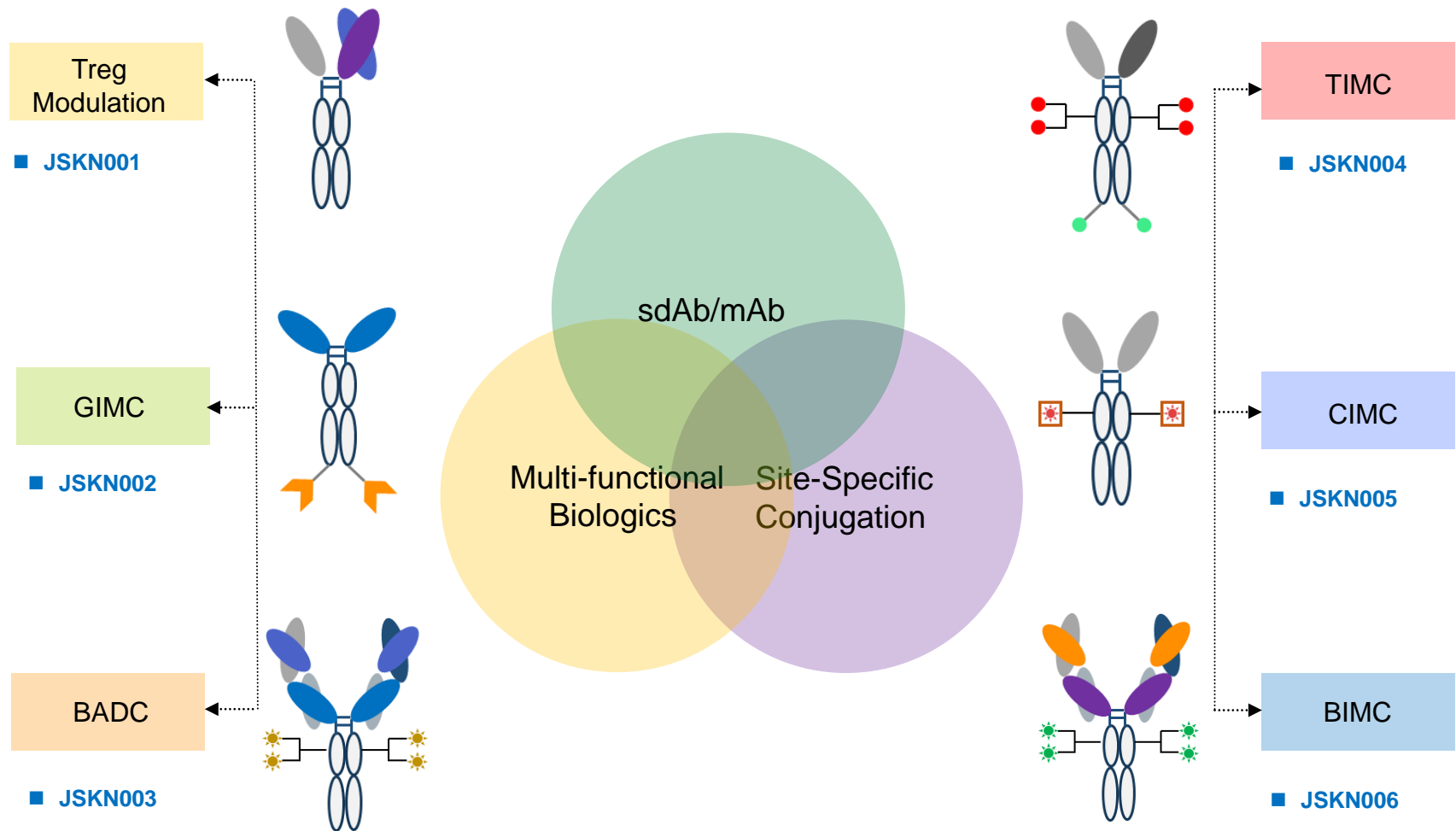
A single streamlined process to produce multiple mAbs with adjustable pre-determined ratio



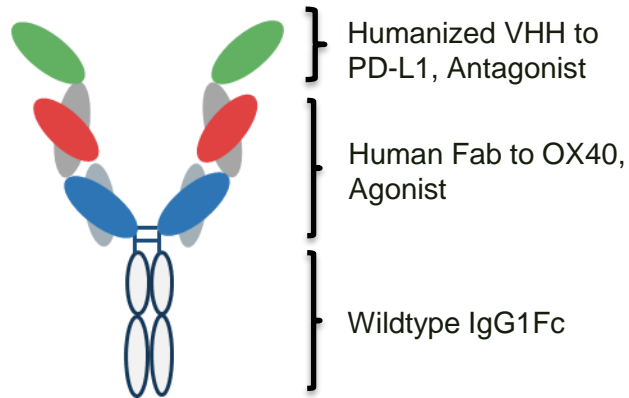
Note:

1. First BLA submitted in 2020
2. Pivotal trial stage
3. Pivotal trial stage

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

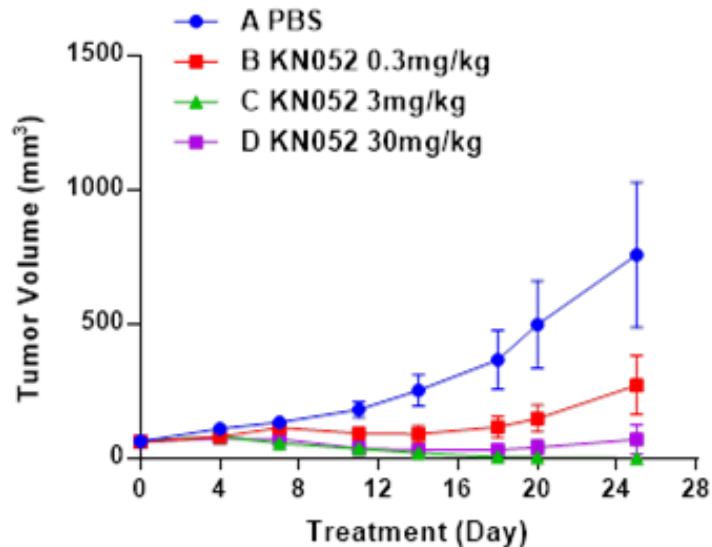


## KN052: Anti-PD-L1/OX40 Bispecific Antibody

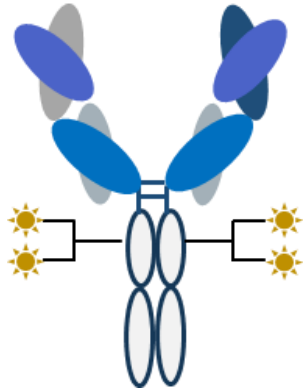


- PD-L1 antagonist and OX40 agonist activity in one molecule
- Tandem structure for antigen binding domain arrangement to attenuate anti-OX40 toxicity
- Wildtype IgG1 Fc with full Fc function

### KN052 shows synergistic antitumor activity in MC38 tumor model

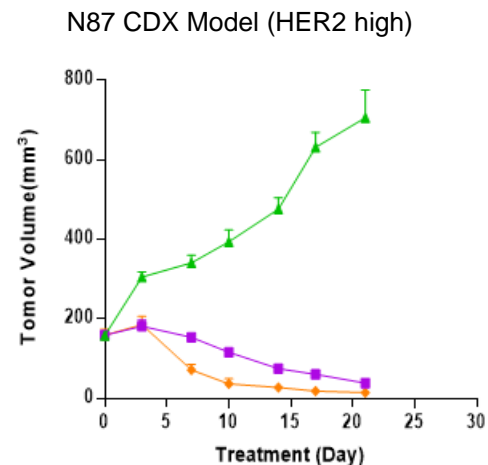
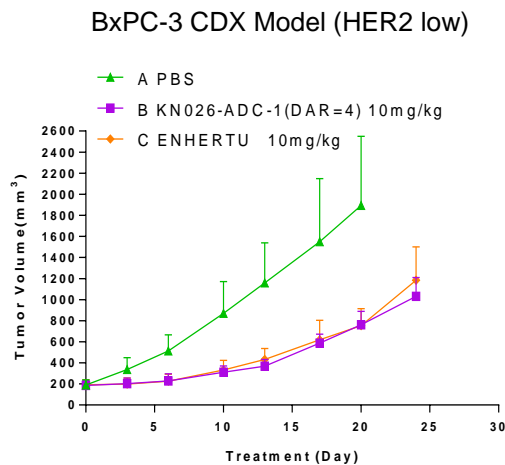


# JSKN003: Anti-HER2 Paratopes Bispecific ADC



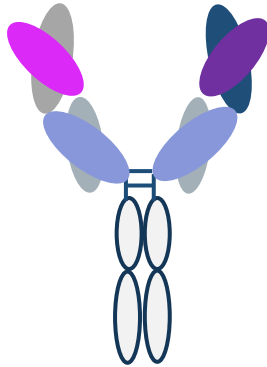
- ❑ Targeting two different paratopes of HER2 (KN026)
- ❑ Site specific conjugation, DAR 3-4
- ❑ Better serum stability for better safety potential
- ❑ Strong activity in HER2 high and low expression cells in CDX Model

## JSKN003 shows strong anti-tumor activity in CDX model



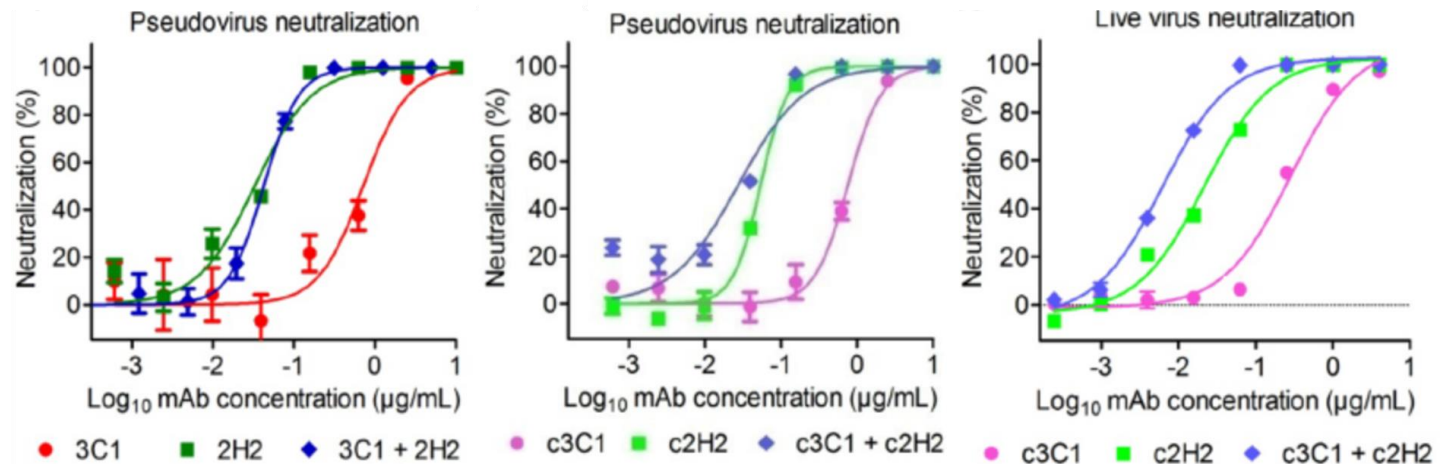


# KN062: Bispecific COVID-19 Neutralization Antibody



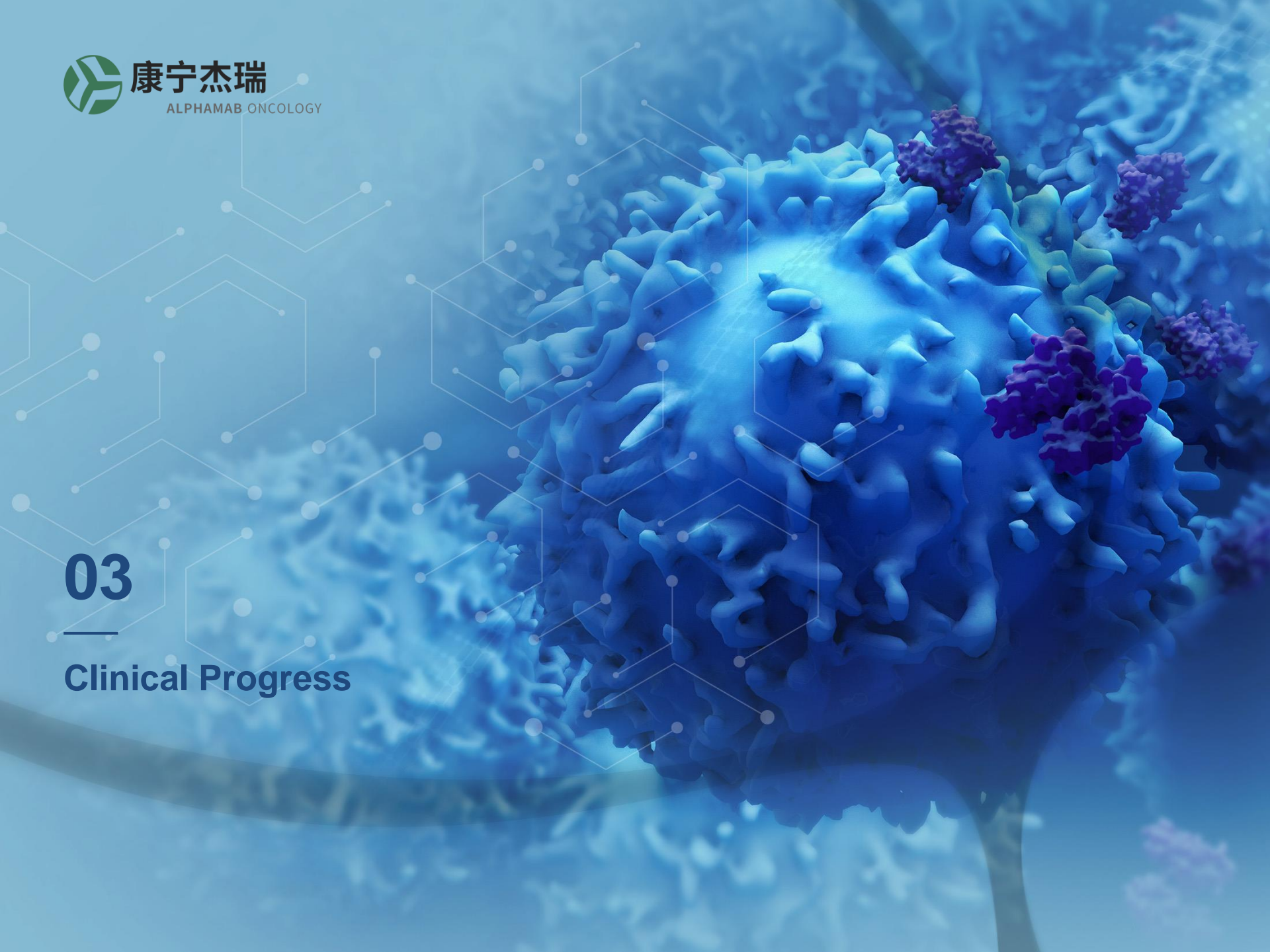
- Combination of two antibodies targeting different paratopes outside of escaping mutant
- Potential to combo with approved COVID-19 antibodies

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



# 03

## Clinical Progress



# Clinical Updates

## KN046

Dual blockade of PD-L1 and CTLA-4

## KN026

Dual blockade of HER2 domain II and IV

## KN035

Subcutaneous PD-L1

## KN019

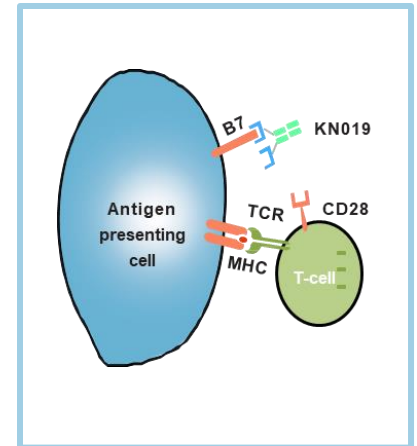
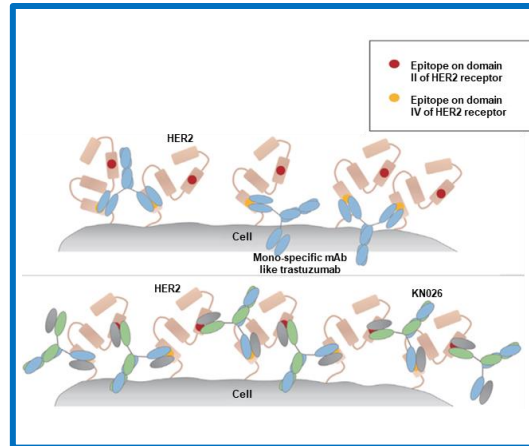
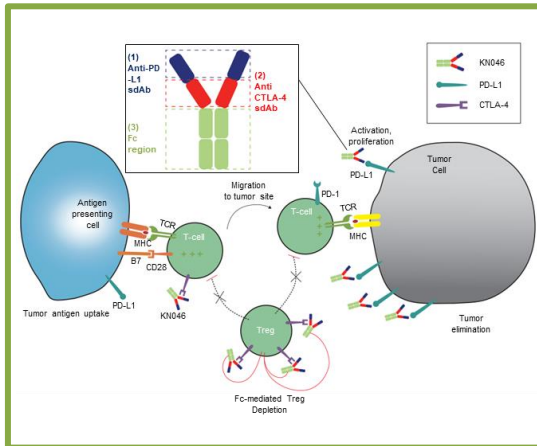
A safe option for autoimmune diseases

Enable earlier lines of therapies for improved efficacy and safety

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

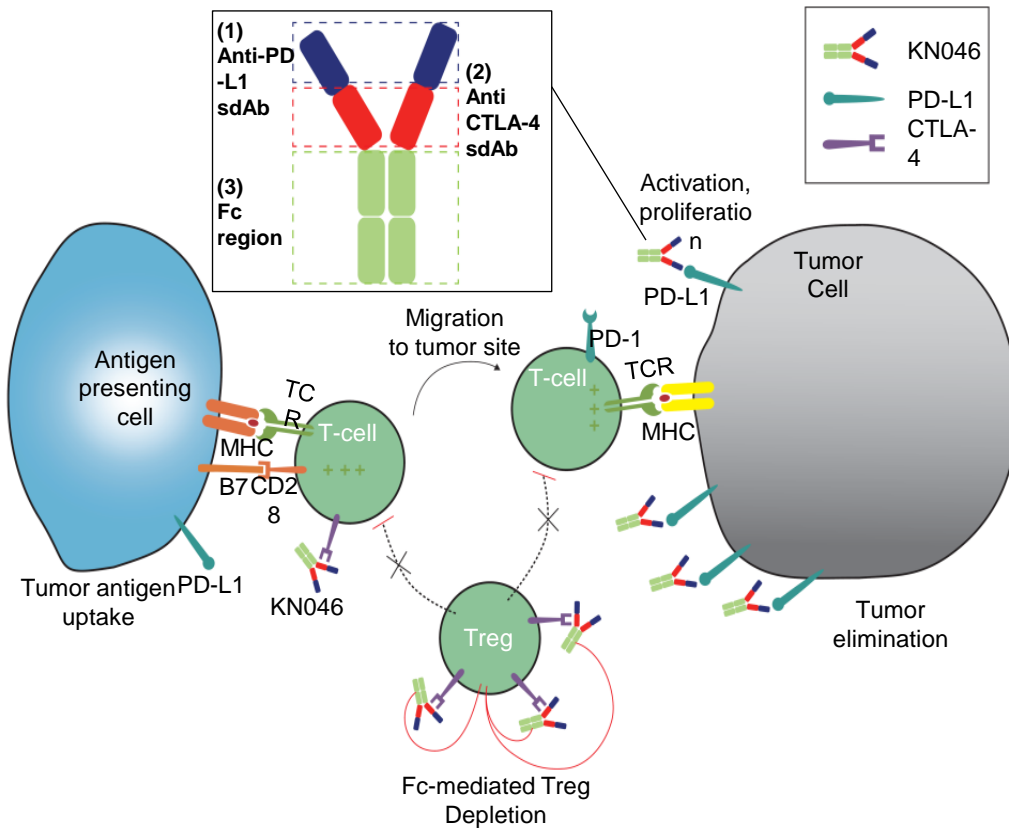
Subcutaneous PD-L1 for maintenance therapy

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

Stage	Indication	Mono/Combo	Pre-clinical	Dose escalation	Proof of concept	Pivotal	NDA	Expected timeline
4 Pivotal trials	1L NSCLC, sq	+chemo					★	BLA 2022H1
	Thymic carcinoma	Mono					★	BLA 2022H1
	PD-(L)1 refractory NSCLC	+Lenvatinib					★	BLA 2023H2
	1L Pancreatic Cancer	+chemo					★	FPI 2021H2
Key phase 2 trials ongoing	1L Pancreatic Cancer	+chemo						Ongoing
	Driver mutation positive NSCLC	+chemo						Ongoing
	Stage III NSCLC	+RT						Ongoing
	1L TNBC	+nab-paclitaxel						Ongoing
	1L ESCC	+chemo						Ongoing

★ Pivotal Trial

Note: FPI – first patient in

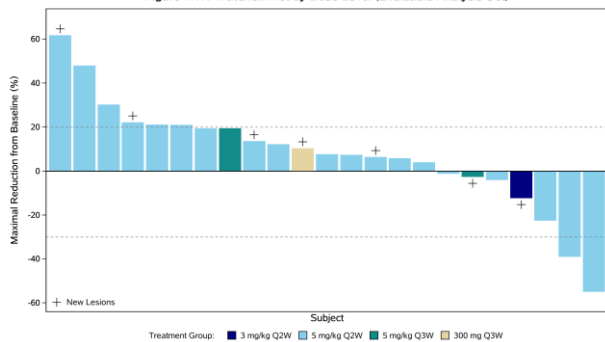


# KN046-CHN-001 and KN046-201 in ICI Refractory Patients

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

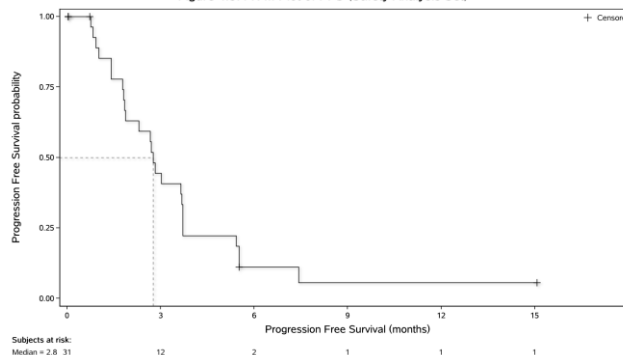
### Waterfall plot (DCR 50%)

Figure 4.1.1 Waterfall Plot by Dose Level (Evaluable Analysis Set)



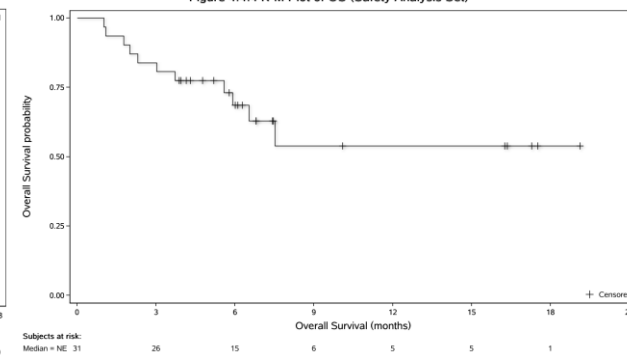
### Progression-free survival (2.8 months)

Figure 4.5.4 K-M Plot of PFS (Safety Analysis Set)



### Overall survival (mOS not reached yet)

Figure 4.4.4 K-M Plot of OS (Safety Analysis Set)



## 2 Comparable trials in NSCLC

	KN046-CHN-001 & KN046-201*	Fujita 2019	Yuki Katayama 2019	ENCOR-601
Drug	KN046 monotherapy	Atezolizumab	Anti-PD-1 I-O	Entinostat+ Pembrolizumab
Patients #	24	18	35	72
ORR	8.3% (DCR 50%)	0 (DCR 38.9%)	5.9% (DCR 42.9%)	10% (DCR 60%)
mPFS	2.8 months	1.7 months	2.7 months	2.8 months
mOS	Not reached 12-month OS: 54%	Not reported	7.4 months	Not reported

### Notes:

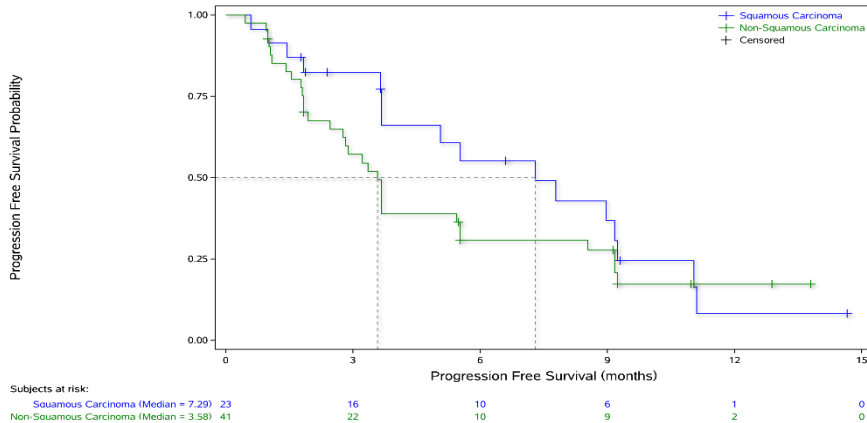
1. Data not mature yet

# KN046-201 2L NSCLC (2021 WCLC)

## 1 PFS and OS benefits for squamous and non-squamous NSCLC patients

### PFS

Kaplan-Meier Plots of Progression Free Survival (Safety Analysis Set) (Cohort A+B)

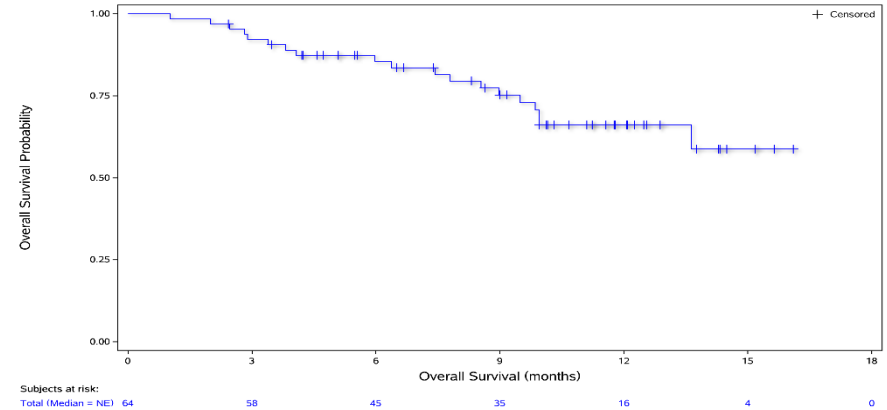


mPFS 3.68 months (95%CI 3.35, 7.29):

- non-sq NSCLC **3.58 months** (2.46, 5.52)
- sq NSCLC **7.29 months** (3.68, 9.23)

### OS

Kaplan-Meier Plots of Overall Survival (Safety Analysis Set) (Cohort A+B)



mOS not reached yet:

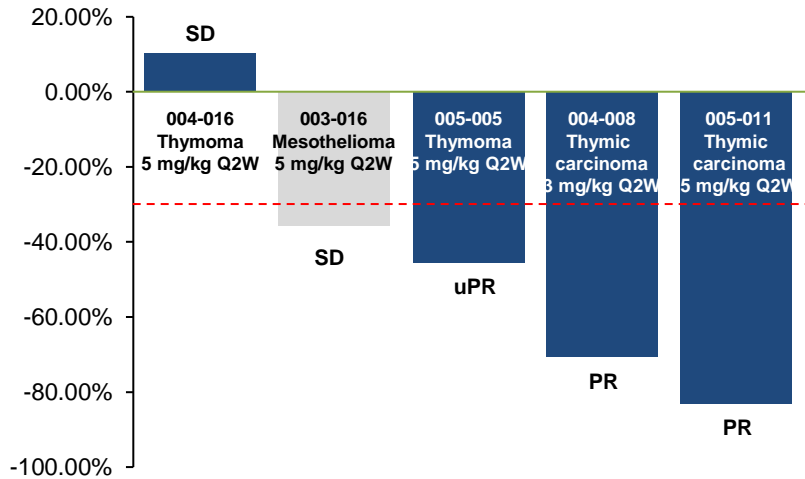
- 6-month OS rate **85.6%**
- 12-month OS rate **69.7%**

## 2 Numerically higher mPFS and mOS than PD-1s

	KN046-201	Keynote001	CheckMate057	CheckMate017
Indication	NSCLC 2L	NSCLC 2L	NSCLC (non-sq) 2L	NSCLC (sq) 2L
Drug	KN046	Pembrolizumab	Nivolumab	Nivolumab
Patients #	64	394	292	135
mPFS	7.3 (sq), 3.6 (non-sq)	3	2.3	3.5
mOS	13.6 (sq), Not reached (non-sq)	9.3	12.2	9.2

## KN046-AUS-01 Rare Thoracic Tumors (2021 WCLC)

Waterfall plot



**ODD (Orphan Drug Designation) awarded by US FDA**



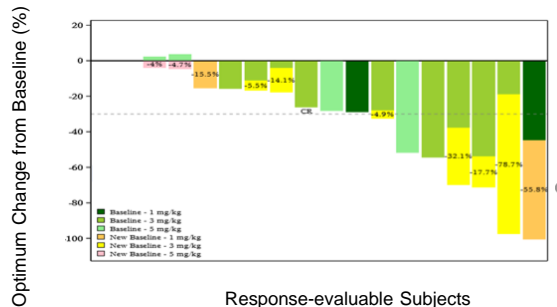
**Phase II pivotal trial in China and US ongoing**

Response observed in 3 patients with thymic epithelial out of 4 in total :

- ORR: **75% (3/4)**
- DCR: **100% (4/4)**

# KN046-IST-01 ESCC (with concurrent chemoradiation therapy) (2021 ASCO GI)

## 1 Waterfall plot before & after KN046 treatment



	1mg/kg (N=3)	3mg/kg (N=11)	5mg/kg (N=4)	All (N=18)
ORR	1 (33.3%)	6 (54.5%)	1 (25.0%)	8 (44.4%)
DCR	2 (66.7%)	11 (100.0%)	4 (100.0%)	17 (94.4%)

**Efficacy:** Overall ORR 44.4%, DCR 94.4% (n=18)

In the 3mg/kg group, **2 CR, 4 PR**, ORR **54.5%**, DCR **100%** (n=11)

**Safety:** Grade 3 and above **irAE 16.7%** (3/18)

Grade 3 and above **KN046-related TRAEs 16.7%** (3/18)

**Relevant clinical progress:** A phase II clinical study (KN046-204) of ESCC is ongoing; data to be released in ESMO (Sep 2021)

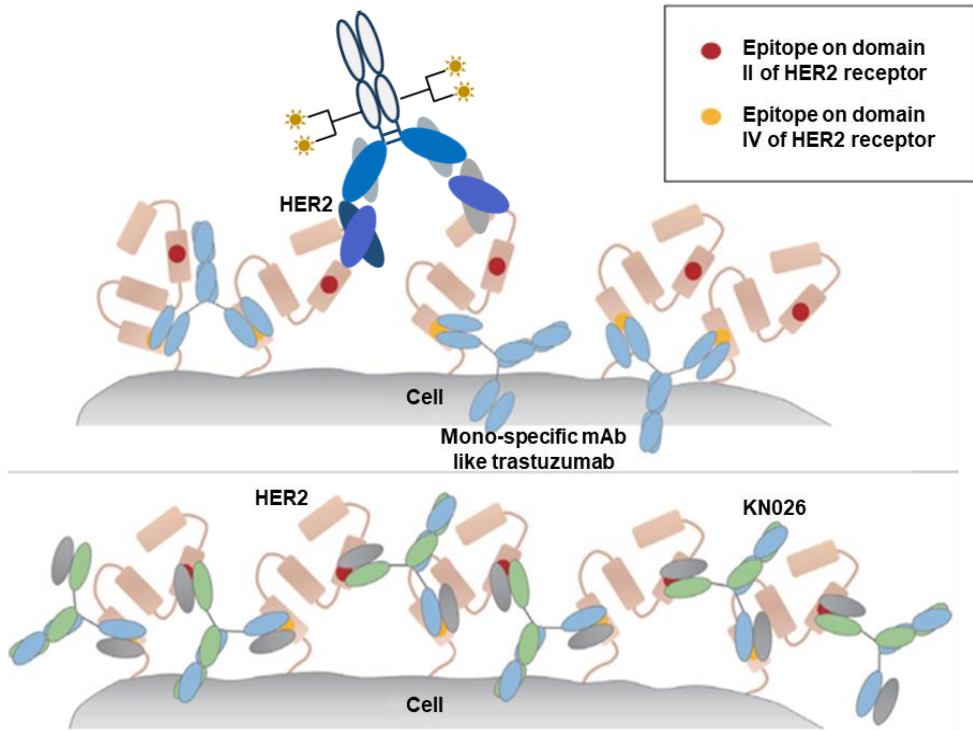
## 2 Comparable trials

	KN046-IST-01	KEYNOTE 590	RATIONALE 205
Drug	KN046+ concurrent chemoradiation	Pembrolizumab + chemo VS chemo	Tislelizumab + chemo
Patients #	11	548	15
ORR	<b>54.5% (2 CR, 4 PR)</b>	45% VS 29.3%	46.7% (7 PR)

**Notes:** 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).

# KN026: HER2/HER2 BsAb

## Mechanism of action





## Highlights

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



## KN026, JSKN003, KN026+KN046 Combo Major Clinical Trials

Tumor Type	Trial	Combo/Mono	Expected timeline		
HER2+BC	KN026-304	≥ 2L: KN026-based combination	BLA 2023H1	★	
	KN026-203, exploratory phase	≥ 2L: KN026 + KN046	Ongoing		
	KN026-201		1L: KN026 + docetaxel		Ongoing
			≥ 2L: KN026 + pyrotinib/capecitabine		FPI 2021Q2
KN026-205		≥ 2L: KN026 + palbociclib (+/- fulvestrant)	FPI 2021Q2		
HER2+GC/GEJ	KN026-203, primary efficacy phase	≥ 2L: KN026 + KN046	BLA 2023H2	★	
	KN046-IST-02	1L: KN026 + KN046	Ongoing		
		1L: KN026 + KN046 + reduced chemo	FPI 2021Q2		
KN026-202		≥ 2L: mono	Ongoing		
HER2+ solid tumors	JSKN003-101	Late line: mono	BLA 2023H2	★	
	KN026-US-01	Late line: mono	Ongoing		
	KN046-IST-02, exploratory phase	≥ 2L: KN026 + KN046	Ongoing		
	KN026-203, exploratory phase	≥ 2L: KN026 + KN046	Ongoing		
HER2-low solid tumors	JSKN003-101	Late line: mono	FPI 2022Q2		

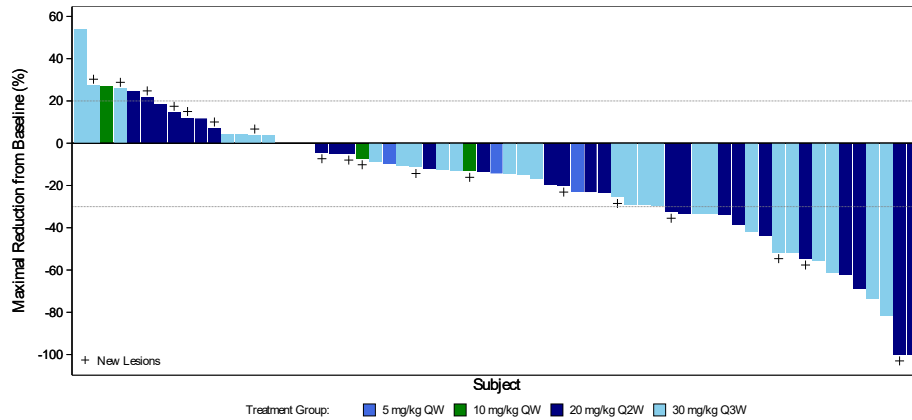
★ Pivotal Trial

Note: FPI – first patient in

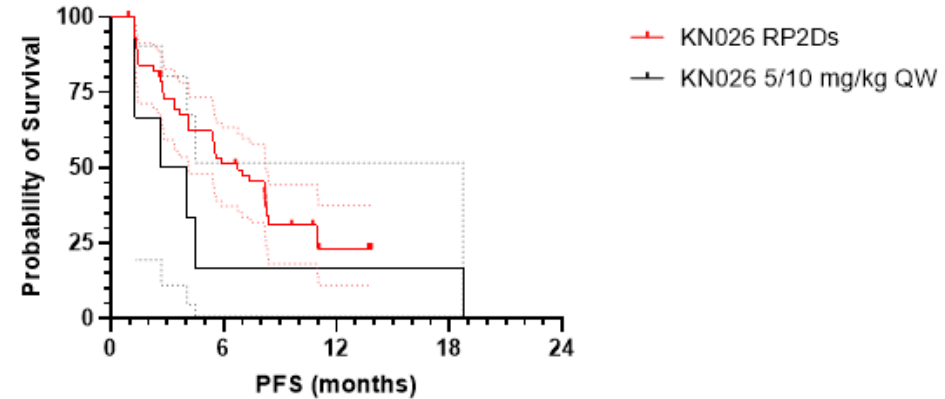
# KN026-CHN-001

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

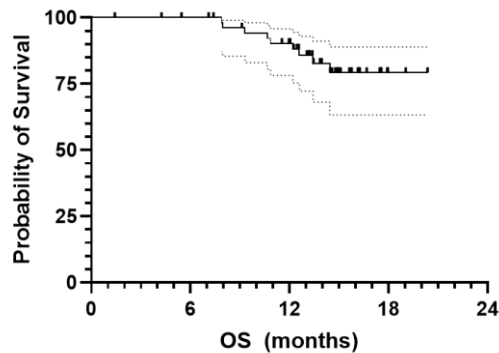
**Waterfall plot**



**Progression-free survival (6.8 months at RP2Ds)**



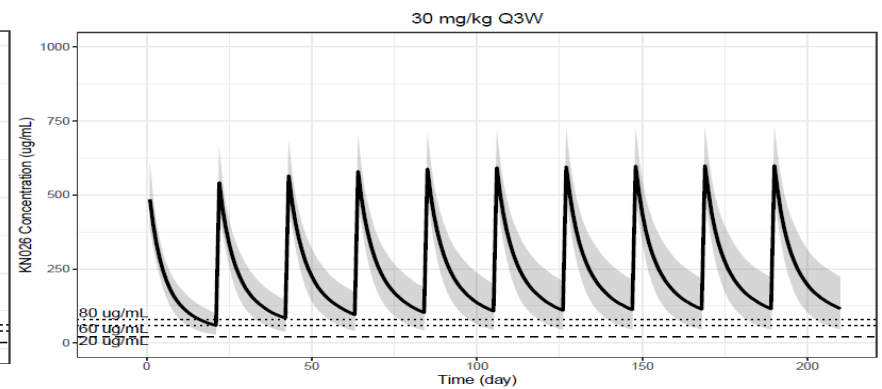
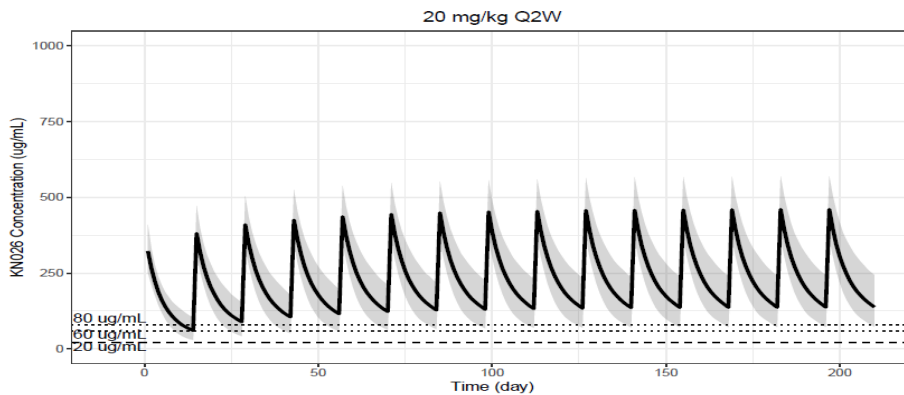
**Overall survival (1-year OS rate at RP2Ds 90.3%)**



- 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%**

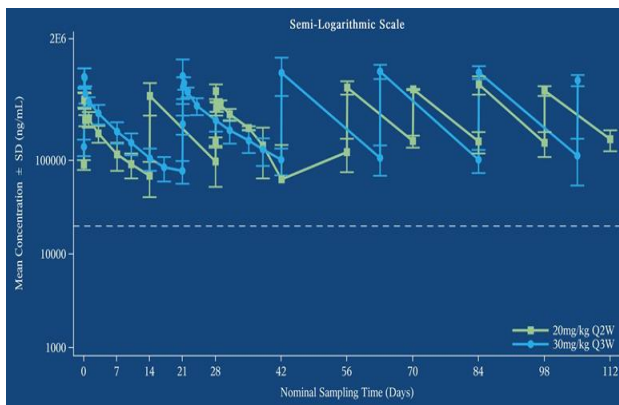
# A PK Model to Predict Efficacious Doses for KN026 (2020 AACR)

20 mg/kg Q2W and 30 mg/kg Q3W provide adequate steady state trough concentration for efficacy



Facilitate decision of effective dose and dose schedule, improve efficiency of R&D

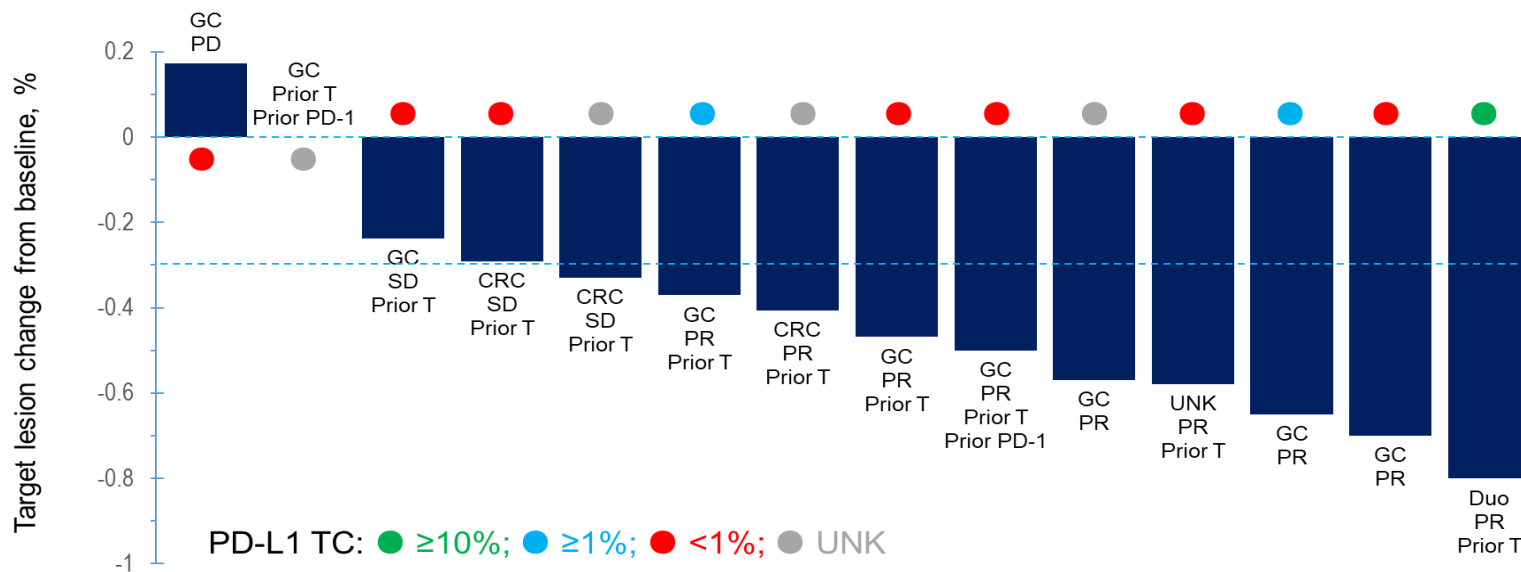
KN026 has shown favorable PK profile compared with ZW25



Favorable PK profile of KN026: 30 mg/kg Q3W

## KN046+KN026: KN046-IST-02 HER2 Positive Solid Tumors (2020 SITC)

- ✓ ORR **64.3%**, DCR **92.9%** (n=14)
- ✓ Responses were observed in 10 patients who failed previous HER2 and/or ICI treatment



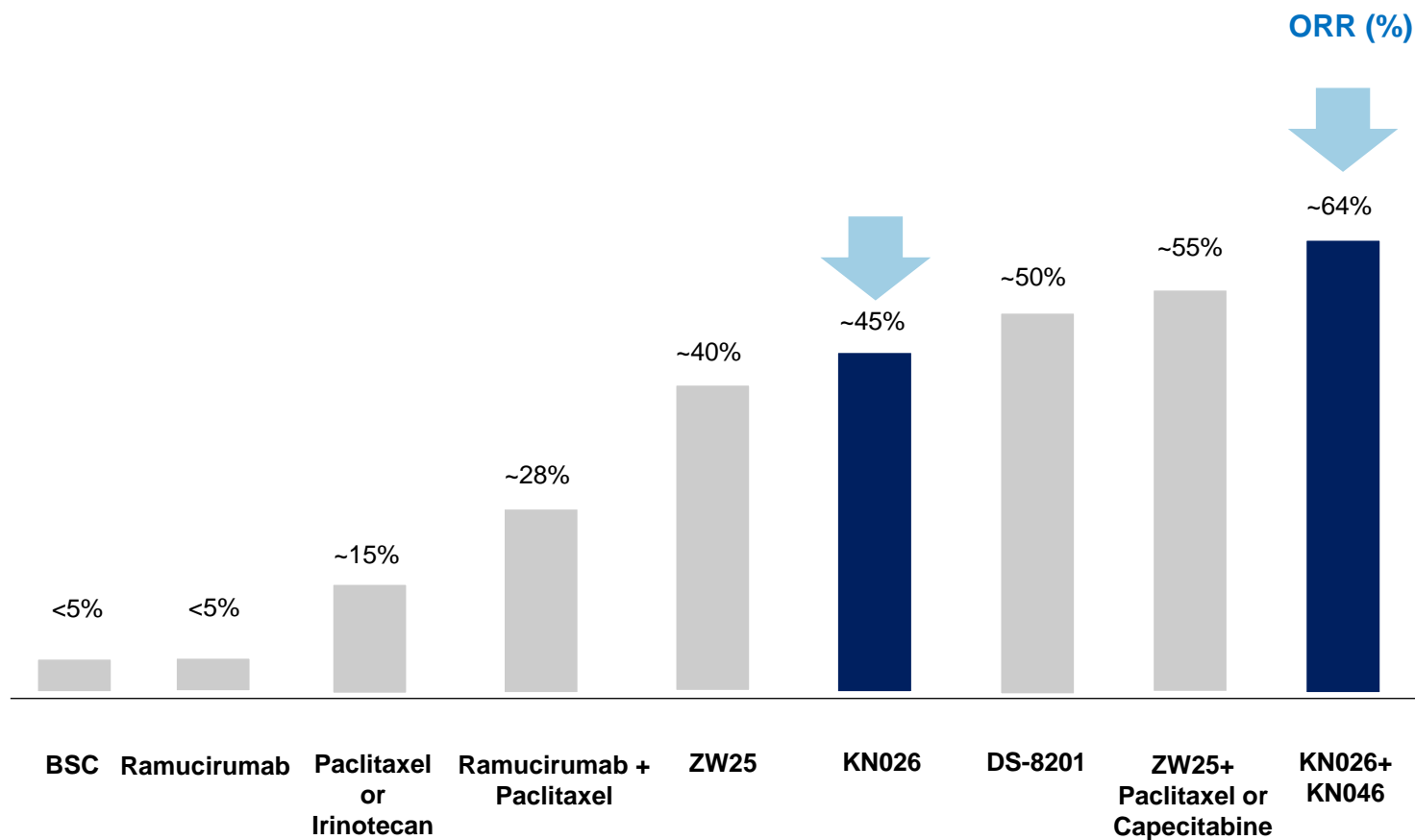
	20 mg/kg Q2W + 3 mg/kg Q2W (N=13)	20 mg/kg Q2W + 5 mg/kg Q3W (N=1)	30 mg/kg Q3W + 5 mg/kg Q3W (N=0)	Total (N=14)
<b>Best Overall Response</b>				
<b>Complete Response (CR)</b>	0	0	0	0
<b>Partial Response (PR)</b>	8 (61.5%)	1 (100%)	0	9 (64.3%)
<b>Stable Disease (SD)</b>	4 (30.8%)	0	0	4 (28.6%)
<b>Progressive Disease (PD)</b>	1 (7.7%)	0	0	1 (7.1%)
<b>Not Evaluable (NE)</b>	0	0	0	0
<b>Objective Response Rate (ORR)</b>	8 (61.5%)	1 (100%)	NA	<b>9 (64.3%)</b>
<b>95% CI</b>	31.6%, 86.1%	2.5%, 100.0%	NA	35.1%, 87.2%
<b>Disease Control Rate (DCR)</b>	12 (92.3%)	1 (100.0%)	NA	<b>13 (92.9%)</b>
<b>95% CI</b>	64.0%, 99.8%	2.5%, 100.0%	NA	66.1%, 99.8%

### Notes:

1. Prior T: previously treated by trastuzumab; Prior PD-1: previously treated by anti-PD-1 agent; Duo: duodenum; UNK: unknown origin

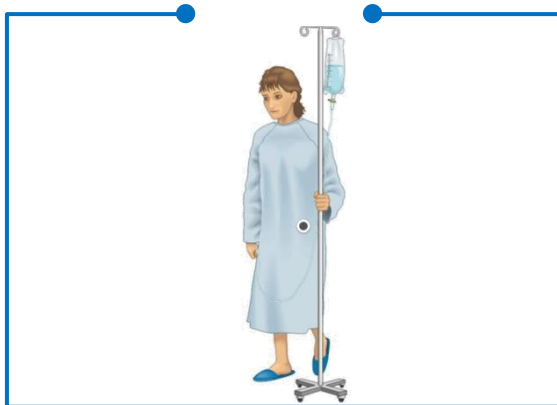
## Potential Superior Efficacy: $\geq 2L$ Gastric Cancer Studies

Target best in class profile with near-term US and China registration studies



# KN035: Potential First-global SubQ PD-L1 with BLA Submitted in China

## Intravenous infusion vs. subcutaneous Injection



Intravenous Infusion



subcutaneous Injection

- BLA (MSI-H/dMMR advanced solid tumors) submitted in China in 2020Q4
- Priority review granted by NMPA
- BLA approval expected by the end of 2021

## Advantages



Easier administration



More convenient for maintenance usage



More efficient utilization of medical resources
















Preferred for patients with limited vein access and infusion related reactions



Better safety profile

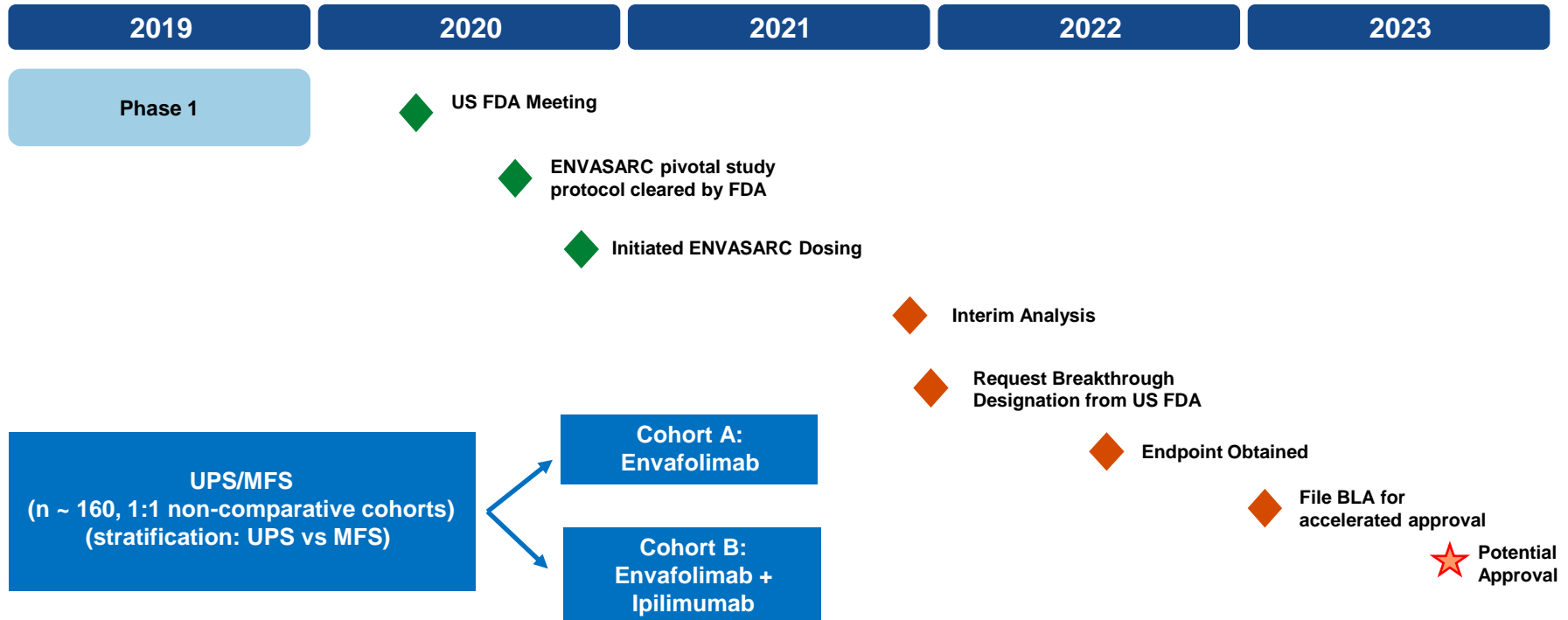


## KN035: Clinical Development Summary – Collaboration with 3DMed

Study	Phase 1	Phase 1b	Phase 2	Pivotal Study (Phase 2/3)	BLA	Progress
CN006	Pan-cancer (>15 solid tumors) with MSI-H				 	BLA submitted in China
CN005	Monotherapy   Single-arm, ORR   2L/3L Biliary tract cancer					>95% recruitment
CN007	Combo with chemo   Open-labeled, randomized, two-arm parallel, OS   1L Gastric cancer					Completed
CN001	Combo with chemo   Single-arm, exploratory   1L Dose escalation/expansion					Completed
JP001	Monotherapy   Safety and efficacy Dose escalation/exploration					Completed
US001	Monotherapy   Safety and efficacy Dose escalation/exploration					Full enrolled
CN008	PD1 failure NSCLC (+chidamide)					IND
CN009	Randomized, 1 <sup>st</sup> line NSCLC (Non-inferiority Ph3)					Pre registration meeting
CN010	-PD(L)1 failure NSCLC, RCC, HCC (+lenvatinib) -1 <sup>st</sup> line RCC (+lenvatinib)					Pre-IND
CN011	Single arm, 2 <sup>nd</sup> line MSS Endometrial Cancer (+lenvatinib)					Pre registration meeting
CN012	Single arm, 2 <sup>nd</sup> line TMB high tumors					Preliminary response rec'd
CN013	Randomized, 1 <sup>st</sup> line maintenance, UC					Pre registration meeting

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

## Key Milestones



- ✓ US FDA Type B meeting on May 2021
- ✓ 10 patients enrolled as of Mar 2021

# KN035 Efficacy Comparison: VS Pembrolizumab and Nivolumab in Advanced dMMR/MSI-H Solid Tumors

	Pembrolizumab			Nivolumab <sup>3,4</sup>	Envafolelimab		
	KEYNOTE-164 <sup>1</sup>		KEYNOTE-158 <sup>2</sup>	CHECKMATE-142	KN035-CN-006		
Study population	CRC-cohort A (≥2 prior therapies CRC) • Local/central lab verified MSIH/dMMR;	CRC-cohort B (overall CRC) • Local/central lab verified MSIH/dMMR;	non-CRC (prior ≥ 1 line) • Local/central lab verified MSIH/dMMR	≥2 prior therapies CRC • Local/central lab verified MSIH/dMMR	≥2 prior therapies CRC • Central lab verified MSIH;	Overall CRC • Central lab verified MSIH;	Overall population (prior ≥ 1 line) • Site/central lab verified MSIH/dMMR;
Sample size	61	63	233	53	41	65	103
ORR, %; IRC	33% (27.9%*)	33% (32%*)	34.3%	28%	31.7%	43.1%	42.7%
mPFS, months	2.3	4.1	4.1	—	4.9	7.2	11.1
6-m PFS rate	— (43%*)	— (49%*)	—	—	48.8%	53.8%	57.7%
mOS (months)	31.4	not reached	23.5	—	not reached	not reached	not reached
6-m OS rate	— (87%*)	— (84%*)	—	—	80.5%	84.5%	82.4%
12-m OS rate	72%	76%	60.7%	73%	64.7%	72.9%	74.6%

\*: KEYNOTE164 early published data<sup>15,16</sup>

3 drugs failed: failed with Fluorouracil, Oxaliplatin, Irinotecan

2 drugs failed: failed with Fluorouracil combined with oxaliplatin/irinotecan

1. J Clin Oncol. 2020 Jan 1;38(1):11-19.

2. J Clin Oncol. 2020; 38 (1): 1-10.

3. Overman MJ, et al. Lancet Oncol. 2017; 18(9): 1182-1191.

4. Opdivo (nivolumab). Highlights of Prescribing Information. Reference ID: 44277501e

5. Annals of Oncology. 2017; 28(S5): 128-129.

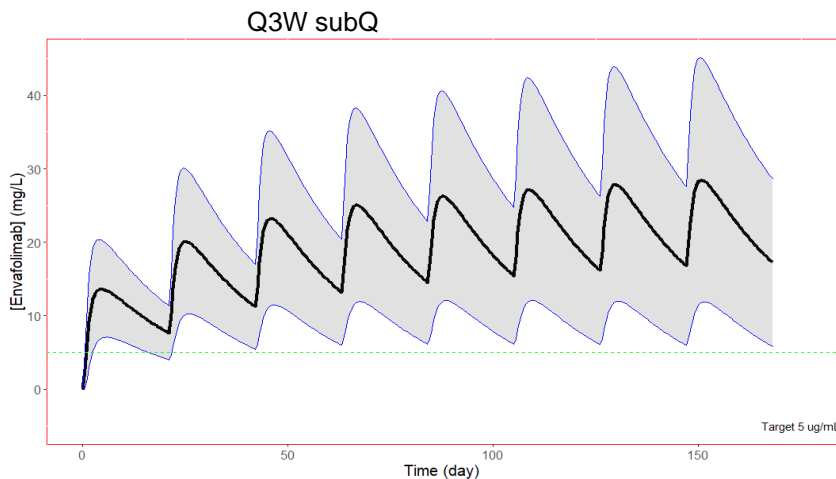
6. ASCO 2018 Annual Meeting, 3514.

# KN035: Superior Safety Profile and Dosing Schedule

## 1 irAE Comparison of KN035 and similar products

All levels of incidence (%)	PD-1 inhibitor					PD-L1 inhibitor			
	Nivolumab <sup>1</sup> (n=1994)	Pembrolizumab <sup>2</sup> (n=2799)	Sintilimab <sup>3</sup> (n=540)	Toripalimab <sup>4</sup> (n=598)	Camrelizumab <sup>5</sup> (n=986)	Avelumab <sup>6</sup> (n=1629)	Durvalumab <sup>7</sup> (n=1889)	Atezolizumab <sup>8</sup> (n=2616*)	KN035 (n=390)
Immune-related pneumonia	3.1%	3.4%	6.9%	1.8%	2.7%	1.2%	5%	2.5%	0.5%
Immune-related colitis	2.9%	1.7%	0%	0%	0.2%	1.5%	-	1.0% <sup>9*</sup>	0%
Infusion reaction	6.4%	3.0% <sup>10*</sup>	-	-	-	25%	2.2%	1.3%	NA <sup>#</sup>
Immune-related endocrine diseases									
Hypothyroidism	9%	8.5%	8.5%	12.9%	20.5%	5%	11%	4.6%	11.8%
Hyperthyroidism	2.7%	3.4%	4.3%	4.8%	6.7%	0.4%	7%	1.6%	7.2%
Immune related myocarditis	< 1%	< 1%	0.6%	-	0.3%	< 1%	< 1%	< 1%	0.3%
Immune related hepatitis	1.8%	0.7%	3.5%	3.5%	9.1%	0.9%	12%	9%	2.8%

## 2 PK simulation support future change from QW to Q3W

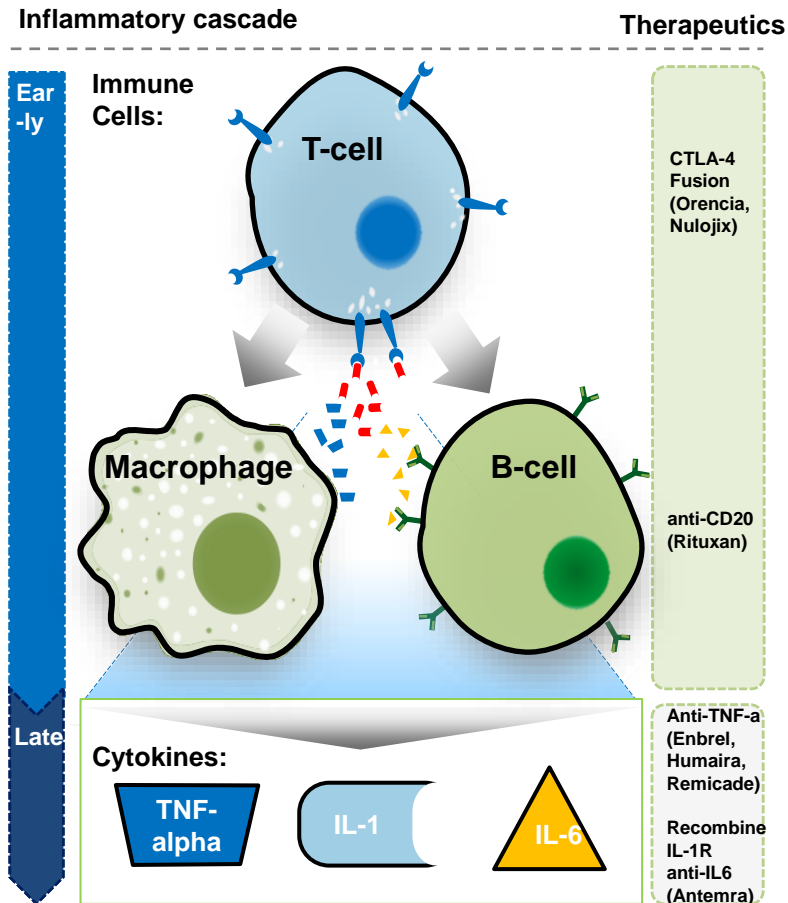


\*: Atezolizumab's immune-related colitis (1.0%; n+729); pembrolizumab's infusion reaction (3.0%; n=495)  
 -: Not reported  
 #: KN035 has no infusion reaction due to subcutaneous injection, and the incidence of injection site reaction is 5.1% (all Grade 1-2)

- OPDIVO (nivolumab). HIGHLIGHTS OF PRESCRIBING INFORMATION. Reference ID: 4400635
- KEYTRUDA (pembrolizumab). HIGHLIGHTS OF PRESCRIBING INFORMATION. Reference ID: 4492828
- March 2019, Sintilimab (CXSS1800008) BLA technical review report by NMPA CDE
- March 2019, Toripalimab (CXSS1800006) BLA technical review report by NMPA CDE
- July 2019, Camrelizumab (CXSS1800009) BLA technical review report by NMPA CDE
- BAVENCIO (avelumab). HIGHLIGHTS OF PRESCRIBING INFORMATION. Reference ID: 4433254
- IMFINZI (durvalumab). HIGHLIGHTS OF PRESCRIBING INFORMATION. Reference ID: 4465139
- TECENTRIQ (atezolizumab). HIGHLIGHTS OF PRESCRIBING INFORMATION. Reference ID: 4527935
- Wang DY, et al. Onco 2017; 6: e1344805
- Garon E B, et al. N Engl J Med, 2015, 372(21)

# KN019: CTLA-4 Fusion Protein - Immunosuppressant Drug

## Mechanism of action

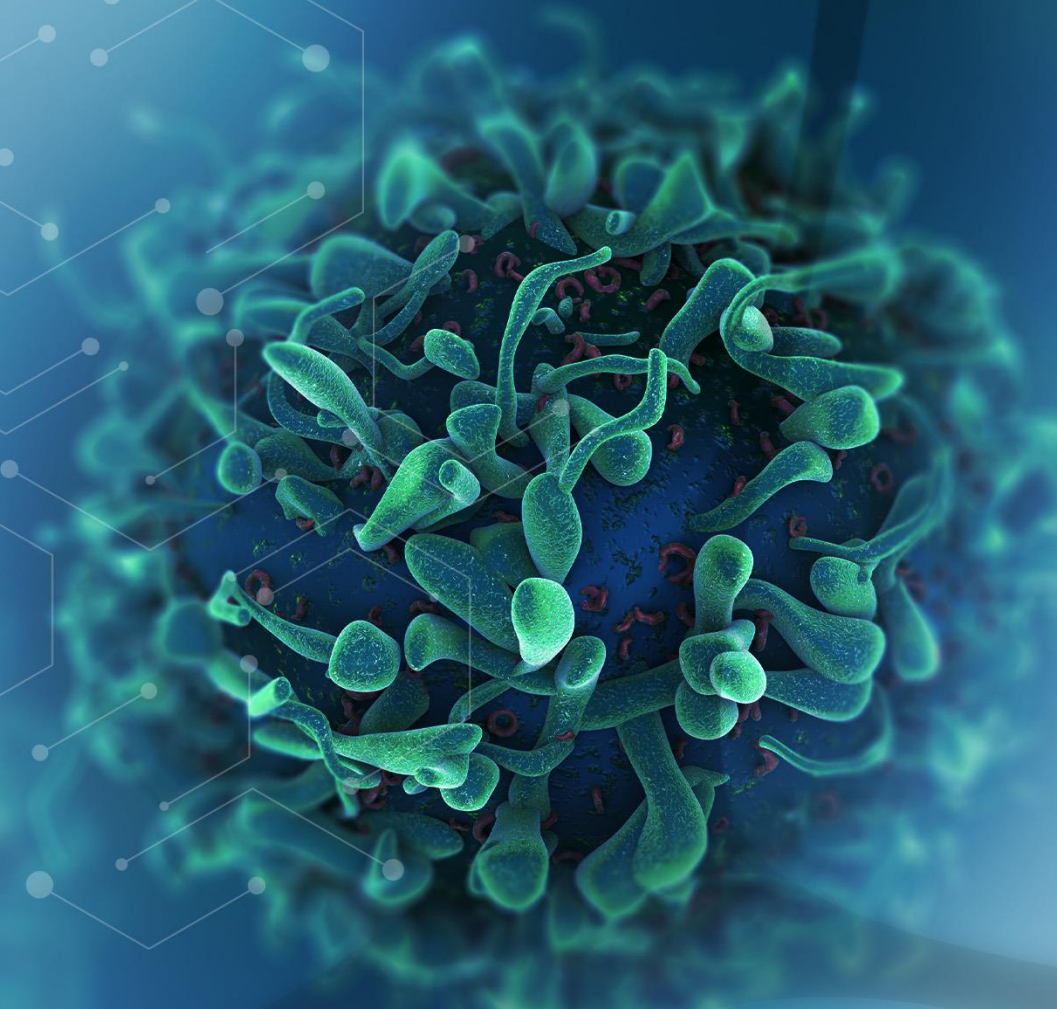


## Clinical development progress

- ✓ China phase II RA study :  
Completed patients enrollment (N~140)
- ✓ Expected data readout in 2021Q3
- ✓ Plan to initiate a bioavailability study to switch from IV formulation to subQ in 2021
- ✓ Plan to initiate phase III for RA in 2022H2

# 04

## Operation Progress





# Expansion of Management Team



## Chief Medical Officer Dr. Johannes Nippgen

- 25+ years of pharmaceutical industry and clinical oncology experience
- Served as senior and consultant oncologist in German Dresden University and in R&D leadership positions in various international biopharma and biotech companies, most recently as Head of R&D in China for Merck
- Doctoral degree in Medicine from Wurzburg- and Clinical Medicine degree from Mainz- University (Germany), German and European board certifications in Urology/GU-oncology



## Vice President, Clinical Operation Han Fu

- 15+ years of clinical research and team management, especially in the field of oncology
- Served as the Executive Director of clinical operations at Hutchison MediPharma, and worked for Roche China, AstraZeneca plc. and Innovent Biologics
- Master degree in Clinical Cardiovascular from Liaoning University of Traditional Chinese Medicine



# Expansion of Management Team

## Vice President, Biometrics Xia Yi, Ph.D.

- 18+ years of Biostatistics experience
- Served as Senior Director of Biostatistics & Clinical Development at Luye Pharma Group, and worked for the top global pharmaceutical companies including Daiichi Sankyo and Eisai in the US prior to Luye Pharma
- Doctoral degree in Statistics from Rutgers University and master and bachelor degree in Computer Science from Nankai University



## Vice President, Regulatory Affairs Li Wan, Ph.D., RAC

- 15+ years of industry experience in global regulatory affairs and project management
- Served various positions in a number of pharmaceutical companies including Pfizer and Novartis in the US, and Luye Pharma
- Led many global IND/CTA/NDA submissions and obtained approvals for small molecules and biologics products, with expert knowledge of the FDA, EMA, NMPA, PMDA, and ICH regulations
- Doctoral degree in Pharmaceutical Science from Rutgers University, MS/BS degrees in Biology from Nanjing University



# Expansion of Management Team



## Vice President, Quality Weidong Ma

- 25 years of extensive experience in Quality Management
- Served various positions in a number of pharmaceutical companies including WuXi Biologics, Amgen China and Roche Shanghai
- Led team to pass several audits from FDA, EMA and NMPA
- B.S in Chemistry from Shanghai Normal University



# Business Development: Comprehensive Combo Strategy

*..to unlock KN046's full potential*

Target	Combo Drug	Partner
VEGFR-1, -2, -3; c-CRAF, BRAF, mBRAF; FLT3; KIT; PDGFR $\beta$ ; RET, RET/PTC	Donafenib Tosylate	<b>Zelgen</b> 泽璟制药
MET; VEGFR-2; AXL; MER; FLT-3	Ningetinib Toluenesulfonate CT053	<b>Sunshine Lake</b> 广东东阳光
ALK-1 (Activin Receptor-Like Kinase-1)	GT90001	<b>Kintor Pharmaceutical</b> 开拓药业
Wnt pathway Porcupine protein	XNW7201	<b>Sinovent</b> 信诺维
Focal adhesion kinase inhibitor	IN10018	<b>InxMed/Cornell University</b> 应世生物/康奈尔大学

# Business Development: Strong MNC Interest in KN026

HER2-positive, HER2-int/low and HER2-mutation, KN026-based combination

Target

Combo Drug

Partner

CDK4/6

Ibrance® (palbociclib)



Microtubule inhibitor

Taxotere®<sup>(3)</sup> (Docetaxel)



## Notes:

1. Herceptin's label only covers Her-2 High, about 25% of breast cancer patients. While total Her-2 High, Midium and Low is about 80% of patients
2. Herceptin's label only covers Her-2 High, about 10-18% of gastric cancer patients. While total Her-2 High, Midium and Low is about 40% of patients
3. Sanofi has an exclusive option agreement for the strategic collaboration to advance clinical studies investigating 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
- ✓ Jiangsu Alphamab passed on-site inspection of **EU Qualified Person** in February, 2020
- ✓ Current capacity: **6,000L** (2x2,000L, 2x1,000L)
- ✓ Extra **6,000L** to be retrofit to current facility in 2022
- ✓ Construction of additional **30,000L** manufacturing to be initiated in 2022







康宁杰瑞

ALPHAMAB ONCOLOGY

05

2021 Catalyst

# Key Upcoming Milestones and Catalyst in 2021



## Pivotal Trials

- ✓ To complete enrollment and generate interim readout for ENREACH-LUNG-01: KN046+chemo, **1L sq-NSCLC**
- ✓ To complete enrollment for ENREACH-THYMIC: KN046 ≥ **2L thymic carcinoma**
- ✓ To initiate pivotal trial: KN046+lenvatinib, **PD-(L)1 refractory NSCLC**
- ✓ To initiate pivotal trial: KN046+chemo, **1L pancreatic cancer**



## Key Data Release

- ✓ AACR (Apr, 2021, presentation accepted): KN046-203 TNBC
- ✓ ASCO (Jun, 2021, presentation submitted):
  - 1) KN046-202 1L NSCLC
  - 2) KN026-202 GC
  - 3) KN026-203 KN046+KN026 HER2-positive solid tumors
  - 4) KN046-204 1L ESCC
  - 5) KN046-202 driver mutation positive NSCLC
  - 6) KN046-IST-04 1L pancreatic cancer
- ✓ ESMO (Sep, 2021, planning-stage): KN046-IST-05 1L HCC
- ✓ SITC (Dec, 2021, planning-stage):
  - 1) KN026-203 KN046+KN026 ≥2L HER2+ BC
  - 2) KN046-302 trial design for KN046+Ningetinib in PD-(L)1 refractory NSCLC
- ✓ SABC (Dec, 2021, planning-stage): KN026-201 1L BC

**AACR**  
American Association  
for Cancer Research

**ASCO**

**ESMO**

**sitc**

**SAN ANTONIO  
BREAST CANCER  
SYMPOSIUM**

# Key Upcoming Milestones and Catalyst in 2021



## IND

- ✓ 2-3 IND applications for new drug candidates: **Her-2 ADC**, **KN052** and **COVID-19 antibody**
- ✓ **KN019** to be converted to subcutaneous injection form for cancer/non-cancer indications



## Business Development

- ✓ Co-development/out-license deal for **KN035** and **KN026**



## Commercialization

- ✓ KN035 (Envafolimab) **BLA approval**
- ✓ Building a **core commercial team**



## Manufacturing and Quality

- ✓ Pilot plant with advanced process technology
- ✓ **Extra 6,000L** to be retrofit to current facility



## Other

- ✓ State-of-art 12,000 m<sup>2</sup> **research lab** to enable protein design, engineering, process development, cell therapy and gene therapy



06

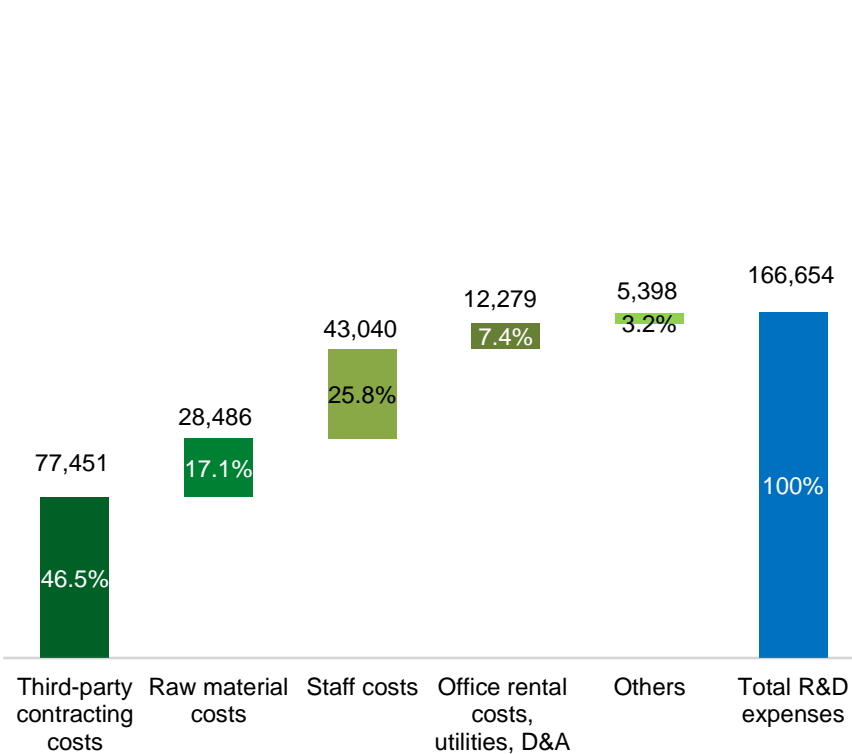
Financial Highlight



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

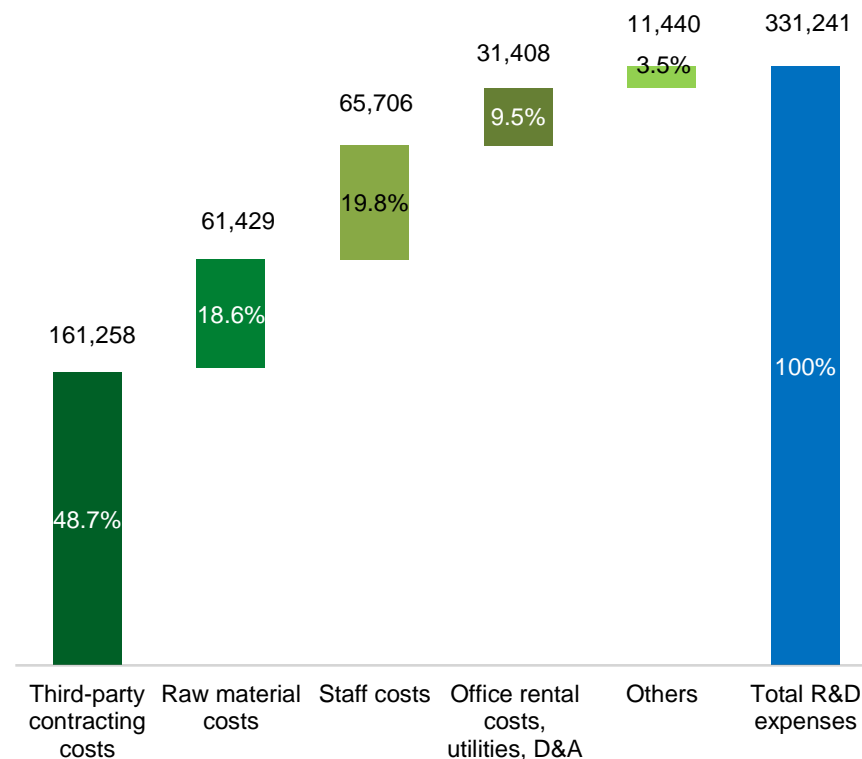
For the year ended December 31, 2019

RMB ('000) (audited)



For the year ended December 31, 2020

RMB ('000) (audited)



## Consolidated Statement of Comprehensive Income

	For the year ended December 31	
	2019 (audited)	2020 (audited)
<i>(RMB'000)</i>		
Other income	34,429	111,136
Other losses	(321)	(117,627)
Fair value change of convertible redeemable preferred shares	(542,291)	-
Research and development expenses	(166,654)	(331,241)
Administrative expenses	(117,736)	(78,208)
Finance costs	(3,606)	(11,826)
Listing expenses	(36,561)	-
Loss before taxation	(832,740)	(427,766)
Income taxation	-	-
<b>Loss for the year</b>	<b>(832,740)</b>	<b>(427,766)</b>





07

Q&A

