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ALPHAMAB ONCOLOGY

# 2021 Interim Results Investor Presentation

August, 2021

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# Agenda

1. 2021 H1 Overview
2. Clinical Progress
3. R&D Progress
4. Operation Progress
5. Financial Overview
6. Q&A

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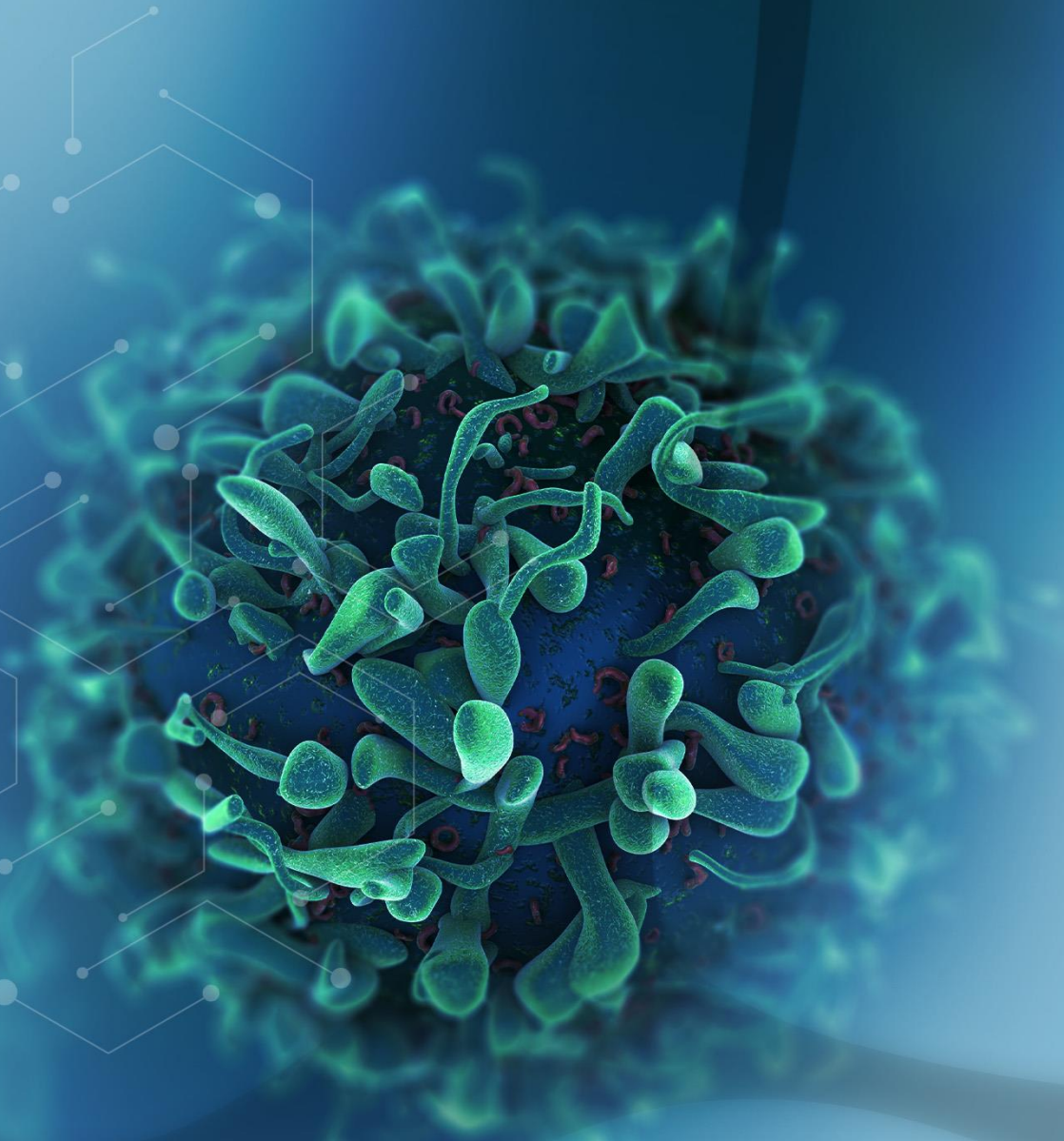

# 01

# 2021H1 Overview

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

# Clinical Pipeline overview

| Stage | Drug candidates | Target(s) | Platform | Rights | Key Indications | Pre-clinical | Dose escalation | Proof of concept | Pivotal | NDA |
|---|---|---|---|---|---|---|---|---|---|---|
| Post-clinical | **KN046** | PD-L1/CTLA-4 bispecific | sdAb/mAb | Global | NSCLC, Thymic, Pancreatic, HCC, ESCC, TNBC | | | | | |
| | **KN026** | HER2/HER2 bispecific | CRIB | Global | HER2-positive BC, GC/GEJ | | | | | |
| | **KN026 +KN046** | Target therapy +IO combo | Biomarker driven | Global | HER2-positive solid tumors | | | | | |
| | **KN019** | B7 | Fusion protein | Global | RA, lupus, renal transplant, GvHD | | Phase II ongoing | | | |
| Pre-Launch | **KN035** | subQ PD-L1 | sdAb/mAb | Global Co-development | MSI-H, BTC, Sarcoma, TMB-H, MSS endometrial | | | | | 2021H2 to be launched |
| Pre-IND | **JSKN-003** | HER2 ADC | BADC | Global | HER2 solid tumors | | | | | |
| | **KN052** | PD-L1/OX40 bispecific | CRIB | Global | Solid tumors | | | | | |
| | **KN062** | None RBD conformation bispecific | CRIB | Global | COVID-19 | | | | | |

# Principal Speakers: Dr. Ting Xu

## Dr. Ting Xu Founder, Chairman & CEO

- **20+ years** of experience in pharmaceutical research and development
- Served as principal investigator and project leader in Archemix, Serono and Biogen successively
- Authored **14 papers** published in high-impact journals, including Cancer Cell and Immunity
- Bachelor's degree in biochemistry from **Nanjing University**, Master's and doctoral degree in molecular biology and Biochemistry from **Chinese Academy of Science and** Post-doctoral fellow of **Harvard University**
- Successively won the "**National Major Talent Project Selected**", "**Third Place in China Entrepreneurship Competition** ", "**2018 Jiangsu Top Ten Science and Technology Innovation and Entrepreneurship Figures**", "the 6th **Suzhou Outstanding Talent**" award and other awards

南京大学

中国科学院 CHINESE ACADEMY OF SCIENCES

HARVARD UNIVERSITY

Biogen

serono biotech & beyond

# Principal Speakers: Mr. Weihao Xu & Dr. Johannes Nippgen

## Mr. Weihao Xu Chief Financial Officer

- **15+** years experiences in global capital market, equity investment and financial management
- Served as Chief Financial Officer for CASI Pharmaceuticals and 111 Inc.. In the area of investment, he served as a Portfolio Manager and analyst in Matthews International and several other international funds
- Master of Philosophy degree in Finance and Accounting from Columbia Business School and also completed High Impact Cancer Research, a postgraduate program at Harvard Medical School

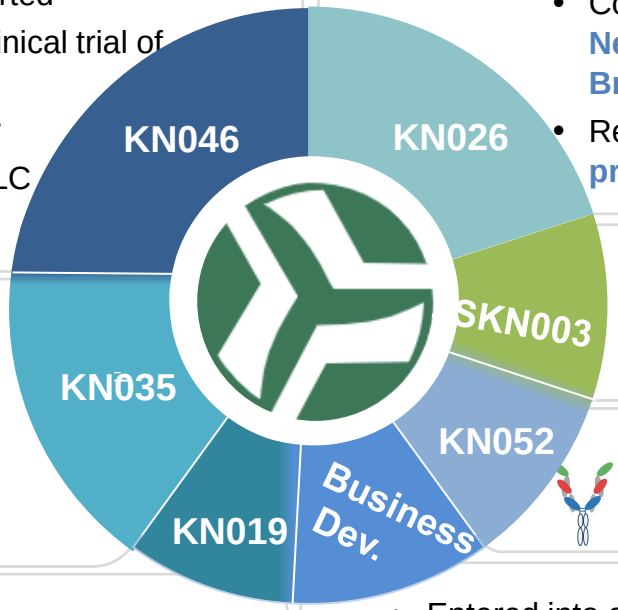
## Dr. Johannes Nippgen Chief Medical Officer

- **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

# 2021.01-2021.08 Major progresses

- Submitted IND application for phase III clinical trial of **PD-(L)1 Refractory NSCLC** and was accepted
- Completed the communication meeting with CDE about the pivotal clinical trial for **pancreatic cancer**, phase III clinical trial is agreed to be started
- Received IND approval for a phase II clinical trial of **Thymic carcinoma** by FDA
- Presented **6** clinical data in the e-poster session at 2021 ASCO, AACR and WCLC annual meeting

- Shows positive efficacy in **gastric cancer and breast cancer** in the clinical trials
- Presented the key data of **HER2+ GC/GEJ** in the e-poster session at 2021 ASCO annual meeting
- Completed FPI of Phase II clinical trial for **Neoadjuvant treatment of HER2+ Breast Cancer**
- Received IND approval of **Liquid-based preparations (LBP)**




- Completed the pre-approval registration inspection
- Obtained orphan drug designation for **Soft tissue sarcoma** by the US FDA
- Presented the study design of the ENVASARC pivotal trial in the U.S. at 2021 ASCO annual meeting

Completed drug efficacy confirmation and process development

- Completed pre-clinical study
- Submitted IND Application

- Completed the enrollment of Phase II clinical trial

- Entered into a clinical trial collaboration and supply agreement with **Pfizer**
- Entered into an exclusive licensing agreement with **CPSC** to develop and commercialize KN026 for the treatment of BC, GC/GEL in Mainland China

# 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 the Chinese 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**
- To complete the US FDA EoP2 Communication: KN046+Lenvatinib, **1L HCC**

## Key Data Release

- **CSCO**(Sep., 2021, planning-stage): KN046-IST-04: 1L PDA
- **ESMO** (Sep, 2021, planning-stage):

  1) KN046-202 driver mutation positive NSCLC

  2) KN046-IST-02 KN046+KN026 HER2-positive solid tumors

  3) KN046-IST-05 1L HCC
- **SABC** (Dec, 2021, planning-stage): KN046+KN026 ≥2L HER2+ BC

## IND Application

- 2 IND applications for new drug candidates: **JSKN003**, **KN052**
- **KN019** to be converted to subcutaneous injection form for cancer/non-cancer indications

## Business Development

- Co-development/out-license deal for **KN026**, **KN035** and **KN019**

## Commercialization

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

## Manufacturing & Quality

- Pilot plant with advanced process technology
- **Extra 6,000L** to be increased to current facility
- State-of-art **7,500 ㎡** research lab to enable protein design, engineering, process development, cell therapy and gene therapy
- Phase 2 construction of **6*5,000L**to be set up

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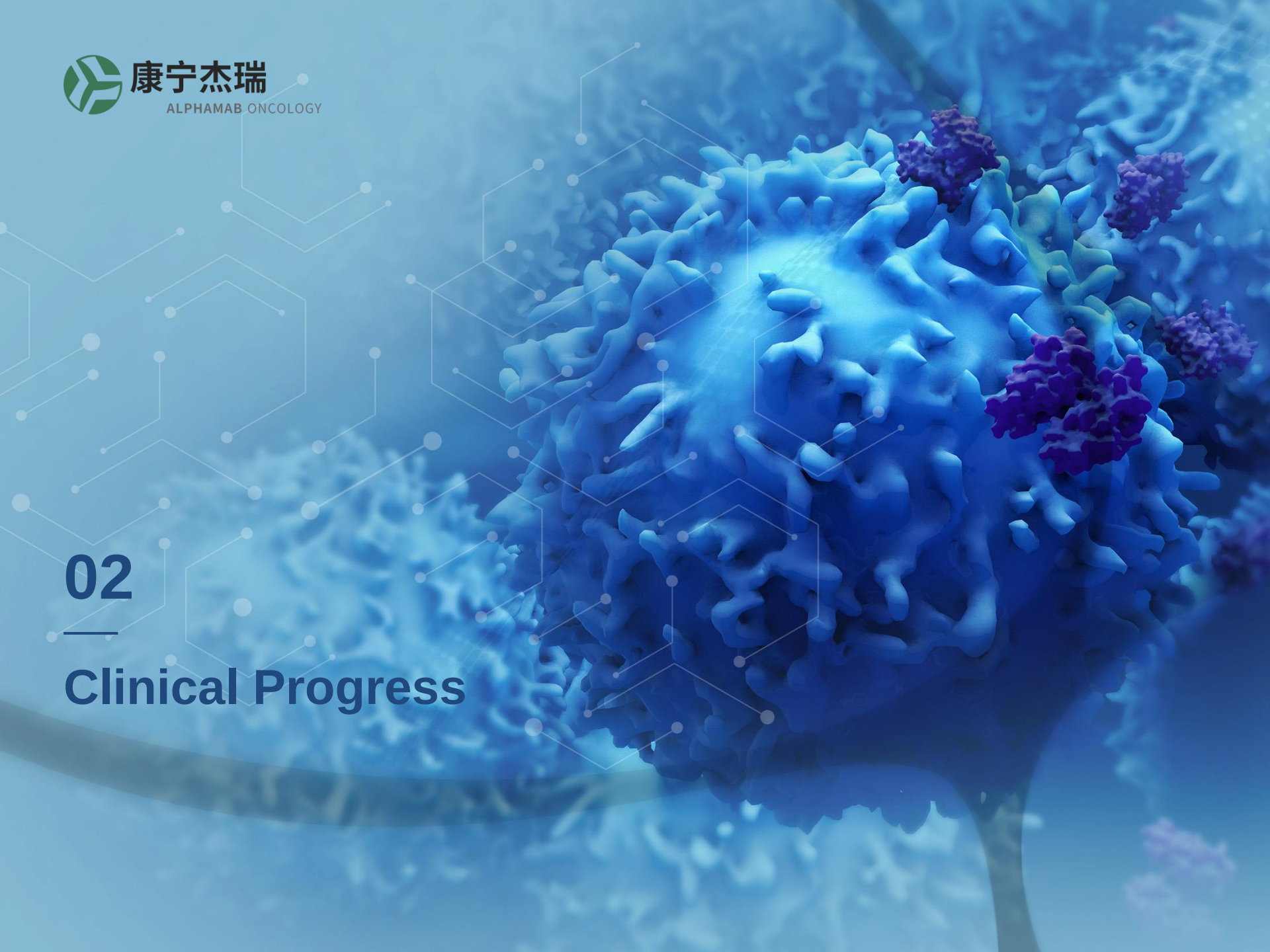


# 02

# Clinical Progress

# Clinical Progress

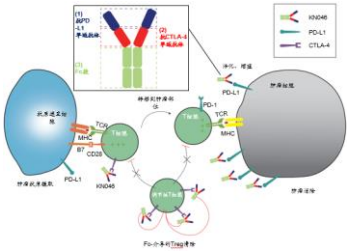
## KN046

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

- More efficacy and safety

**Clinical Positioning**

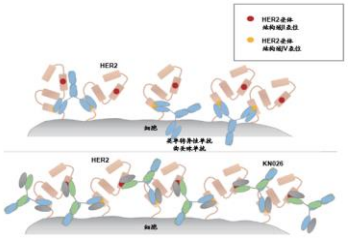
– Large Indications
– PD-(L)1 refractory
– PD-(L)1 Inadequate response



## KN026

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

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




## KN035

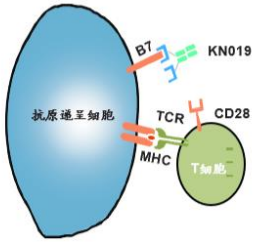
**Subcutaneous PD-L1**

- The world's leading PD-L1that can be used for subcutaneous injection

## KN019

**A safe option for autoimmune diseases**

- Supplement to immunotherapies for AE management



# Clinical Progress-KN046

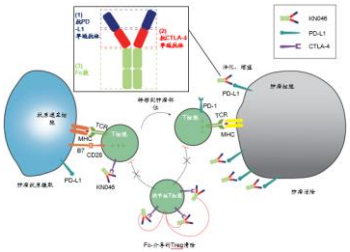
## KN046

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

- More efficacy and safety

**Clinical Positioning**

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



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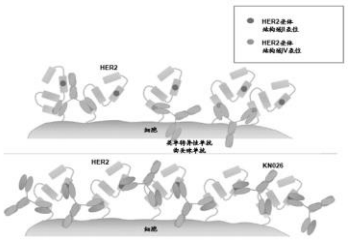


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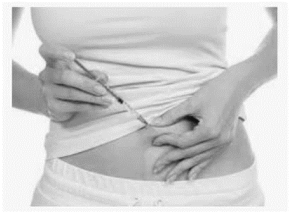

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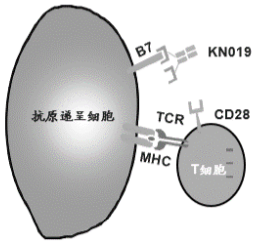
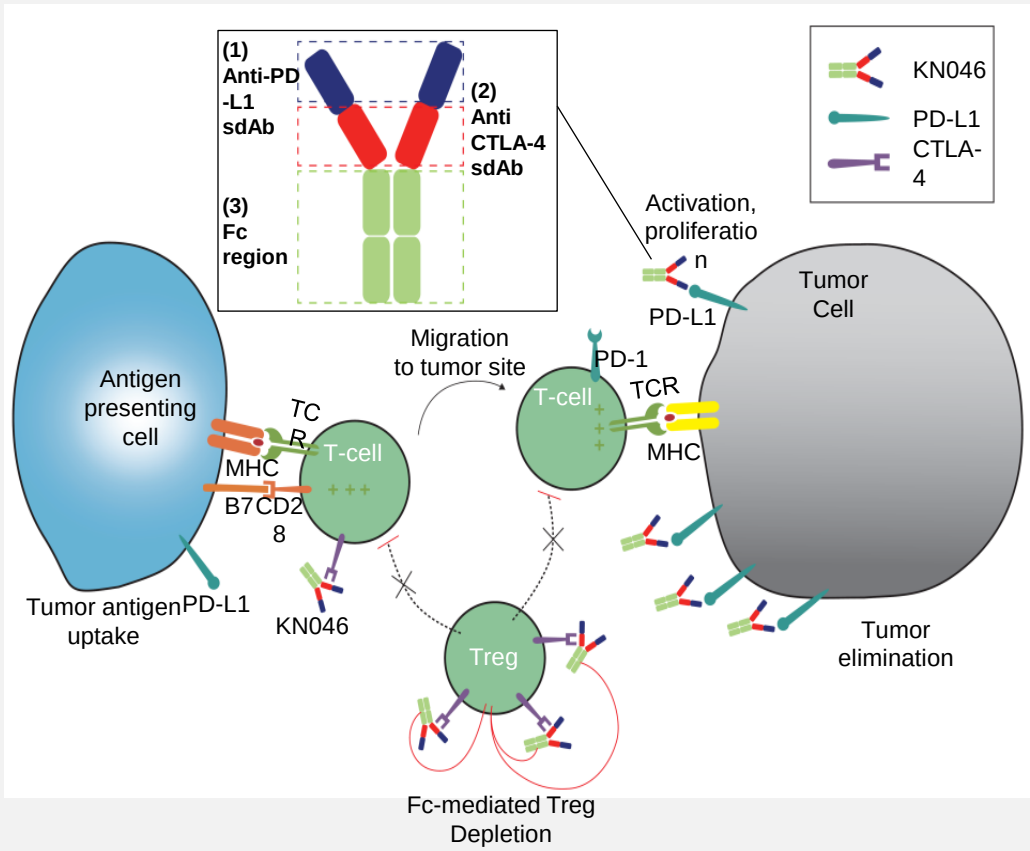


# KN046: PD-L1/CTLA-4 BsAb

## Mechanism of Action




## Highlights

**1) Targeted drug delivery**

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

**2) Different CTLA-4 binding epitope**

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

**3) Preservation of Fc-mediated effector functions**

- Preserves the full Fc functions for Treg Depletion

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

# KN046 Major Clinical Trials

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


Pivotal Trial

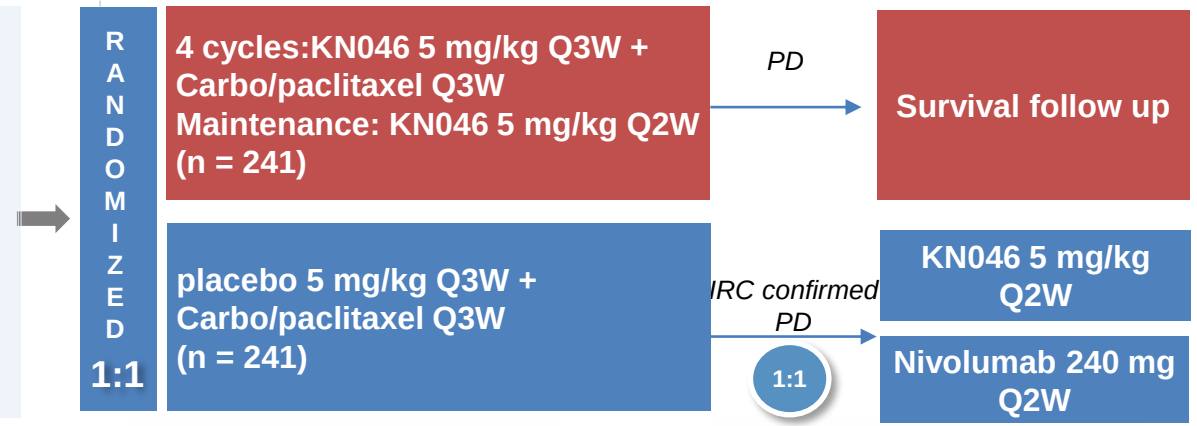
# I. KN046 in large indication: NSCLC

# KN046 Pivotal Trial: 1L NSCLC (ENREACH-LUNG-01) Ongoing-1/3

## Inclusion criteria

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

## Trial design




**Stratification**

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

**Primary endpoint**

- PFS
- OS

**Key secondary endpoints**

- ORR
- DCR
- DOR etc.

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

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

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

## Comparison chart with other study data

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

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

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

**Subgroup analysis by PD-L1 expression level:**

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

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

**Safety:**

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

**Notes:**

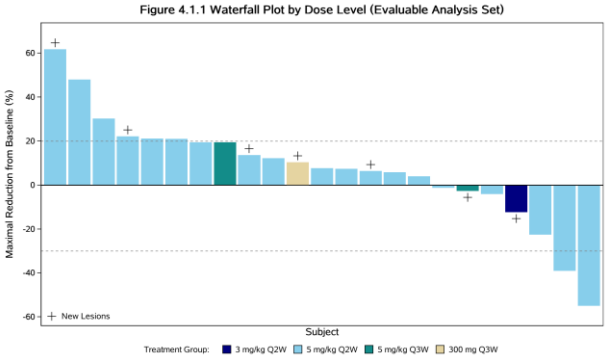
1. The trial is ongoing and the data is as of January 19, 2021

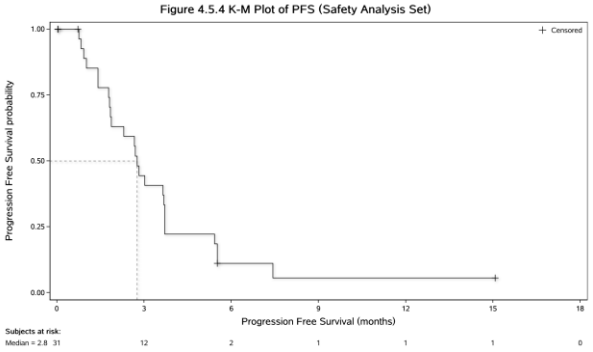
# II. KN046 in PD-(L)1 refractory patients:  NSCLC

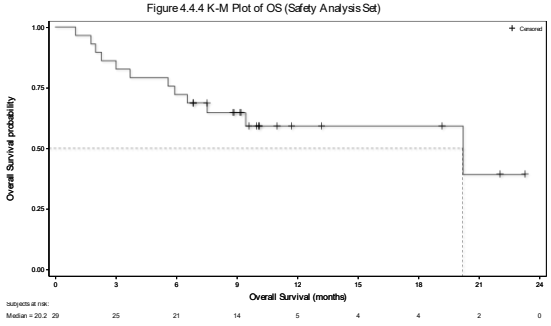
# KN046-CHN-001 and KN046-201 in ICI Refractory Patients

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

**Waterfall plot (DCR 50%)** | **Progression-free survival (2.8 months)** | **Overall survival (20.2 month)**




## 2 Comparable trials in NSCLC

| Comparable trials | KN046-CHN-001 & KN046-201 | Yuki Katayama 2019 | Fujita 2019 | ENCOR-601 |
|---|---|---|---|---|
| Drug | KN046 monotherapy | Anti-PD-1 I-O | Atezolizumab | Entinostat+ Pembrolizumab |
| Patients # | 24 | 35 | 18 | 72 |
| ORR | 8.3% (DCR 50%) | 5.9% (DCR 42.9%) | 0 (DCR 38.9%) | 10% (DCR 60%) |
| mPFS | 2.8 months | 2.7 months | 1.7 months | 2.8 months |
| mOS | 20.2 months | 7.4 months | NA | 11.7 |

**Notes:**

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

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

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

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

**Patient Status:** 17 patients were enrolled, median age (range) 56 (36-75) years, 52.9% ECOG PS score 1, and 41.2% with liver metastases at baseline; n=9 evaluable for efficacy analysis, median exposure of KN046 is 9.5 weeks

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

**Efficacy:** ORR was **55.6%** and DCR was **88.9%** (n=9)

| Drugs | KN046+chemo | Nivo+chemo | Pembro+chemo | Durva+Treme+ chemo |
|---|---|---|---|---|
| Stage | II | I | Ib/II | II |
| N | 9 | 50 | 11 | 119 |
| ORR | **55.6%** | 18% | 27% | 30% |
| DCR | **88.9%** | 64% | 100% | 71% |

**Safety:** The TRAE related to KN046 at grade 3 and above is **29.4%**

Only one SAE (rash) was related with KN046. No grade 4 or 5, and no patient discontinued treatment due to TRAE with KN046

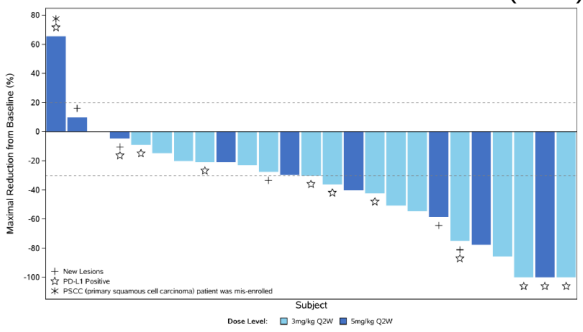
**Notes:**
1. The trial is ongoing and the data is as of January 15, 2021
2. Will release updated data in CSCO presentation

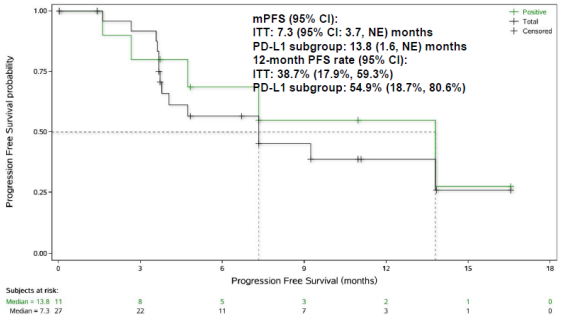
# KN046-203 1L TNBC (2021 AACR)

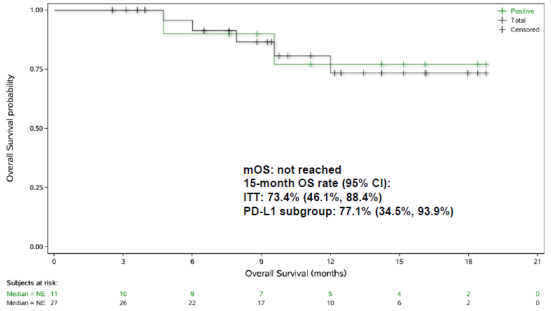
## 1 Preliminary efficacy of KN046 plus nab-paclitaxel in 1L TNBC

**Waterfall plot (DCR 96%)** | **PFS (13.8 months in PD-L1 positive group)** | **OS (15 months OS rate 77.1%)**

(n=25)




## 2 Comparable trials in 1L TNBC

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

**Notes:**

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

# KN046-204: 1L ESCC (2021 ASCO)

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

12 of them could be evaluated for efficacy analysis

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

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

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

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

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

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

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

**Notes:**

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

# Clinical Progress-KN026

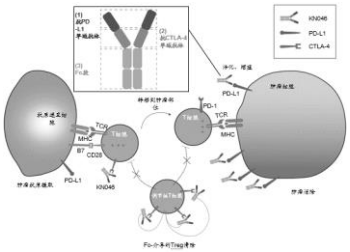
## KN046

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

- More efficacy and safety

**Clinical Positioning**

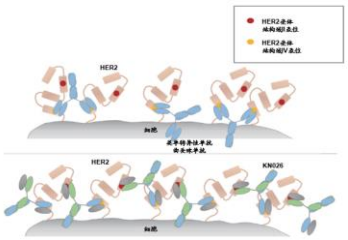
– Large Indications
– PD-(L)1 refractory
– PD-(L)1 Inadequate response



## KN026

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

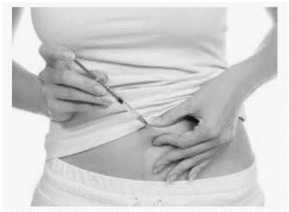
- Potential for all settings of HER2 aberration
- Synergy with KN046 through immune modulation




## KN035

**Subcutaneous PD-L1**

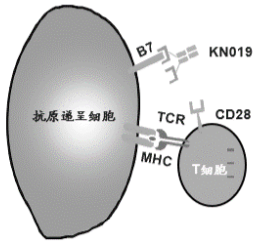
- The world's leading PD-L1that can be used for subcutaneous injection



## KN019

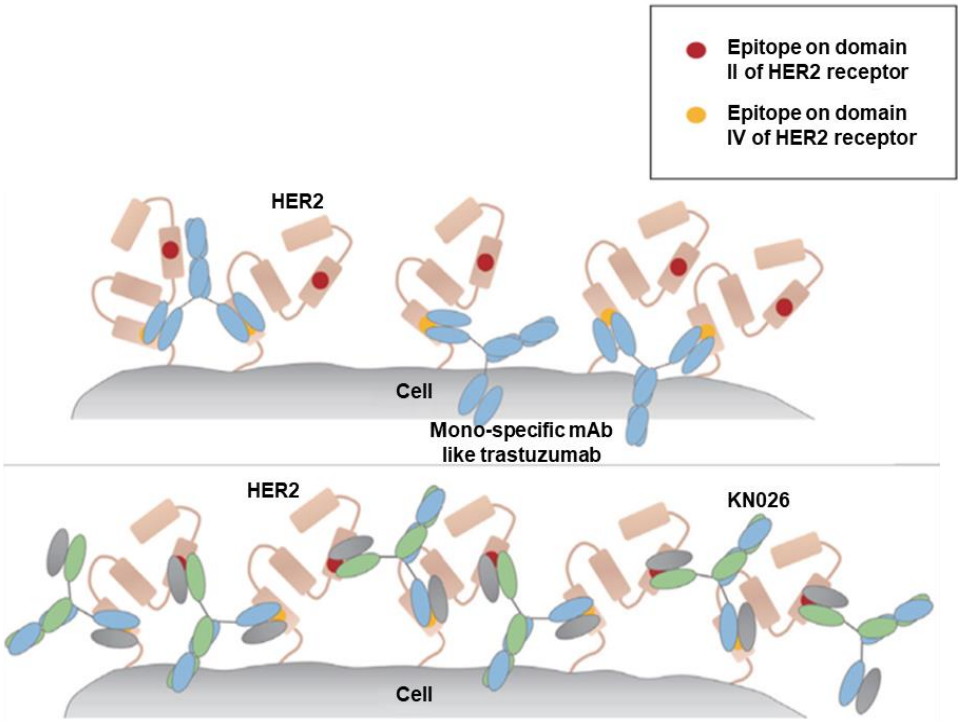
**A safe option for autoimmune diseases**

- Supplement to immunotherapies for AE management



# 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

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

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CSPC 石药集团

## Agreement Amount (up to RMB1billion)

| Upfront Payment | Development Milestone Payment | Sales Milestone Payment |
|---|---|---|
| RMB 150 million | RMB 450 million | RMB 400 million |

**a double-digit tiered sales commission**

## Agreement Points

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

# KN026 Major Clinical Trials

| Tumor Type | Combo/Mono | Line NO. | Proof of concept | Pivotal | NDA |
|---|---|---|---|---|---|
| HER2+BC | + KN046 | ≥ 2L | | ★ | |
| | + docetaxel (SANOFI) | 1L | | ★ | |
| | + docetaxel | Neoadjuvant therapy | FPI in August 2021 | ★ | |
| | + palbociclib (Pfizer) | ≥ 2L | FPI 2021H2 | | |
| HER2+GC/GEJ | + chemo | ≥ 2L | | ★ | |
| | +KN046 | 1L | | ★ | |
| | mono | ≥ 2L | | | |
| HER2+ solid tumors | + KN046 | Late line | | ★ | |

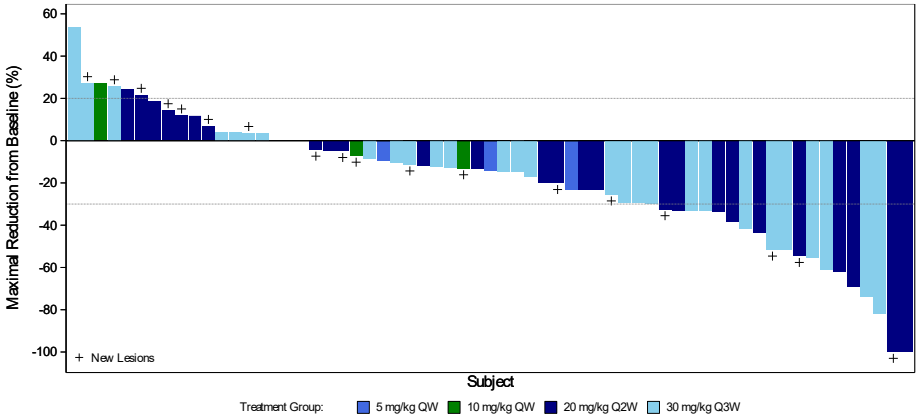
★ Pivotal Trial

**Notes:**
1. FPI – first patient in

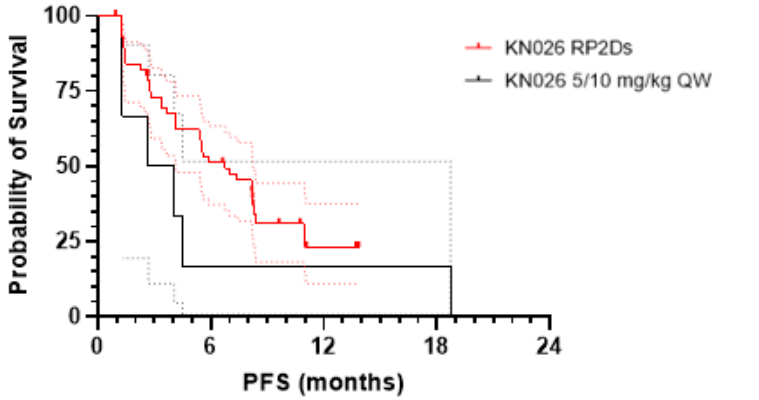
# KN026-CHN-001

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

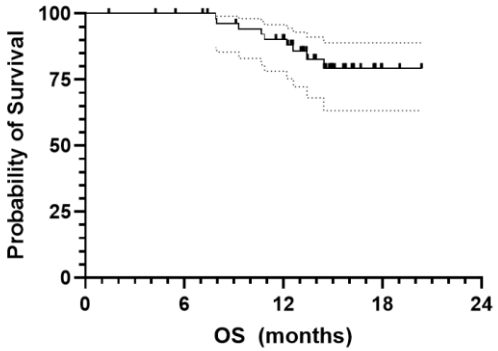
## Waterfall plot




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




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




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

**Notes:**
1. Data cut-off 21-Dec-2020

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

**KN026+KN046 for the treatment of GC/GEJ has been granted orphan drug designation by the US FDA and Plan to initiate ≥2L GC/GEJ registration trial in 2021H2**

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

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

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

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

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

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

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

**Notes:**

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

# Clinical Progress-KN035

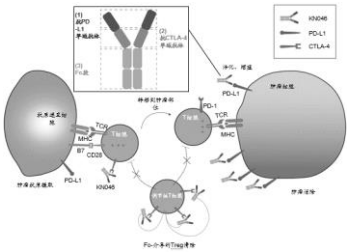
## KN046

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

- More efficacy and safety

**Clinical Positioning**

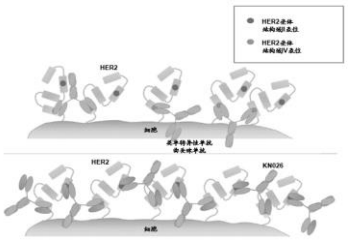
– Large Indications
– PD-(L)1 refractory
– PD-(L)1 Inadequate response



## KN026

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

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




## KN035

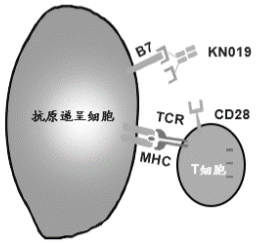
**Subcutaneous PD-L1**

- The world's leading PD-L1that can be used for subcutaneous injection

## KN019

**A safe option for autoimmune diseases**

- Supplement to immunotherapies for AE management



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

## Intravenous infusion vs. subcutaneous Injection

Intravenous Infusion

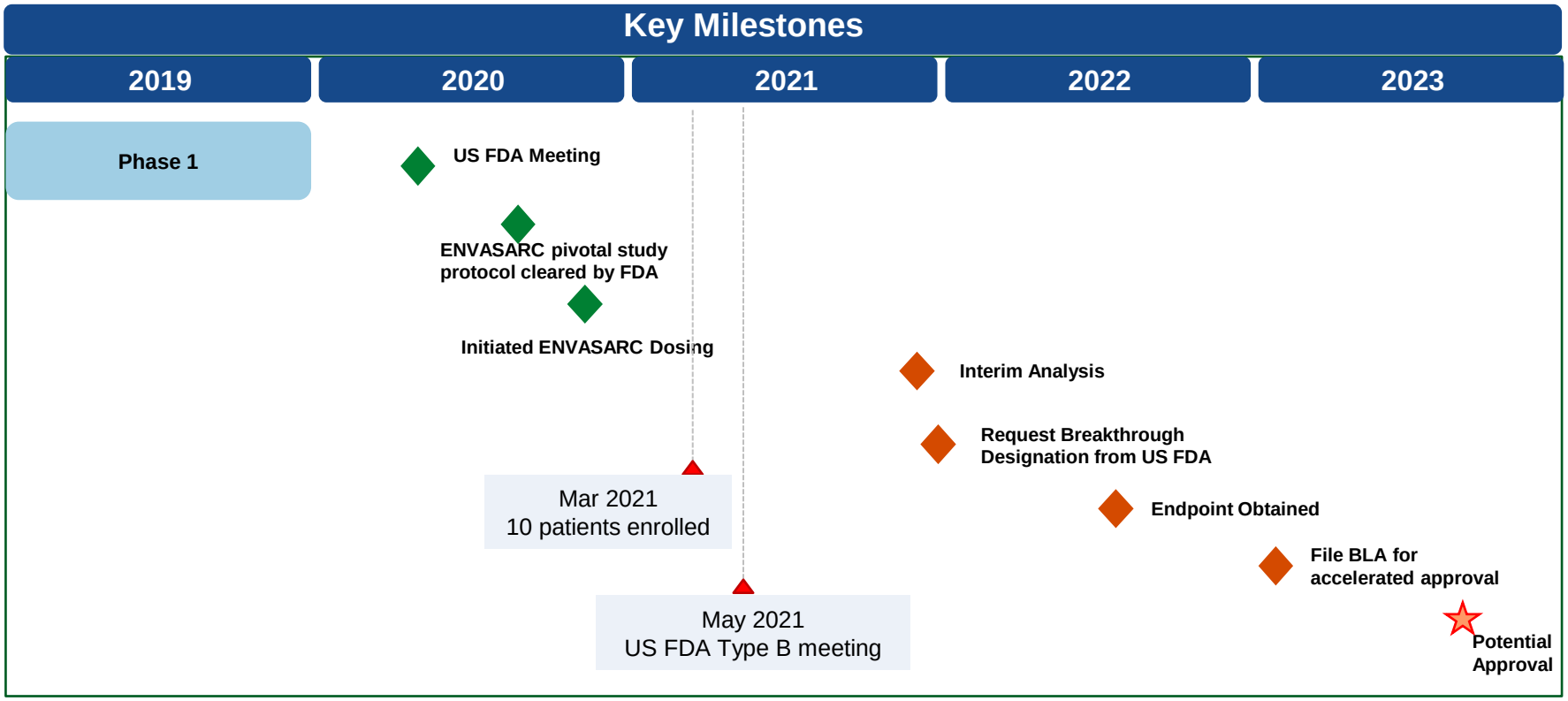
subcutaneous Injection

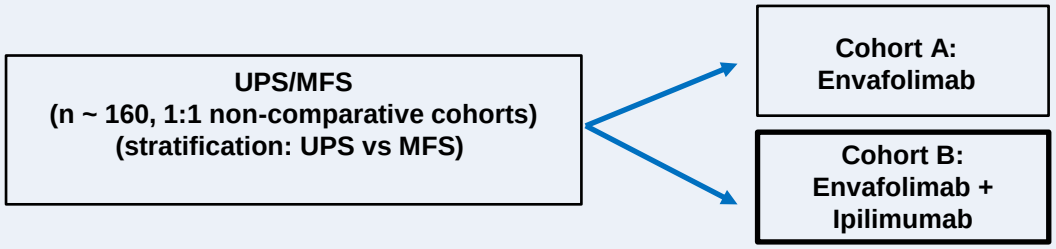
## Advantages

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

- 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

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



# Clinical Progress-KN019

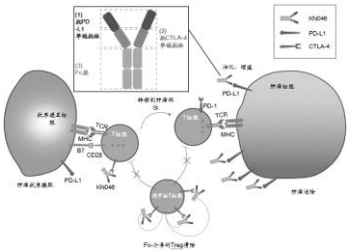
## KN046

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

- More efficacy and safety

**Clinical Positioning**

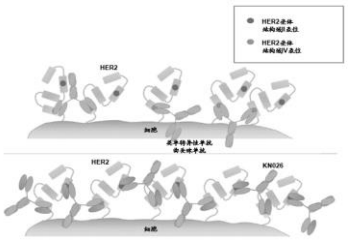
– Large Indications
– PD-(L)1 refractory
– PD-(L)1 Inadequate response



## KN026

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

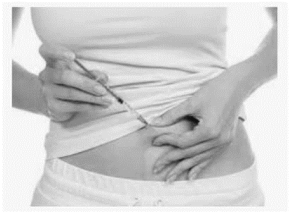
- Potential for all settings of HER2 aberration
- Synergy with KN046 through immune modulation




## KN035

**Subcutaneous PD-L1**

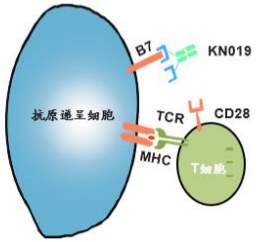
- The world's leading PD-L1that can be used for subcutaneous injection



## KN019

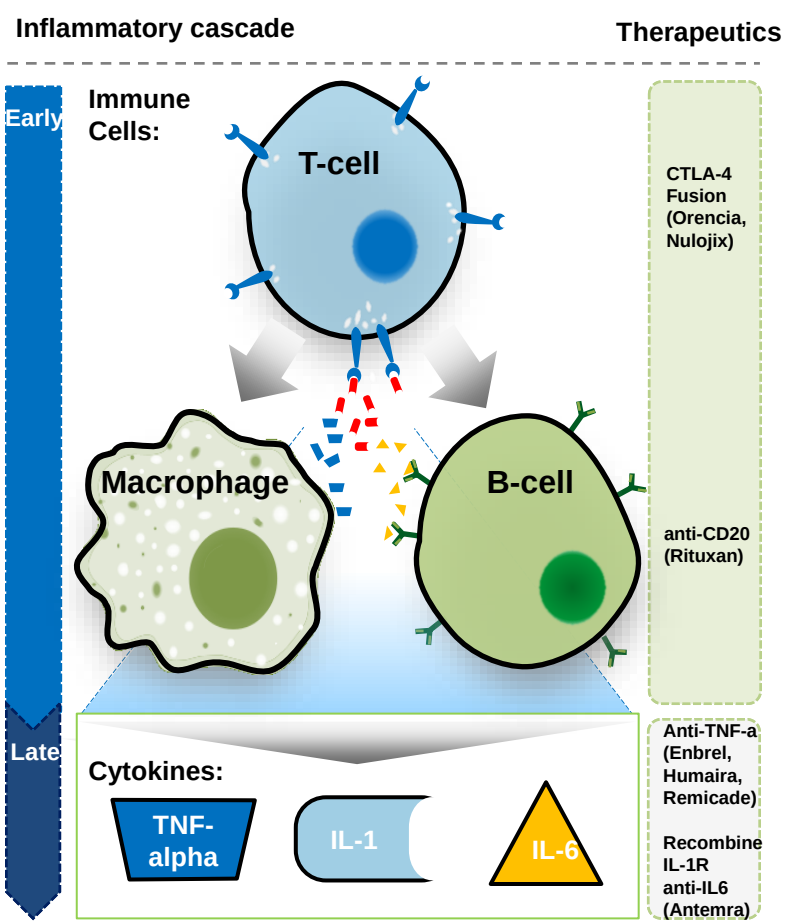
**A safe option for autoimmune diseases**

- Supplement to immunotherapies for AE management



# KN019: CTLA-4 Fusion Protein - Immunosuppressant Drug

## Mechanism of action




## Clinical development progress

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

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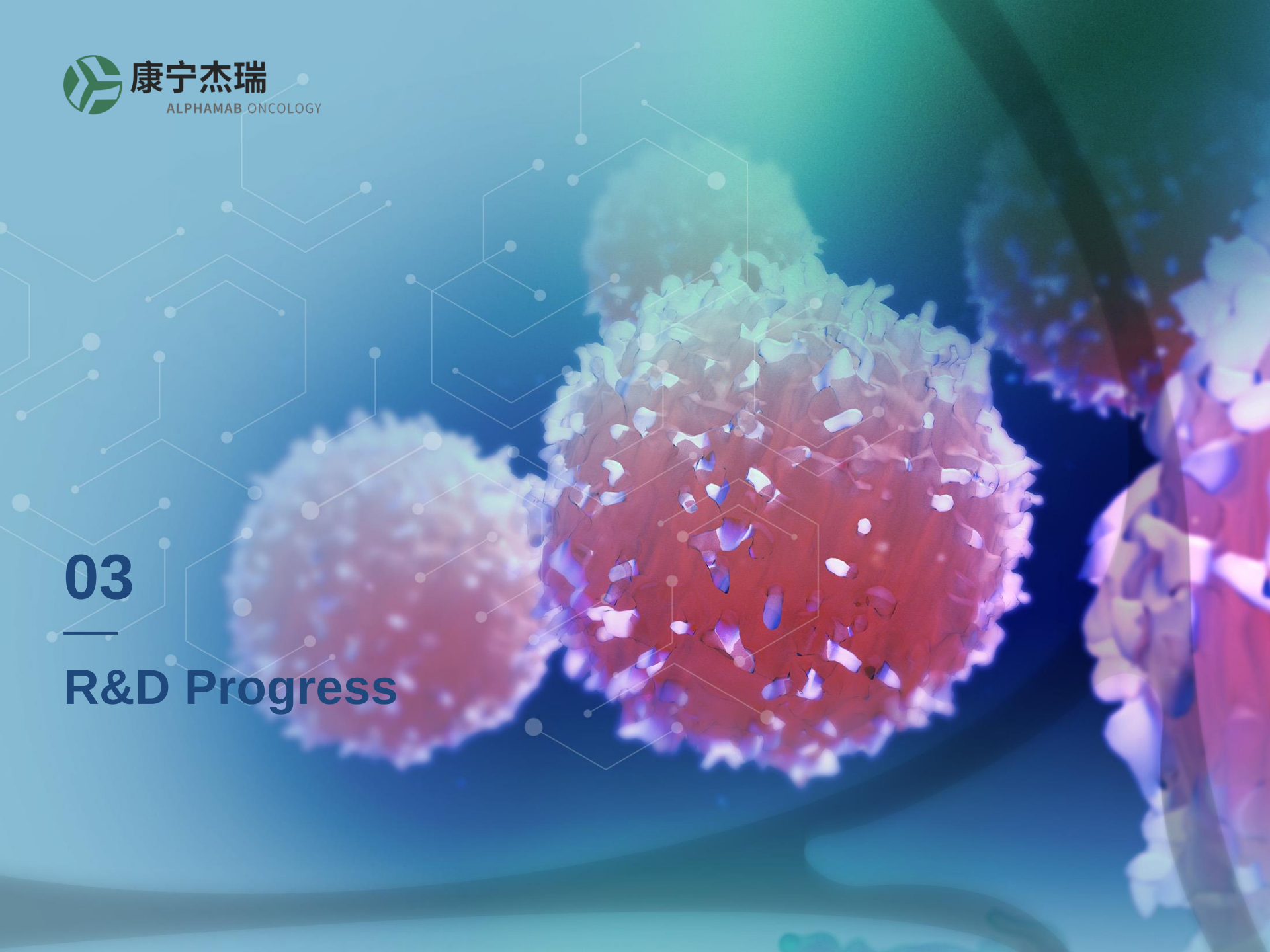


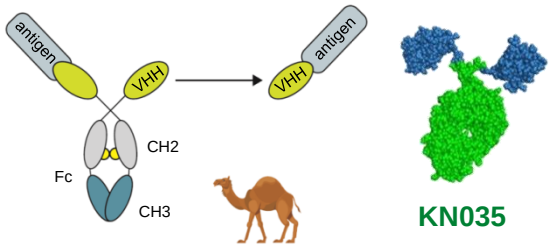
# 03

# R&D Progress

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

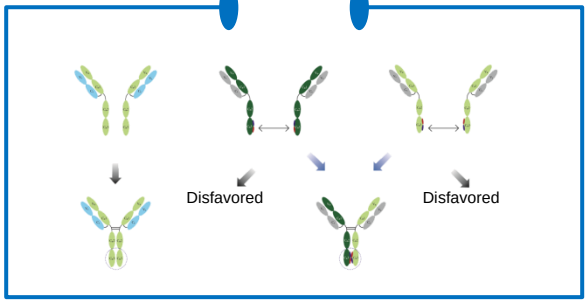
**sdAb**

- Smaller and more stable with a compact structure
- Ideal building blocks for multifunctional biologics
- Proof-of-concept: KN035[1], KN046[2], KN052



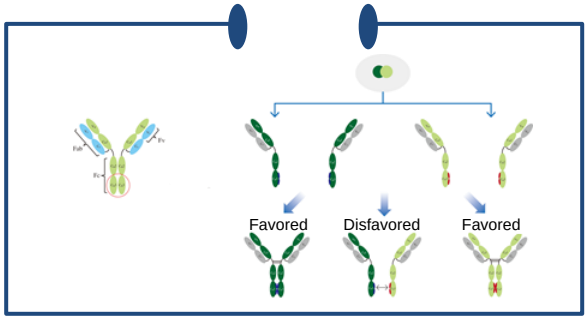

**CRIB**

- Maintain full-length antibody properties
- Optimized for commercial-scale manufacturing
- Proof-of-concept: KN026[3]



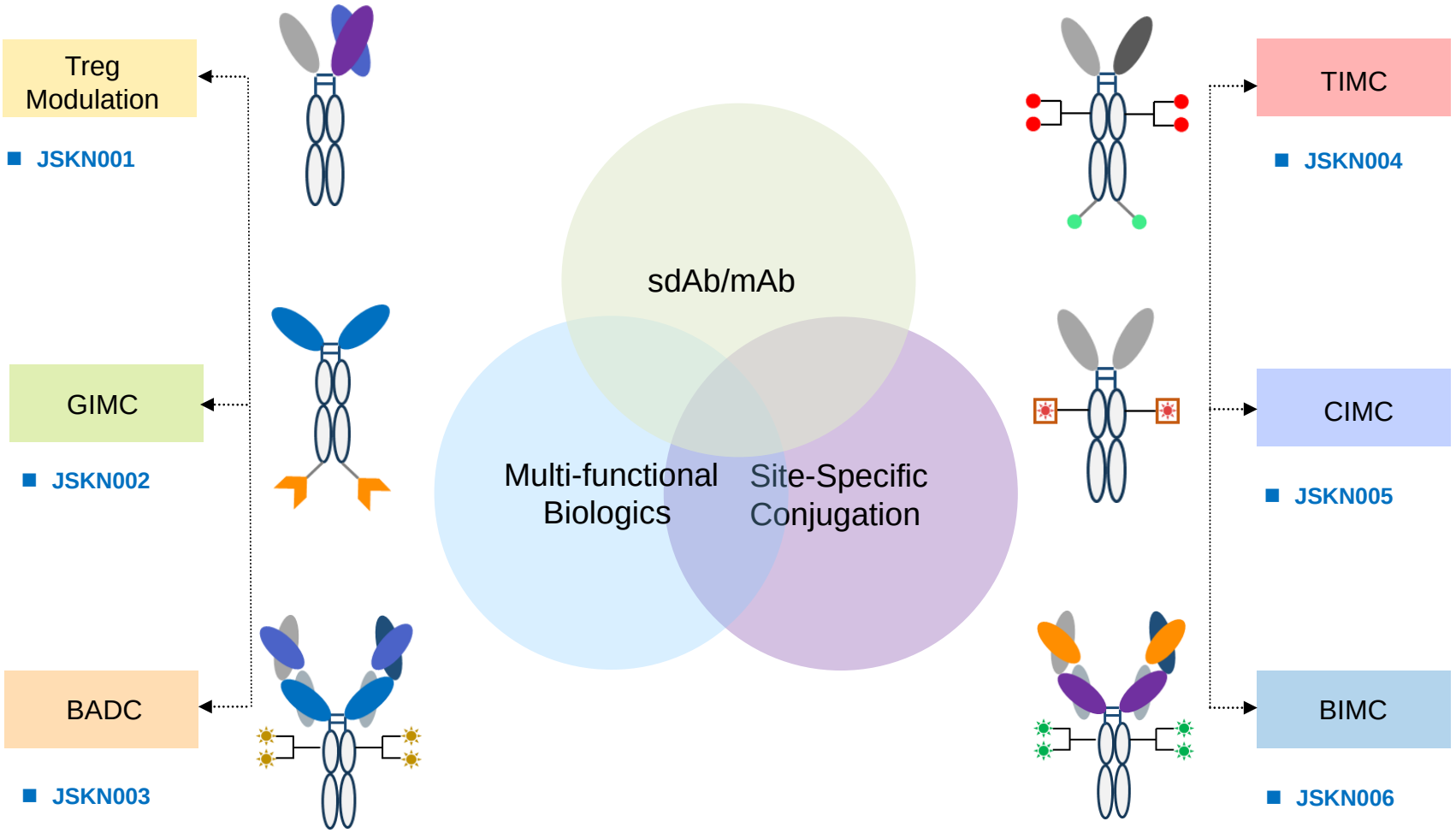

**CRAM**

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




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

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

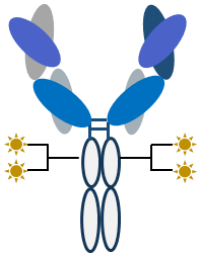


# Pre-IND product overview

## JSKN-003

**Anti-HER2 Paratopes Bispecific ADC**

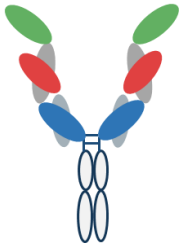
- Shows strong anti-tumor activity in CDX model
- Shows Superior Serum Stability



## KN052

**Anti-PD-L1/OX40 Bispecific Antibody**

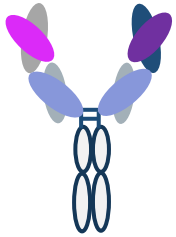
- Shows synergistic antitumor activity in MC38 tumor model



## KN062

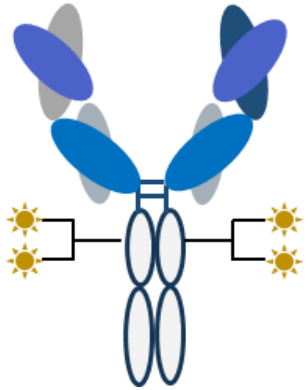
**Bispecific COVID-19 Neutralization Antibody**

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



# JSKN003: Anti-HER2 Paratopes Bispecific ADC

## Product Structure

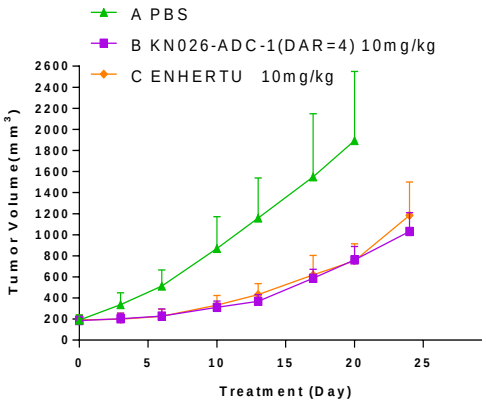


## Highlights

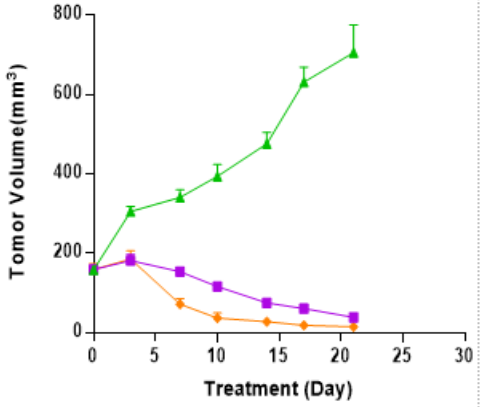
- Targeting two different paratopes of HER2 (KN026)
- Site specific conjugation, DAR 3-4
- Better serum stability for better safety potential
- Strong activity in HER2 high and low expression cells in CDX Model

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

BxPC-3 CDX Model (HER2 low)

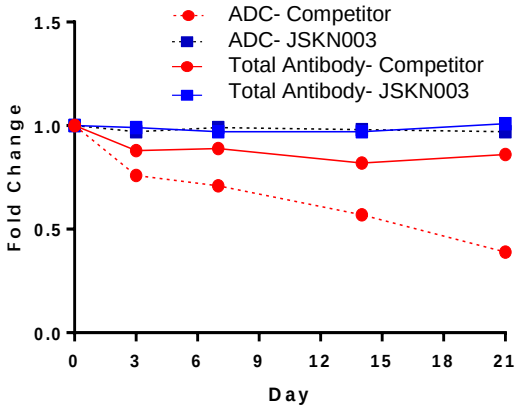



N87 CDX Model (HER2 high)



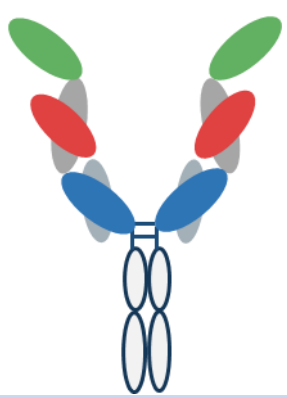

## Shows Superior Serum Stability

Human Serum



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

## Product Structure



Humanized VHH to PD-L1, Antagonist

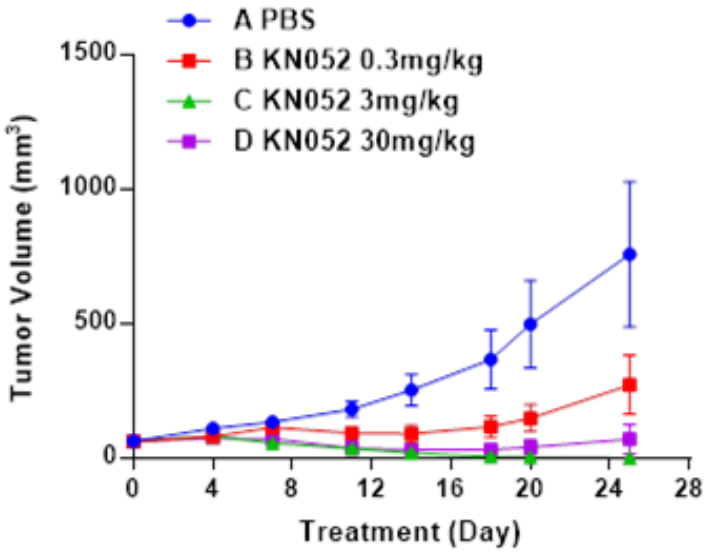
Human Fab to OX40, Agonist

Wildtype IgG1Fc

## Highlights

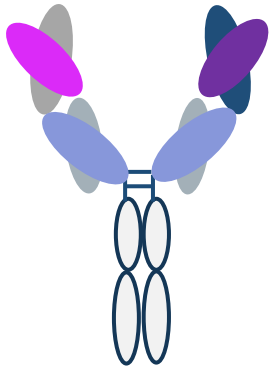
- PD-L1 antagonist and OX40 agonist activity in one molecule
- Tandem structure for antigen binding domain arrangement to attenuate anti-OX40 toxicity
- Wildtype IgG1 Fc with full Fc function

## KN052 shows synergistic antitumor activity in MC38 tumor model



# KN062: Bispecific COVID-19 Neutralization Antibody

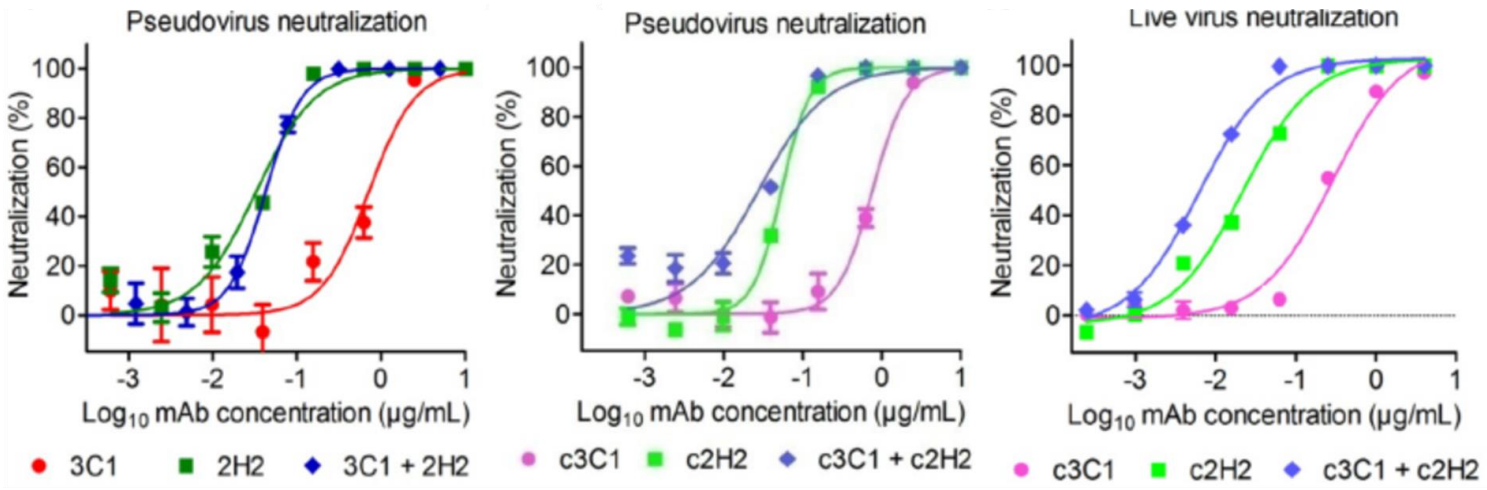
## Product Structure



## Highlights and Strategy

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

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



# Pre-clinical Pipeline overview

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

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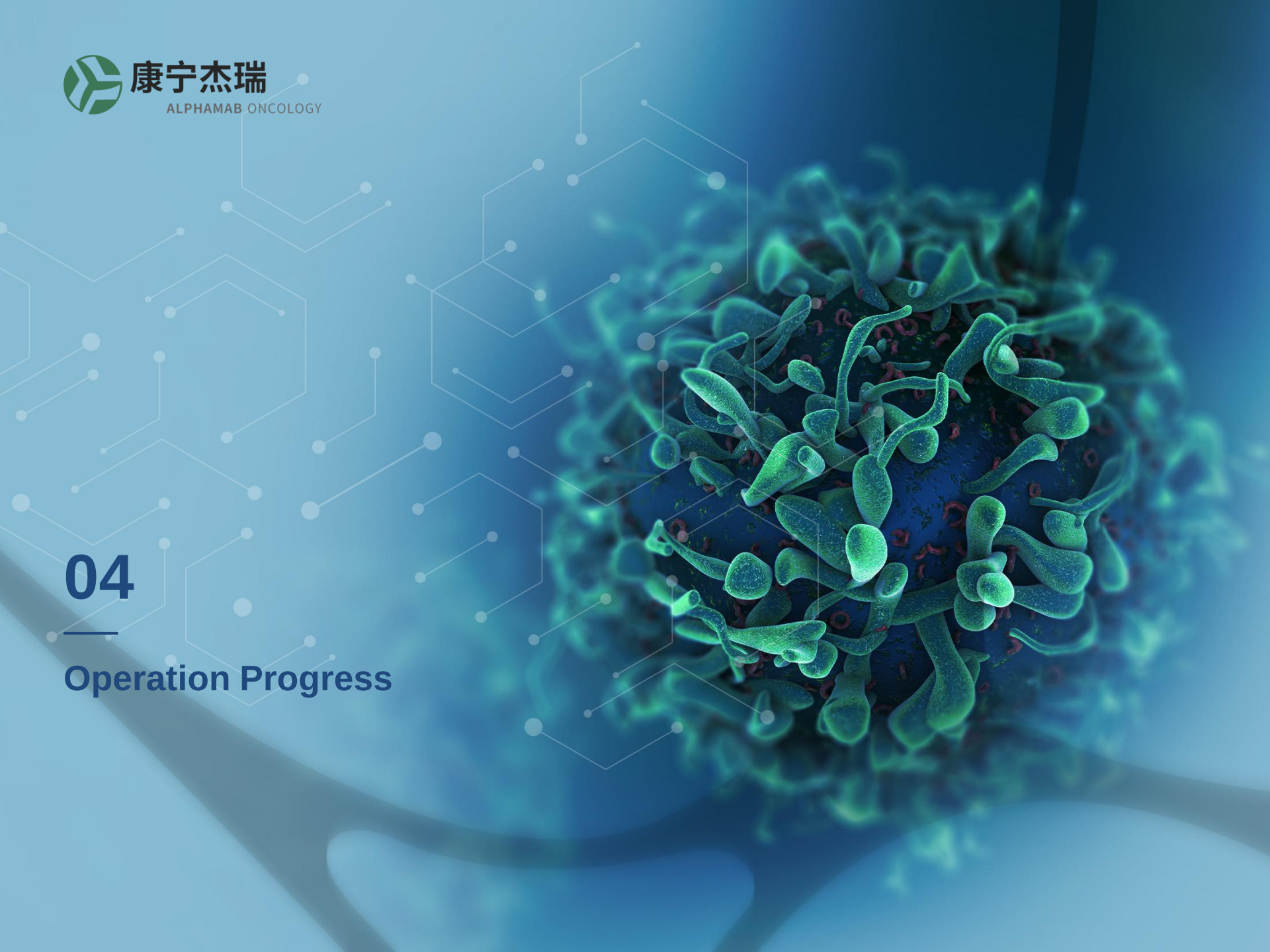

# 04

## Operation Progress

# Business Development: Comprehensive Combo Strategy

*..to unlock KN046 and KN026's full potential*

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

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

# Strong Manufacturing Capabilities

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

**Capacity planning**

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

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

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

**Total capacity**

**42,000L**

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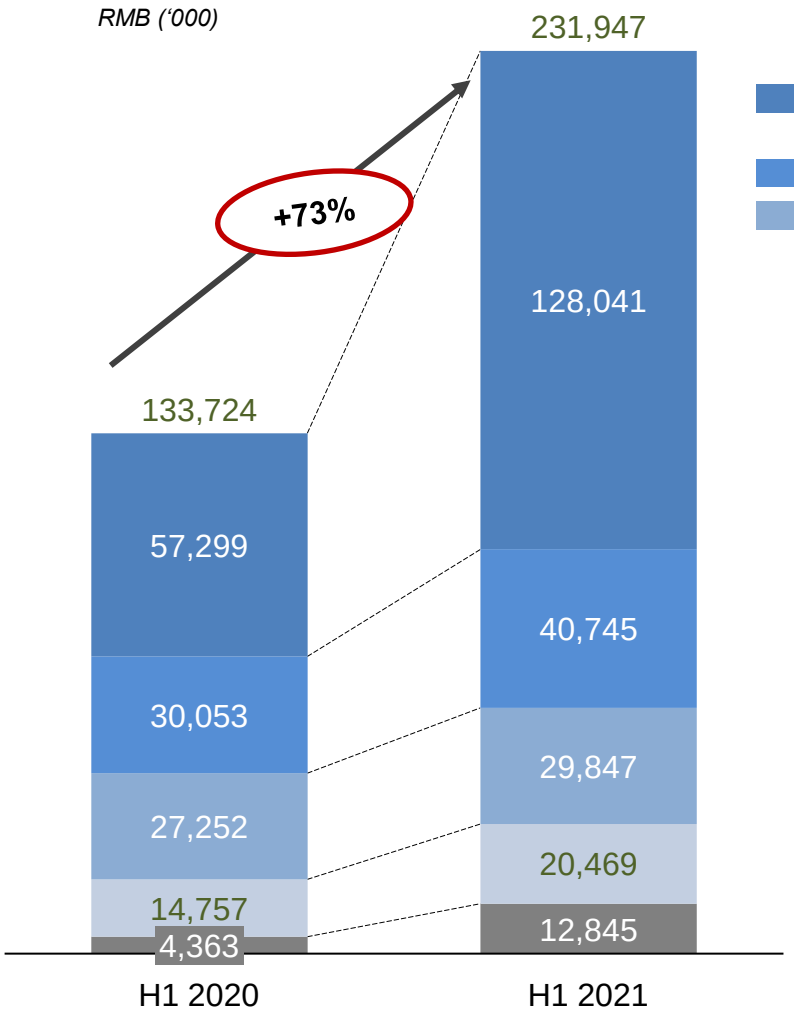
## Financial Highlight

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

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




Third-party contracting costs
Office rental costs, utilities, and depreciation and amortization
Staff costs
Others
Raw material costs

R&D expenses increased by RMB **98.2** million, compared to that in the first half of 2020, primarily due to:

- the increase in the number of ongoing clinical trials
- the expansion of the scale of our clinical studies
- the advancement of clinical trials of our drug candidates
- the increase in staff cost due to the increase in our R&D staff and the increase in the compensation mainly due to options rewarded to the staff

# Consolidated Statement of Comprehensive Income

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

# Balance Sheet

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

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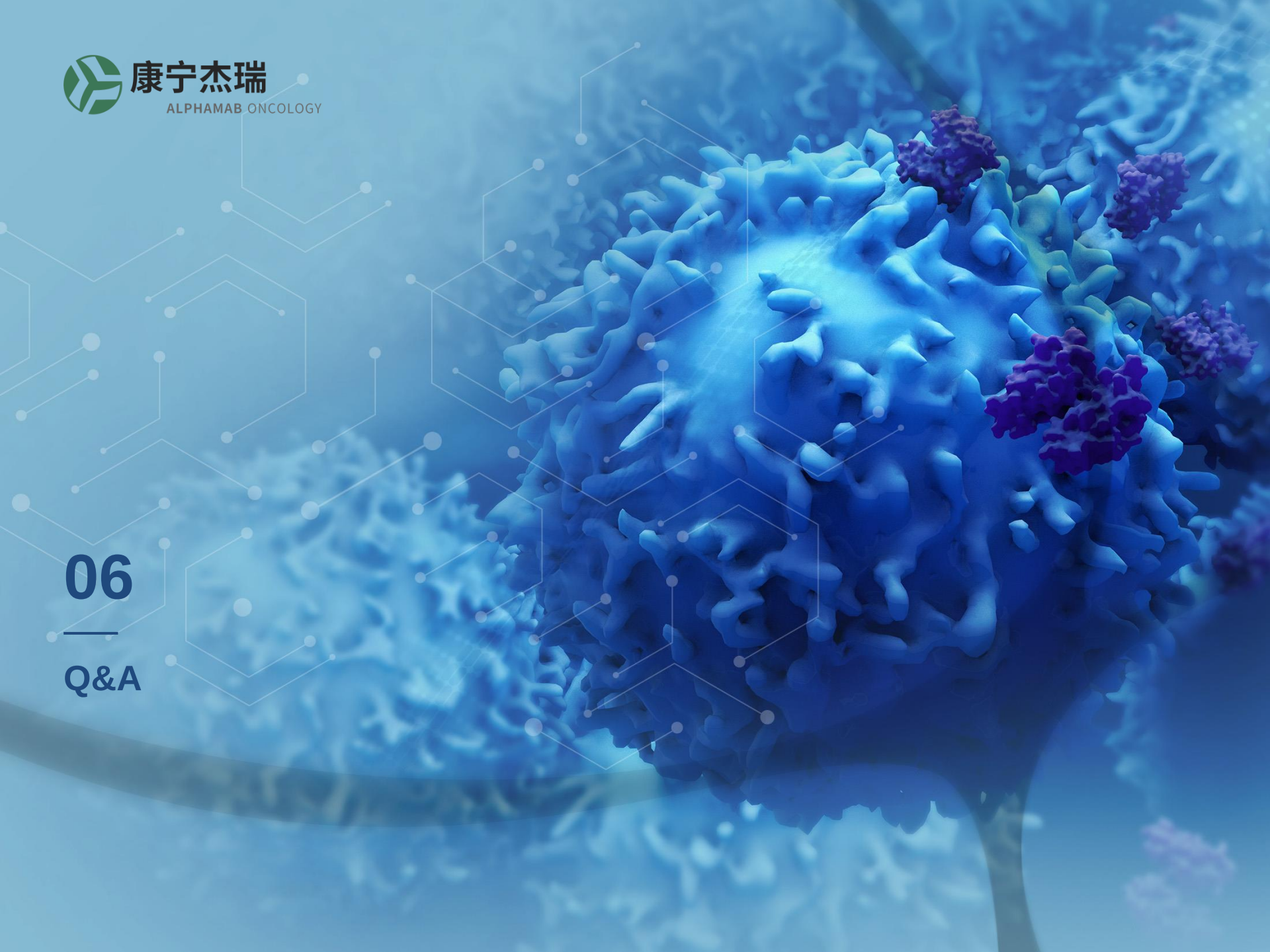

# 06

## Q&A