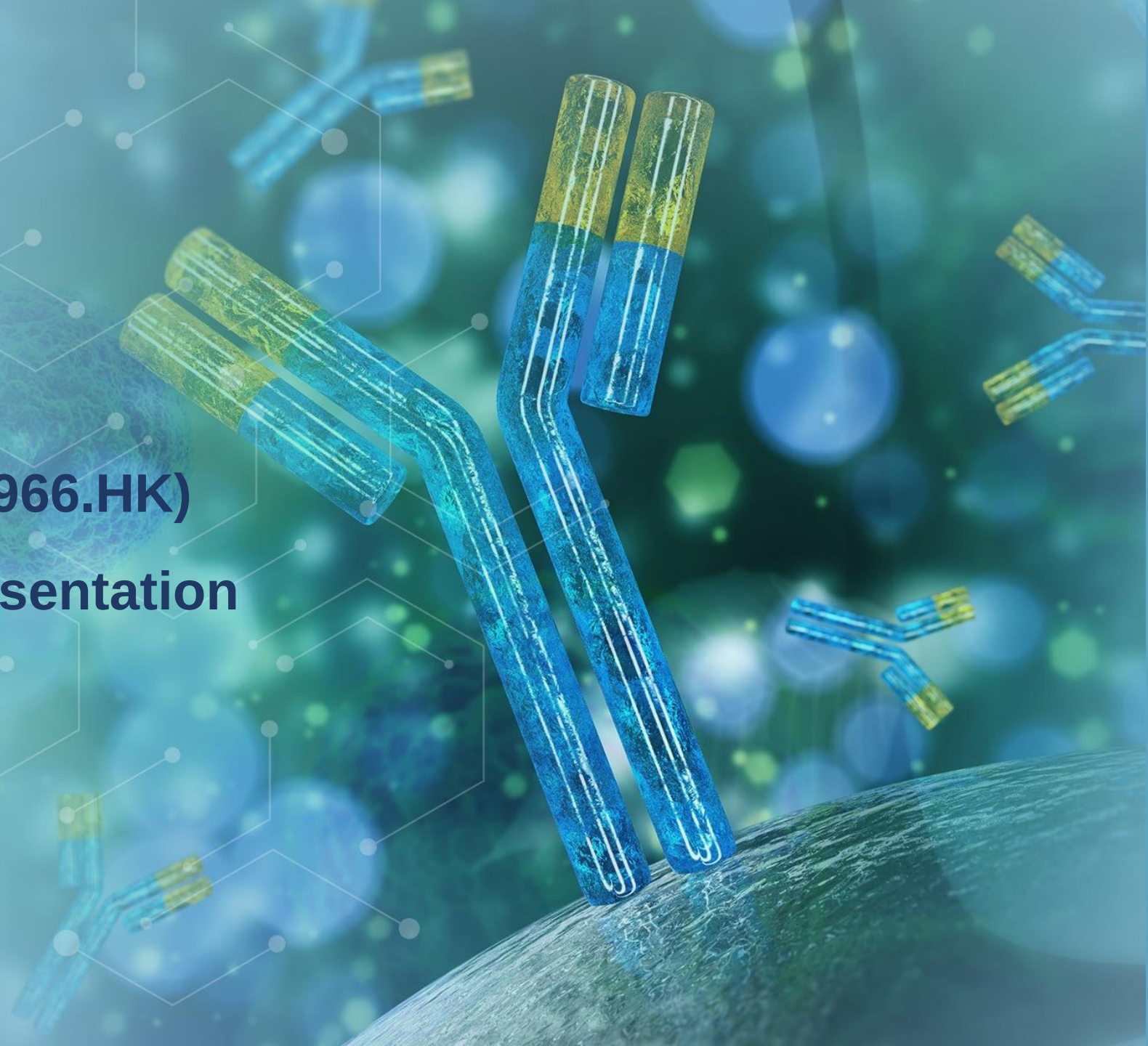
康宁杰瑞
ALPHAMAB ONCOLOGY

# Alphamab Oncology(9966.HK)

# 2023 Interim Results Presentation

August 2023



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# Agenda

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1. Financial Overview in 2023H1
2. Business Review
3. Outlook for 2023H2
4. Clinical Progress
5. R&D Strategy
6. Q&A

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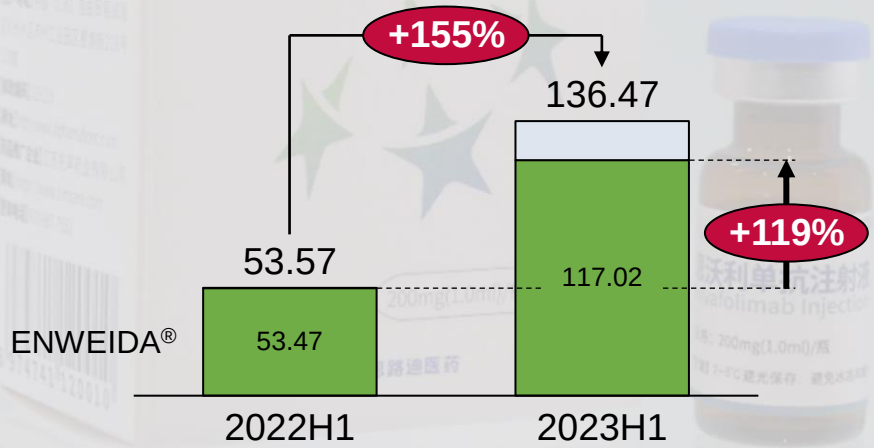
# Financial Overview in 2023H1

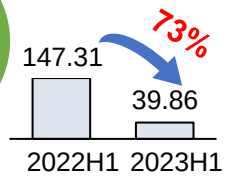
# Overview of Key Financial Data

(RMB)

| Total Revenue : | ENWEIDA®: |
|---|---|
| 136.47 Million | 117.02 Million |
| +155% | +119% |



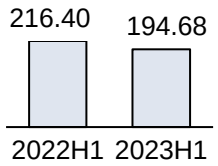

**-39.86Million**




**Loss for the Period**

**194.68Million**

Flat year-on-year




**R&D Expenses**

**33.24Miliion**

**Admin Expenses**

**1.58Billion**

**Cash on Account**

# Consolidated Statement of Comprehensive Income

| *(RMB'000)* | For the year ended June 30 | |
|---|---|---|
| | 2023 | 2022 |
| Revenue | 136,465 | 53,569 |
| Cost of Sales | (33,165) | (14,820) |
| Gross profit | 103,300 | 38,749 |
| Other income | 42,979 | 21,686 |
| Other gains and losses | 48,751 | 63,628 |
| R&D expenses | (194,681) | (216,399) |
| Administrative expenses | (33,244) | (44,097) |
| Finance costs | (6,967) | (10,876) |
| Loss before taxation | (39,862) | (147,309) |
| Income tax expense | - | - |
| **Loss for the period** | **(39,862)** | **(147,309)** |

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# Business Review

# Major Progress of Core Business Operations from January to July 2023

January → July

01 In January, the phase III clinical trial of KN026 in the treatment of ≥2L HER2+ GC/GEJ was ongoing smoothly.

02 In March, the first patient was dosed in the phase I/II clinical trial of JSKN003(HER2 Bispecific ADC) in China.

03 In March, the phase III clinical trial of KN046 in the treatment of PDAC(KN046-303) completed the enrollment.

04 In May, first patient was dosed in the study of KN046 combined with Axitinib (KN046-209) in the treatment of NSCLC patients who failed to respond to prior PD-(L)1 inhibitor.

05 In May, IND application of phase III clinical trial of KN026 combined with HB1801 as 1L treatment of HER2+ BC was approved, and the first patient was dosed in July.

06 In June, Envolimab in the treatment of Sarcoma achieved the positive results in the second interim analysis of more than 80 patients.

07 In June, JSKN016(bispecific ADC) completed the preclinical study.

08 In July, the phase I clinical trial of JSKN003 in Australia entered 8.4mg/kg group.
The phase I clinical trial in China entered 6.3mg/kg group.

09 At the end of July, the phase II clinical trial of JSKN003 was initiated in China and over 30 patients were enrolled in the phase I clinical trial in China and Australia totally.

10 KN052(PD-L1/OX40): The results of preclinical trial study was presented in 2023 AACR.
KN046+KN026: The results of phase II clinical trial in the treatment of HER2+ solid tumor was presented in 2023 ASCO.

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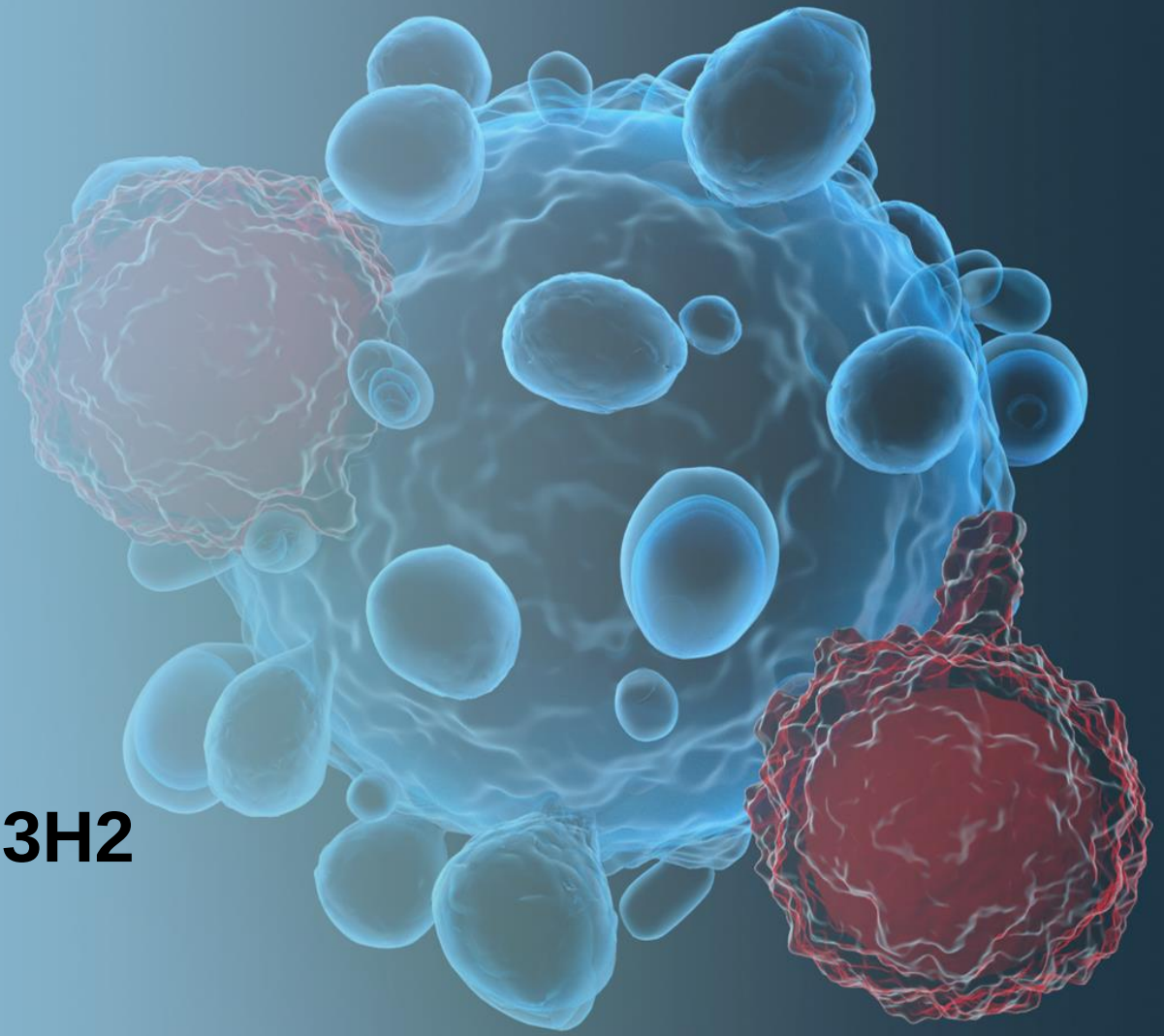

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# Outlook for 2023H2

# Key Milestones and Catalyst in 2023H2

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## Pivotal Trials Progress

- KN046+chemo, 1L sq-NSCLC: OS Data readout in 2024H1
- KN046+chemo, 1L PDAC: Data readout in 2023Q4, and initiate pre-BLA
- KN046+Axitinib, 1L NSCLC(PD-L1 positive): Complete enrollment of phase II clinical trial
- KN046+Axitinib, PD-(L)1 refractory NSCLC: Complete enrollment of most patients in the phase II clinical trial during this year
- KN026+chemo, HER2+1L BC：Advance enrollment in the phase III superiority trial
- KN026+chemo, ≥2L GC/GEJ: Advance enrollment in the phase III superiority trial
- JSKN003, monotherapy: Initiate pivotal trials in 2023Q4
- KN035, Sarcoma: Complete the administration of all patients in the pivotal trial in America, and perform the third interim analysis

## Clinical Trial Data Plan to Release

**ESMO**: October 2023

1. KN046+Axitinib: phase II clinical trial, 1L NSCLC(PD-L1 positive)
2. KN046, monotherapy: phase II clinical trial, late-line Thymic carcinoma
3. KN046, monotherapy: phase II clinical trial, wide-type advanced NSCLC who failed prior PD-(L)1 inhibitor treatment
4. KN046, monotherapy: phase II clinical trial, EGFR mutant advanced NSCLC who failed prior EGFR-TKI(s) treatment
5. KN026+Docetaxel: phase II clinical trial, neoadjuvant HER2+ BC
6. KN026+Docetaxel: phase II clinical trial, 1L HER2+ BC

**CSCO:** September 2023

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

**SABCS**：December 2023

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

## New Candidates Progress and Others

- **KN052:** Complete the dose escalation stage of phase I clinical trial
- **JSKN016:** Submit IND application at the year end of 2023
- Add **2** new clinical candidates
- Drive the revolutionary upgrades of production process

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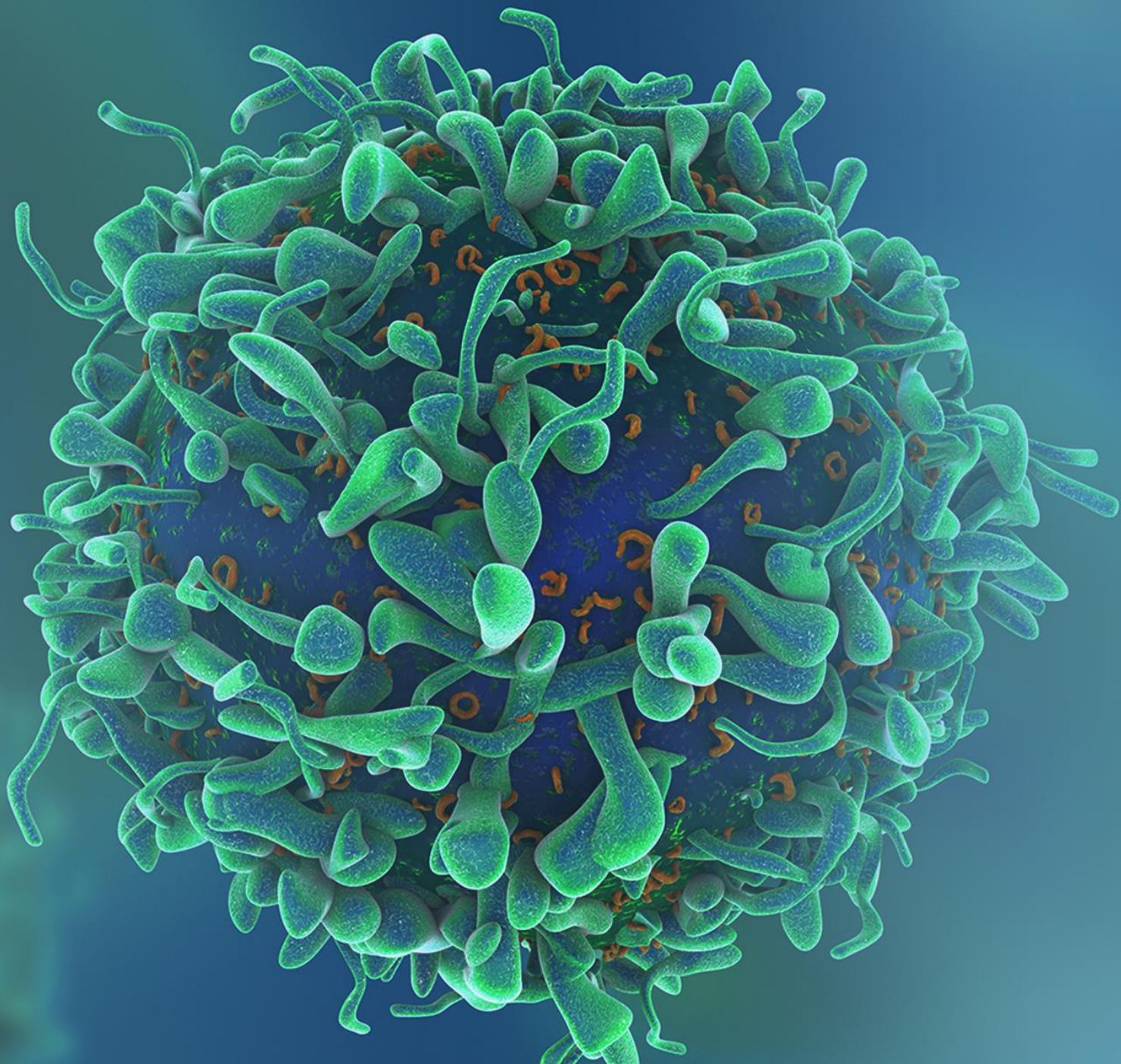

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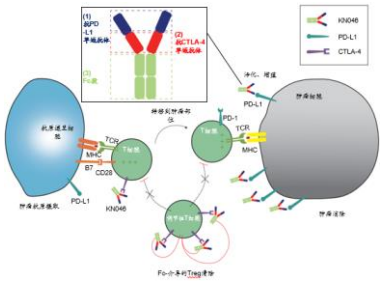
# Clinical Progress

## KN046

**Dual blockade of PD-L1 and CTLA-4**

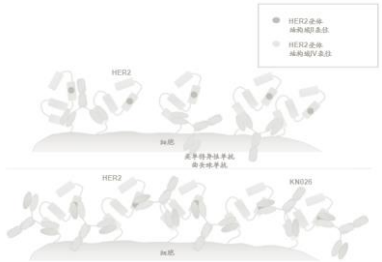
- PD-(L)1 refractory solid tumor
- PD-(L)1 Inadequate response



## KN026

**Dual blockade of HER2 domain II and IV**

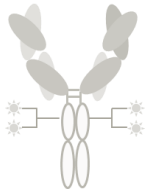
- Solid tumor with high HER2 expression
- Positioning the first line and perioperative period



## 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

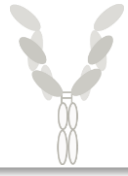
**Subcutaneous PD-L1 mAb**

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

## KN052

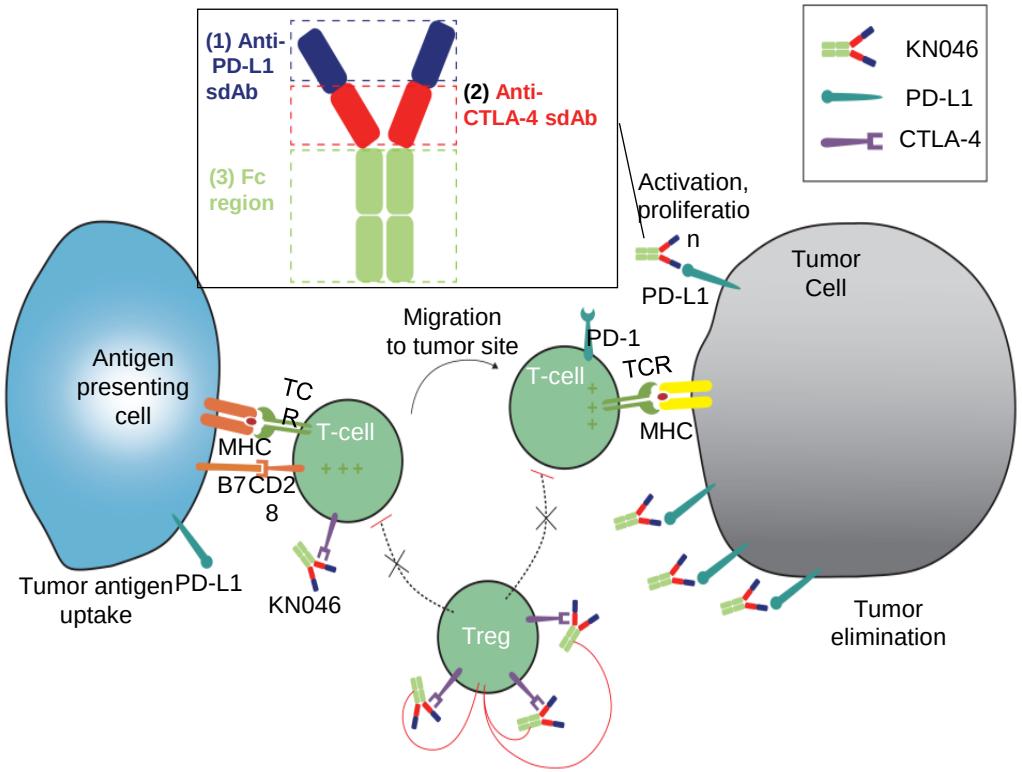
**PD-L1/OX40 BsAb**

- The tandem structure of PD-L1 antagonist and OX40 agonist
- Used as an adjuvant in combination with tumor vaccines and cell therapy



# KN046: PD-L1/CTLA-4 BsAb

## Mechanism of Action




Fc-mediated Treg Depletion

## 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

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

# KN046: Preliminary Results in a Nutshell

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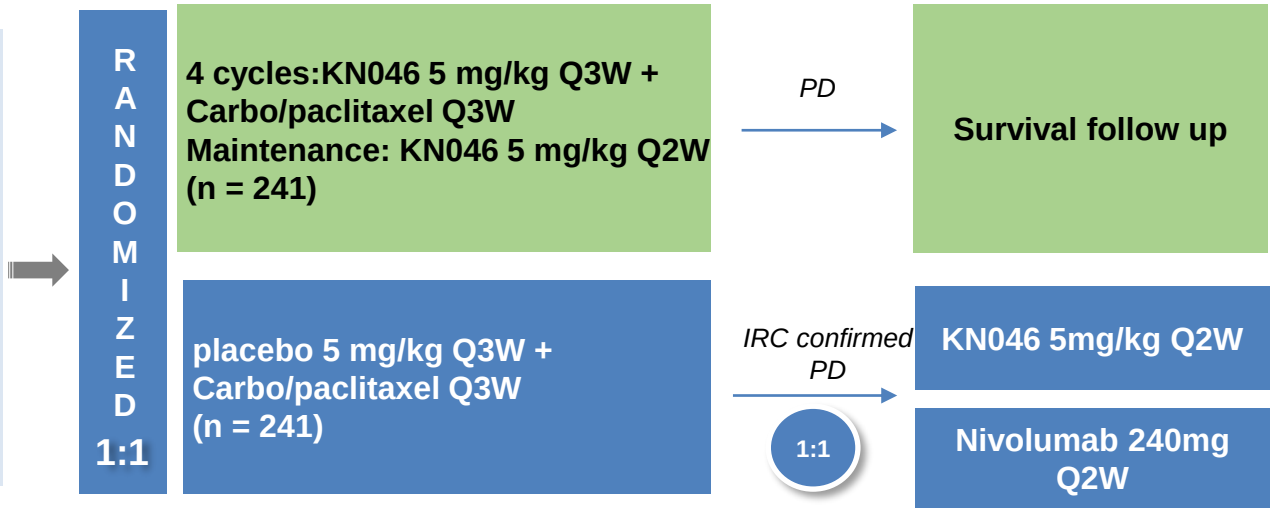
| Indication / Efficacy & Safety | KN046(Over 1,200 patients have been enrolled in clinical studies) | | | | |
|---|---|---|---|---|---|
| | sq-NSCLC 1L (n=87) | PDAC 1L (n=53) | HCC 1L (n=55) | TNBC 1L (n=27) | ESCC 1L (n=15) |
| **Mono/Combo** | +chemo | +chemo | +lenvatinib | +chemo | +chemo |
| **OS** | **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)-Pre-NDA

## 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

## Trial design




**Stratification**

- PD-L1 expression level(PD-L1 ≥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 (2022 ASCO)

**KN046-IST-04 Trial Design(Phase II): 53** newly treated patients (cohort 2) had received one-cycle of KN046 combined with nab-paclitaxel/gemcitabine treatment until disease progression or intolerable toxicity

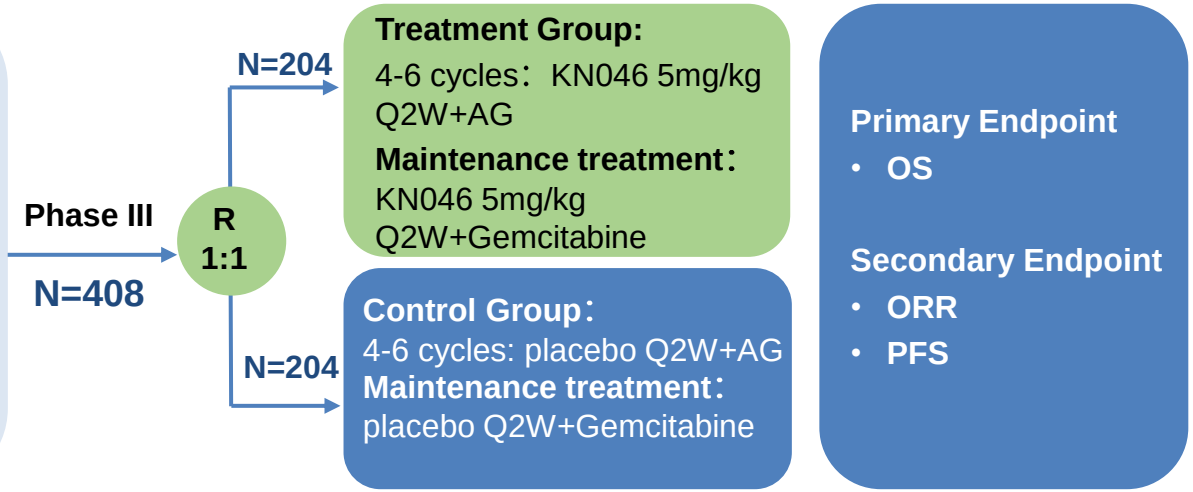
**KN046-IST-04 Efficacy(Phase II):** 53 patients were evaluable for efficacy.ORR was **47.9%**[1], mPFS was **6 months,** mOS was nearly **12 months**[2].

Based on these excellent preliminary results，the trial of KN046-303 (ENREACH-PDAC-01) was designed.

## Inclusion criteria

- Histologically or cytologically confirmed pancreatic ductal adenocarcinoma (including adenosquamous carcinoma)
- No prior systemic therapy for unresectable locally advanced or metastatic pancreatic cancer

## Trial Design




- KN046-303 is a multicenter, randomized, double-blind, placebo-controlled Phase III clinical study
- Completed the sample size enrollment as planned. OS data will be readout in Q4 2023

Note: 1. The data cut-off date is May 26, 2022.
2. Nearly 70% of patients were stage IV advanced PDAC, including those with a relatively poor baseline

# 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

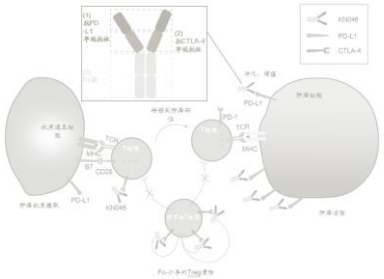
✓ **Cohort B：** For NSCLC patients who progressed after prior PD-(L)1 inhibitor treatment

Note: 1. Cohort A has entered stage II.

## KN046

**Dual blockade of PD-L1 and CTLA-4**

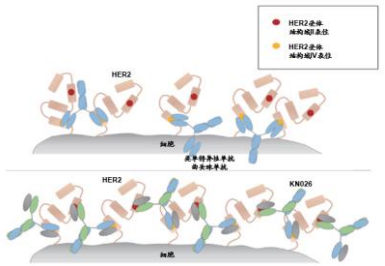
- PD-(L)1 refractory solid tumor
- PD-(L)1 Inadequate response



## KN026

**Dual blockade of HER2 domain II and IV**

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

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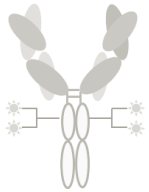
**HER2 bispecific ADC**

- 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 only PD-L1mAb worldwide that can be used for subcutaneous injection

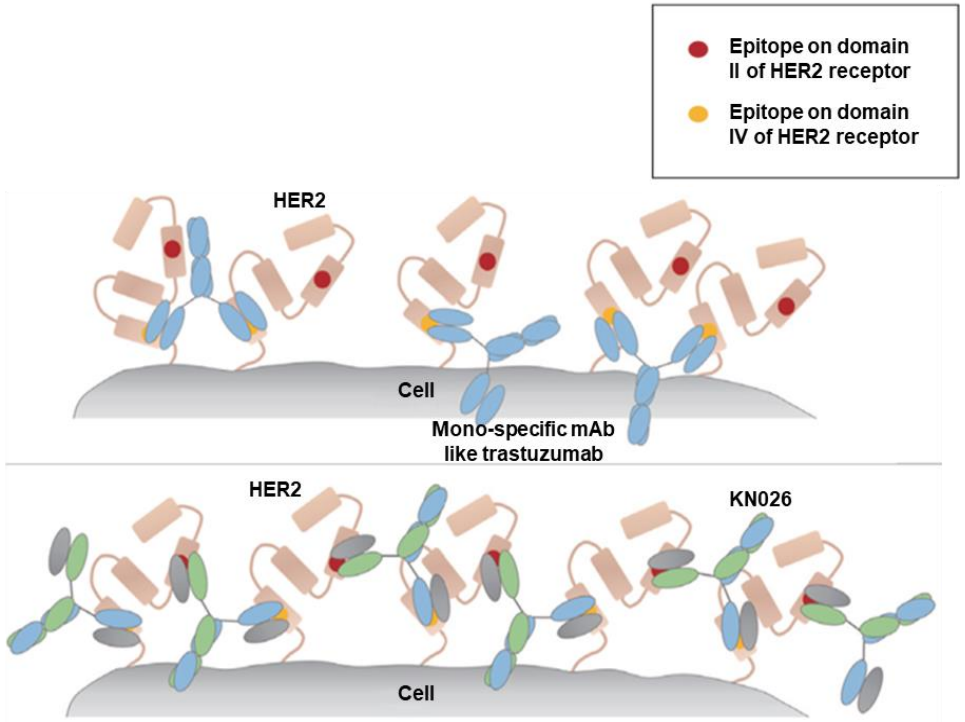
## KN052

**PD-L1/OX40 BsAb**

- The tandem structure of PD-L1 antagonist and OX40 agonist
- Used as an adjuvant in combination with tumor vaccines and cell therapy

# KN026: HER2/HER2 BsAb

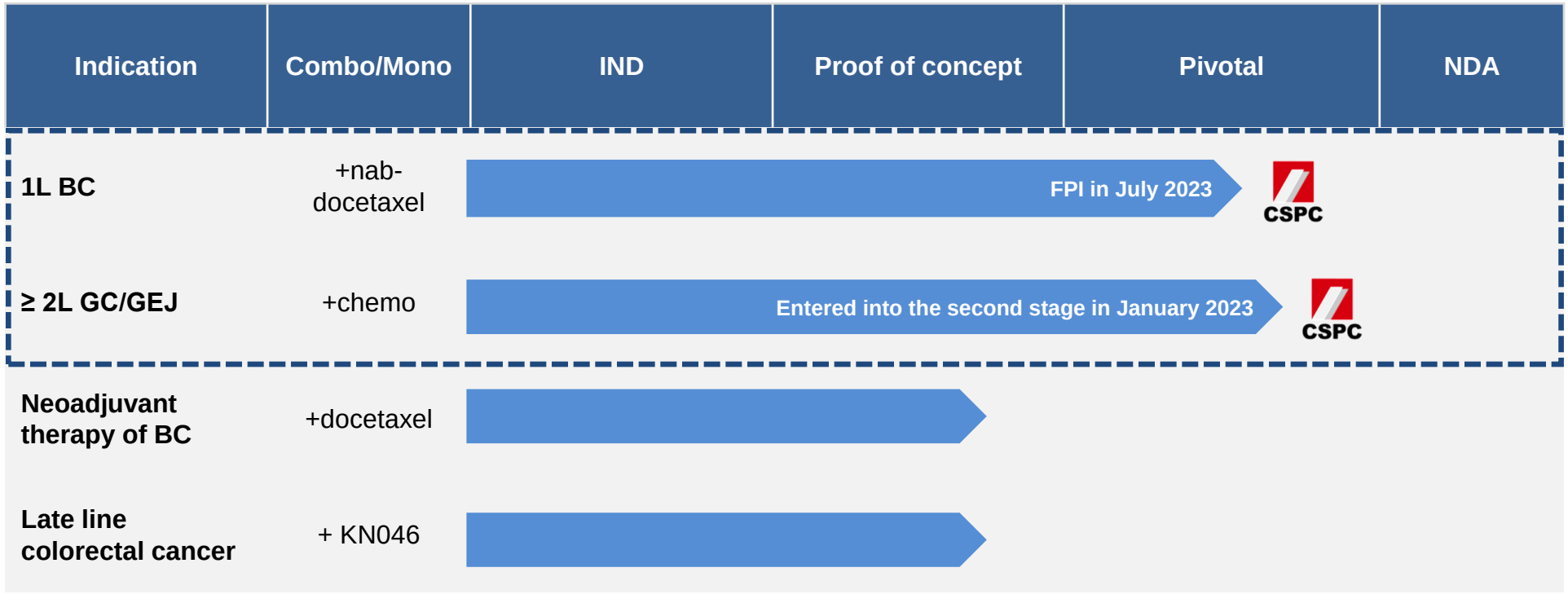
## Mechanism of action




## Highlights

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

# KN026 Major Clinical Trial: HER2 Positive Solid Tumor




- 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

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| 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)** | **91.2%** (24-months rate) | -- | -- | **16.3** | -- |
| **mPFS(months)** | **25.4** (immature) | -- | **10.9** | **8.3** | **12.2** |
| **ORR** | 76.4% | **60.7%（tpCR)** | **71.8%** | **56.0%** | **53.3%** |
| **DCR** | 100% | 100% | 92.6% | 76.0% | 93.3% |
| **≥Grade3 AE** | TEAE: 38.6% (related to KN026) | TEAE: 53.3% | TRAE: 16.1% | TRAE: 11.1% | 7.7% increase in bilirubin<br>7.7% increase in AST |

# KN026-202(Phase II) ≥2L GC/GEJ（2022 ASCO）

**Trial Design:** 45 patients with HER2 expression and previously treated were enrolled. **42%** of patients have received second line and above systemic treatment**.** KN026 (10 mg/kg QW, 20 mg/kg Q2W, or 30 mg/kg Q3W) was given until disease progression or intolerable toxicity.

**Efficacy:** For 25 evaluable patients with **high HER2 expression（IHC3+ or IHC 2+ ISH+)**, ORR was **56%** and DCR was **76%**
For 14 evaluable patients with **low HER2 expression（IHC 1+/2+ ISH- or IHC 0/1+ISH+)** , ORR was **21%** and DCR was **29%**

| ≥2L HER2+GC | KN026 | | DS-8201 | | KN026 |
|---|---|---|---|---|---|
| Level of HER2 expression | High HER2 expression | | High HER2 expression | | Low HER2 expression |
| Comparable Trials | KN026-202 [1] | | DESTINY-Gastric01 [2] | DESTINY-Gastric02[3] | KN026-202[1] |
| n | 25 | | 187（Japan:79.7%、Korea: 20.3%） | 79(Caucasian) | 14 |
| others | n=25 | Prior Trastuzumab treatment, n=14 | 55.6% of patients previously 2L treated | median line of therapy: 2L | - |
| ORR | **56%** | **50%** | 42.9% | 41.8% | **21%** |
| mPFS(months) | **8.3** | **5.5** | 5.6 | 5.6 | **1.4** |
| mOS(months) | **16.3 (11.3-NE)** | **14.9 （11.0-NE）** | 12.5 | 12.1 | **9.2** |

**Safety:** Among 45 patients，5 TRAEs at grade 3 were observed in 4 patients

Note: 1. KN026-202 is ongoing and the cut-off date is May 31, 2022. 2. . The incidence of grade ≥ 3 AE was 85.6%, of which neutropenia was 51%, anemia was 38%, and all grades ILD were 12.8% 3. The incidence of ≥ grade 3 TEAE was 55.7%, the incidence of permanent discontinuation during treatment was 19.0%, and the incidence of all grades of ILD was 10.1%.

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

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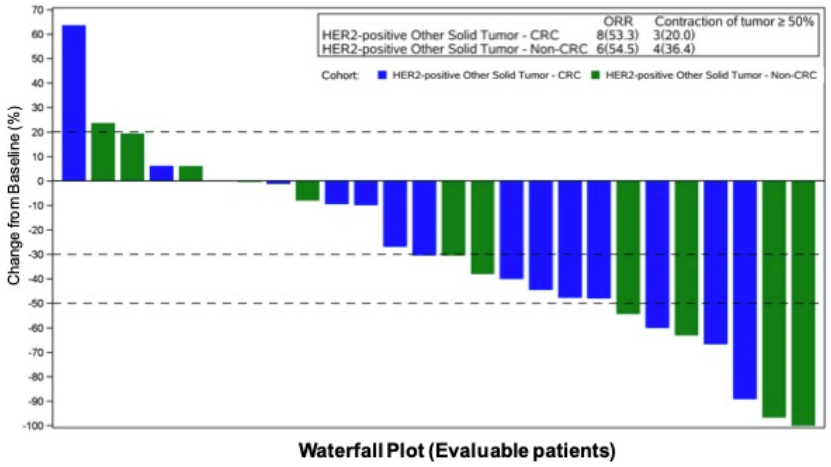
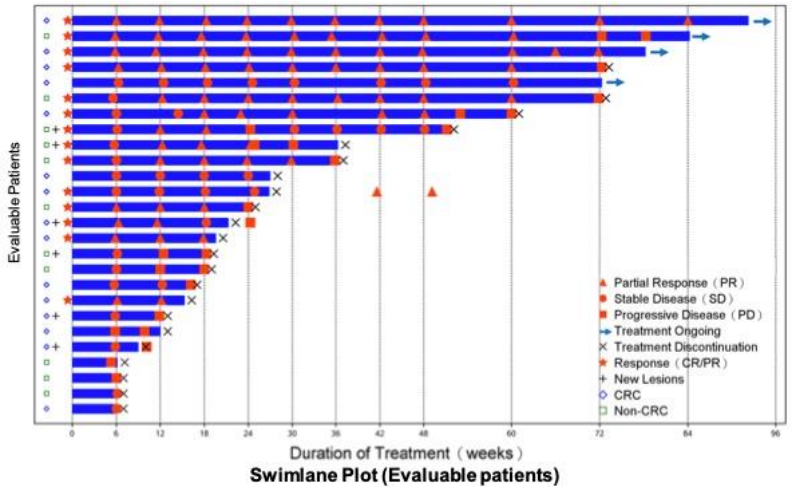
**Waterfall Plot**




**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, **ORR** was **53.3%** , **DCR** was 93.3%, **mPFS** was **12.2 months** and **12-month OS rate** was **80.0%**

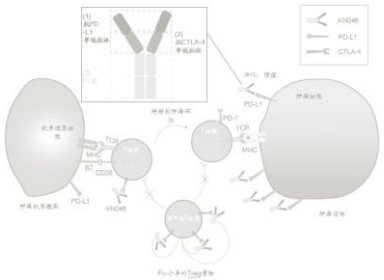
**Safety:** 34.6% of patients had experienced at least one time ≥ grade 3 TRAEs, the most common TRAEs were infusion related reaction(38.5%), diarrhea(19.2%), anemia, AST/ALT increased, etc.

Note: 1. The trial is on going and the cut-off date is November 10 , 2022 and the medium follow-up date is 16.6 months.

## KN046

**Dual blockade of PD-L1 and CTLA-4**

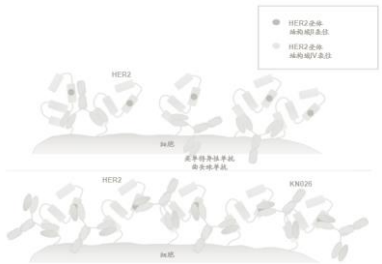
- PD-(L)1 refractory solid tumor
- PD-(L)1 Inadequate response



## KN026

**Dual blockade of HER2 domain II and IV**

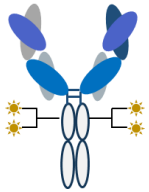
- Solid tumor with high HER2 expression
- Positioning the first line and perioperative period



## 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

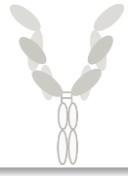
**Subcutaneous PD-L1 mAb**

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

## KN052

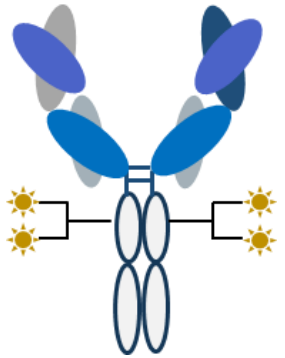
**PD-L1/OX40 BsAb**

- The tandem structure of PD-L1 antagonist and OX40 agonist
- Used as an adjuvant in combination with tumor vaccines and cell therapy



# JSKN003: Anti-HER2 Bispecific ADC

## Product Structure

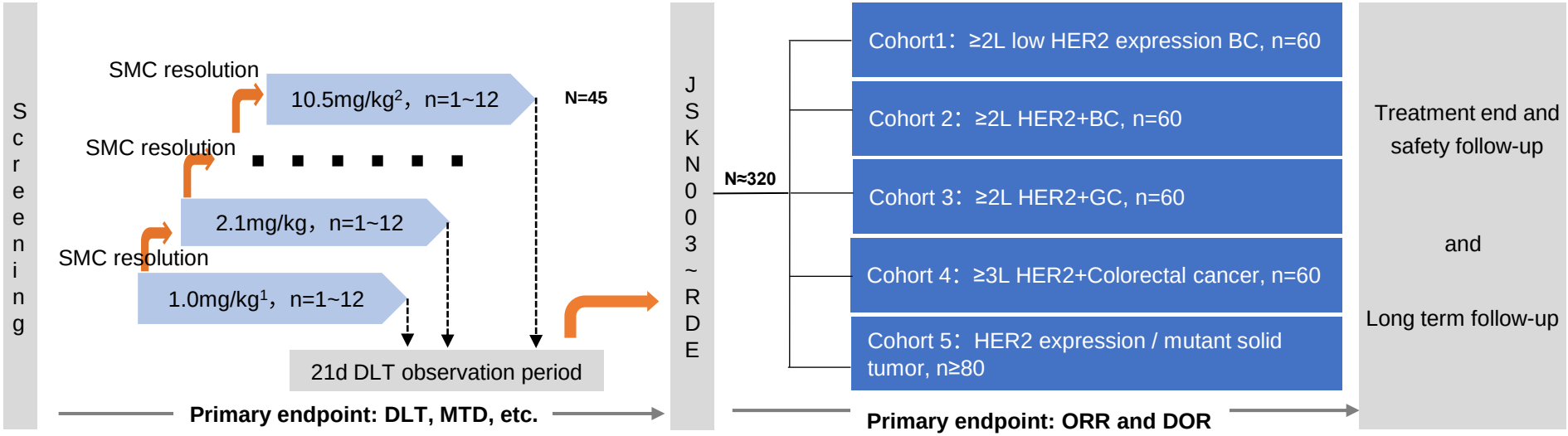


## Feature and clinical strategies

- 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 RDE[3]**




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

# JSKN003: More Efficient Conjugation Process and More Stable Product

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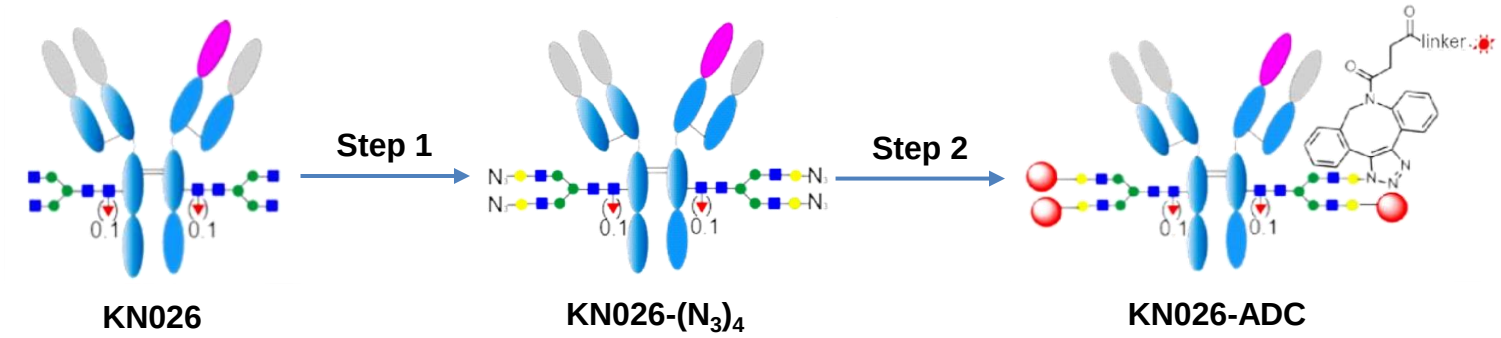
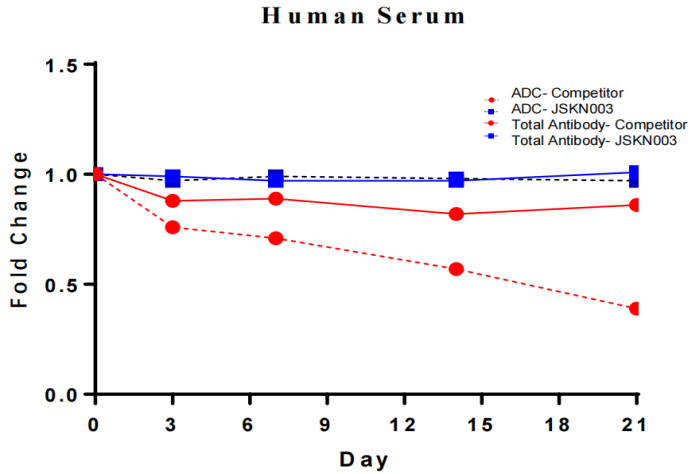
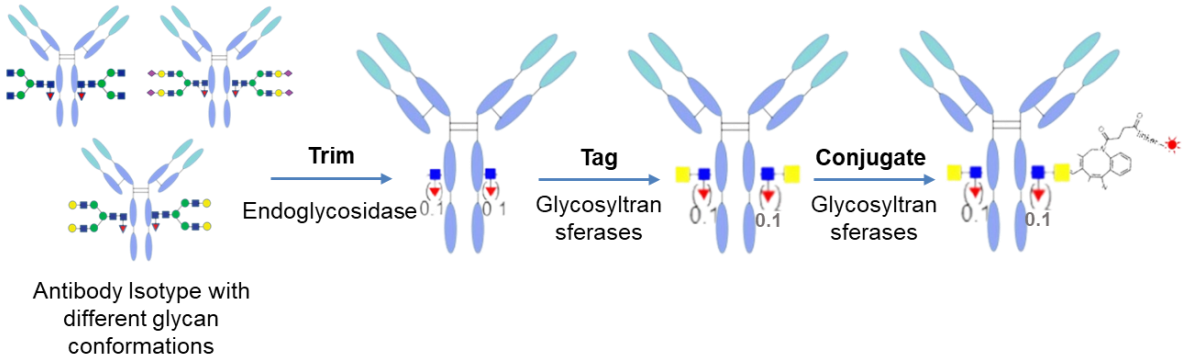
## Alphamab Oncology(JSKN003): One-enzyme two-steps method




## Synaffix: Two-enzyme three-steps method




- JSKN003: More stable in plasma circulation. Pharmacokinetics in vivo is more similar to antibody
- DS-8201: The ratio of toxin shedding is nearly 70% within 21-day plasma circulation
- Our ADC platform with one-enzyme two-steps method is more efficient compared with the process of Synaffix

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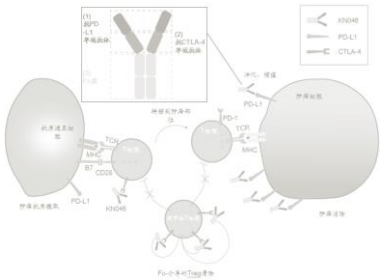

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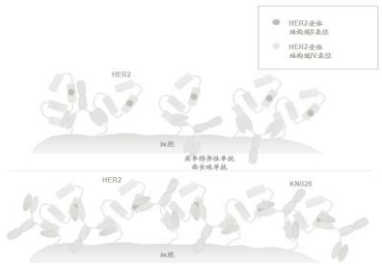

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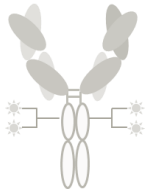

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- Used as an adjuvant in combination with tumor vaccines and cell therapy

# ENWEIDA(KN035): Conducting Multiple Clinical Trials

| Indication | Combo/ Mono | IND | Proof of concept | Pivotal | NDA |
|---|---|---|---|---|---|
| **≥2L MSI-H/dMMR advanced solid tumor** | mono | | | **Launched on November 25, 2021** | |
| **≥2L Sarcoma** | mono | | | **Global** | |
| **1L BTC** | +chemo | | | | |

- Revenue from ENWEIDA® is RMB117million in 2023H1
- Been selected into 6 diagnosis and treatment guidelines of gastric cancer, rectal cancer, immune checkpoint inhibitor, endometrial cancer, cervical cancer and ovarian cancer by China Clinical Oncology Society (CSCO).
- On June 19, 2023, TRACON Pharmaceuticals(our collaboration partner) announced the positive results(a double-digit ORR) of KN035 combined with Ipilimumab or monotherapy in the treatment of ≥2L sarcoma in the ENVASARC phase 2 pivotal trial[1] after IDMC reviewed interim safety and efficacy data from more than 80 patients. Envafolimab was well tolerated without a single > grade 2 drug related adverse event in monotherapy group.

Note: 1. The primary endpoint of the study needs to achieve a minimum 11.25% objective response rate. The ORR of the only medical treatment for sarcoma is currently only 4%, and there is a black box warning.

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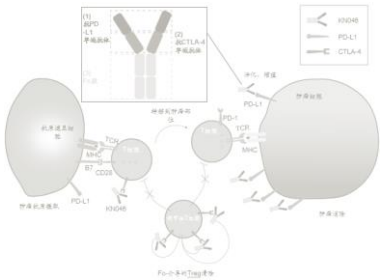

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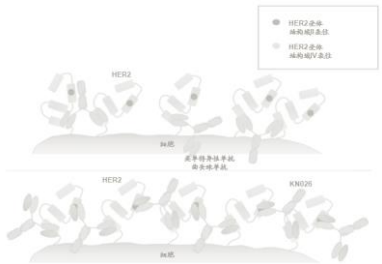

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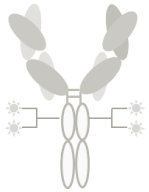

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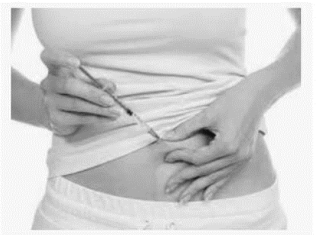

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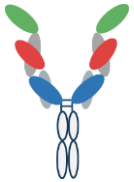
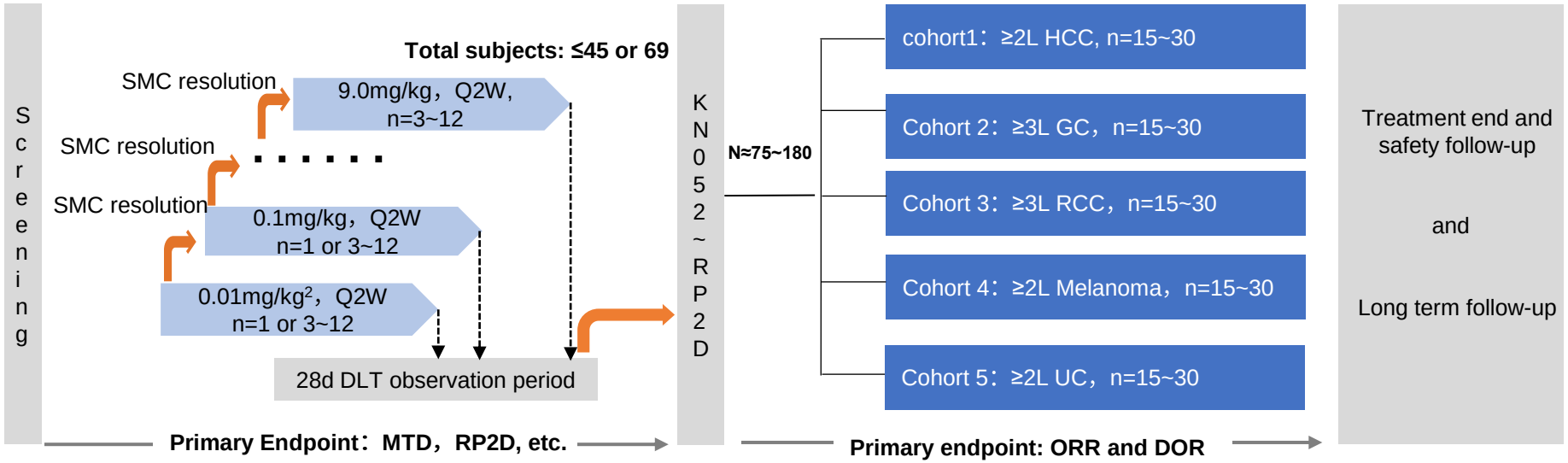


# KN052: Anti-PD-L1/OX40 Bispecific Antibody




## Feature of KN052 and Clinical Value of OX40

- 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
- OX40 is a key class of T cell costimulatory molecules, and OX40 and OX40L combine to increase the survival and expansion of effector T cells and memory T cells, increase cytokine secretion, and reduce the immune activity of Tregs
- Can be used as an adjuvant in combination with tumor vaccines and cell therapy

Note: 1. Phase Ia clinical trial adopts the accelerated titration BOIN design. At the beginning of the dose, only 1 subject enrolls the group, until DLT or the second ≥ level 2 toxicity appears, or the highest dose is reached. 2. A total of 8 doses, the starting dose is 0.01mg/kg

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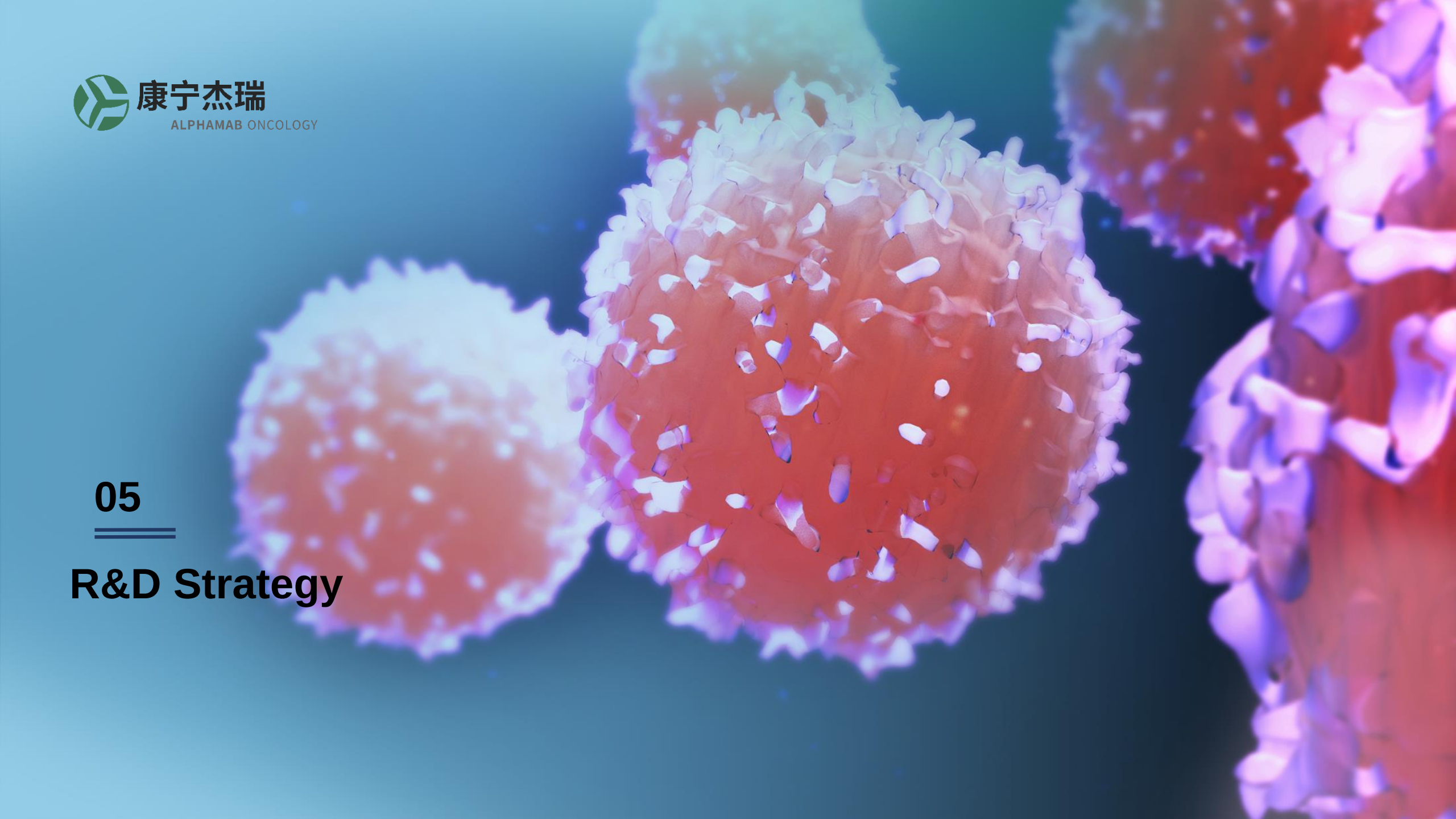

05

# R&D Strategy

# Current Pipeline Development Strategy


**KN046, KN052**

- Use in perioperation period
- Explore combination with other products
- Combined with tumor vaccines, etc.

**KN046+KN026**

**KN046+Axitinib**

- HER2+ GC and other gastrointestinal tumor
- NSCLC, chemo free
- PD-(L)1 resistance solid tumor
- Refractory tumors

**KN046+chemo**

1L NSCLC, PDAC,TNBC, HCC

- Solid tumors with high HER2 expression that do not fully respond to anti-HER2 therapy
- Solid tumors with low HER2 expression
- The front line solid tumors with HER2 expression

**JSKN003**
**Exploration of JSKN003 combined with other products (+IO, +chemo, etc. )**

- ≥2L HER2+GC
- 1L HER2+BC
- Neoadjuvant therapy HER2+BC

**KN026+chemo**

**R&D Strategy:** Modular, multi-functional Biotechnological development platform. Promote the upgrading of core products, Improve the efficacy and safety. Explore the chemo-free-regimen for tumor therapy innovatively

# Expand Multi-Module and Multi-Functional R&D Platforms

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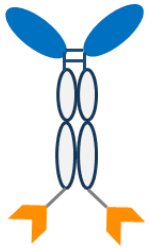
**Treg Modulation**

JSKN001

**GIMC**
(Glyco-Immune Modulator Conjugation)

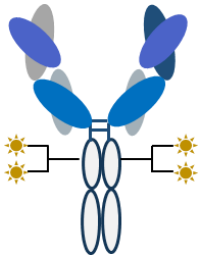
JSKN002

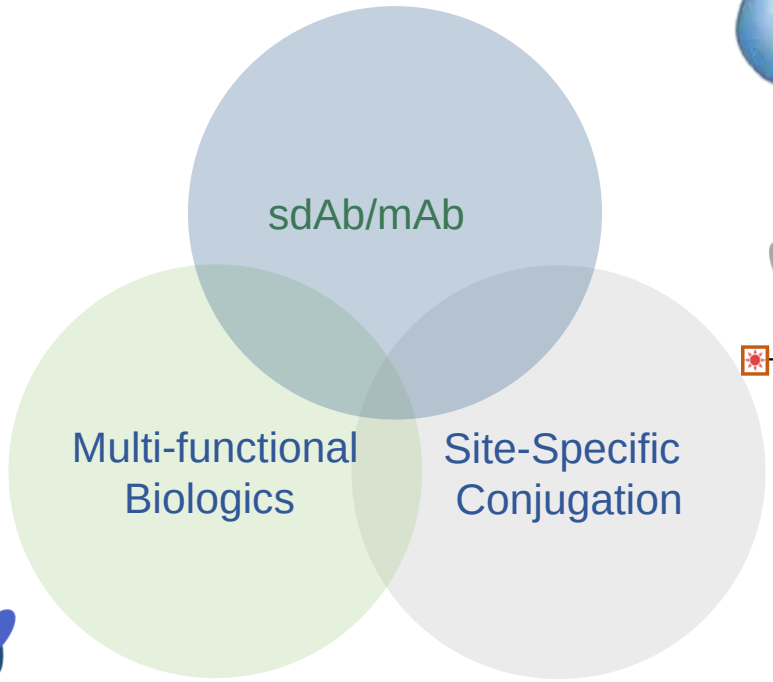


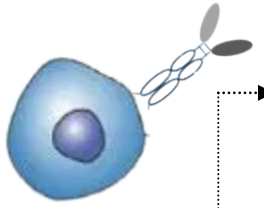
**BADC**
(Bispecific Antibody-Drug Conjugate)

JSKN003

JSKN016

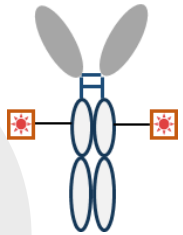




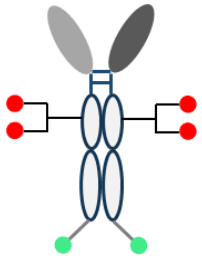
**ACC**
(Antibody-Cell Conjugation)

JSKN005



**CIMC**
(Chemokine Immune Modulator Conjugation)

JSKN024



**BADDC**
(Bispecific Antibody Dual Drug Conjugation)

JSKN021

JSKN023

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# Thank you!

## Q&A