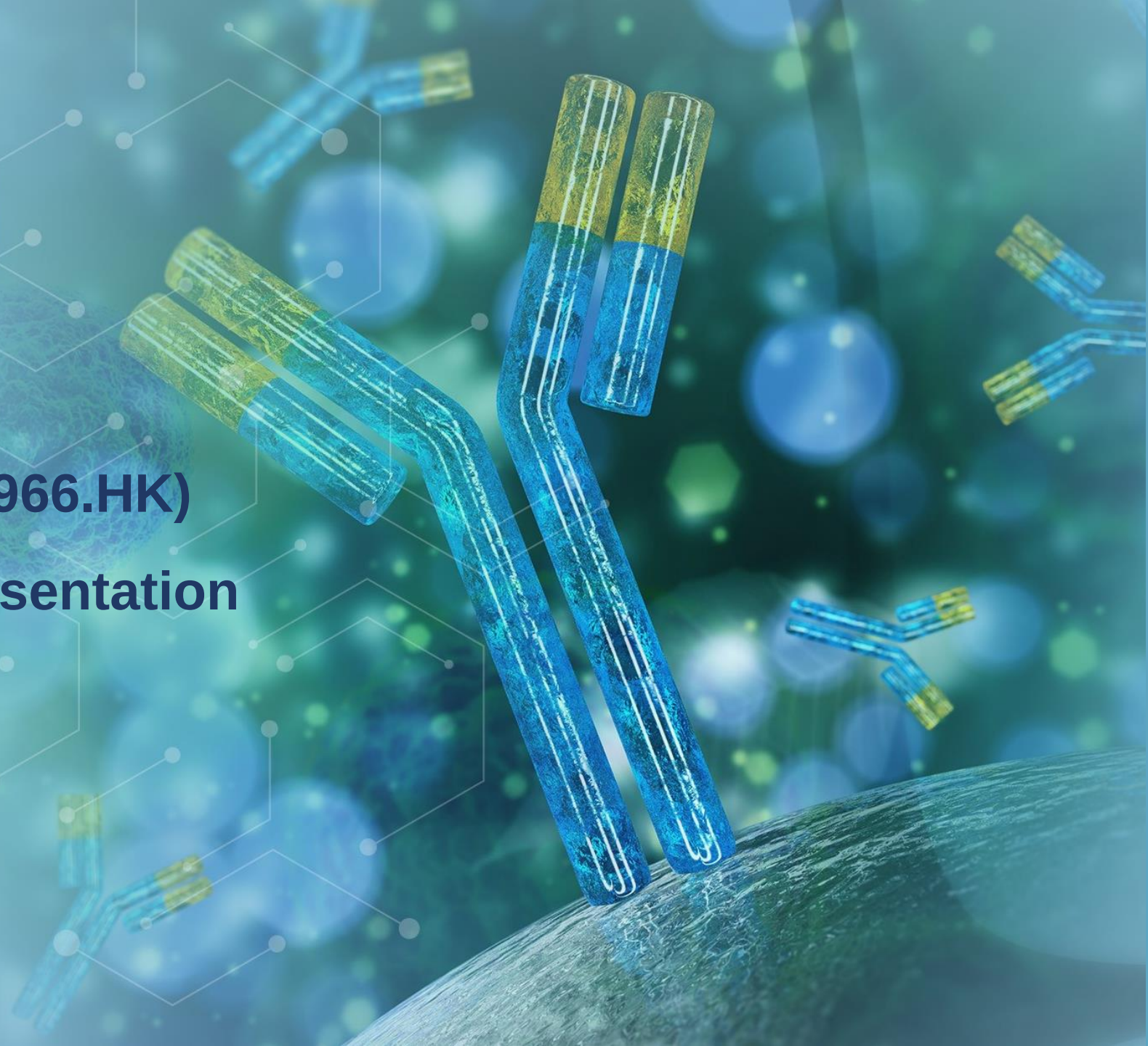
康宁杰瑞
ALPHAMAB ONCOLOGY

Alphamab Oncology(9966.HK)

2022 Annual Results Presentation

April 2023



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Agenda

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1. 2022 Company Overview and Latest Progress
2. Operation Progress
3. Financial Overview
4. Clinical Progress
5. R&D Strategy and Outlook for 2023
6. Q&A

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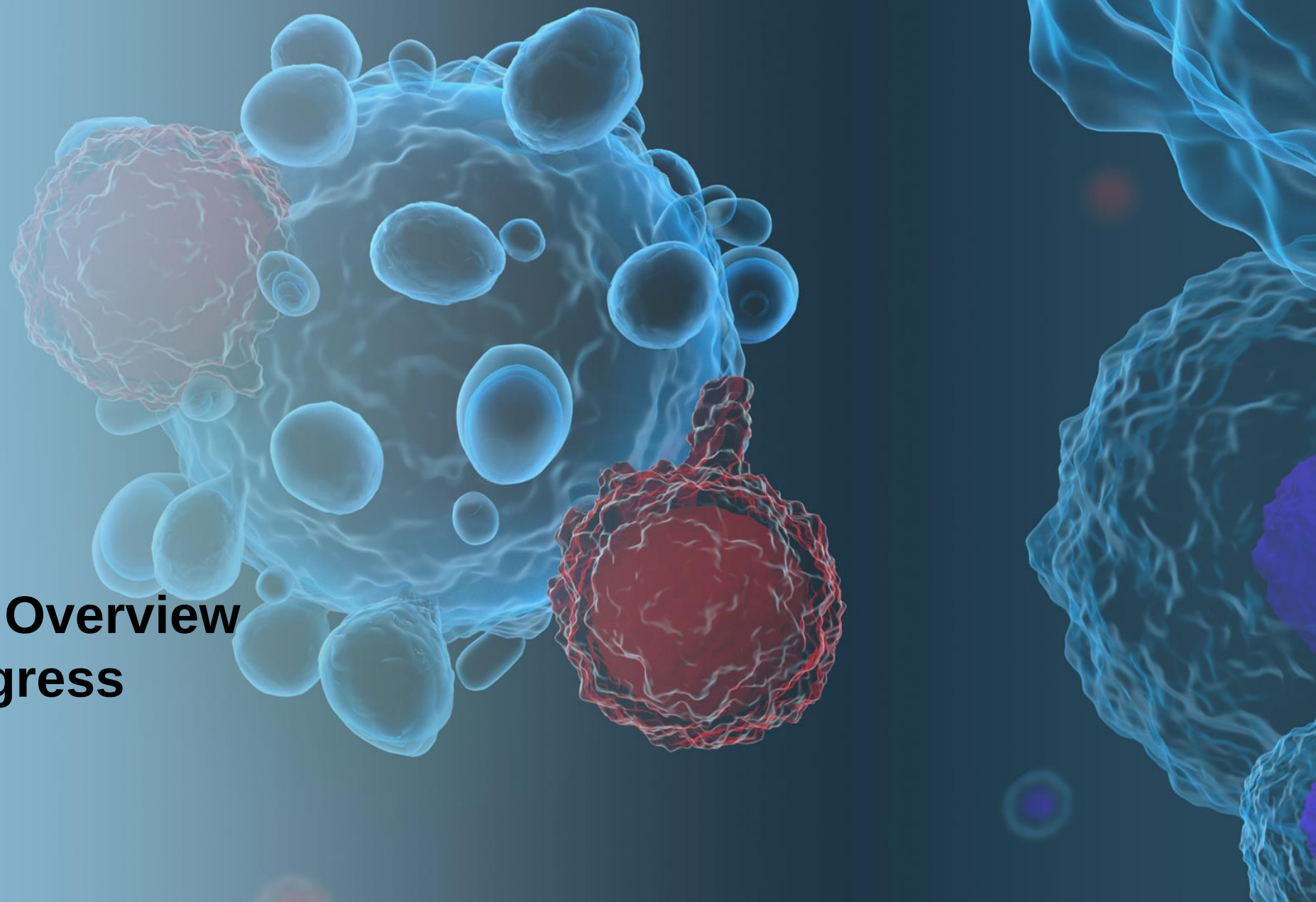

01

2022 Company Overview and Latest Progress

Major Progresses from January 2022 to March 2023

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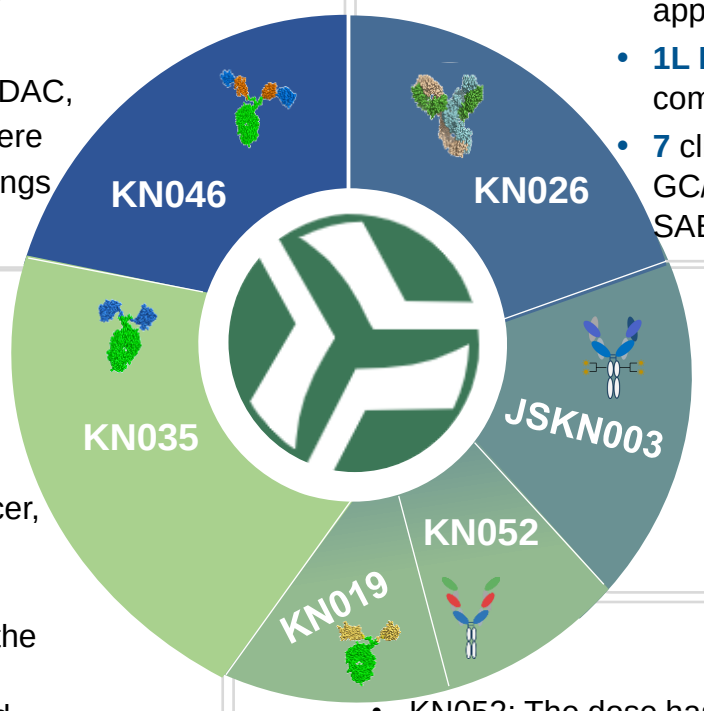
- **1L Sq NSCLC**：Completed the PFS interim analysis. During the follow-up period of OS
- **1L PDAC**：Completed the sample size enrollment as planned. During the follow-up period of OS
- **1L NSCLC**：Combined with **Axitinib.** Over 20 patients were enrolled in Phase II
- **8** clinical data/trial design in the treatment of PDAC, HCC, NSCLC,TNBC and Thymic carcinoma were presented at ASCO, ESMO and SABCS meetings respectively

- **≥2L GC/GEJ**：Combined with chemotherapy. Completed the open-label exploration stage and entered into the randomized and double-blind stage of phase III (CSPC)
- **1L GC/GEJ**：KN026+KN046. Submitted IND application of Phase III clinical trial
- **1L BC**：Initiated the pivotal superiority trial compared with Trastuzumab and Pertuzumab
- **7** clinical data in the treatment of breast cancer and GC/GEJ were presented at ASCO, AACR, ESMO, SABCS meetings and other journals



- **New specification of 300mg every 2 weeks**
- Terminal sales over **RMB600million** in 2022
- 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)
- **Sarcoma:** Completed the internal analysis of the global pivotal trial, and achieved the positive results. The fast-track designation was granted by the FDA
- Updated follow-up data in the treatment of ≥2L MSI-H/dMMR solid tumor was presented at 2022 CSCO Annual meeting

- Phase I clinical trial in Australia: The dose has increased to **5.2mg/kg** in the dose-escalation study
- Phase Ia/Ib clinical trial in China: First patient successfully dosed with **2.1mg/kg**
- Completed the PCT patent application

- KN052: The dose has been increased to the sixth dose of **4.0mg/kg**
- Entered into a strategic collaboration with Stemirna to explore combination therapy with personalized mRNA tumor vaccine in certain types of solid tumor
- KN019 completed the Phase II clinical trial(RA)

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Operation Progress

Manufacturing Capability

- **KN046:** Completed process verification, with a single batch output of more than 37,000 vials(300mg/vial).
- **KN026：** Completed process optimization, with the expected single batch output of nearly 29,000 vials(250mg/vial).
- **KN035：** Completed process amplification, technology transfer and process validation with the single batch output of 50,000 vials(200mg/vial).
- **JSKN003:** The plant will put in commissioning this year. The expected single batch output is 54,000vials(100mg/vial)
- The manufacturing capabilities currently is 12,000L. The total annual DP capacity is 5million vials.

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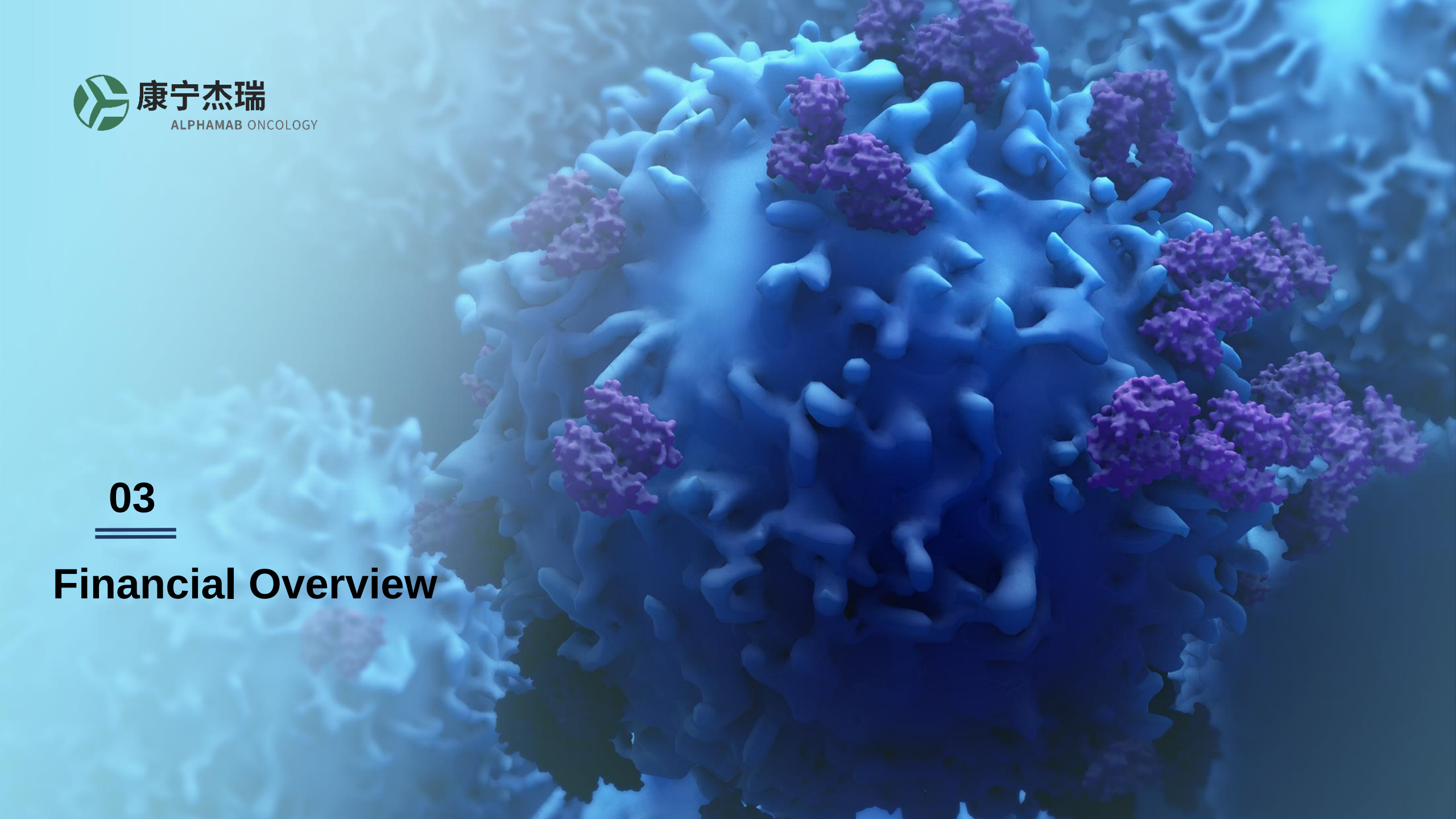

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Financial Overview

Overview of Key Financial Data

(RMB)

167 million
Total Income

148 million
ENWEIDA® Revenue
1171.1%

326 million[1]
Loss for the Period
21.0%

468 million
R&D Expenses
Flat year-on-year

87 million
Admin Expenses

1.66 billion[2]
Cash on Account

Note:1. Loss for the period includes RMB58 million of other income (RMB34 million of interest income and RMB24 million of government grants) and RMB63 million of other gains. 2. The data cut-off date is March 31, 2023, which includes bank borrowings

Consolidated Statement of Comprehensive Income

(RMB'000)	For the year ended December 31, 2022	
	2022	**2021**
Revenue	166,845	*146,021*
Cost of Sales	(44,207)	*(3,028)*
Gross profit	122,638	*142,993*
Other income	57,782	46,954
Other gains and losses	63,073	(30,570)
R&D expenses	(468,238)	(481,361)
Administrative expenses	(86,771)	(77,251)
Finance costs	(14,206)	(13,182)
Loss before taxation	(325,722)	(412,417)
Income taxation	-	-
Loss for the period	**(325,722)**	**(412,417)**

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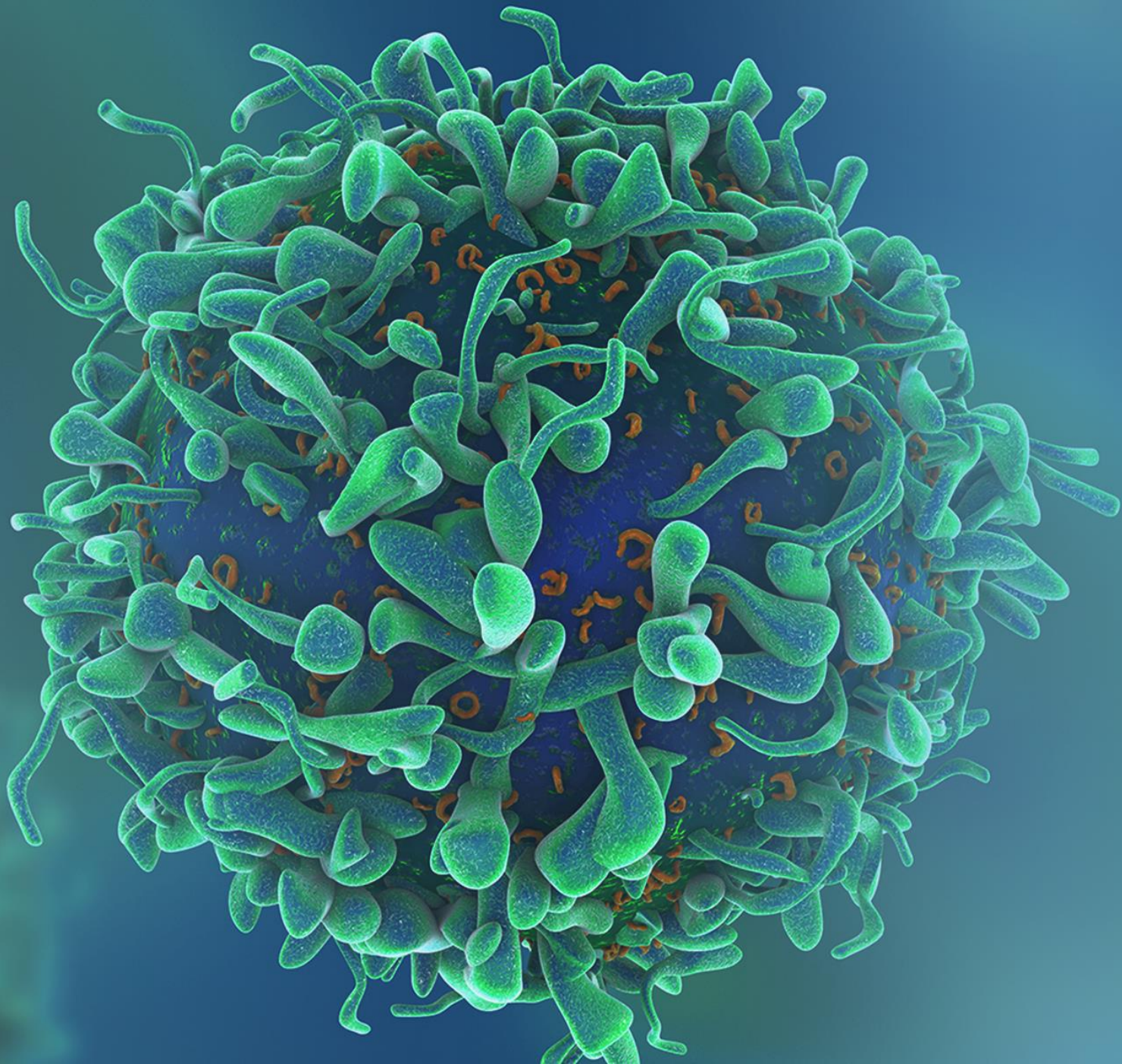

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Clinical Progress

Clinical Pipeline Overview

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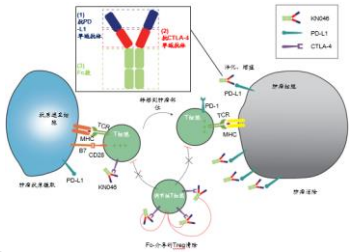
Stage	Drug candidates	Target(s)	Platform	Rights	Key Indications	Pre-clinical	Dose escalation	Proof of concept	Pivotal	NDA
Late-Stage	**KN046**	PD-L1/CTLA-4 bispecific	sdAb/mAb	Global	1L sq NSCLC, PD-(L)1Refractory NSCLC, Thymic carcinoma, PDAC, HCC, ESCC, TNBC				Pre-NDA	
	KN026	HER2/HER2 bispecific	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	Autoimmune					
Launched	**KN035**	subQ PD-L1	sdAb/mAb	Global Co-development	MSI-H, BTC, Sarcoma, TMB-H, MSS endometrial					launched
Early-Stage	**JSKN003**	HER2 ADC	BADC	Global	HER2 solid tumors					
	KN052	PD-L1/OX40 bispecific	CRIB	Global	Solid tumors					

KN046

Dual blockade of PD-L1 and CTLA-4

- More efficacy and safety
- Clinical Positioning
  - Big 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 mAb

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

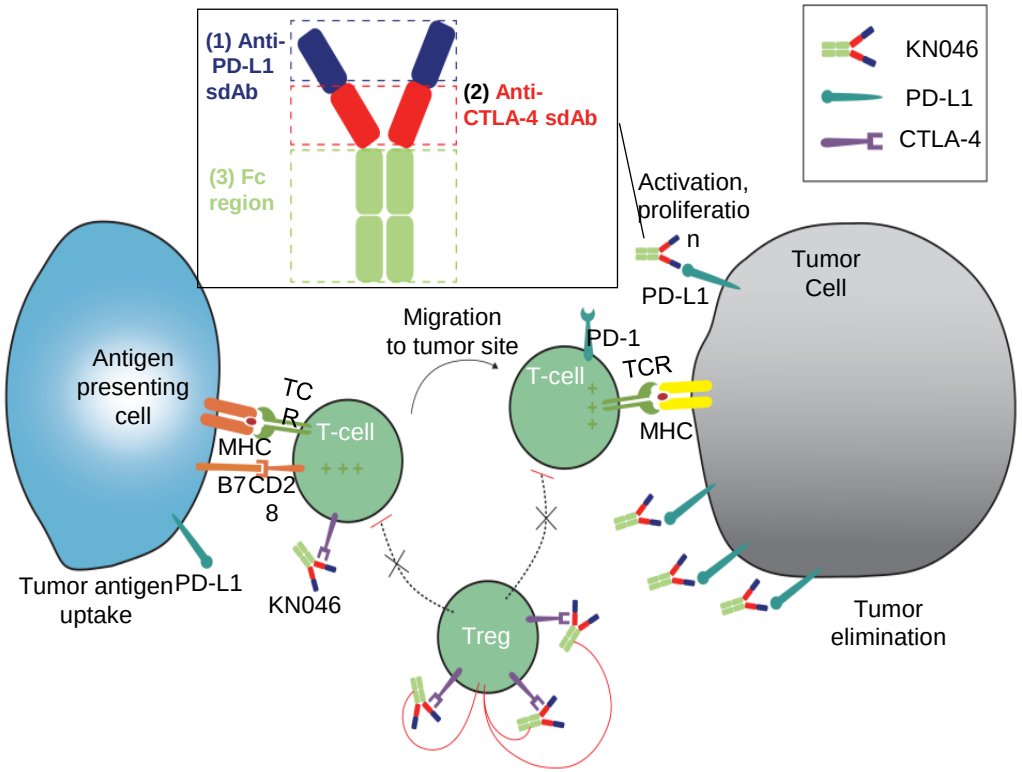
JSKN003& KN052

HER2 bispecific ADC and PD-L1/OX40 BsAb

- JSKN003
  - Glycosite-specific conjugation
  - Benchmark DS-8201
- KN052
  - The tandem structure of PD-L1 antagonist and OX40 agonist

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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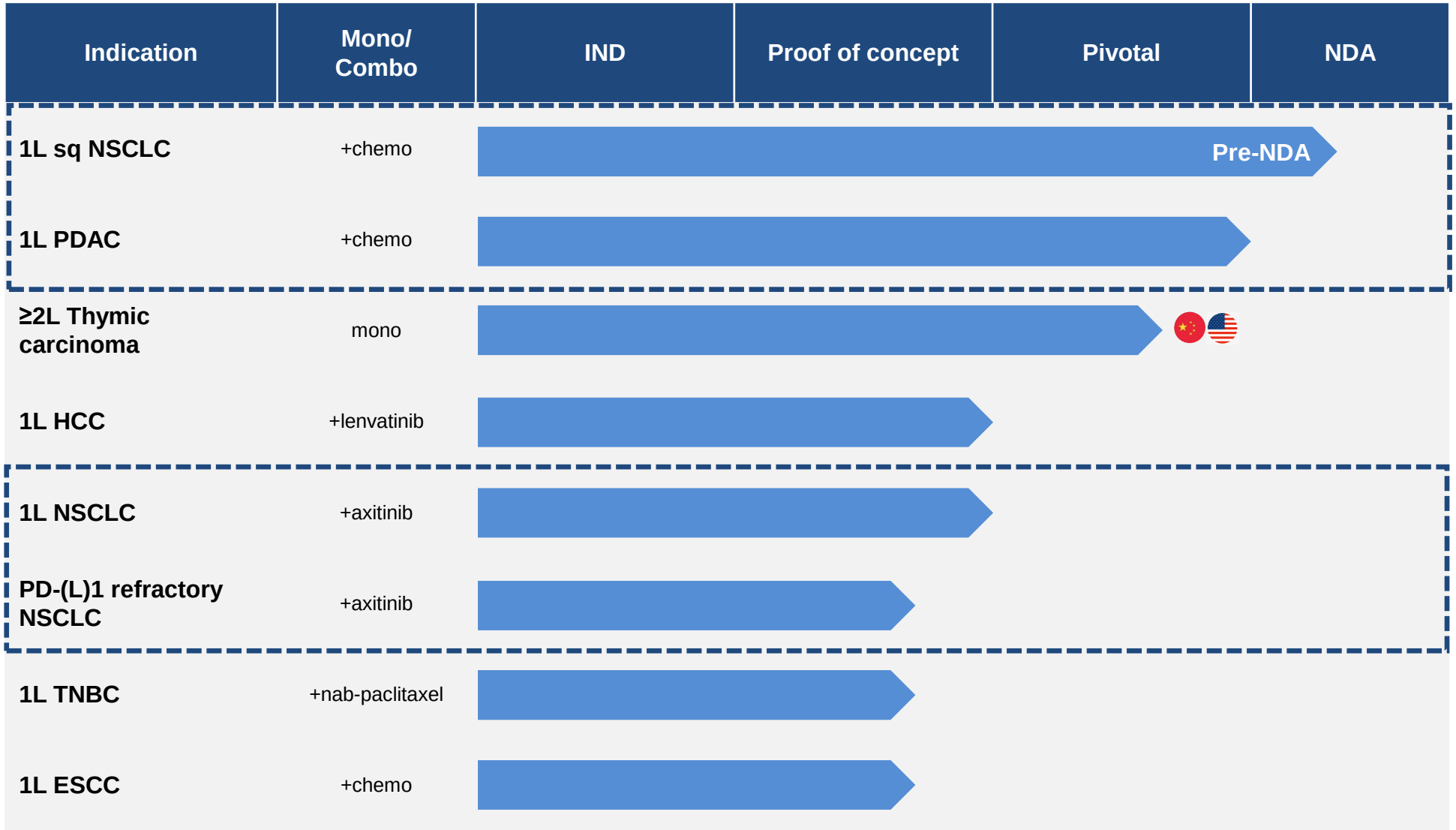

KN046: Preliminary Results in a Nutshell

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Indication / Efficacy & Safety	KN046(Over 1,200 patients have been enrolled in clinical studies)				
	sq-NSCLC 1L	PDAC 1L	HCC 1L	TNBC 1L	ESCC 1L
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)
Trial Status	Pre-NDA	Completed the enrollment of phase III clinical trial	Plan to start the pivotal trial	**--**	**--**

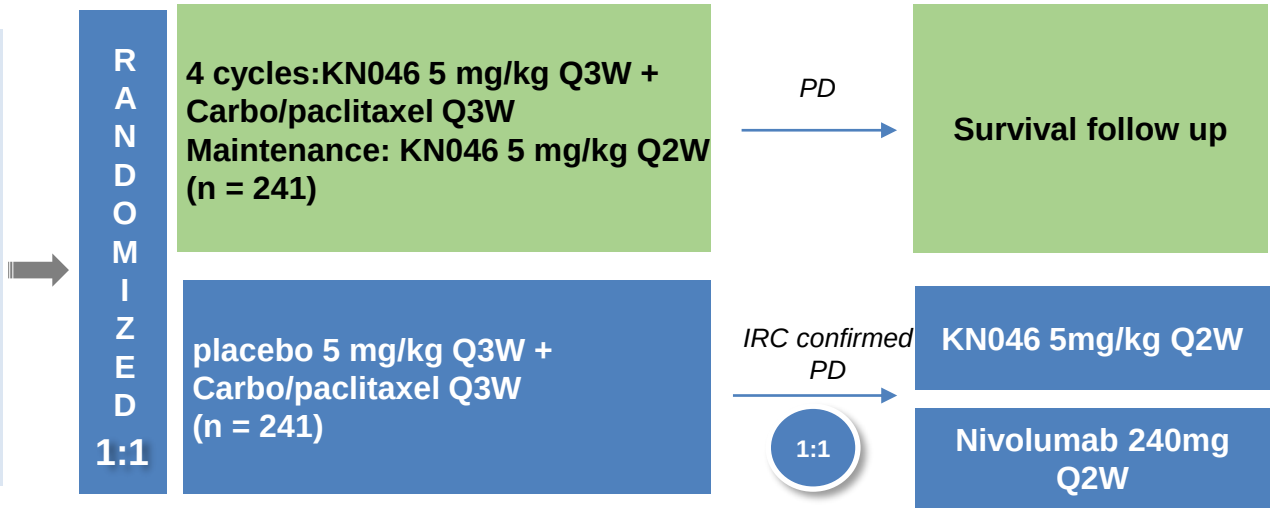
Pivotal Trial

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.

KN046-202 (Phase II) 1L NSCLC (2022 ESMO) -1/2

Subjects Baseline: **87** subjects with **stage IV** NSCLC and systemic treatment naïve enrolled in, among which **51** patients were non-sq NSCLC and **36** patients were sq NSCLC. As of the data cut-off date, March 15, 2022, median follow-up was 23.1 months

Efficacy: The overall ORR was **46%**, DCR was **82.8%**, mPFS was **5.8 months, and** mOS was **26.6 months**

Comparable Trials	KN046-202[1]		Checkmate-9LA		Keynote- 407	GEMSTONE-302		CameL	
Drug	KN046+chemo		Nivo+Ipi+chemo		Pembro+chemo	Sugemalimab+chemo		Camrelizumab+chemo	
Line	1L		1L		1L	1L		1L	
Type	Sq	Non-sq	sq	Non-sq	sq	sq	Non-sq	sq	Non-sq
n	36	51	115	246	278	129	191	193	205
ORR	50%	43.1%	37.7%		62.6%	70.5%	58.6%	64.8%	60.5%
mPFS (months)	5.7	5.8	6.7		8.8	8.3	9.6	8.5	11.3
mOS (months)	**26.6**	**27.2**	14.5	17.0	17.1	23.3	26.9	27.4	27.9
24-month OS rate	**50.2%**	**52.5%**	38%		37.5%	51.7%		53.4%	immature

Safety: Have a good safety data. The incidence rate of TRAEs at grade ≥3 levels was 34.5% , among which, the most common TRAE is diarrhea(6.9%), ALT increase(4.6%), rash(4.6%), infusion related reaction(3.4%), etc.

Note: This trial is ongoing，and the data is as of March 15, 2022.

KN046-202 (Phase II) 1L NSCLC (2022 ESMO) -2/2

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Baseline comparable	Alphamab KN046-202	Cstone GEMSTONE-302	Hengrui CameL-sq	Hengrui CameL-nsq
Median age (years)	61	62	64	59
ECOG 0 1	 17.2% 82.8%	 18.4% 81.6%	 20% 80%	 23% 77%
Clinical Stage -Stage III -Stage IV	 **0%** **100%**	 0% 100%	 **28%** **72%**	 **15%** **85%**
PD-L1 expression ＜1% ≥1% (≥50%)	 **42.5%** **52.9%** **(17.2%)** (2)	 **38.8%** **61.2%** **(32.5%)**	 **47.2%** **49.2%** **(19.2%)** (2)	 **23.9%** **67.3%** **(14.6%)** (2)
Grading 3&2- grade 3 (high degree of malignancy)	55.2%	NA	NA	NA
Metastasis ratio ≥2 places	100% 59.8%	NA	NA	NA
Metastasis classification -Liver -Brain	 **12.6%** **17.2%**	 12.2% 15.6% (1)	 **11%** **2%** (1)	 **0%** **5%** (1)

Note: 1. Stable brain metastases；Key exclusion criteria included patients with active or symptomatic central nervous system metastases.

2. The percentage of ＜1% and ≥1% do not equal to100% due to the evaluation of PD-L1 expression is lost in some patients

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

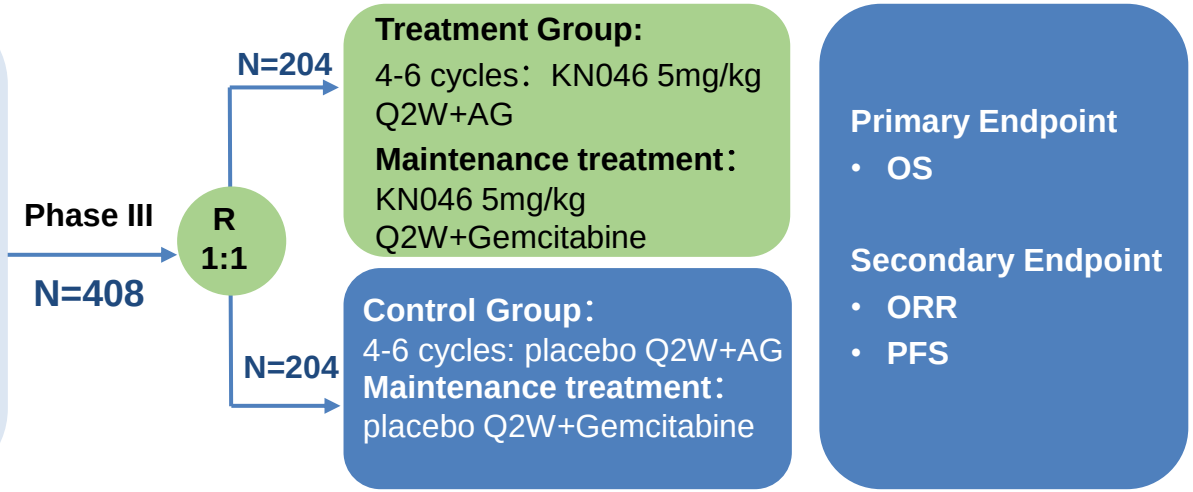
KN046-IST-04 Efficacy(Phase II): 53 patients were evaluable for efficacy.ORR was **47.9%**[1], mPFS was **6 months,** mOS was nearly **12 months**[2].

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 Q3 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

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KN046-209 without chemotherapy: Inclusion criteria overview

- ✓ **NSCLC patients in stage IIIB-IV**
- ✓ **PD-(L)1+（TPS≥1%）(cohort A)**
- ✓ **No EGFR activation-sensitive mutations or ALK rearrangements (non-sq), No known EGFR activation-sensitive mutations or ALK rearrangements (sq)**
- ✓ **measurable lesions at baseline**
- ✓ **ECOG score is 0-1**

- **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 →

Cohort B: over 2/15 patients remission

- **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 have progressed after first- or second-line treatment with immune checkpoint inhibitors such as PD-1/L1 (if immune checkpoint inhibitors such as PD-1/L1 are not used in first-line treatment)

KN046-203(Phase II) 1L TNBC (2022 SABCS)

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Subjects Baseline： 27 patients with treatment-naïve locally advanced inoperable TNBC were enrolled. The median age was 50 years old. **88.9%** of patients were at stage IV. **67%** of patients with PD-L1 expression ＜1% or UNK.

Efficacy: ORR was **44.0%**, DCR was **96.0%**, mPFS was **7.33个月**, DOR was **13.34 months**, mOS was **30.92 months**(not mature), and 3-years OS rate was **44.5%** . Among PD-L1≥1% patients, mPFS was **8.61 months**

Comparable Trials	KN046-203	Impassion-130	Keynote-355	FUTURE-C-Plus
Drug	KN046+nab-paclitaxel[1]	Atezolizumab+ nab-paclitaxel[2]	Pembro+chemo	Camrelizumab+Falmitinib malate+nab-paclitaxel[3]
Line	1L	1L	1L (only patients with CPS≥10% have statistical significant)	1L(all patients were CD8 positive(CD8≥10%))
n	27	451	566	48
ORR	**44.0%**	56.0%	41.0%	81.3%
mPFS (months)	**7.33**	7.2	7.5	13.6
mOS (months)	**30.92 (Immature)**	21.0 (PD-L1≥1%: 25.4 months)	17.2 (CPS≥1: 17.6 months CPS≥10: 23.0 months)	Immature
OS rate	**36-months: 44.5%**	24-months: 42%	24-months: 35.3%	18-months: 54.4%

Safety: Have a good safety data. The incidence rate of TRAE at grade ≥3 levels was 66.7%. The incidence rate of irAE at grade ≥3 levels was 11.1%. The most commonly TRAEs at grade ≥3 levels include neutrophil count decreased (33.3%), white blood cell count decreased (29.6%), GGT aminotransferase increased(14.8%),etc.

Note: #1.This trial is ongoing and the date of cut-off day is 15 November, 2022. #2. Adverse events at grade 3 or 4 was 56.7%. The incidence rate of TRAE at grade 3 or 4 was 28%. The most commonly AEs include stomatitis, hair loss and nausea. #3. 35.4% of patients were PD-L1 positive. The incidence rate of AE at grade 3 or 4 was 50%. 6.3% of patients suffered drug discontinuation due to the AE at grade 3 or 4.

KN046-IST-05(Phase II) 1L HCC (2022 ASCO)-1/2

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

Efficacy: 55 patients with unresectable or metastatic advanced Barcelona Clinic Liver Cancer (BCLC) stage B or C were enrolled，among which 52 patients were evaluable for efficacy analysis according to RECIST v1.1:ORR was **45.5%**; DCR was **89.1%** ; mPFS was **11** months; **mOS and DOR were immature**.

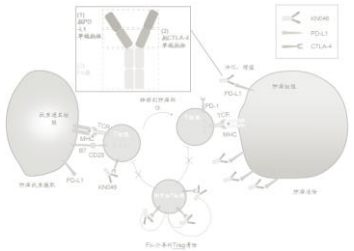
Comparable Trials	KN046-IST-05 [1]	LEAP-002	Imbrave 150	Orient-32	SHR-1210-III-310
Drug	KN046+Lenvatinib	pembrolizumab+ Lenvatinib	Atezolizumab+Bevacizumab	Sinti+ Bevacizumab	Camrelizumab+Apatinib
n	55	794 (Asian:40.8%)	501	571	543
ORR	**45.5%**	26.1% (28.1%)	29.8%	20.5%	25.4%
DCR	**89.1%**	81.3% (86.3%)	74%	72%	78.3%
mPFS (months)	**11[1]**	8.2 (8.3)	6.9 （Chinese subgroup: 5.7）	4.6	5.6
mOS	**Immature**	21.2(26.3)	19.2 （Chinese subgroup: 24.0）	Immature	22.1

Note: 1. KN046-IST-05 trial is ongoing, and the data cut-off date is February 2023
2. All above data was related to 1L HCC. Evaluation criteria is RECIST v1.1

KN046

Dual blockade of PD-L1 and CTLA-4

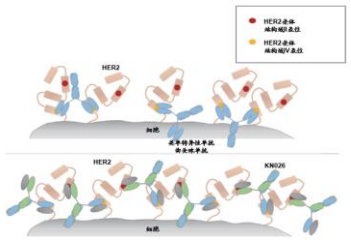
- More efficacy and safety
- Clinical Positioning
  - Big Indications
  - PD-(L)1 refractory
  - PD-(L)1 Inadequate response



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 mAb

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

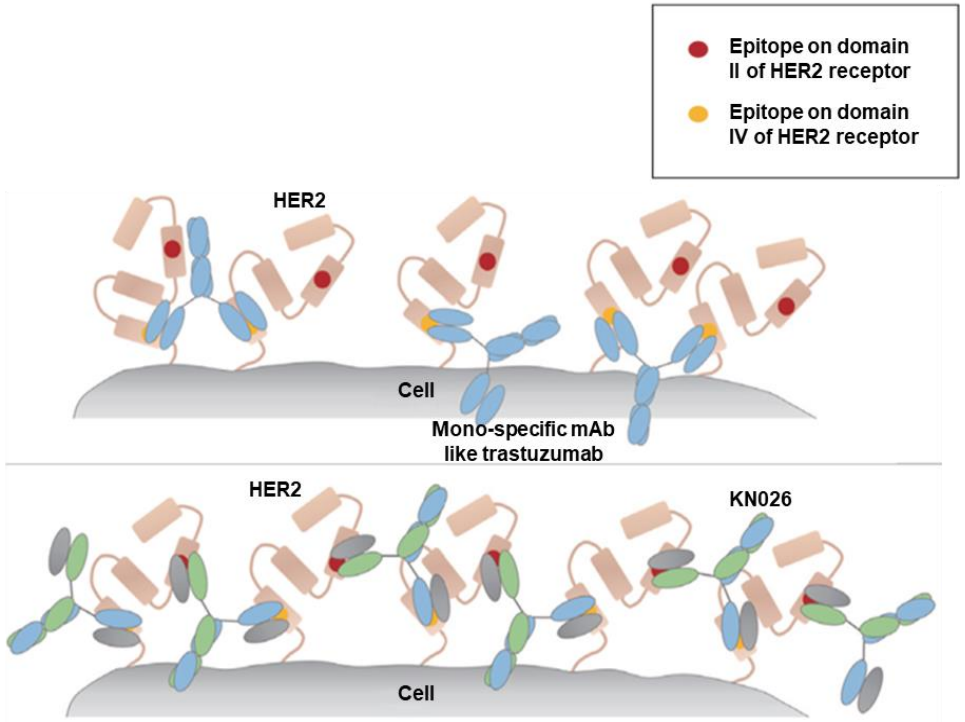
JSKN003& KN052

HER2 bispecific ADC and PD-L1/OX40 BsAb

- JSKN003
  - Glycosite-specific conjugation
  - Benchmark DS-8201
- KN052
  - The tandem structure of PD-L1 antagonist and OX40 agonist

KN026: HER2/HER2 BsAb

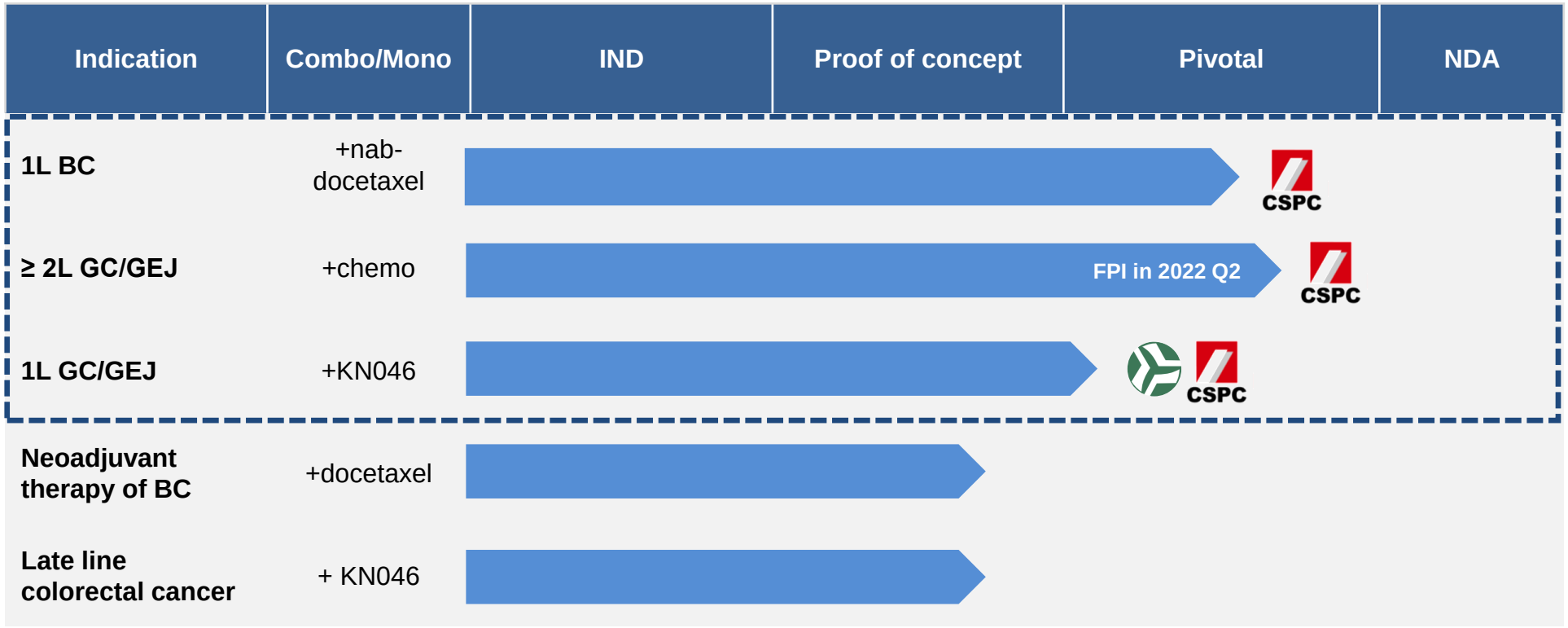
Mechanism of action



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

Indication / Efficacy & Safety	KN026 (Over 300 patients have been enrolled in clinical studies)				
	HER2+ BC 1L	**HER2+ BC NAT**	**HER2+ GC 1L**	**HER2+ GC ≥2L**	**HER2+ CRC ≥3L**
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**	--
ORR	76.4%	**60.7%（tpCR)**	**71.8%**	**56.0%**	**45.5%**
DCR	100%	100%	92.6%	76.0%	90.9%
≥Grade3 AE	TEAE: 38.6% (related to KN026)	TEAE: 53.3%	TRAE: 16.1%	TRAE: 11.1%	7.7% increase in bilirubin 7.7% increase in AST
Trial Status	Initiate phase III clinical trial in 2023Q2	Preparation for pivotal trial IND application	Submitted the IND application of pivotal trial	Completed the exploration stage of KN026+Chemo and started the randomized and double-blind stage	--

Pivotal Trial

KN026-201(Phase I) 1L HER2+BC (2022 SABCS)

Subjects: 57 patients with HER2+ recurrent or metastatic BC were enrolled. The median age was 52 years old. **91.2%** of patients were at stage **IV,** and a total of 45.5% of patients were treated with trastuzumab or taxanes in the early stage.

Efficacy: The confirmed ORR was **76.4%**, DOR was **24.0 months** and mPFS was **25.4 months (immature)**

Comparable trials	KN026-201	PHILA	PUFFIN(China)	CLEOPATRA
Drug	KN026+docetaxel[1]	Pyrotinib+Trastuzumab+nab-paclitaxel[2]	Trastuzumab+Pertuzumab +docetaxel[3]	Trastuzumab+Pertuzumab +docetaxel[4]
Line	1L	1L	1L	1L(8.4% of patients were IHC1+/ IHC2+)
n	57	297	122	402
ORR	**76.4%**	82.8%	79.0%	80.2%
DCR	**100%**	93.2%	94.2%	94.7%
mPFS(months)	**25.4(immature)**	24.3	16.5	18.5
24-months OS rate	**91.2%**	-	79.5%	80%

Safety: Have good safety. The incidence rate of TRAE at grade ≥3 levels and SAE was 38.6% and 8.8%, respectively. The most commonly SAEs include febrile neutropenia(5.3%), white blood cell count decreased(3.5%), etc. The incidence rate of diarrhea was only 1.8%, and only one patient(1.8%) incurred arrhythmia

Note: 1. This trial is ongoing and the cut-off date is 18 August, 2022. 2. The incidence of AE at grade ≥3 were 89.9%, including diarrhea(46.5%). 3. The incidence of AE at grade ≥3 were 74%. 4. In HPT and HT groups, the incidence of diarrhea at grade ≥3 were 7.9% and 5.0%, respectively, the incidence of neutropenia at grade ≥3 were 48.9% and 45.8%, 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%.

KN026-208(Phase II) Neo-adjuvant HER2+BC (2022 SABCS)

Subjects: 30 patients with treatment-naïve HER2+ early or locally advanced BC were enrolled. **86.7%** of patients with lymph node metastases, **53.5%** of patients were at stage II and **46.7%** of patients were at stage III. HR+, ER+ and PR+ patients accounted for 50.0%, 50.0% and 43.3%, respectively.

Efficacy: Updated data, 28 patients completed the surgery and pathological evaluation updated. The tpCR was **60.7%**. The bpCR was **64.3%**. The ORR was **96.4%** and CR was **21.4%**[1]

Comparable trials	KN026-208	PHEDRA	PEONY(Asia Pacific)	NEOSPHERE
Drugs	KN026+docetaxel	Pyrotinib+Trastuzumab+ docetaxel[2]	Trastuzumab+Pertuzumab +docetaxel[3]	Trastuzumab+Pertuzumab+ docetaxel[4]
Line	Neo-adjuvant	Neo-adjuvant	Neo-adjuvant	Neo-adjuvant
n	30	178(Lymph node metastases: 70%)	219	107
ORR	**96.4%**	91.6%	88.6%	-
pCR	bpCR：**64.3%** tpCR：**60.7%** (1)	bpCR：43.8% tpCR：41.0%	tpCR：39.3%	bpCR：45.8% tpCR：39.3%
The incidence of diarrhea, ≥ grade 3	**3.3%**	40%	40.8% (Any level)	8.9%

Safety: Demonstrated to have a good safety profile. The incidence rate of TEAE at grade ≥3 levels was 53.3%, including neutropenia (50.0%), white blood cell count decreased (40.0%), and lymphocyte count decreased (10.0%). **The incidence rate of diarrhea at grade ≥3 levels was only 3.3% and no patient experienced cardiac toxicity.**

Note: 1. This trial is ongoing and the cut-off date is November 21, 2022, EAS data collection. 2. The incidence of grade ≥ grade 3 adverse events was 71%, and the adverse reactions of the combination of pyrotinib regimen were mainly diarrhea, which ≥ grade 3 diarrhea occurred in 40% . 3. The incidence of grade ≥ 3 adverse events was 70.6%. 4. 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%

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

≥2L HER2+GC	KN026		DS-8201		Trastuzumab+Ramucirumab+Paclitaxel	KN026
Level of HER2 expressing	HER2 high expressing		HER2 high expressing		HER2 high expressing	HER2 low expressing
Comparable Trials	KN026-202 [1]		DESTINY-Gastric01 [2]	DESTINY-Gastric02[3]	HER-RAM	KN026-202[1]
n	25		187（Japan:79.7%、Korea: 20.3%）	79(Caucasian)	45	14
others	n=25	Prior Trastuzumab treatment, n=14	55.6% of patients previously 2L treated	median line of therapy: 2L	median line of therapy: 2L	-
ORR	**56%**	**50%**	42.9%	41.8%	55.6%	**21%**
mPFS(months)	**8.3**	**5.5**	5.6	5.6	7.2	**1.4**
mOS(months)	**16.3 (11.3-NE)**	**14.9 （11.0-NE）**	12.5	12.1	13.6	**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 9.6% 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 HER2+GC/GEJ (2022 ESMO)

Subjects: **39** subjects without prior systemic treatment were enrolled. The median age was 64 years old with 14 patients(45.2%) aged ≥65 years, 26 patients (83.9%) were HER2 IHC3+, and the other 5 patients(16.1%) were HER2 IHC2+/FISH+. More than 80% of patients were ECOG 1. 61.3% of patients had liver metastasis and 12.9% of patients had lung metastasis.

Efficacy: 39 patients were evaluable for efficacy at least one time. **ORR** was **71.8%**, **DOR** was **12.6 months**, **PFS was 10.9 months**[2]

Comparable Trials	KN026-203	ToGA	KEYNOTE-811	ZW1-ZW25-201	JACOB
Durgs	KN026+KN046	Trastuzumab+Capecitabine /Fluorouracil+cisplatin	Pembrolizumab+Trastuzumab+chemo	ZW25+chemo	Trastuzumab+Pembrolizumab+Capecitabine/ Fluorouracil+cisplatin
n	39	294	133	38	388
ORR	**71.8%**	47.3%	74.4%	79.0%	56.7%
mDOR (months)	**12.6**	6.9	10.6	20.4	10.2
mOS (months)	**10.9**	6.7	NA	12.5	8.5
18-month OS rate	NA	13.8	NA	NA	17.5
Comparable Trials	**84.7%**	40%	NA	87.3%	48.5%

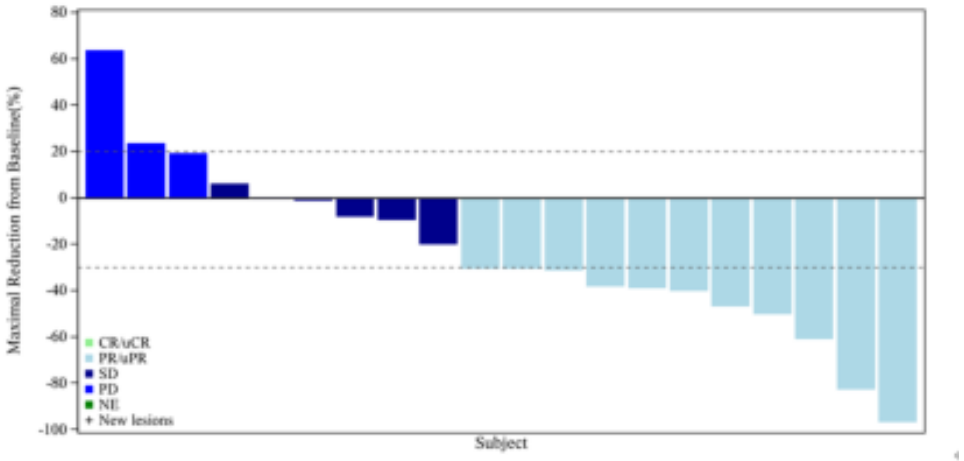
Safety: 16.1% of patients experienced ≥grade 3 TRAEs and most of them had been relieved or recovered. The most common was diarrhea(6.5%) and pyrexia(3.2%) .

Comparable in safety: The incidence rate of AE ≥grade 3 in T+C combo was 57.4%, in K+T+C combo was 57.1%

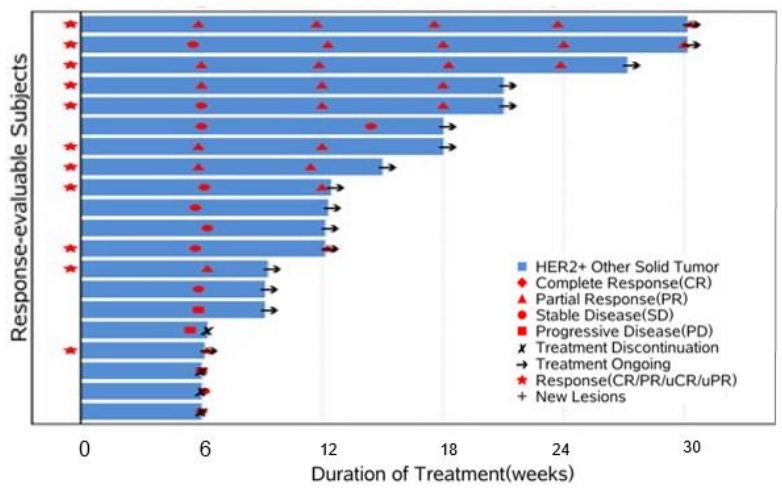
Note: 1. This data combined the results of KN026-203 and KN046-IST-02, 2. The data cut-off date is March 2023.

KN026-203(Phase II): KN046+KN026 HER2+ Solid Tumor (2022 AACR)

Waterfall Plot



Swimming lane



Enrolled **24** patients with progression after ≥1L of prior systemic therapy, including **14** CRC patients, **4** NSCLC patients, **4** gallbladder cancer patients, **1** renal pelvis cancer patient and **1** pancreatic cancer patient

Efficacy: For **20** evaluable patients，**ORR** was **55%**，**DCR** was **85%**，**6-months PFS rate** was **84.1%**，Out of 11 evaluable CRC patients, **ORR** was **45.5%** and **DCR** was **90.9%**，

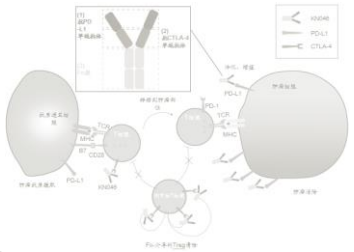
Safety:16.7% of patients had experienced ≥ grade 3 TRAEs, the most common TRAEs were infusion related reaction(29.2%), diarrhea(19.4%), vomiting, decreased appetite, etc.

Note: 1. The trial is on going and the cut-off date is August 10 , 2021.

KN046

Dual blockade of PD-L1 and CTLA-4

- More efficacy and safety
- Clinical Positioning
  - Big 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 mAb

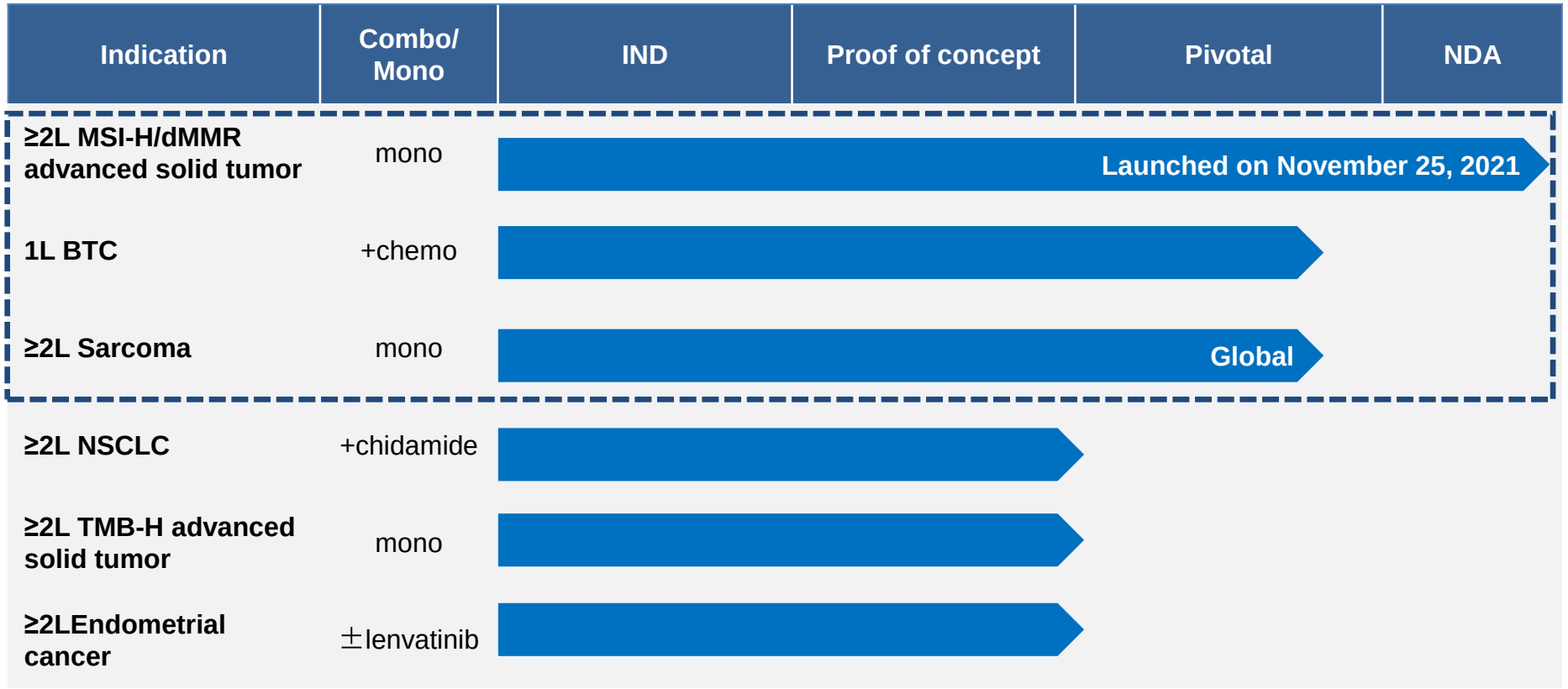
- The only PD-L1mAb worldwide that can be used for subcutaneous injection

JSKN003& KN052

HER2 bispecific ADC and PD-L1/OX40 BsAb

- JSKN003
  - Glycosite-specific conjugation
  - Benchmark DS-8201
- KN052
  - The tandem structure of PD-L1 antagonist and OX40 agonist

ENWEIDA(KN035): Conducting Multiple Clinical Trials



- Revenue from ENWEIDA® is RMB148million in 2022
- In August 2022, new specification of 300mg once every two weeks was approved
- 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).
- In December 2022, the interim analysis of KN035 combined with Ipilimumab or mono in the treatment of ≥2L sarcoma reached positive results according to the announcement of our American partner Tracon.

KN046

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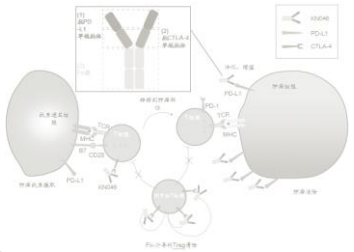

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JSKN003 & KN052

HER2 bispecific ADC and PD-L1/OX40 BsAb

- JSKN003
  - Glycosite-specific conjugation
  - Benchmark DS-8201
- KN052
  - The tandem structure of PD-L1 antagonist and OX40 agonist

JSKN003: Anti-HER2 Paratopes Bispecific ADC

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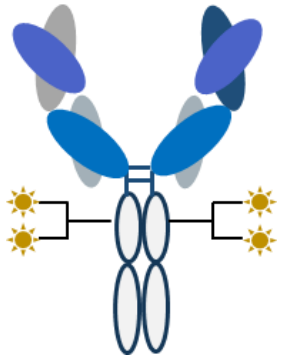
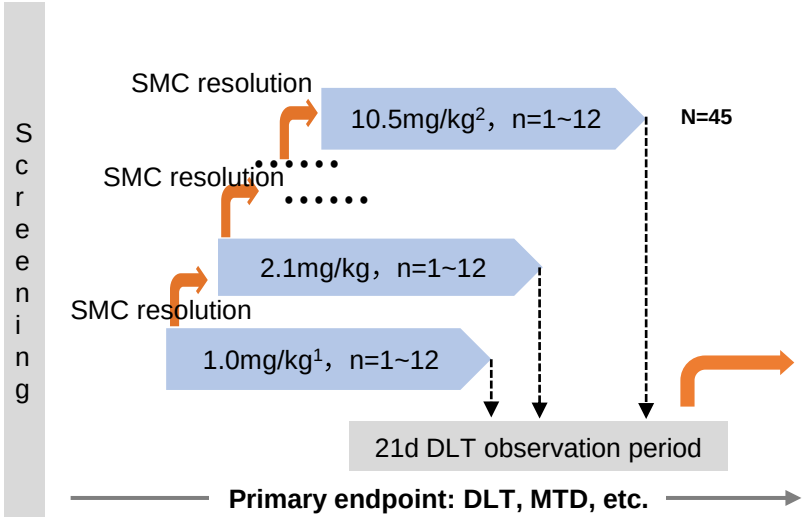
Product Structure



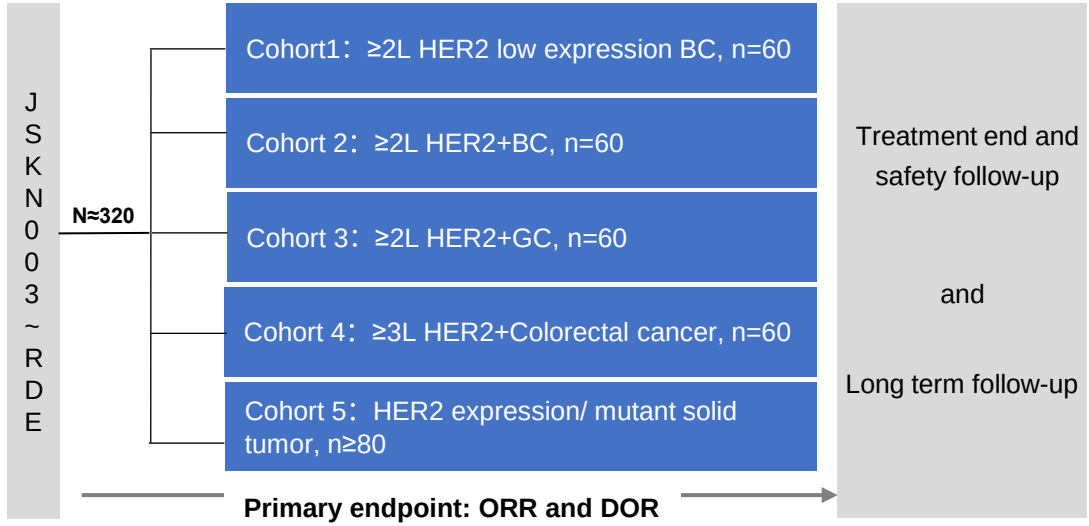
Feature and clinical strategies

- 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
- Pre-clinical studies have shown good tolerance
- Cover the HER2 high, medium and low expressing solid tumors
- To accelerate the product launch, prioritize the late line treatment with single-arm development and advance the front line study simultaneously

Ia Dose Escalation Stage- accelerated titration BOIN design



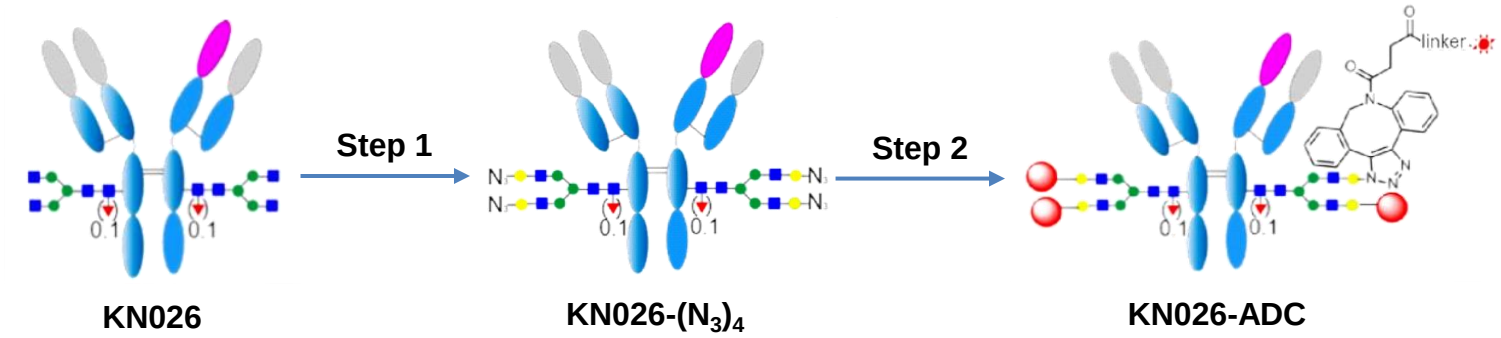
Ib Expansion Stage at RDE[3]

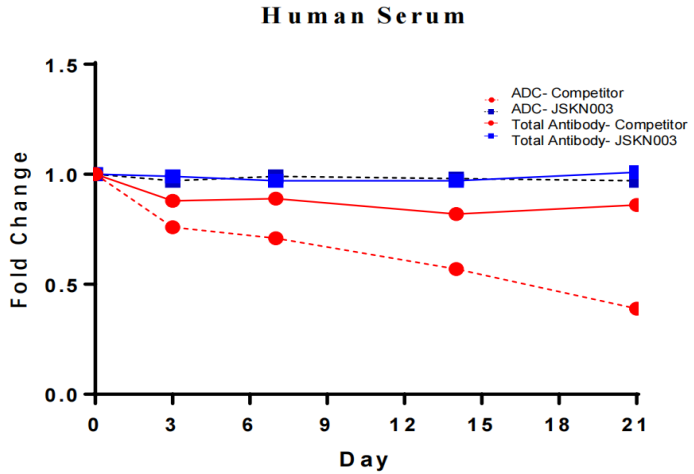


Note: 1. A total of 9 doses, the starting dose is 1.0mg/kg
2. If the dose increases to 10.5mg/kg, it still does not reach MTD. The SMC decides whether to continue the dose increase
3. RDE: The recommended dose of cohort extension is selected by SMC according to Phase Ia data. Different cohort/tumor species can choose different RDE for extension

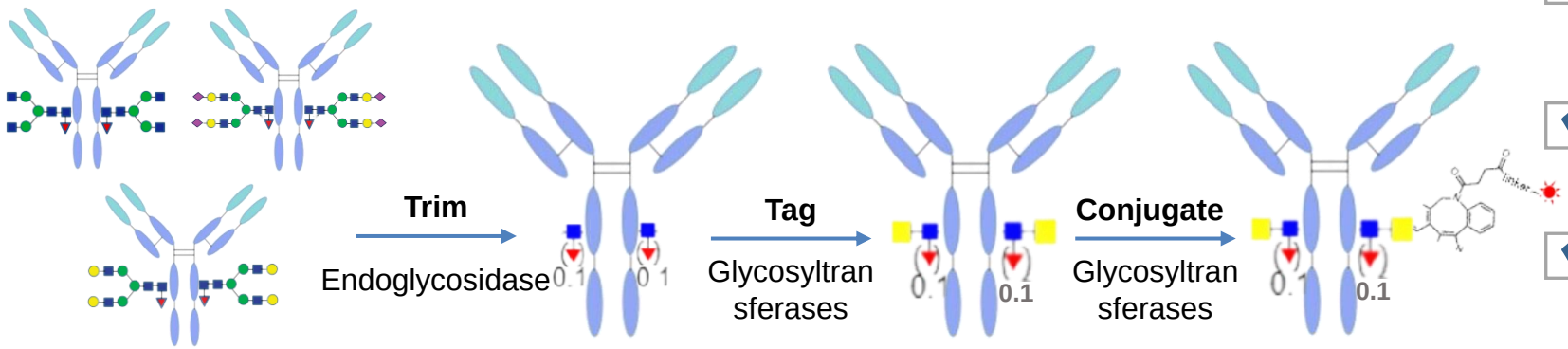
JSKN003: More Efficient Conjugation Process and More Stable Product

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





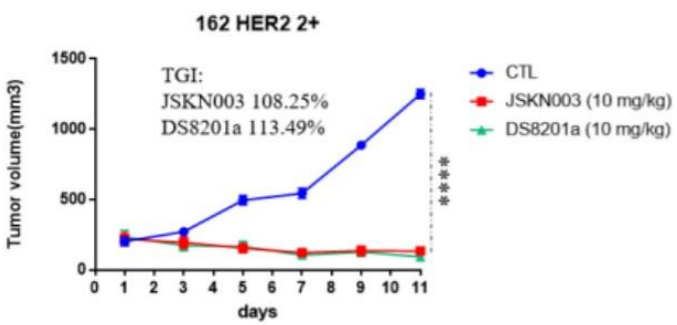
Synaffix: Two-enzyme three-steps method

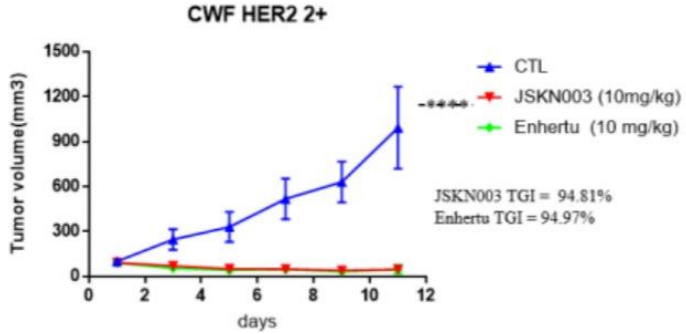


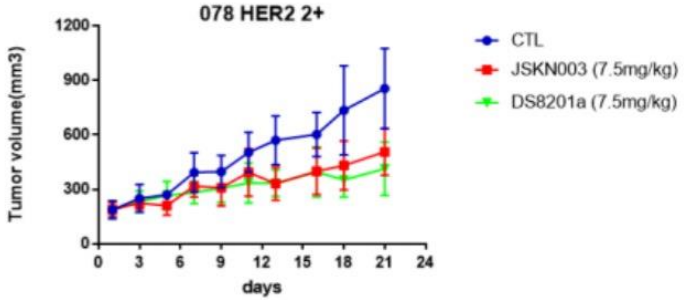
Antibody Isotype with different glycan conformations

- 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

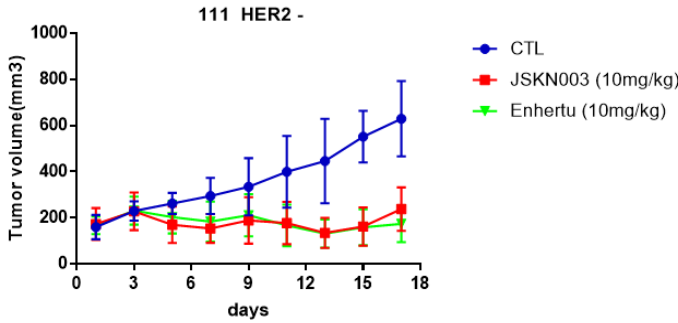
Comparable Efficacy with DS8201 in Different HER2 Expression PDX Models



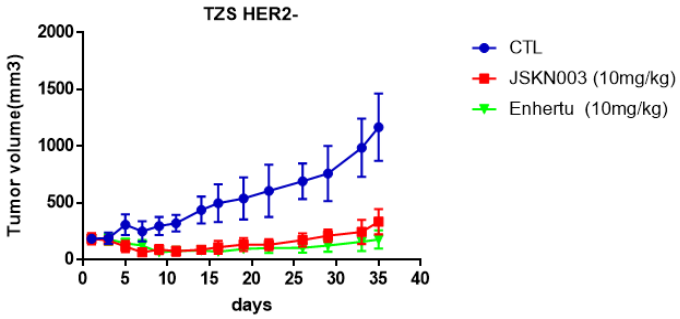




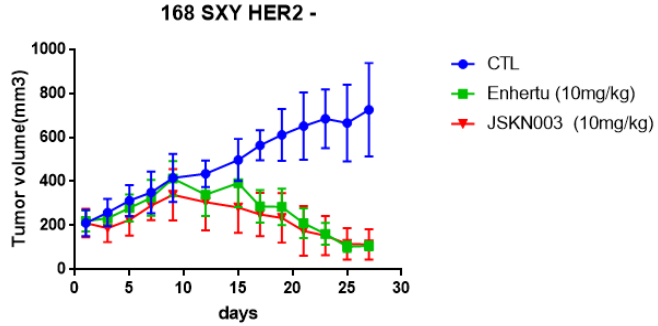
Note: day 11 for secondary administration, Dose: 7.5mg/kg, completed



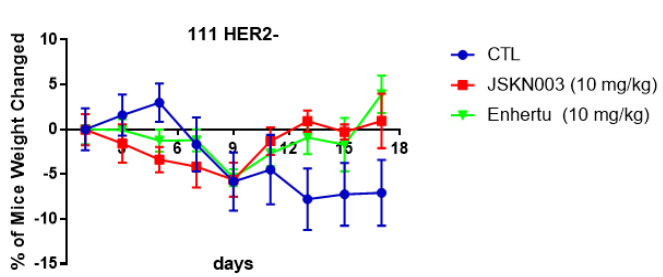
Note: administrated only once, Dose: 10mg/kg, completed

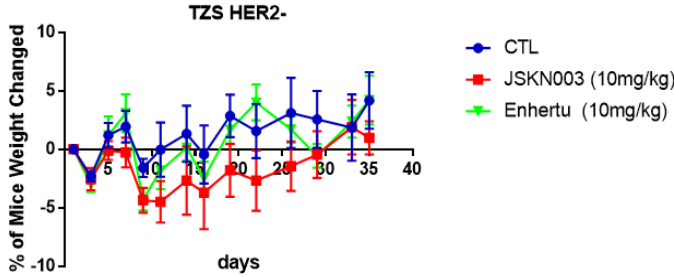


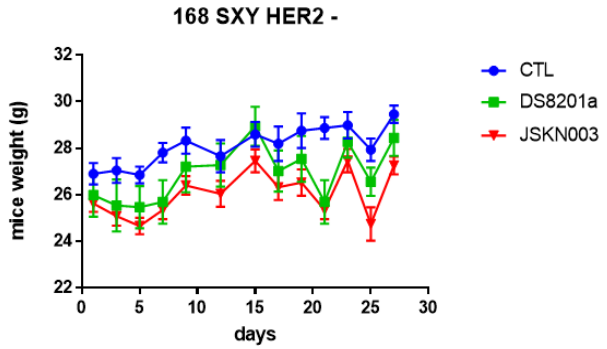
Note: administrated only once at day 1, Dose: 10mg/kg, completed



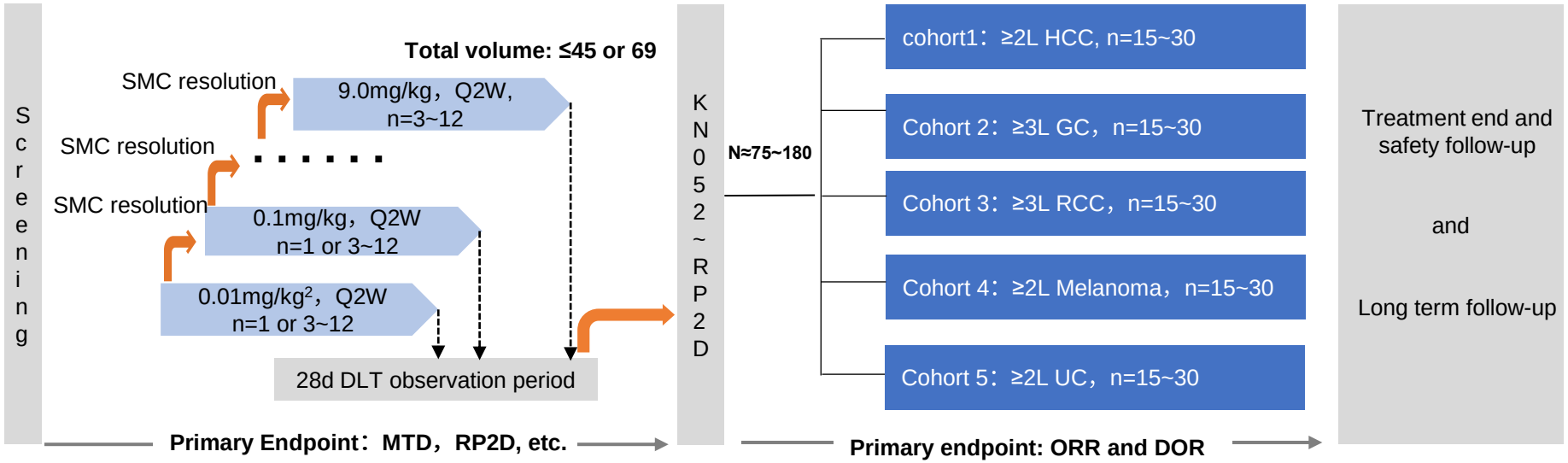
Note: day 10 for secondary administration, Dose: 10mg/kg







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

05

R&D Strategy and Outlook for 2023

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

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Treg Modulation

JSKN001

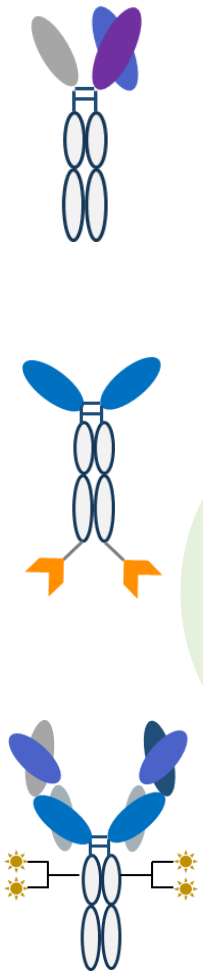
GIMC
(Glyco-Immune Modulator Conjugation)

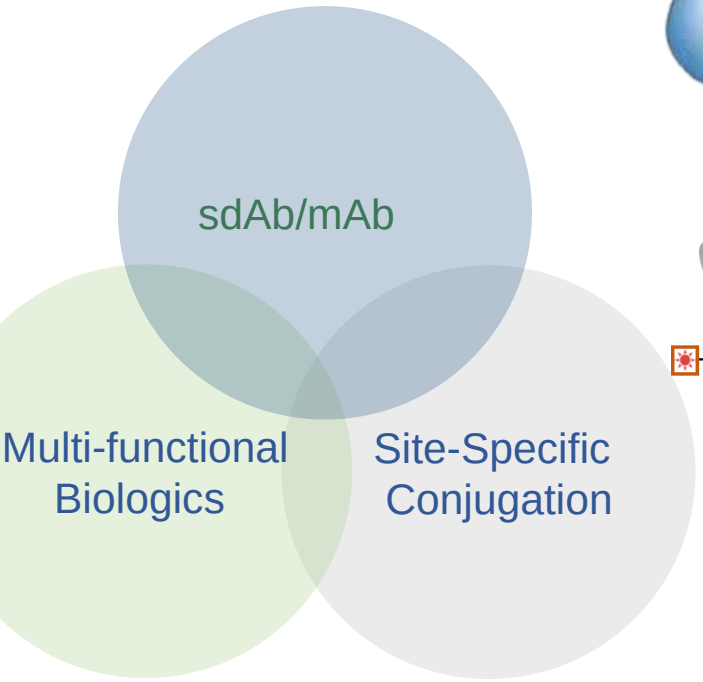
JSKN002

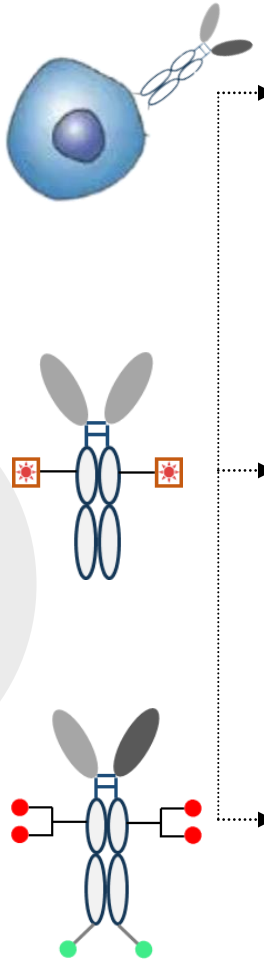
BADC
(Bispecific Antibody-Drug Conjugate)

JSKN003

JSKN016







ACC
(Antibody-Cell Conjugation)

CIMC
(Chemokine Immune Modulator Conjugation)

JSKN005

JSKN018

BADDC
(Bispecific Antibody Dual Drug Conjugation)

JSKN023

Pipeline Development Strategy and Cash Flow Relationships

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Before 2021 | 2022~2024 | 2025~2027

KN046, KN052

JSKN-016, JSKN-018, NK therapy

- EGFR-resistant NSCLC
- Cold tumors, eg.MSS Colorectal cancer
- Use in peri operation period
- Combined with the tumor vaccines, etc.

KN046+KN026

KN046+Axitinib

- HER2+ GC and other gastrointestinal tumor, chemo free
- 1LNSCLC, chemo free vs. SOC
- PD-(L)1 resistance
- Refractory tumors: PDAC, Cervical cancer

KN046+chemo

1L NSCLC, PDAC,TNBC, HCC

- Late line HER2+ solid tumor
- Full coverage of HER2 medium and low expressing solid tumors
- 1L HER2 expressing solid tumor

JSKN-003

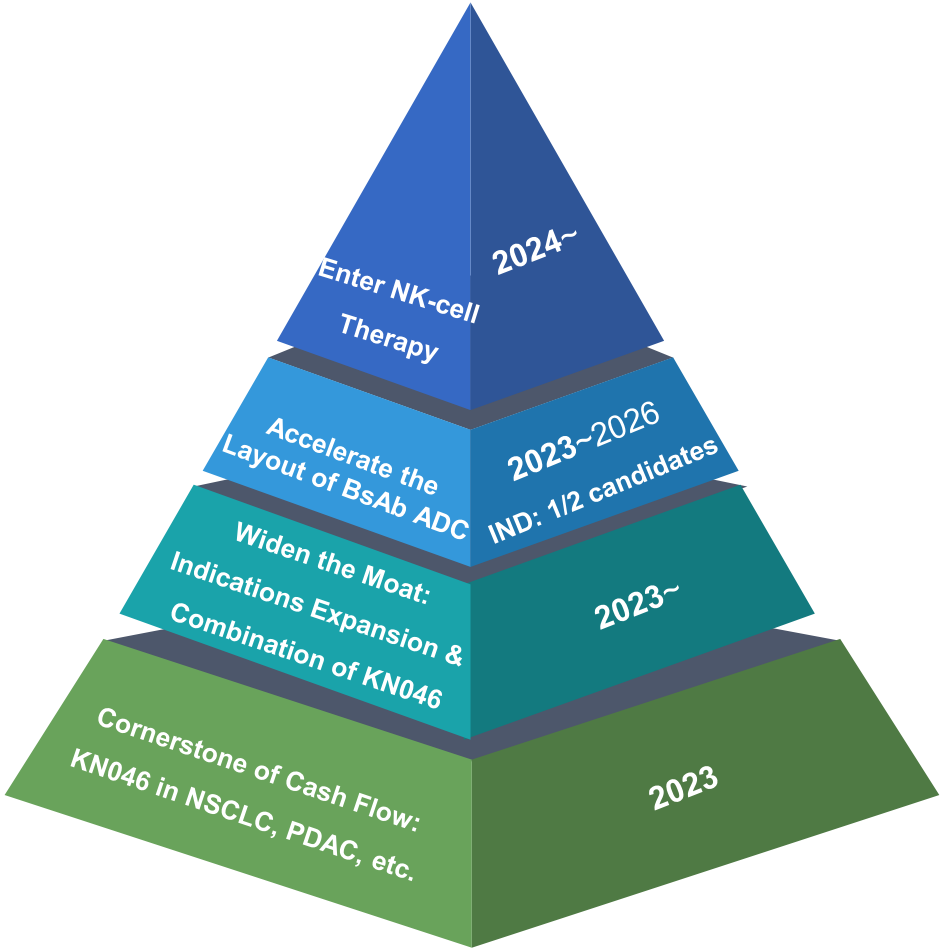
JSKN-003+IO treatment

- 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

Strive for Breakeven in Fiscal Year 2025



Cash Flow Relationships Between Core Products

Key Upcoming Milestones and Catalyst in 2023

Pivotal Trials Progress

- KN046+chemo, 1L sq-NSCLC: Data readout in 2023Q2, and submit BLA in 2023Q3
- KN046+chemo, 1L PDAC: Data readout in 2023Q3, and submit BLA in 2023Q4
- KN046+Axitinib, 1L NSCLC: Some data readout in 2022Q2, and complete the enrollment of phase II clinical trial
- KN046+Axitinib, PD-(L)1 refractory NSCLC: Initiate the phase II clinical trial
- KN046 + Axitinib,1L NSCLC: Plan to initiate the head-to-head pivotal superiority comparative study with PD-1+chemo at the year end of 2023
- KN046+KN026, HER2+1LGC：Advance the pivotal trial
- KN026+chemo, HER2+1L BC：Initiate the phase III superiority trial in 2023Q2
- KN026+chemo, ≥2L GC/GEJ: Advance phase III clinical trial in 2023Q2
- JSKN003: Plan to initiate two pivotal trials in 2023Q4
- KN035, Sarcoma: Complete patients enrollment of pivotal trial in America

Clinical Trial Data Plan to Release

AACR: April 2023

1）KN052: pre-clinical trial data

ASCO: June 2023

1）KN046+KN026: phase II clinical trial, HER2+ solid tumor

2）KN026+Docetaxel: phase II clinical trial, HER2+ BC Neoadjuvant therapy

CSCO: September 2023

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

ESMO: October 2023

1）KN046+Axitinib: phase II clinical trial, 1L NSCLC

2）KN026+Docetaxel: phase II clinical trial, 1L HER2+ BC

SABCS：December 2023

1）JSKN003：phase I clinical trial in Australia and phase Ia/Ib 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

康宁杰瑞
ALPHAMAB ONCOLOGY

Thank you!

Q&A