



Alphamab Oncology (9966.HK) 2023 Annual Results Presentation

March 2024

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Agenda

- 1 Financial Overview in 2023
- 2 Business Review
- 3 Outlook for 2024
- 4 Clinical Progress
- 5 Q&A

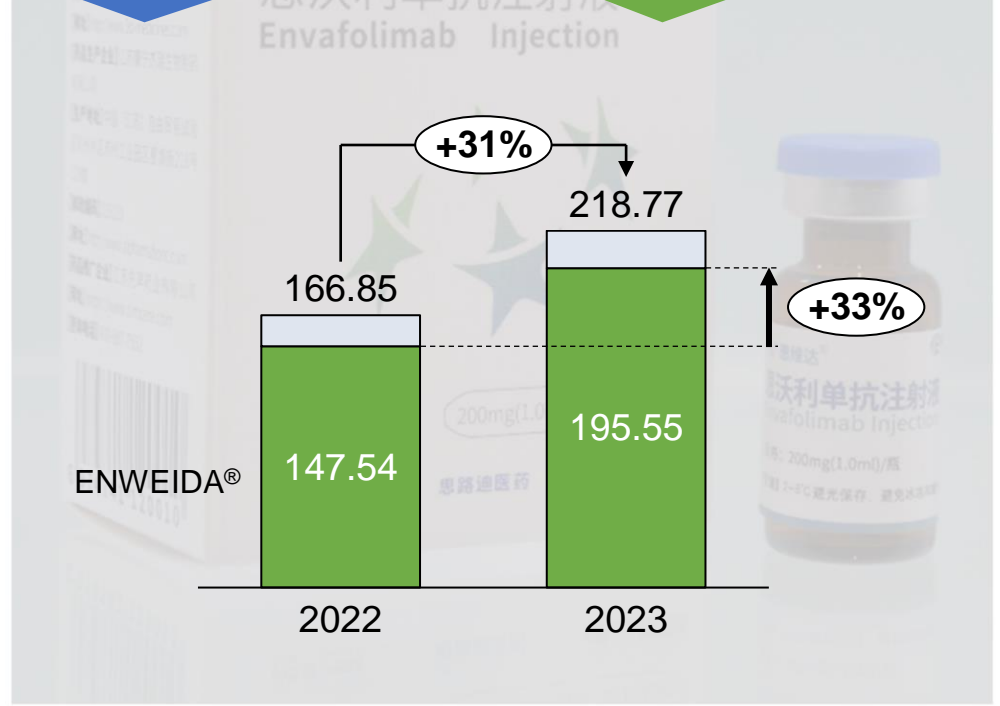
01

Financial Overview in 2023

Overview of Key Financial Data

(RMB)

Total Revenue : 218.77 Million +31%	ENWEIDA®: 195.55 Million +33%
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<p>-210.59 Million</p> <p>325.72 (2022) → 210.59 (2023) -35%</p> <p>Loss for the Period</p>	<p>407.52 Million</p> <p>468.24 (2022) → 407.52 (2023) -13%</p> <p>R&D Expenses</p>
<p>79.34 Million</p> <p>86.77 (2022) → 79.34 (2023)</p> <p>Admin Expenses</p>	<p>1.41 Billion</p> <p>Cash on Account</p>

Consolidated Statement of Comprehensive Income



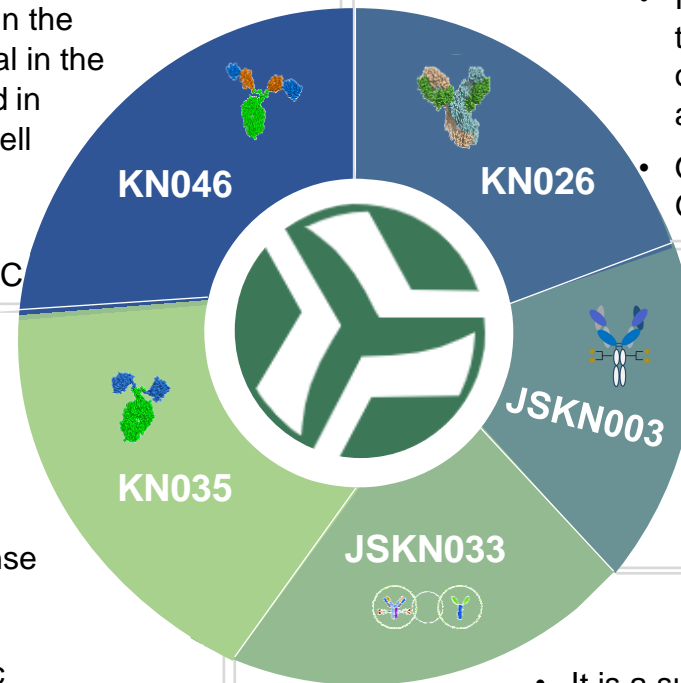
(RMB'000)	For the year ended December 31	
	2023	2022
Revenue	218,774	166,845
Cost of Sales	(55,237)	(44,207)
Gross profit	163,537	122,638
Other income	91,817	57,782
Other gains and losses	33,094	63,073
R&D expenses	(407,524)	(468,238)
Administrative expenses	(79,338)	(86,771)
Finance costs	(12,179)	(14,206)
Loss before taxation	(210,593)	(325,722)
Income tax expense	-	-
Loss for the period	(210,593)	(325,722)

02

Business Review

Major Progress of Core Business Operations from January 2023 to March 2024

- Four phase II clinical trial data were presented at the ESMO Congress.
- Four clinical trial data of a phase I clinical trial as monotherapy in China, a phase II clinical trial in the treatment of NSCLC, a phase II clinical trial in the treatment of TNBC and a phase II clinical trial in the first-line treatment of NSCLC were published in JITC¹, EJC¹, Nature Communications and Cell Reports Medicine, respectively.
- Two phase III clinical trials were in the final OS follow-up stage: 1L sq-NSCLC, 1L PDAC



- The phase III clinical trial for the first-line treatment of HER2+ Breast Cancer was conducted, and the first patient was successfully dosed in July 2023. Also we are conducting the phase III clinical trial of ≥2L GC/GEJ
- Four clinical trial data of the HER2-positive solid tumors(excluding BC and GC/GEJ), the first-line treatment of BC and the neoadjuvant therapy for BC were presented at ASCO, ESMO and SABCS annual meetings.
- One breakthrough therapy designation: ≥2L HER2+ GC/GEJ.

- One breakthrough therapy designation: non-MSI-H²/non-dMMR² advanced endometrial cancer that has failed or intolerant of at least one prior line of platinum-based chemotherapy.
- One license agreement: entered into a license agreement with Glenmark in respect of developing and commercializing oncology indications of KN035 in in India, Asia Pacific (except Singapore, Thailand and Malaysia), Middle East and Africa, Russia, Commonwealth of Independent States and Latin America.

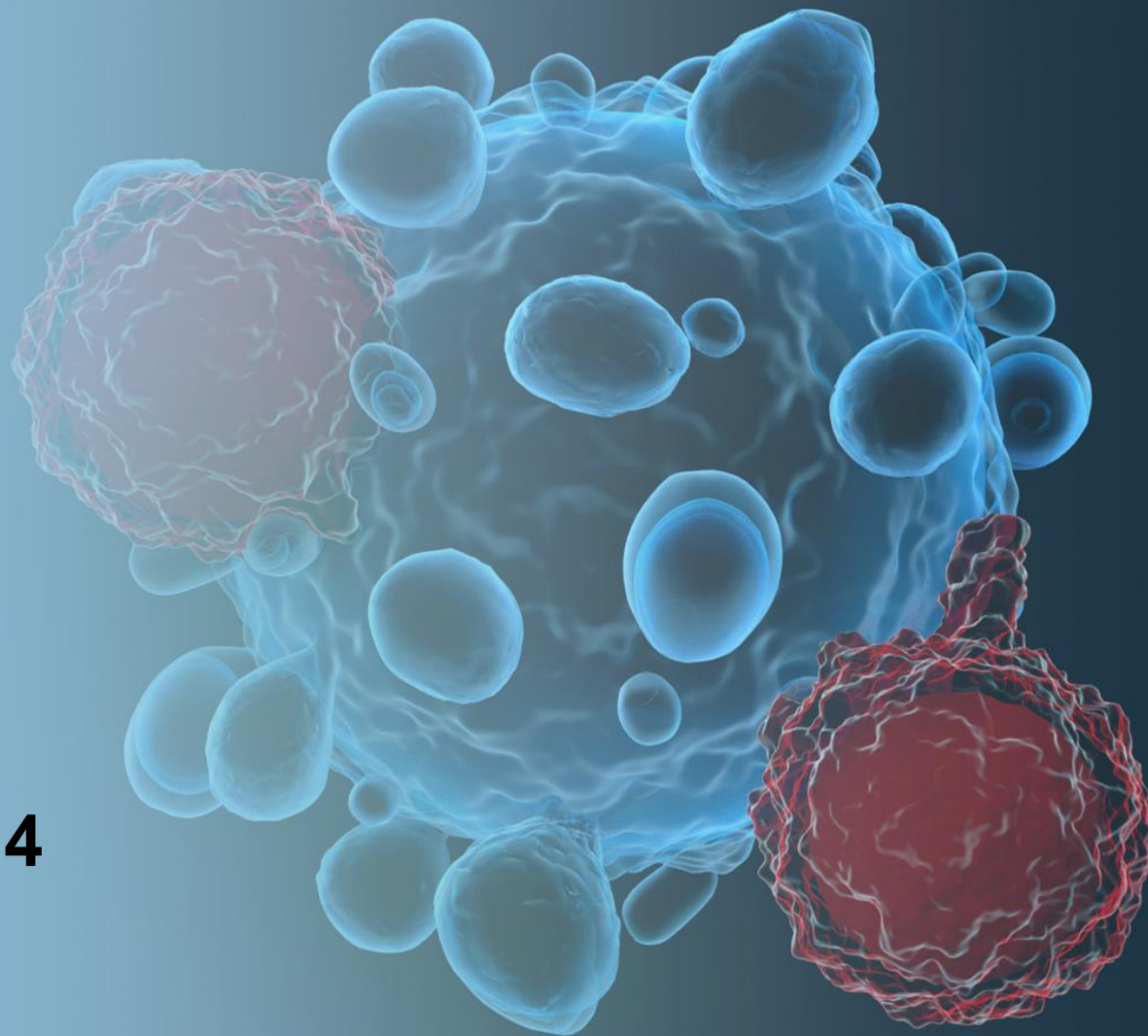
- The phase I/II clinical trial and phase I clinical trial were conducted in China and Australia, respectively. And we are conducting the phase III clinical trial in China.
- As of October 26, 2023, according to the announcement, JSKN003 has shown an initial efficacy in the phase I clinical trial in Australia.

- It is a subcutaneous co-formulation consisting of JSKN003 and KKN035. The phase I/II clinical trial is ongoing in Australia.

Note:1. JITC: Journal for ImmunoTherapy of Cancer , the official journal of the Society for Immunotherapy of Cancer; EJC: European Journal of Cancer , the official journal of the European Organization for Research and Treatment of Cancer and the European Society of Breast Cancer Specialists 2. MSI-H: metastatic advanced microsatellite instability-high; dMMR: mismatch-repair deficiency

03

Outlook for 2024



Key Milestones and Catalyst in 2024



Key Clinical Trials Progress

- KN046+chemo, 1L sq-NSCLC: Continue the data follow-up till the final OS analysis
- KN046+chemo, 1L PDAC: Continue the data follow-up till the final OS analysis
- JSKN003, monotherapy: To advance the phase III clinical trial enrollment and initiate 2 pivotal trials
- JSKN033: Complete the dose escalation stage of phase I clinical trial in Australia
- KN046+Axitinib: Partial clinical data readout



Clinical Trial Data Plan to Release

AACR (April 2024)



1. JSKN003: phase I clinical trial in Australia, HER2 expression solid tumor

ASCO (Plan to release, June 2024)



1. JSKN003: partial data of phase I clinical trial in Australia and phase I/II clinical trial in China, HER2 expression solid tumor

ESMO (Plan to release, October, 2024)



1. KN046+Axitinib: phase II clinical trial, NSCLC

SABCS (Plan to release, December 2024)

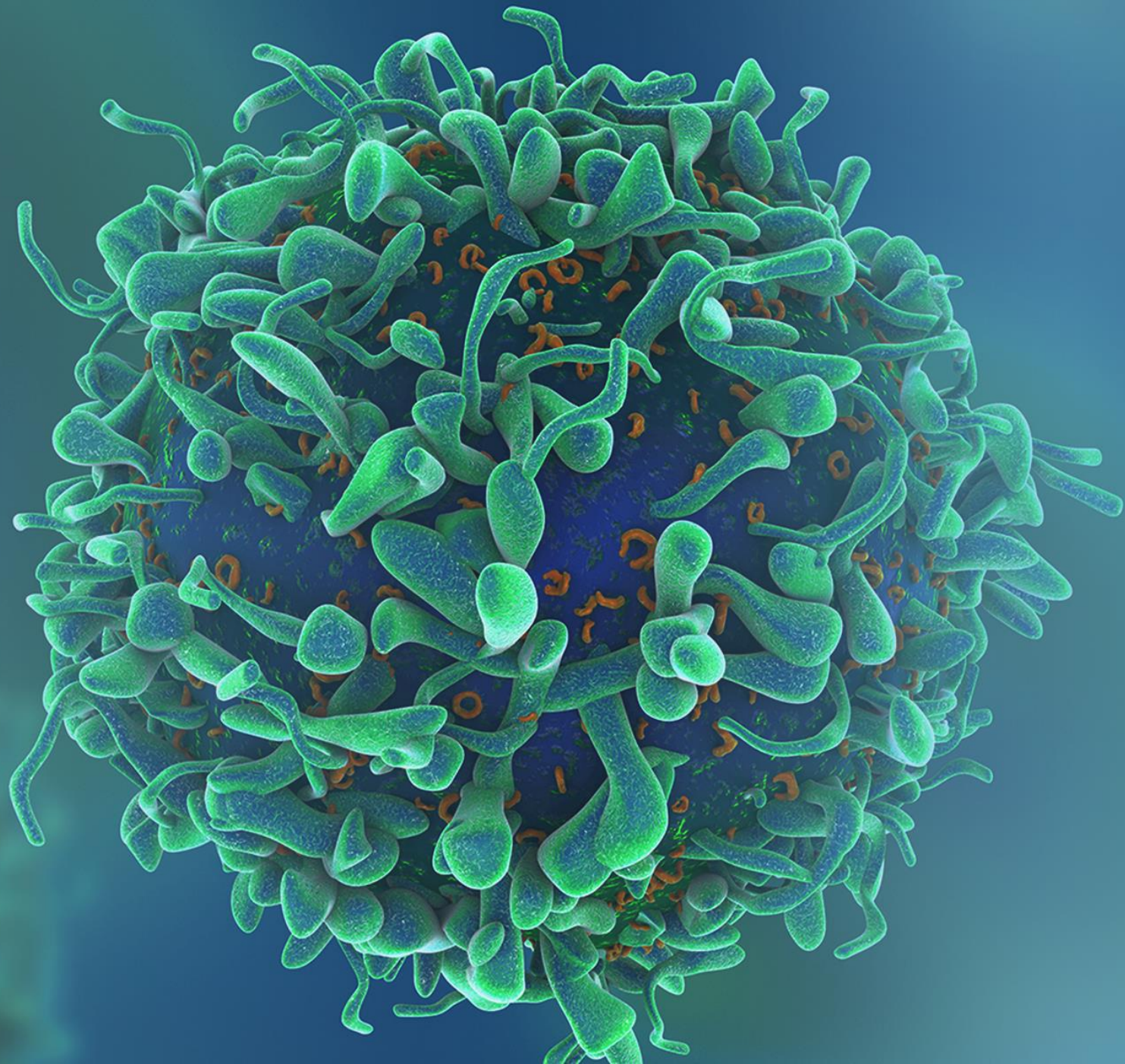


1. JSKN003: HER2 expression BC



New Candidates Progress and Others

- **JSKN016**: IND approved, and advance phase I clinical trial
- Drive the upgrading of ADC drug research and development and production process



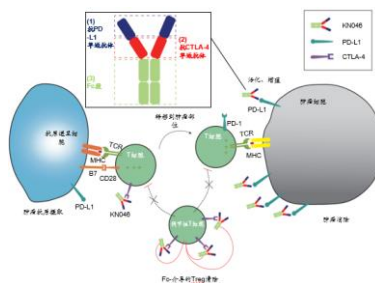
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Clinical Progress

KN046

Dual blockade of PD-L1 and CTLA-4

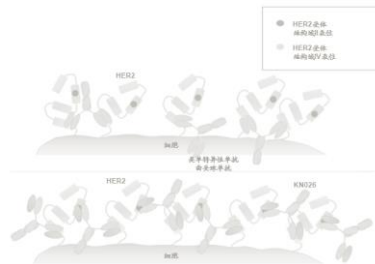
- PD-(L)1 refractory solid tumor
- PD-(L)1 Inadequate response



KN026

Dual blockade of HER2 domain II and IV

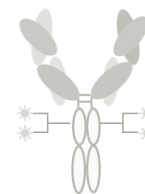
- Solid tumor with high HER2 expression
- Positioning the first line and perioperative period



JSKN003

HER2 bispecific ADC

- Highly expressed tumor that do not fully respond to anti-HER2 therapy
- Solid tumor with low HER2 expression
- In combination with products of other mechanisms



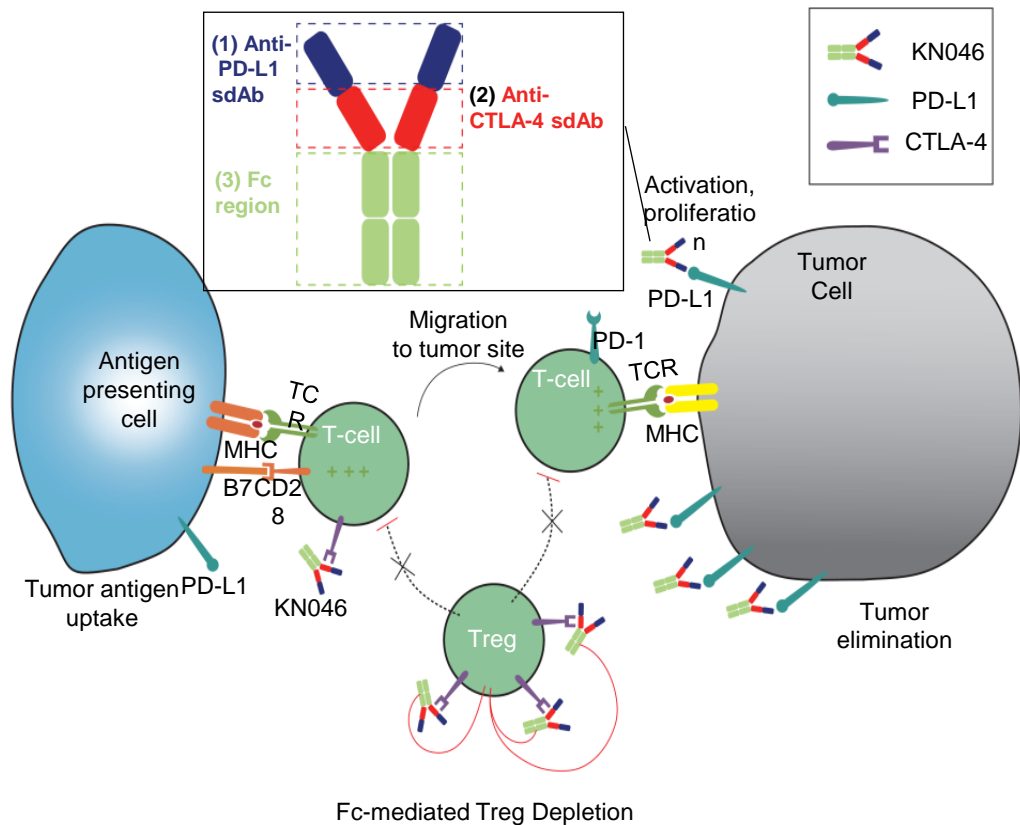
KN035

Subcutaneous PD-L1 mAb

- The first PD-L1mAb worldwide that can be used for subcutaneous injection



Mechanism of Action



Highlights

- ✔ **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
- ✔ **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
- ✔ **Preservation of Fc-mediated effector functions**
 - Preserves the full Fc functions for Treg Depletion
- ✔ **Strong Scientific base to support targeting CTLA-4 and PD-L1 with Bispecifics**

KN046: Major Clinical Trials

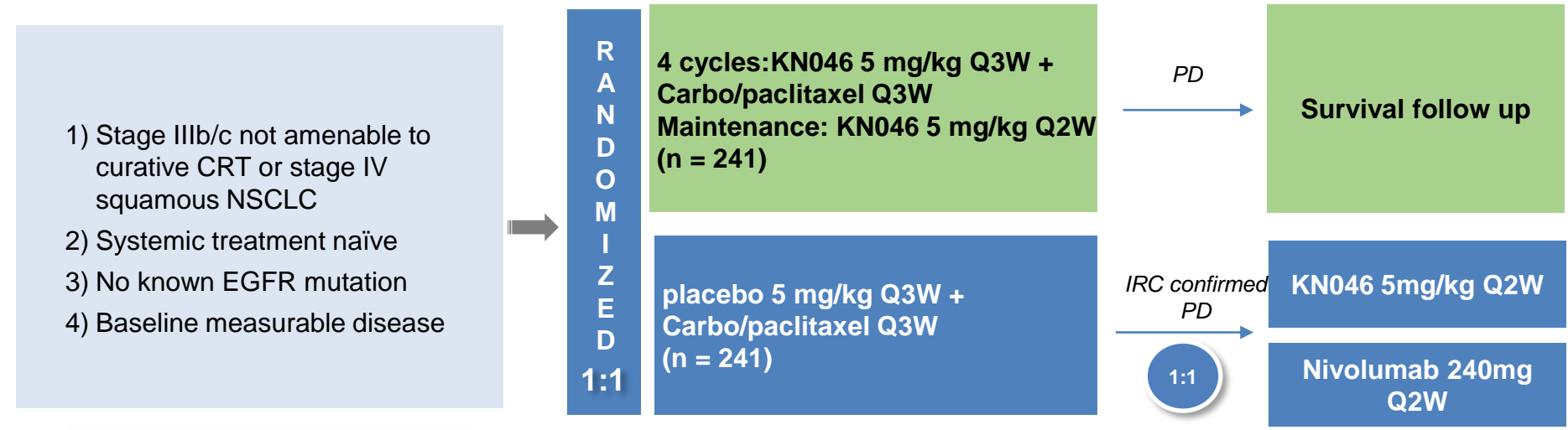
Indication	Mono/ Combo	IND	Proof of concept	Pivotal	NDA
1L sq NSCLC	+chemo	▶			
1L PDAC	+chemo	▶			
1L NSCLC	+axitinib	▶			
PD-(L)1 refractory NSCLC	+axitinib	▶			

KN046: Preliminary Results in a Nutshell

Indication Efficacy & Safety	KN046(Over 1,200 patients have been enrolled in clinical studies)				
	sq-NSCLC 1L (n=87)	PDAC 1L (n=53)	HCC 1L (n=55)	TNBC 1L (n=27)	ESCC 1L (n=15)
Mono/Combo	+chemo	+chemo	+lenvatinib	+chemo	+chemo
OS	26.6 months	12 months	--	30.92 months (immature)	--
mPFS	5.7 months	6 months	11 months	7.33 months	--
ORR	50%	47.9%	45.5%	44%	58.3%
DCR	80.6%	93.5%	89.1%	96%	91.6%
TRAE≥Grade3	34.5%(TEAE)	27.6%	47.3%	66.7%	29.4% (related to KN046)

KN046-301 (phase III) 1L NSCLC (ENREACH-LUNG-01)-Trial Design

Inclusion criteria ————— **Trial design**



Stratification

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

Primary endpoint

- PFS
- OS

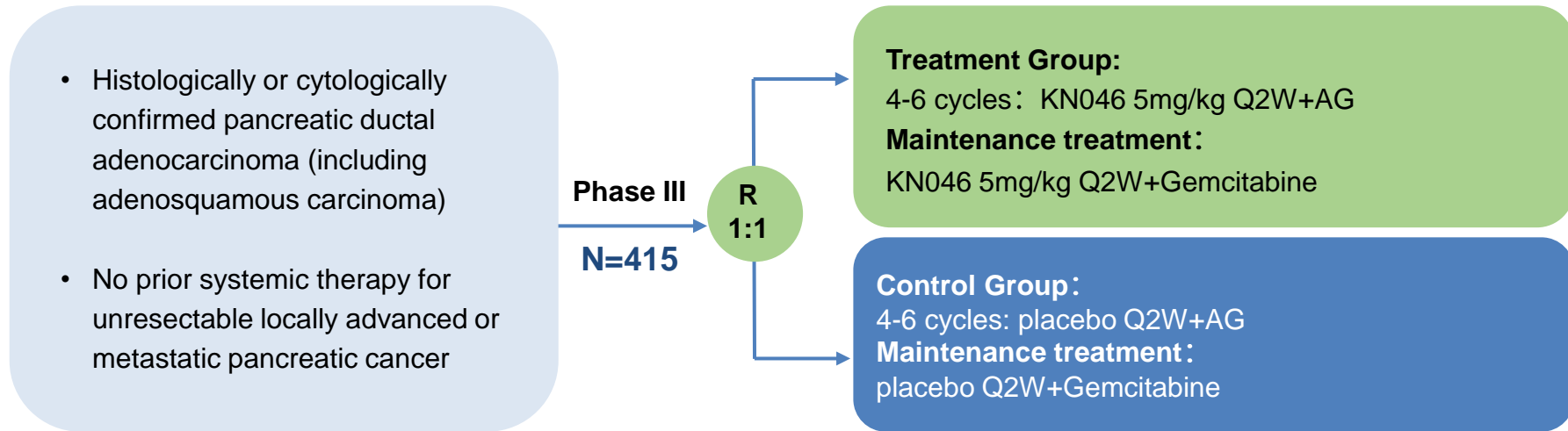
Key secondary endpoints

- ORR
- DCR
- DOR etc.

KN046-303 (Phase III) 1L PDAC-Trial Design

Inclusion criteria

Trial Design



Stratification

- Tumor Staging
- Location of the primary lesion
- ECOG score, etc.

Primary Endpoint

- OS

Secondary Endpoint

- ORR
- PFS

KN046-209 (Phase II) 1L & PD-(L)1 Refractory NSCLC-Trial Design

KN046-209 without chemotherapy: Inclusion criteria overview

- ✓ NSCLC patients in stage IIIB-IV
- ✓ PD-(L)1+ (TPS≥1%) (cohort A)
- ✓ No driver gene mutations

- KN046 5mg/kg Q3W + Axitinib 5mg bid po
- Stage I
 - Cohort A: n=17 (1L NSCLC)
 - Cohort B: n=15 (PD-(L)1 refractory)

Cohort A: over 5/17 patients remission, then moves on to the next stage

Cohort B: over 2/15 patients remission, then moves on to the next stage

- KN046 5mg/kg Q3W + Axitinib 5mg bid po
- Stage II
 - Cohort A: n=37 (1L NSCLC)
 - Cohort B: n=31 (PD-(L)1 refractory)

- ✓ **Cohort A:** For patients with treatment-naïve locally advanced (cannot be surgically removed and radical chemoradiotherapy) or metastatic PD-L1 positive NSCLC
- ✓ **Cohort B:** For NSCLC patients who progressed after prior PD-(L)1 inhibitor treatment

Note: 1. Cohort A has entered stage II.

KN046-209(phase II) Cohort A 1L NSCLC (2023 ESMO)



Trial Design: 38 subjects with 1L NSCLC, systemic treatment-naïve and PD-L1 positive(TPS≥1) were enrolled. Among them, 86.8% of patients were at stage IV and 94.7% of patients had an ECOG PS=1. **26.3%** of patients had 50% or higher PD-L1 expression, **65.8%** of patients had 1%~49% PD-L1 expression and **5.3%** had less than 1% PD-L1 expression. Squamous and non-squamous NSCLC patients accounted for 42.1% and 52.6% respectively.



Efficacy: Among **29** evaluable patients, the **ORR** was **58.6%**, the **DCR** was **96.6%**, the **mPFS** was **8.35** months(not mature)¹. The **mOS** was not reached yet. The **ORR** in patients with high PD-L1 expression was **83.3%**. And the **mPFS** in non-squamous NSCLC patients was **9.20** months(not mature).

Comparable trials	KN046-209			SUNRISE
Drug	KN046+axitinib	Camrelizumab+famitinib	Toripalimab+surufatinib ²	Sintilimab+anlotinib ³
Line	1L	1L	1L	1L
n	29	41 (PD-L1 high expression account for 48.8%)	23 (PD-L1 high expression account for 43.5%)	40
ORR	58.6% (PD-L1 high expression: 83.3%)	53.7% (PD-L1 high expression: 60.0%)	57.1% (PD-L1 high expression: 66.7%)	50.0% (regardless of the PD-L1 expression)
mPFS	8.35 months (not mature)	16.6 months	9.6 months	10.8 months
OS rate	—	24-month: 76.8%	—	—



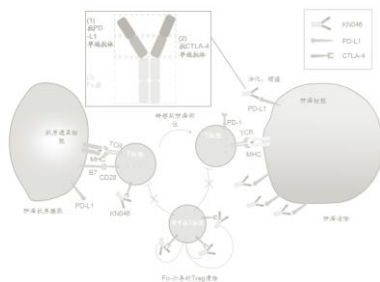
Safety: It has a good safety profile. Among 38 patients, the incidence of KN046-related TRAEs at grade 3 or higher levels was 23.75. The most frequent TRAEs include AST increased(7.9%), ALT increased(5.3%) and diarrhoea (5.3%).

Note: 1. KN046-209 is ongoing currently and the date cut-off date is August 8, 2023. The median follow-up was 4.17 months. 2. The dose regimen of Surufatinib is 250mg, one a day. The AE incidence at grade 3 or higher levels was 73.9%. 3. The incidence of TRAE at grade 3 or 4 levels was 11.6%.

KN046

Dual blockade of PD-L1 and CTLA-4

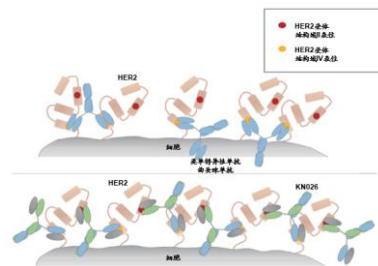
- PD-(L)1 refractory solid tumor
- PD-(L)1 Inadequate response



KN026

Dual blockade of HER2 domain II and IV

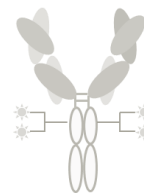
- Solid tumor with high HER2 expression
- Positioning the first line and perioperative period



JSKN003

HER2 bispecific ADC

- Highly expressed tumor that do not fully respond to anti-HER2 therapy
- Solid tumor with low HER2 expression
- In combination with products of other mechanisms



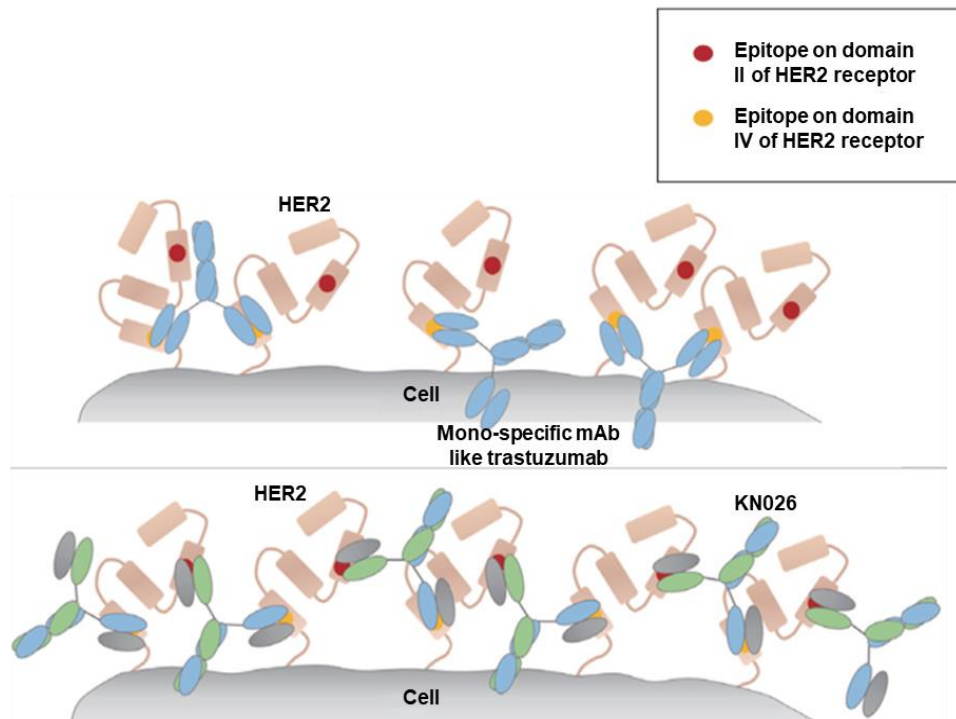
KN035

Subcutaneous PD-L1 mAb

- The first PD-L1mAb worldwide that can be used for subcutaneous injection





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 Major Clinical Trial: HER2 Positive Solid Tumor

Indication	Combo/Mono	IND	Proof of concept	Pivotal	NDA	
1L BC	+nab-docetaxel	FPI in July 2023				
≥ 2L GC/GEJ	+chemo	Entered into the second stage in January 2023				
Neoadjuvant therapy of BC	+docetaxel					
Late line colorectal cancer	+ KN046					

- In August 2021, we reached collaboration with CSPC related to breast cancer and GC/GEJ of KN026 in Chinese mainland, involving upfront payment of RMB150million and milestone payment of RMB850million and a double-digit sales commission
- CSPC is responsible for the clinical development and registration application under the joint development committee and pay the cost

KN026: Preliminary Results in a Nutshell

Indication Efficacy & Safety	KN026 (Over 300 patients have been enrolled in clinical studies)				
	HER2+ BC 1L (n=57)	HER2+ BC NAT (n=30)	HER2+ GC 1L (n=39)	HER2+ GC ≥2L (n=39)	HER2+ CRC ≥3L (n=15)
Mono/Combo	+chemo	+chemo	+KN046	mono	+KN046
OS(months)	78.5% (30-months rate)	--	--	16.3	--
mPFS(months)	27.7 (immature)	--	10.9	8.3	12.2
ORR	76.4%	56.7% (tpCR)	71.8%	56.0%	53.3%
DCR	100%	100%	92.6%	76.0%	93.3%
≥Grade3 AE	TEAE: 43.9% (related to KN026)	TEAE: 53.3%	TRAE: 16.1%	TRAE: 11.1%	7.7% increase in bilirubin 7.7% increase in AST

KN026-201 (Phase II) 1L HER2+BC (2023 SABCS)



Trial design: 57 patients with HER2+ recurrent or metastatic BC were enrolled. Among them, 91.2% of patients were stage IV.



Efficacy: Among 55 evaluable patients, the **confirmed ORR** was **76.4%**. The **mPFS** was **27.7** months. The **mOS** was not mature, and the **12-month, 24-month, 30-month OS rates** were **93%, 84.1%** and **78.5%**, respectively.

Comparable trials	KN026-201 ¹	CLEOPATRA		PUFFIN (China)	PHILA
Drug	KN026+docetaxel ¹	Trastuzumab+Pertuzumab+docetaxel vs Trastuzumab+docetaxel ²		Trastuzumab+Pertuzumab+docetaxel ³	Pyrotinib+Trastuzumab+nab-paclitaxel ⁴
Line	1L	1L (8.4% of patients with IHC1+ / IHC2+)		1L	1L
N	57	402	406	122	297
ORR	76.4%	80.2%	69.3%	79.0%	82.8%
mPFS	27.7 (not mature)	18.5 months	12.4 months	16.5 months	24.3 months
24-month OS rate	84.1%	80% (57.1 months)	70% (40.8 months)	79.5%	-



Safety: Among 57 patients, the incidence rate of TEAE at grade 3 or higher levels was 63.2%. The incidence of TRAE related to KN026 was 43.9%, including neutrophil count decreased(24.6%), white blood cell count decreased (12.3%), etc.

Note: 1. The data cut-off date is September 15, 2023. 2. In HPT and HT groups, the incidence of diarrhea at grade ≥3 were 7.9% and 5.0%, respectively. The incidence of neutrophil count decreased at grade 3 or higher levels were 48.9% and 45.8%, respectively. The incidence of febrile neutropenia decreased t grade 3 or higher levels were 13.8% and 7.6%, respectively. In addition, the incidence of left ventricular ejection fraction decreased were 7.8% and 8.6%, respectively and the incidence of heart failure were both 2%. 3. The incidence of AE at grade 3 or higher levels was 74%. 4. The incidence of AE at grade 3 or higher levels was 89.9%, among which diarrhea at grade 3 or higher levels was **46.5%**.

KN026-208 (Phase II) Neoadjuvant HER2+BC (2023 ESMO)

Trial design: 30 patients with HER2+ early or locally advanced BC and without any systemic treatment were enrolled. 86.7% of patients were with biopsy-confirmed lymph node metastases. 53.3% of patients were stage II and 46.7% of patients were stage III.

Efficacy: Among all patients, the pCR rate was 56.7%, the bpCR rate was 60.0%. The ORR was 90.0%, and the confirmed ORR was 86.7%.

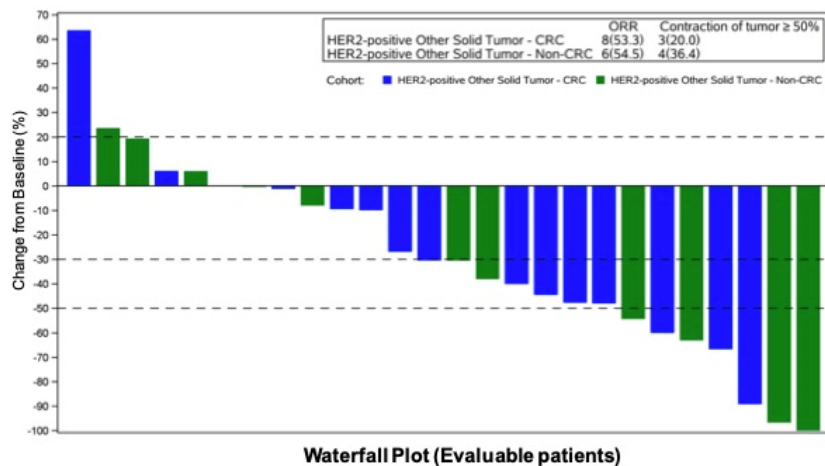
Comparable trials	KN026-208 ¹	Neosphere (phase II)		PEONY (Asia Pacific)	PHEdra
drug	KN026+docetaxel	Trastuzumab+Pertuzumab+docetaxel vs Trastuzumab+docetaxel		Trastuzumab+Pertuzumab+docetaxel ²	Pyrotinib+Trastuzumab+docetaxel ³
n	30	107	107	219	178 (lymph node metastases:70%)
ORR	90.0%	-	-	88.6%	91.6%
pCR	bpCR: 60.0% tpCR: 56.7%	bpCR: 45.8% tpCR: 39.3%	bpCR: 29.0% tpCR: 21.5%	tpCR: 39.3%	bpCR: 43.8% tpCR: 41.0%
others	AE ≥ grade 3: 53.3%	5-year PFS rate: 86%	5-year PFS rate: 81%	AE ≥ grade 3: 70.6%	AE ≥ grade 3: 71% ²

Safety: Among all 30 patients, the incidence of TEAE at grade 3 or higher levels was 53.3%, including neutrophil count decreased (50.0%), white blood cell count decreased (40.0%) and lymphocyte count decreased (10.0%). The incidence rate of SAE at grade 3 or higher levels was 6.7%. SAE related to KN026 occurred in only one patient.

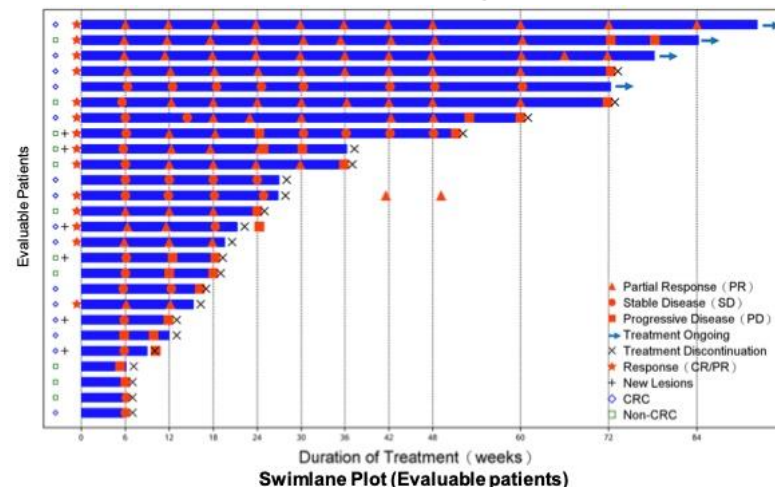
Note: 1. The data cut-off date is November 21, 2022. 2. According to the Pertuzumab instructions, the incidence of diarrhea at grade 3 to 4 levels of the Pertuzumab plus trastuzumab was 8.9%, and the incidence of all levels diarrhoea was 67.9%. 3. The incidence of cardiotoxicity such as trastuzumab was 7%~8%, while the adverse reactions in the pyrotinib combination group were mainly diarrhea. The incidence of diarrhea at grade 3 or higher levels was 40%.

KN026-203(Phase II): KN046+KN026, ≥3L HER2+ Solid Tumor (2023 ASCO)

Waterfall Plot



Swimming lane



Enrolled **26** patients, including **15** CRC patients, **5** NSCLC patients, **4** gallbladder cancer patients, **1** renal pelvis cancer patient and **1** pancreatic cancer patient. **92.3%** of patients including all CRC patients had received two or more lines of prior treatment



Efficacy: The confirmed **ORR** was **53.8%**, **DCR** was **88.4%**, **12-month PFS rate** was **80.4%**, Out of 15 evaluable CRC patients, the **ORR** was **53.3%**, **DCR** was 93.3%, the **mPFS** was **12.2 months** and the **12-month OS rate** was **80.0%**

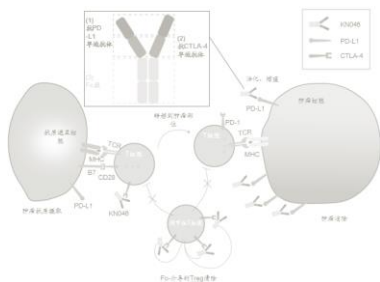


Safety: 34.6% of patients had experienced at least one time ≥ grade 3 TRAEs, the most common TRAEs were infusion related reaction(38.5%), diarrhea(19.2%), anemia, AST/ALT increased, etc.

KN046

Dual blockade of PD-L1 and CTLA-4

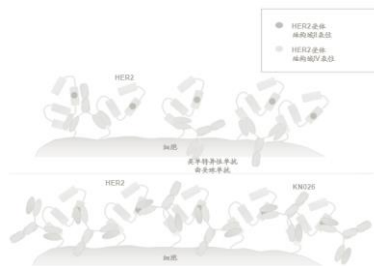
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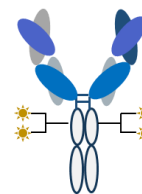
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- Solid tumor with low HER2 expression
- In combination with products of other mechanisms



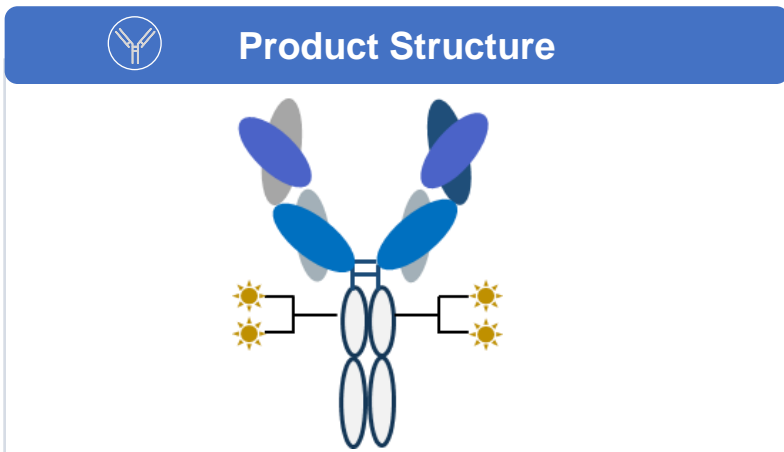
KN035


Subcutaneous PD-L1 mAb

- The first PD-L1 mAb worldwide that can be used for subcutaneous injection



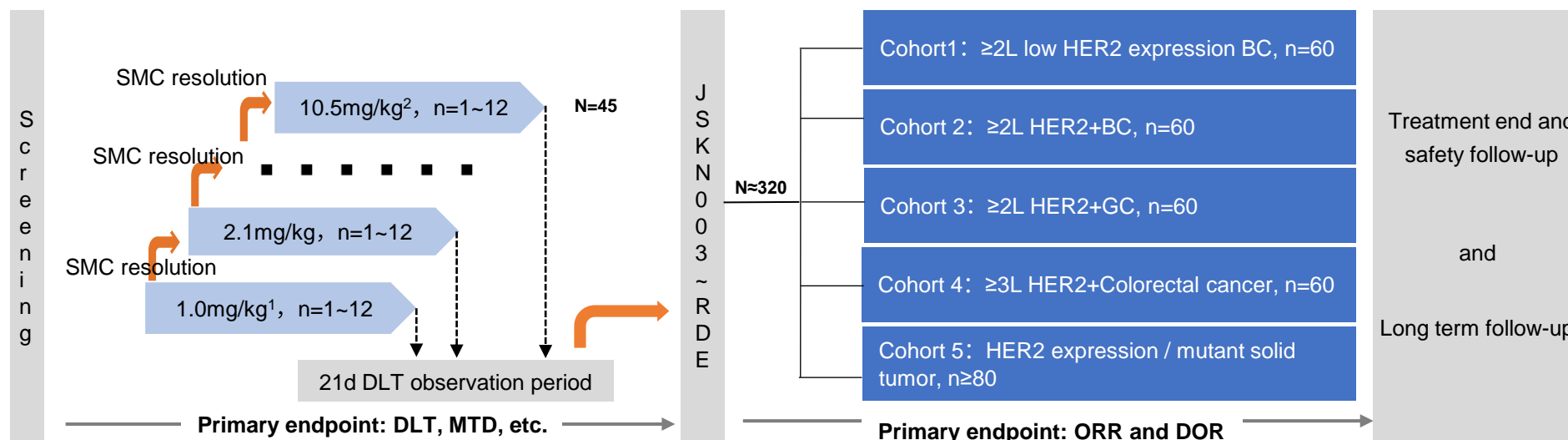
JSKN003: Anti-HER2 Bispecific ADC



- 
- Feature and clinical strategies**
- Targeting two different paratopes of HER2
 - Glycosite-specific conjugation, DAR was 3-4
 - Better serum stability for better safety potential
 - Benchmark against DS8201 and comparable with DS8201 in efficacy Models
 - Showed good tolerance in pre-clinical studies
 - Full coverage of HER2-expressing solid tumors
 - To accelerate the product launch, prioritize the late line and advance the front line study simultaneously

Phase I: Dose Escalation Stage- accelerated titration BOIN design

Phase II: Expansion Stage at RDE³



Note: 1. A total of 9 doses, the starting dose is 1.0mg/kg

2. If the dose increases to 10.5mg/kg, it still does not reach MTD. The SMC decides whether to continue the dose increase

3. RDE: The recommended dose of cohort extension is selected by SMC according to Phase Ia data. Different cohort/tumor species can choose different RDE for extension

Comparison of JSKN003-101 and DS-8201 in Efficacy and Safety

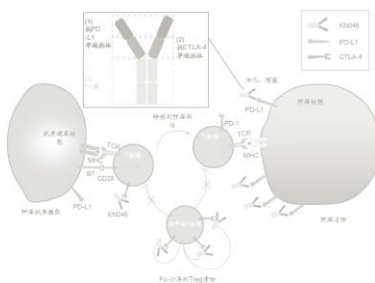
	JSKN003-101 (Australia) n=32 ¹	DS-8201 Phase I n=24 ²
ECOG score	ECOG≥1 53.1%	ECOG≥1 41.7%
Tumor type and proportion ³	BC 46.9%、GC 3.1%、OC 15.6%、 UC 12.5%、EC 6.3%、LC 6.3%、 other 9.4%	BC 67.0%、GC 33.0%
Tumor metastasis proportion	90.6%	100.0%
Proportion of HER2 status	IHC 3+ 21.9%、IHC 2+ 50.0%、 IHC 1+/0 28.1%	IHC 3+ 62.5%、IHC 2+ 16.7%、 IHC 1+/0 20.8%
Number of treatment lines	≥3 line 62.5%	≥3 line 79.2%
The proportion of frontline treated with trastuzul or T-DM1	21.9%	75.0%
Grade ≥3 TRAE incidence rate	6.3%	75.0%
SAE	none	12.5%
Hematological toxicity incidence rate	3.1%	Decreased platelet count 33%、Decreased neutrophil count 25%、Decreased white blood cell count 21%、Decreased lymphocyte count 13%、Febrile neutropenia 4%
Overall ORR、DCR	46.7%、90.0%	43.0%、91.3%
HER2-High BC ORR	75.0%	54.5%
HER2-Low BC ORR	40.0%	16.7%

Notes: 1. COD: October 26, 2023, The median follow-up time is 4.2 months, with a median administration cycle of 5 cycles (1-18 cycles), and the longest administration time exceeding 1 year; 2. The median follow-up time is 6.7 months; 3. BC: breast cancer, GC: gastric cancer, OC: ovarian cancer, UC: urinary tract cancer, EC: esophageal cancer, LC: lung cancer

KN046

Dual blockade of PD-L1 and CTLA-4

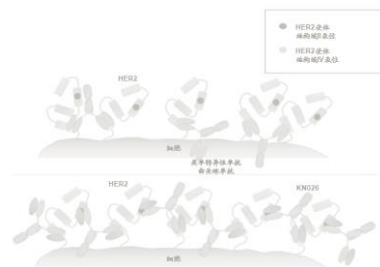
- PD-(L)1 refractory solid tumor
- PD-(L)1 Inadequate response



KN026

Dual blockade of HER2 domain II and IV

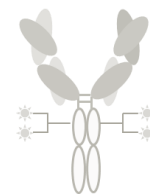
- Solid tumor with high HER2 expression
- Positioning the first line and perioperative period



JSKN003

HER2 bispecific ADC

- Highly expressed tumor that do not fully respond to anti-HER2 therapy
- Solid tumor with low HER2 expression
- In combination with products of other mechanisms



KN035

Subcutaneous PD-L1 mAb

- The first PD-L1mAb worldwide that can be used for subcutaneous injection



ENWEIDA(KN035): Conducting Multiple Clinical Trials



Indication	Combo/ Mono	IND	Proof of concept	Pivotal	NDA
≥2L MSI-H/dMMR advanced solid tumor	mono	Launched in November, 2021			
≥2L Sarcoma	mono				Global
1L BTC	+chemo				
Neoadjuvant/adjuvant NSCLC	+chemo				

- The company revenue from ENWEIDA® is RMB196 million in 2023
- In November 2023, KN035 in combination with lenvatinib was granted breakthrough therapy designation for the treatment of non-MSI-H¹/non-dMMR² advanced endometrial cancer that has failed or intolerant of at least one prior line of platinum-based chemotherapy.
- In January 2024, we entered into a license agreement with Glenmark to develop and commercialize the oncology indications of KN035 in India, Asia Pacific (except Singapore, Thailand and Malaysia), Middle East and Africa, Russia, Commonwealth of Independent States and Latin America.

Note: 1. non-metastatic advanced microsatellite instability-high; 2. non-mismatch-repair deficiency



Thank you!

Q&A