



康宁杰瑞

ALPHAMAB ONCOLOGY

Alphamab Oncology Presentation

November 2020



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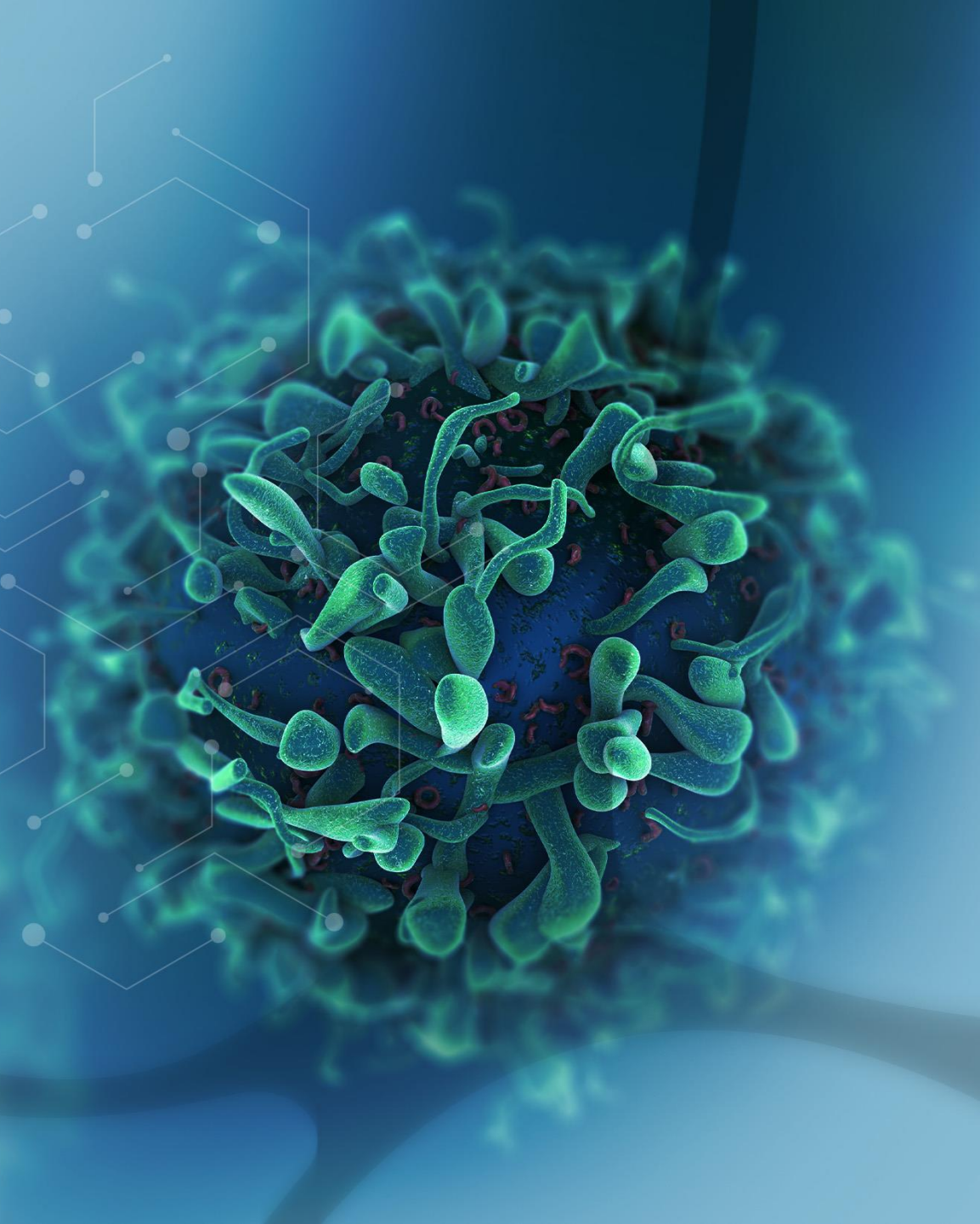
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Agenda

- 1 **Company Overview**
- 2 **Clinical Progress**
- 3 **Operation Progress**
- 5 **Q&A**

01

Company Overview





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ALPHAMAB ONCOLOGY

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

Track Record

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

Global Rights

- All in-house developed candidates
- Global rights (IP, Commercial)
- ~20 ongoing global or China clinical trials

Innovation

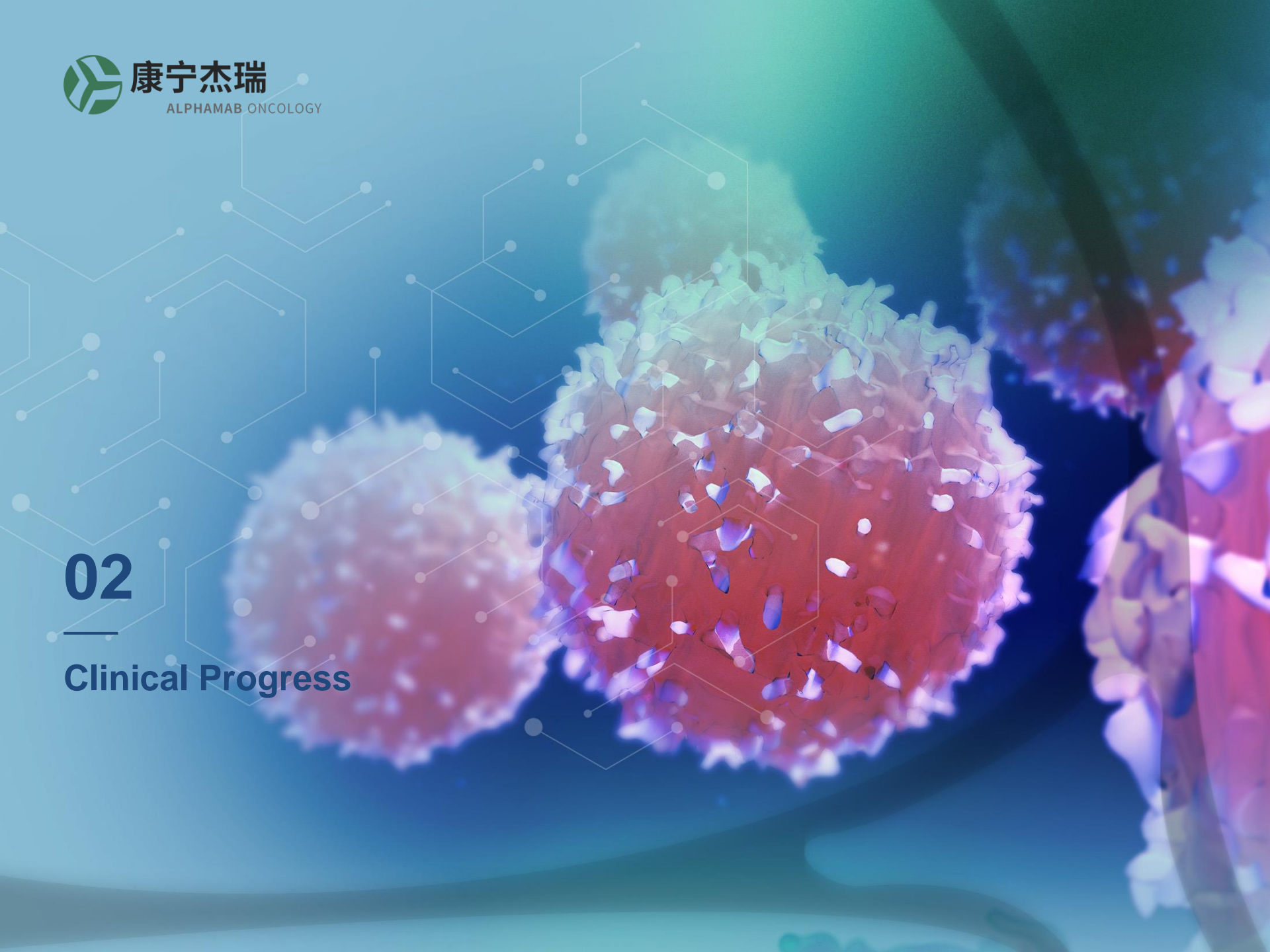
- All in-house developed proprietary sdAb, CRIB and CRAM
- Robust first-in-class global next-generation product pipeline

Integrated Platform

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

02

Clinical Progress



Strategy : Develop Next Gen Antibody to Enable Innovative Cancer Therapy

KN035

Subcutaneous
PD-L1

KN046

Dual blockade of PD-L1 and CTLA-4

KN026

Dual blockade of HER2 domain II and IV

KN019

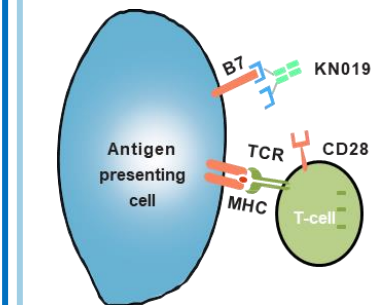
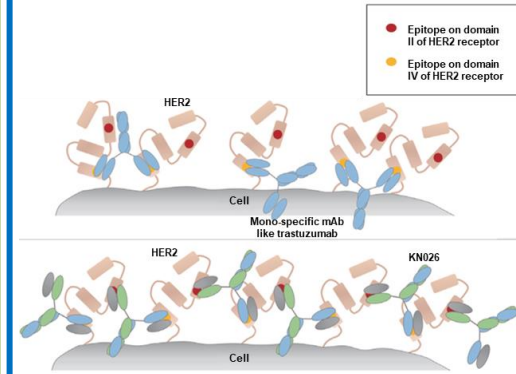
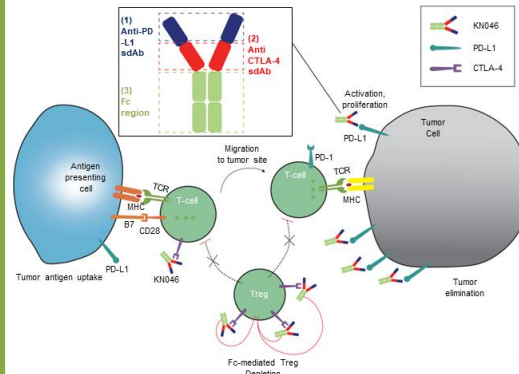
A safe option for autoimmune
diseases

Subcutaneous
PD-L1 for
maintenance
therapy

Enable earlier lines of therapies for
improved efficacy and safety

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

Supplement to
immunotherapies
for AE
management



Pipeline overview

Drug Candidate	Target(s)	Commercial Rights	Key Indications	NCT Number	Status				Expected First BLA Submission
					Pre-Clinical	Phase I	Phase II	Phase III	
KN046	PD-L1/CTLA4	Global	NSCLC, 1L (<i>KN046+CT</i>)	NCT04474119	China → Phase III				H1 2022
			Thymic carcinoma	NCT04469725	China, U.S. → Phase II				
			TNBC, 1L (<i>KN046+nab-paclitaxel</i>)	NCT03872791	China → Phase II				
			ESCC, 1L (<i>KN046+CT</i>)	NCT03925870	China → Phase II				
			NSCLC, ≥2L (<i>KN046 or KN046+CT</i>)	NCT03838848	China, U.S. → Phase II				
			NSCLC, stage III (<i>KN046+RT</i>)	NCT04054531	China → Phase II				
KN026	HER2/HER2	Global	HER2-positive/low mGC/GEJ, late line	NCT03925974	China → Phase II				4Q 2022
			HER2-positive, 1L (<i>KN026+docetaxel</i>)/HER2 low mBC	NCT04165993	China → Phase II				
			HER2-positive mBC, mGC/GEJ, late line	NCT03847168	U.S. → Phase I				
KN046+KN026 combo	PD-L1/CTLA4 + HER2/HER2	Global	HER2-low mBC	NCT04165993	China → Phase II				H2 2022
			HER2-positive solid tumors	NCT04521179	China → Phase II				
KN019	B7	Global	RA	NCT04038970	China → Phase II				Planning stage
KN035	PD-L1	Co-development	MSI-H or dMMR solid tumors	NCT03667170	China → Phase II completed				By the End of 2020
			BTC (<i>KN035+Gemcitabine+oxaliplatin</i>)	NCT03478488	China → Phase III				
			Sarcoma and others	NCT04480502	Rest of the World				
KN052	Undisclosed bispecifics	Global	Not available		→				Not available
KN053					→				
KN055					→				
KN058					→				
Antibody for COVID-19	Undisclosed	Co-development	COVID-19 treatment		→				Not available

Pivotal trials summary

Drug candidate	Indication	Trial No.	Site	Status	Sample size	Primary Endpoint	Kickoff date (investigator meeting date)
KN046	1L squamous NSCLC	ENREACH-LUNG-01	China	Pivotal Phase III	~500	PFS	Aug 18, 2020
KN046	thymic carcinoma	ENREACH-THYMIC	China, US	Pivotal phase II	~60	ORR	Sep 2, 2020
KN046+KN026 combo	HER2-positive solid tumors	SEARCH-01/KN026-203	China, US	Pivotal phase II	~300	ORR, OS	Oct 14, 2020

KN046: 1L NSCLC (ENREACH-LUNG-01)

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

KN046 5 mg/kg Q3W +
Carbo/paclitaxel Q3W

PD

Safety and long-term
follow up

1:1

Placebo + Carbo/paclitaxel
Q3W

IRC confirmed
PD

KN046 5 mg/kg Q2W
Nivolumab 240 mg
Q2W

1:1

Stratification

- PD-L1 ($\geq 1\%$ vs $< 1\%$)
- Stage III vs IV

Primary endpoint

- PFS per IRC

Key secondary endpoints

- OS
- PFS2

KN046: Thymic Carcinoma (ENREACH-THYMIC)

Inclusion criteria

- 1) Pathology confirmed thymic carcinoma
- 2) Recurrent inoperable or metastatic disease
- 3) Fail at least one prior line of systemic treatment
- 4) Baseline measurable disease

Trial design

KN046 5 mg/kg IV Q2W

Primary endpoint

- ORR per IRC

Key secondary endpoints

- DOR
- PFS
- OS
- Safety and tolerability

KN046+KN026: HER2-positive solid tumors (SEARCH-01/KN026-203)

Inclusion criteria

- 1) Centrally confirmed HER2 positive (HER2 IHC3+ or HER2 IHC2+/ISH+) GC/GEJ or EAC
- 2) Progression on or after fluoropyrimidine and platinum-containing regimen(s)
- 3) Baseline measurable disease

Trial design

KN026 30 mg/kg Q3W + KN046 5 mg/kg Q3W

2:1

Physician choice of therapy

Stratification

prior treatment line (2L versus ≥ 3 L), region (Asia versus non-Asia), prior anti-PD(L)-1 (yes versus no)

Physician choice of therapy include below options

- Irinotecan 150 mg/m² Q2W
- Paclitaxel 80 mg/m² QW
- Paclitaxel 80 mg/m² d1, 8, 15 Q4W+ ramucirumab 8 mg/kg Q2W

Primary endpoint

- ORR per IRC

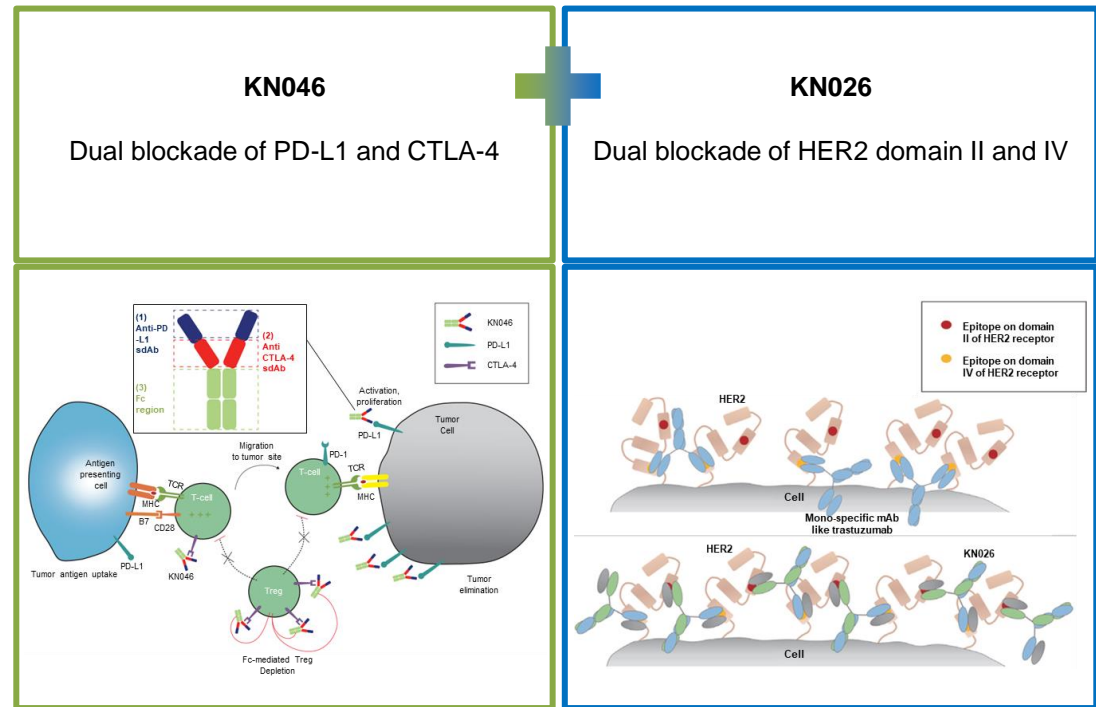
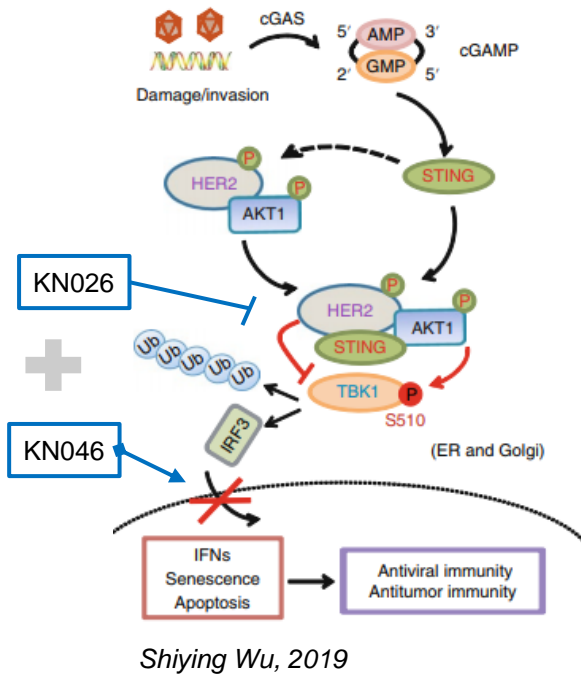
Co-primary endpoint

- OS

Secondary endpoints

- PFS (key secondary)
- Safety and tolerability
- Pharmacokinetics and immunogenicity

KN026 + KN046 : Synergistic MOA



Rational of the synergistic effect from KN026 plus KN046

- Activation of HER2 pathway interferes STING pathway, key component in innate immunity
- Blocking HER2 pathway lift the inhibition to the innate immunity
- Anti-tumor activity further enhanced by activation of adaptive immunity by KN046
- Supported by early efficacy from IST in Her2 expression/mut late line solid tumor

Study Design: KN046-IST-02

KN026 and KN046 combination in HER2-positive solid tumors



- KN046-IST-02 is a dose escalation and expansion study of KN026 in combination with KN046 in Chinese patients with solid tumors who have failed available standard of care
- Status of HER2 pathway aberration (HER2 mutation, HER2 amplification and/or HER2 overexpression)
- Three ascending doses examined
 - DL1: KN026 20 mg/kg Q2W + KN046 3 mg/kg Q2W
 - DL2: KN026 20 mg/kg Q2W with loading on Days 1, 8 of Cycle 1 + KN046 5 mg/kg Q3W
 - DL3: KN026 30 mg/kg Q3W with loading on Days 1, 8 of Cycle 1 + KN046 5 mg/kg Q3W
- Tumor response was evaluated Q8W per RECIST 1.1. Primary endpoint was DLT and key secondary endpoints were efficacy parameters (ORR, DOR, PFS)

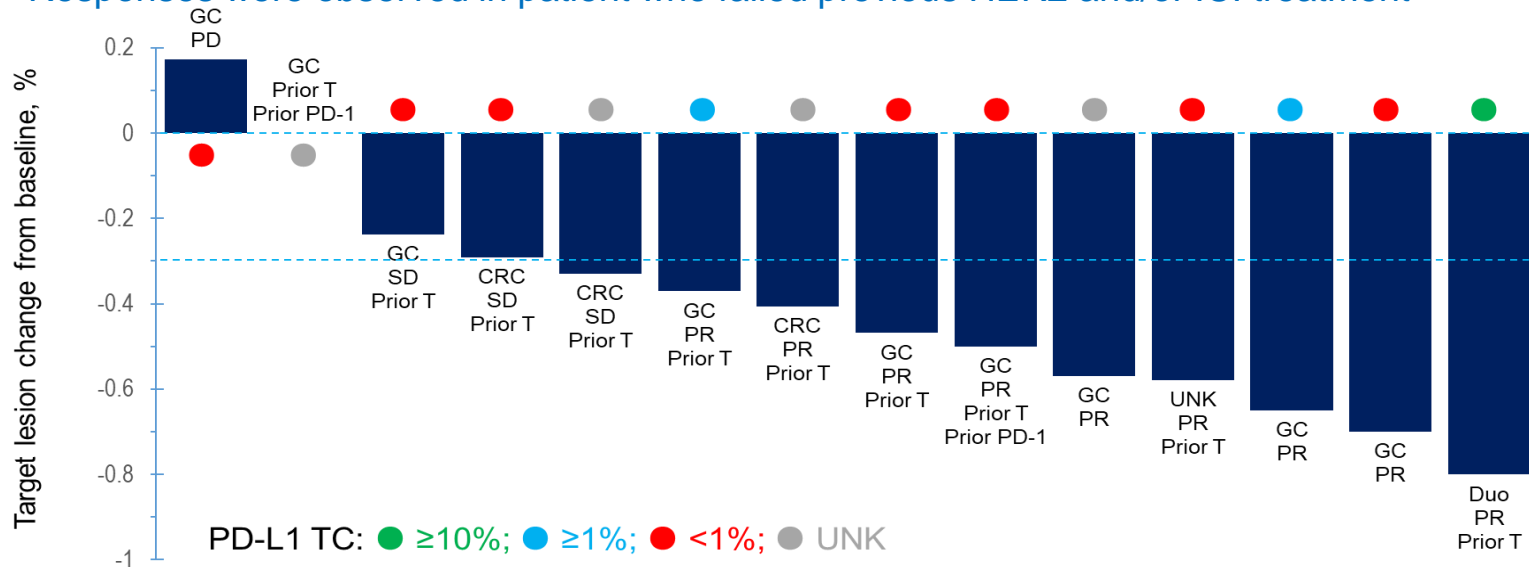
Notes:

1. As of 3-Sep-2020. Trial ongoing

Efficacy Result : KN046-IST-02

KN026 and KN046 combination in HER2-positive solid tumors

- ✓ Objective response rate was 64.3% and disease control rate was 92.9%
- ✓ Responses were observed in patient who failed previous HER2 and/or ICI treatment



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

Notes:

- As of 3-Sep-2020. Trial ongoing
- Prior T: previously treated by trastuzumab; Prior PD-1: previously treated by anti-PD1 agent; Duo: duodenum; UNK: unknown origin

Safety Result : KN046-IST-02

KN026 and KN046 combination in HER2-positive solid tumors

- ✓ No DLTs were observed in all 3 dose levels; No pts experienced LVEF decreased or other clinically meaningful cardiac AEs; Minimal lung toxicity
- ✓ Majority of AEs were Grade 1 or 2. Grade 3 or above treatment related AEs 23.1%

	20 mg/kg Q2W+3 mg/kg Q2W (n=19)	20 mg/kg Q2W+5 mg/kg Q3W (n=3)	30 mg/kg Q3W+5 mg/kg Q3W (n=4)	Total (n=26)
Subjects with at least 1 TEAE	16 (84.2%)	3 (100%)	2 (50.0%)	21 (80.8%)
Related to KN026	16 (84.2%)	3 (100%)	2 (50.0%)	21 (80.8%)
Related to KN046	15 (78.9%)	3 (100%)	1 (25.0%)	19 (73.1%)
Subjects with at least 1 TEAE of CTCAE grade 3 or 4	6 (31.6%)	2 (66.7%)	0	8 (30.8%)
Related to KN026	4 (21.1%)	1 (33.3%)	0	5 (19.2%)
Related to KN046	5 (26.3%)	1 (33.3%)	0	6 (23.1%)
Subjects with at least 1 IRR	6 (31.6%)	1 (33.3%)	2 (50.0%)	9 (34.6%)
Related to KN026	6 (31.6%)	1 (33.3%)	2 (50.0%)	9 (34.6%)
Related to KN046	3 (15.8%)	0	1 (25.0%)	4 (15.4%)
Subjects with at least 1 irAE	9 (47.4%)	0	0	9 (34.6%)
Subjects with at least 1 CTCAE grade ≥ 3 irAE	1 (5.3%)	0	0	1 (3.8%)
Subjects with at least 1 treatment-emergent SAE	3 (15.8%)	2 (66.7%)	0	5 (19.2%)
Related to KN026	3 (15.8%)	0	0	3 (11.5%)
Related to KN046	3 (15.8%)	0	0	3 (11.5%)
Subjects with at least 1 CTCAE grade ≥3 treatment-emergent SAE	2 (10.5%)	2 (66.7%)	0	4 (15.4%)
Related to KN026	2 (10.5%)	0	0	2 (7.7%)
Related to KN046	2 (10.5%)	0	0	2 (7.7%)
Subjects with at least 1 TEAE leading to drug withdrawn	3 (15.8%)	2 (66.7%)	0	5 (19.2%)
Related to KN026	2 (10.5%)	0	0	2 (7.7%)
Related to KN046	3 (15.8%)	0	0	3 (11.5%)
Subjects with at least 1 TEAE Leading to Death	0	2 (66.7%)	0	2 (7.7%)
Related to KN026	0	0	0	0
Related to KN046	0	0	0	0

Notes:

1. As of 3-Sep-2020. Trial ongoing

KN046 update

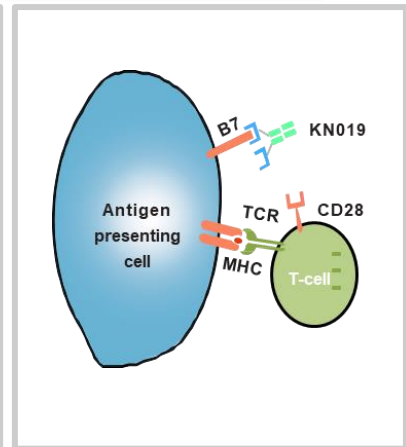
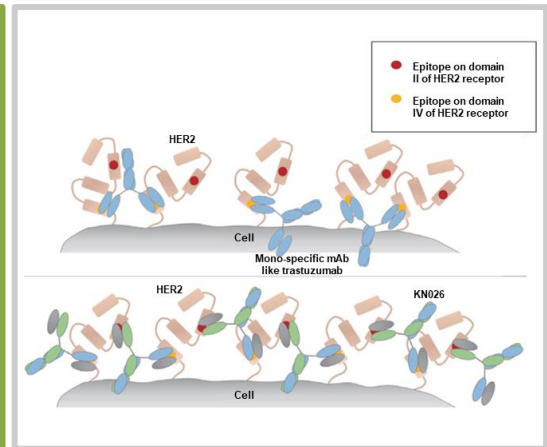
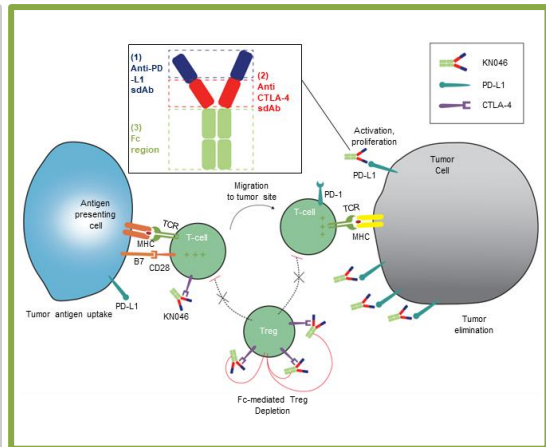
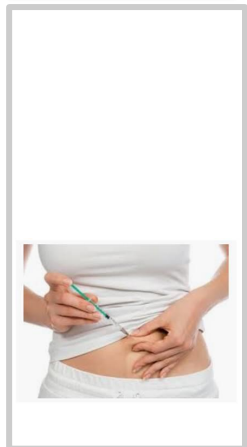
<p>KN035</p> <p>Subcutaneous PD-L1</p>	<p>KN046</p> <p>Dual blockade of PD-L1 and CTLA-4</p>	<p>KN026</p> <p>Dual blockade of HER2 domain II and IV</p>	<p>KN019</p> <p>A safe option for autoimmune diseases</p>
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Subcutaneous PD-L1 for maintenance therapy

Enable earlier lines of therapies for improved efficacy and safety

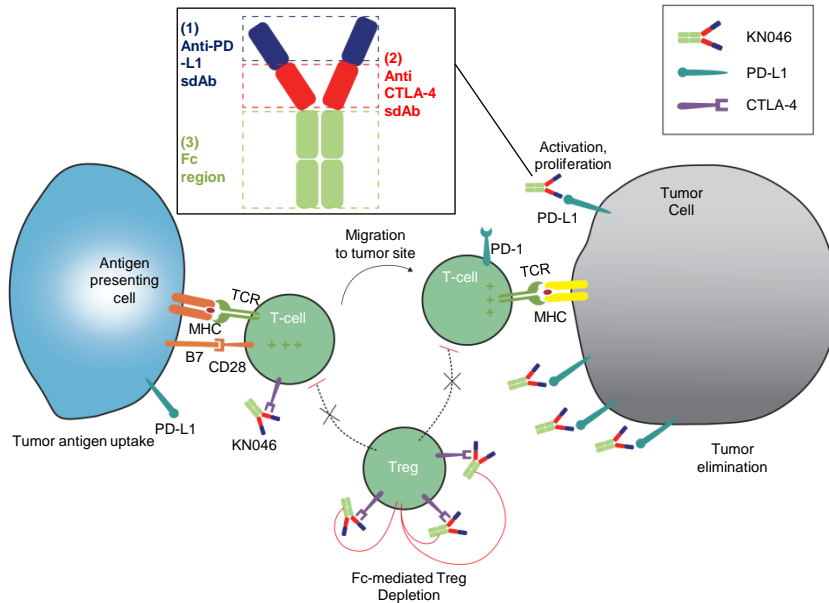
Potential for all settings of HER2 aberration
Synergy with KN046 through immune modulation

Supplement to immunotherapies for AE management



KN046 – PD-L1/CTLA-4 BsAb

Mechanism of action



Solid scientific rationale for co-targeting

Science

RESEARCH ARTICLES

Cite as: D. Sugiura et al., *Science* 10.1126/science.aav7062 (2019).

Restriction of PD-1 function by *cis*-PD-L1/CD80 interactions is required for optimal T cell responses

SCIENCE TRANSLATIONAL MEDICINE | RESEARCH ARTICLE

CANCER

Dendritic cells dictate responses to PD-L1 blockade cancer immunotherapy

Highlights

1) Targeted drug delivery

- Engineered to enable the anti-PD-L1 sdAb to dominate drug distribution
- Targeted drug delivery to tumor and limit exposure to non-tumor tissues

2) Different CTLA-4 binding epitope

- Our anti-CTLA-4 sdAb blocks the CTLA-4/B7 ligands interaction with steric hindrance instead of direct competition as Ipilimumab
- Lead to a potentially improved safety profile

3) Preservation of Fc-mediated effector functions

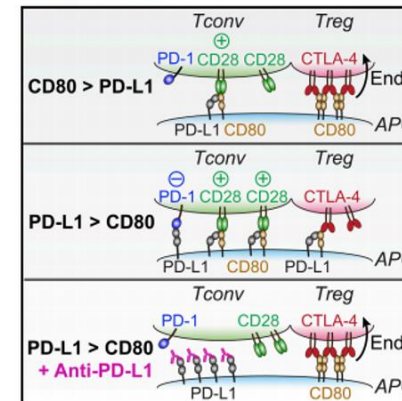
- Preserves the full Fc functions for Treg depletion

Article

Immunity

PD-L1:CD80 *Cis*-Heterodimer Triggers the Co-stimulatory Receptor CD28 While Repressing the Inhibitory PD-1 and CTLA-4 Pathways

Graphical Abstract



Authors

Yunlong Zhao, Calvin K. Lee, Chia-Hao Lin, ..., Li-Fan Lu, Jack D. Bui, Enfu Hui

Correspondence

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In Brief

Combined immunotherapy targeting the checkpoint receptors CTLA-4 and PD-1, or CTLA-4 and the PD-1 ligand (PD-L1) results in superior anti-tumor responses. Zhao et al. show that PD-L1 heterodimerizes with CD80, a shared ligand for CTLA-4 and CD28, to selectively weaken CD80:CTLA-4 interaction but not CD80:CD28 interaction. Thus, PD-L1 can repress the CTLA-4 axis; this has implications to the synergy observed in combination immunotherapies.

KN046's ongoing clinical trials

Drug Candidate	Target(s)	Commercial Rights	Key Indications	NCT Number	Status				Expected First BLA Submission
					Pre-Clinical	Phase I	Phase II	Phase III	
KN046	PD-L1/ CTLA4	Global ⁽²⁾	NSCLC, 1L (<i>KN046+CT</i>)	NCT04474119	China			Phase III	★ ⁽¹⁾
			Thymic carcinoma ⁽³⁾	NCT04469725	China, U.S.		Phase II	★ ⁽¹⁾	
			TNBC, 1L (<i>KN046+nab-paclitaxel</i>)	NCT03872791	China			Phase II	
			ESCC, 1L (<i>KN046+CT</i>)	NCT03925870	China		Phase II		
			NSCLC, >=2L ⁽⁴⁾ (<i>KN046 or KN046+CT</i>)	NCT03838848	China, U.S.		Phase II		
			NSCLC, stage III (<i>KN046+RT</i>)	NCT04054531	China		Phase II		

H1 2022

Notes:

1. Future BLA submission. Some indications may not require a non-pivotal phase II clinical trial prior to beginning the pivotal phase II/III clinical trials in China. Based on our experience, the need for comparison studies for our drug candidates is determined on a case-by-case basis and based on communications with the regulators including NMPA or US FDA.
2. No licensing partner as of the Latest Practicable Date.
3. US FDA just awarded ODD (Orphan Drug Designation) status
4. This trial comprises of using KN046 or KN046 in combination with other therapy to treat various cohorts of NSCLC patients including patients who have relapsed from first line platinum-based chemotherapy, patients who have failed prior PD-(L)1 treatment and patients whose tumor bear EGFR mutation.

Clinical data : KN046-CHN-001 in ICI Refractory Patient

- **KN046 showed a favorable safety profile and promising clinical benefit in advanced solid tumor patients who failed on prior ICIs therapy**

Patients enrolled are those who failed on prior immune checkpoint inhibitors therapy

Grade ≥ 3 related TRAEs were experienced in 2 out of 29 patients (6.9%)

Median progression free survival was 2.69 months (95%CI 1.31, 5.52)

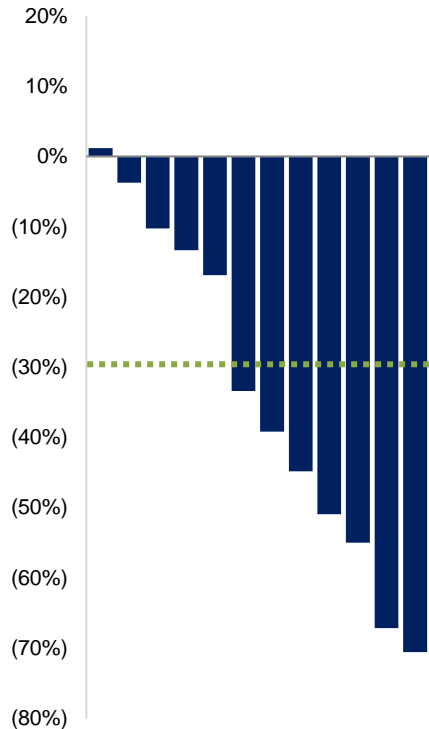
Median overall survival was not reached

Objective responses rate was 12.0%



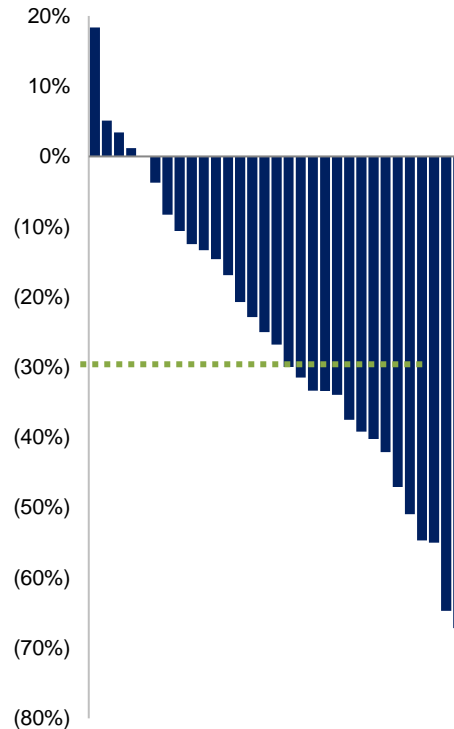
Clinical data : promising 1L and 2L NSCLC led to the launch of Pivotal Phase 3 Trial KN046-301

KN046+carbo/paclitaxel in 1L sq-NSCLC



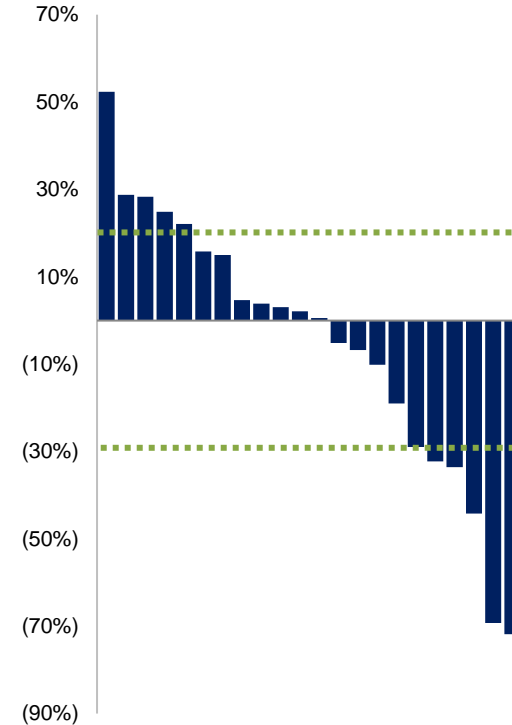
**: preliminary efficacy data. Only 5/12 subjects have more than 2 post baseline tumor assessments*

KN046+carbo/pemetrexed in 1L non-sq NSCLC



**: preliminary efficacy data. Only 15/31 subjects have more than 2 post baseline tumor assessments*

KN046 in 2L NSCLC (5 mg/kg)

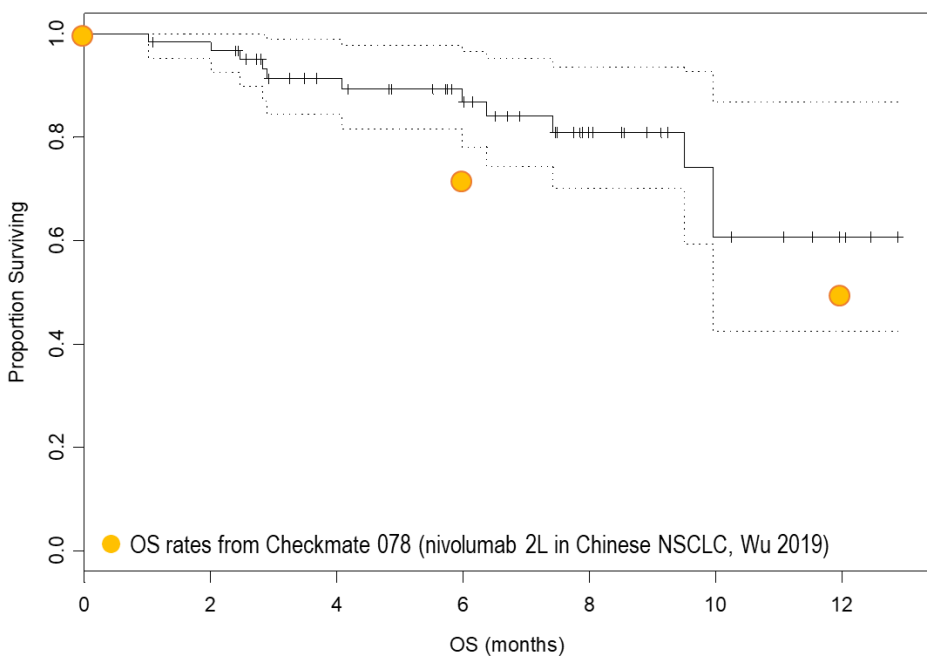


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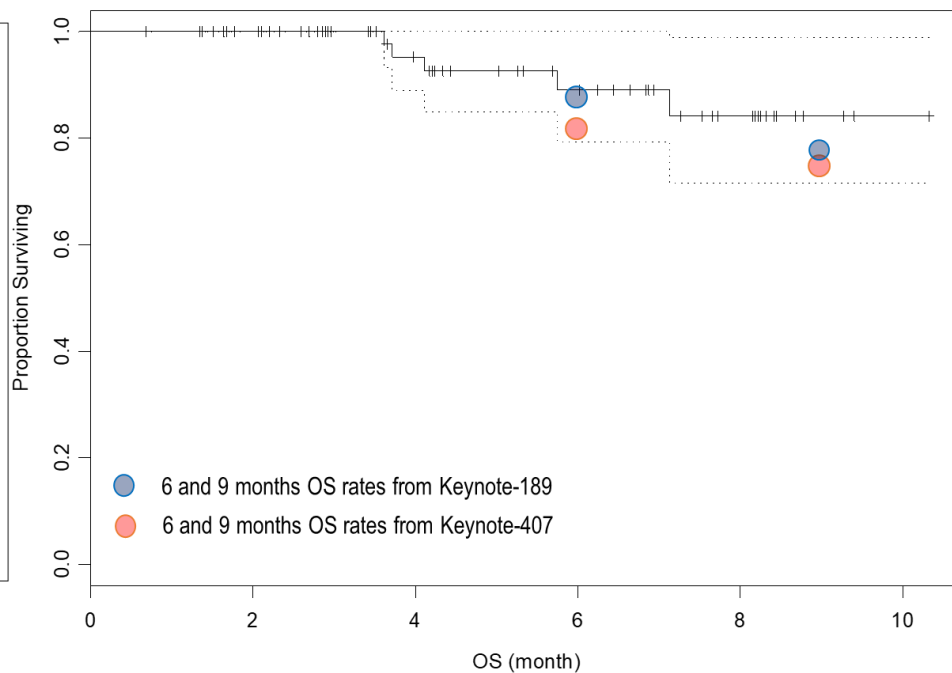
1. As of May-2020. Trial ongoing

OS comparison in NSCLC

OS data comparison in 2L NSCLC



OS data comparison in 1L NSCLC



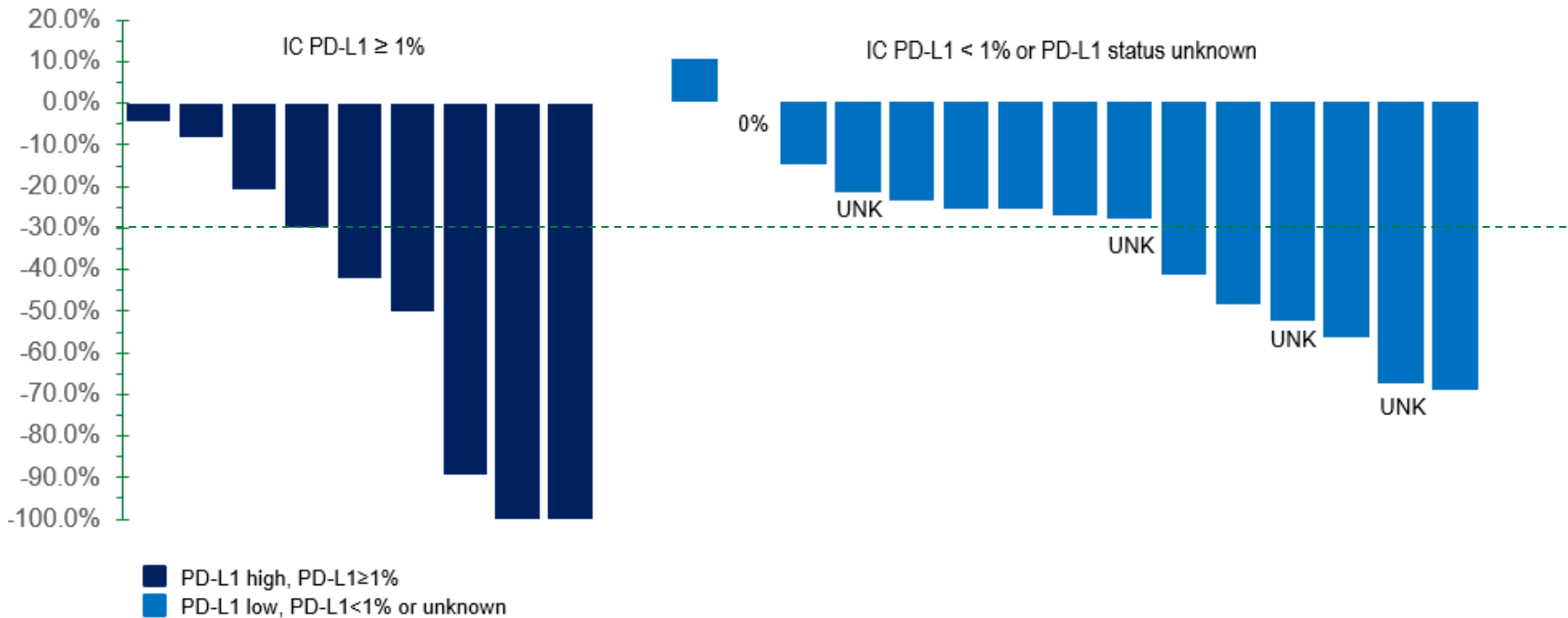
Notes:

1. As of 07-Aug-2020. Trial ongoing

Clinical data : KN046-203 TNBC

KN046 in combination with nab-paclitaxel in TNBC, 1L

- Deeper response is observed in IC PD-L1 $\geq 1\%$ subgroup

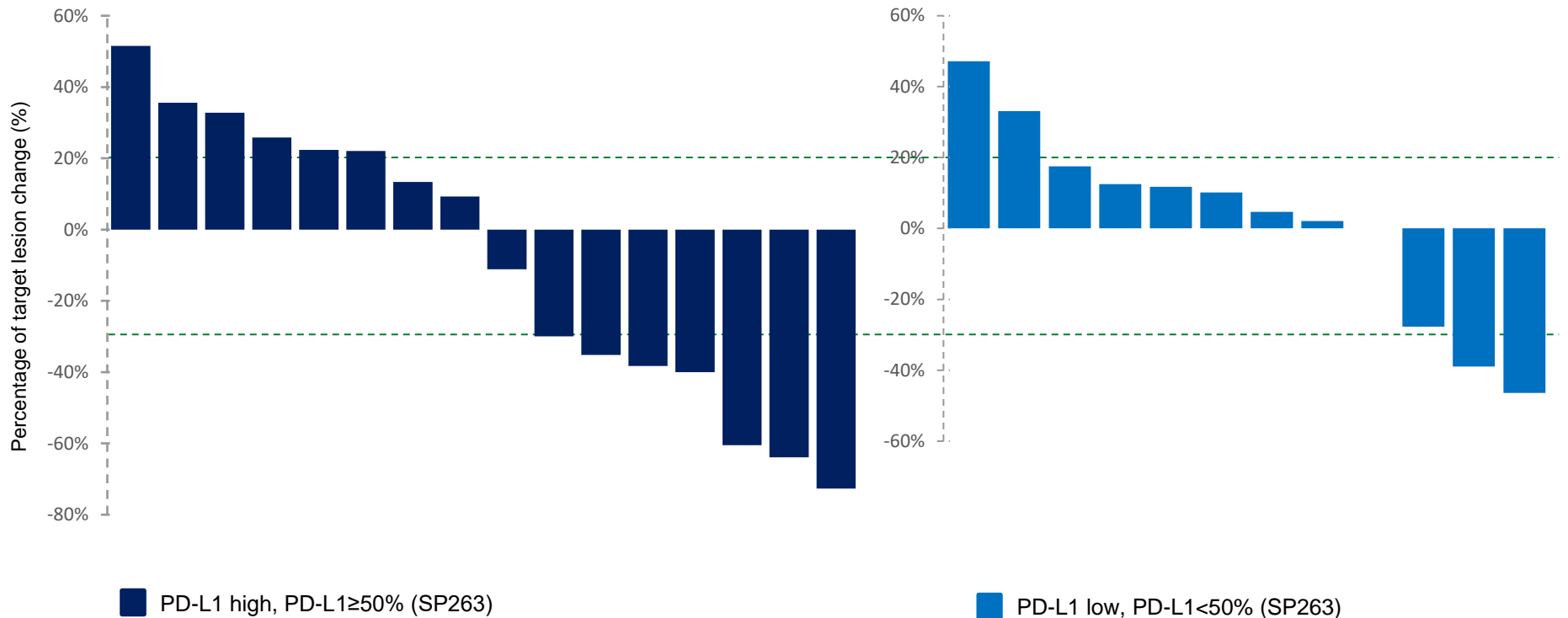


Notes:
1. As of 17-Aug-2020. Trial ongoing
2. UNK: PD-L1 status unknown

Clinical data : KN046-CHN-001 NPC

NPC unselected population: anti-PD-1 naïve, late line

- Encouraging efficacy observed particularly in PD-L1 high group
- 7/16 ORR (confirmed and unconfirmed) in PD-L1 high group

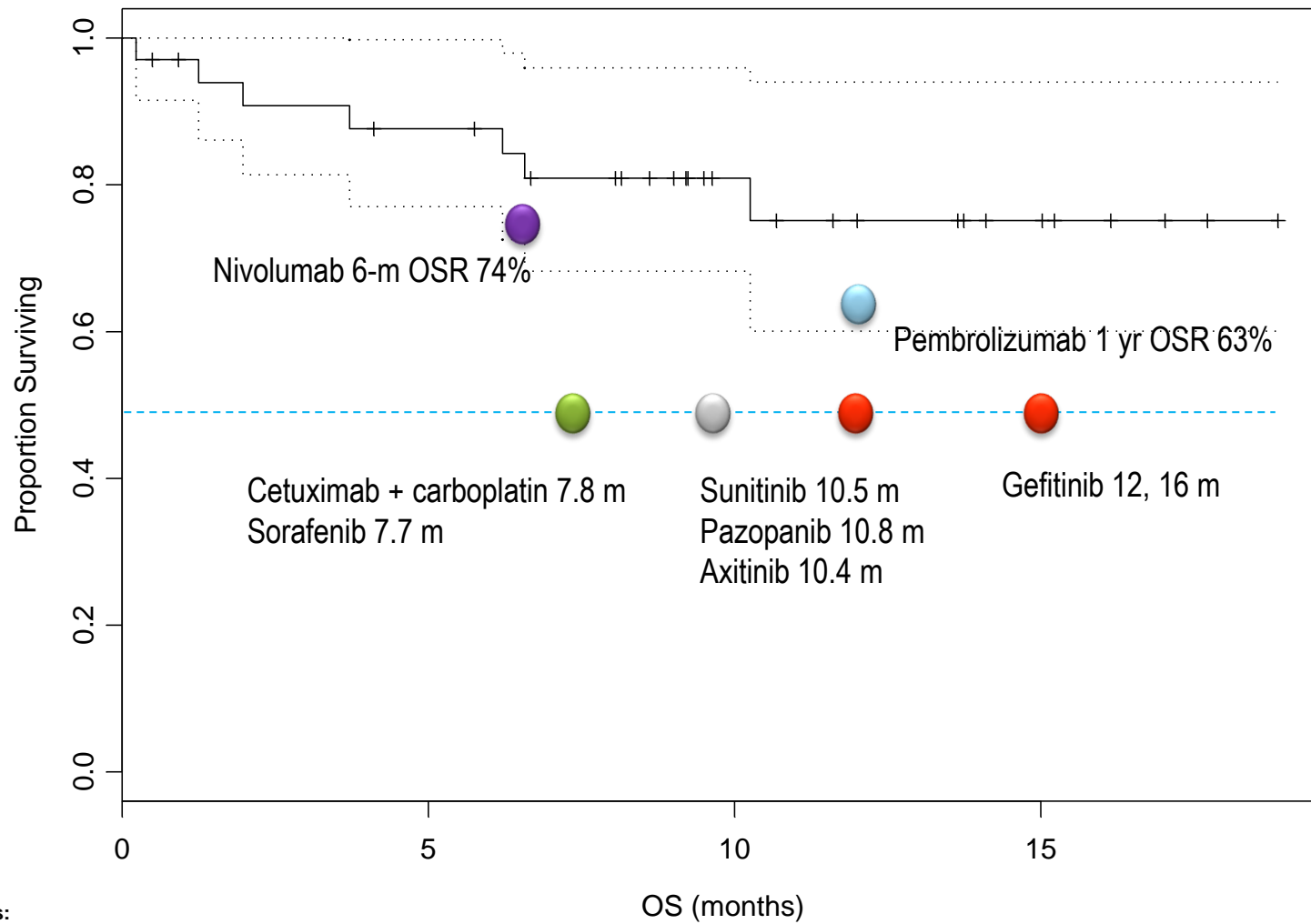


Notes:

1. As of 20-Aug-2020 (data retrieved from EDC)

OS comparison in NPC

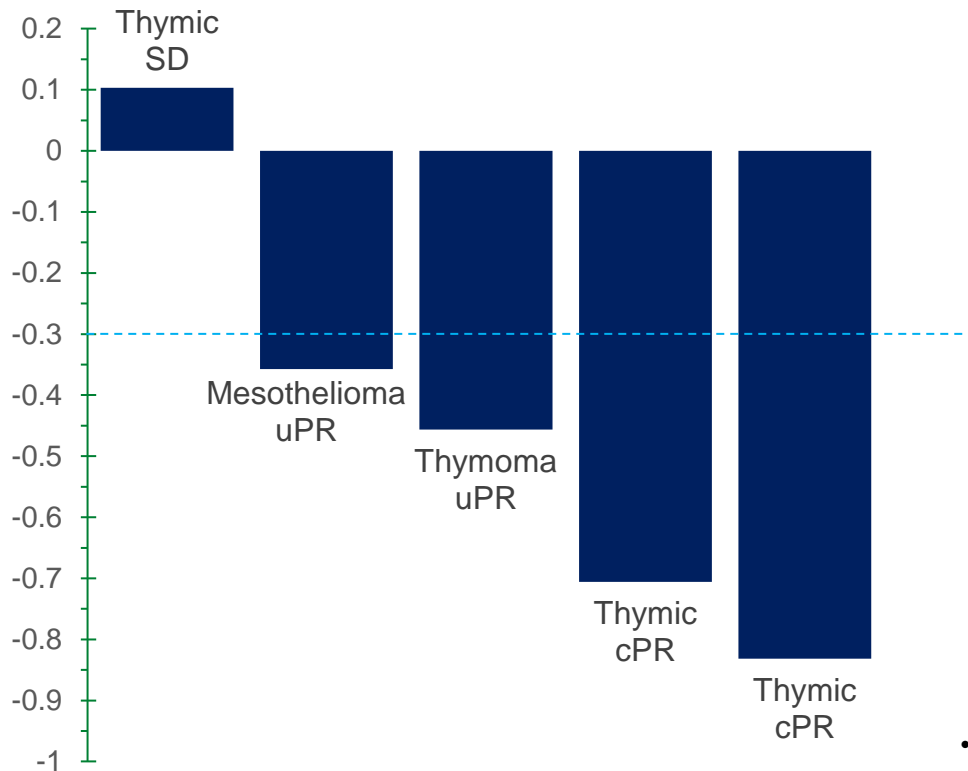
NPC unselected population: anti-PD-1 naïve, late line



Notes:

1. As of 20-Aug-2020 (data retrieved from EDC)

Efficacy data in thymic epithelial tumor (TET)



- **ODD (Orphan Drug Designation) awarded by US FDA**
- **Phase II registration trial in China and US initiated**

Left to right (prior anti-cancer treatment)

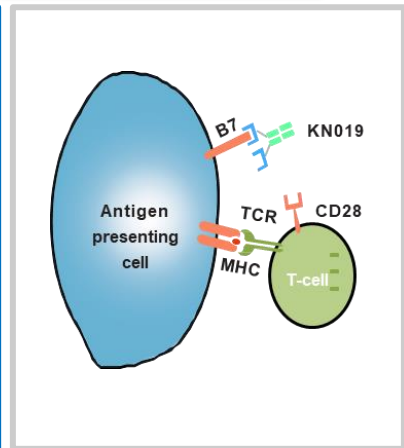
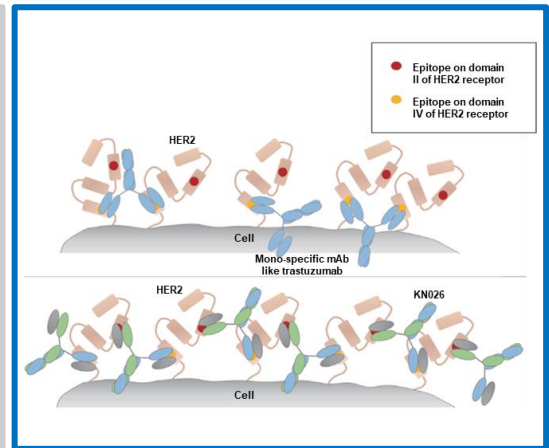
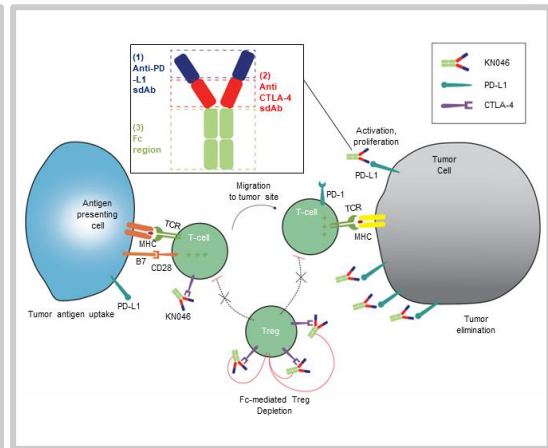
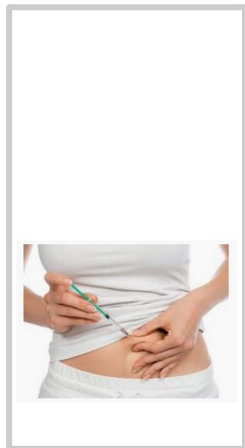
- 004-016: carboplatin/etoposide
- 003-016: palliative
- 005-005: cisplatin, adriamycin, cyclophosphamide
- 004-008: carboplatin/etoposide
- 005-011: carboplatin/paclitaxel

Notes:

1. As of 06-Jul-2020. Data retrieved from EDC

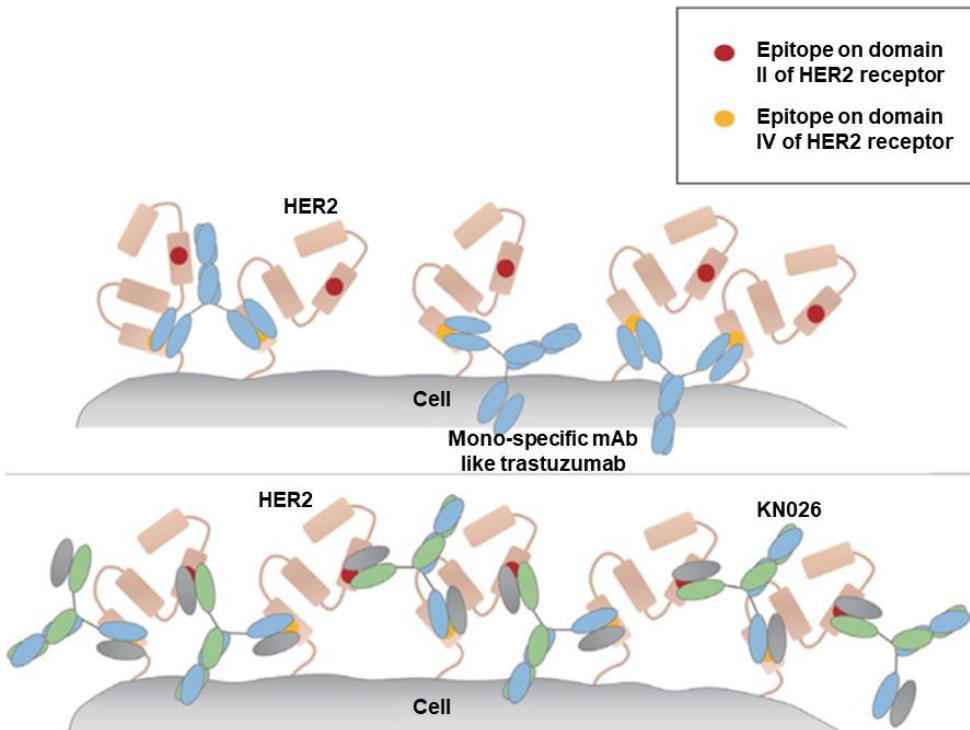
KN026 update

<p>KN035</p> <p>Subcutaneous PD-L1</p>	<p>KN046</p> <p>Dual blockade of PD-L1 and CTLA-4</p>	<p>KN026</p> <p>Dual blockade of HER2 domain II and IV</p>	<p>KN019</p> <p>A safe option for autoimmune diseases</p>
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KN026 – HER2/HER2 BsAb

Mechanism of action



Highlights

- 1) Dual blockade of parallel HER2-related signaling pathways**
 - Binds two distinct epitopes of HER2 receptors which have been clinically validated by the Herceptin and Perjeta combination therapy
 - Can induce synergistic inhibitory activities and potentially reduce drug resistance and relapse
- 2) Enhanced multiple HER2 receptor binding**
 - Crosslinking multiple HER2 receptors on the cell surface and promote HER2 internalization
 - Binds Her2 more efficiently, particularly in low/intermediate expression
- 3) Fc-based BsAb with full effector functions**
 - Recruit immune cells to destroy HER2-overexpressing target cells
 - Increased presence of KN026 on tumor cells leads to increased tumor killing by effector functions

KN026 ongoing clinical trials

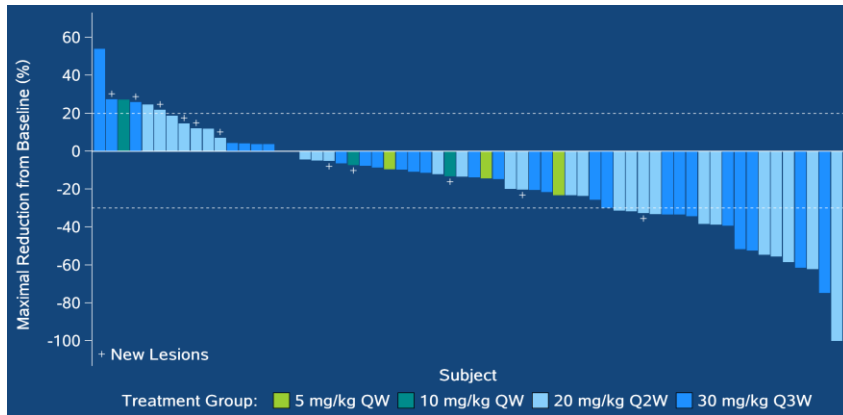
Drug Candidate	Target(s)	Commercial Rights	Key Indications	NCT Number	Status				Expected First BLA Submission
					Pre-Clinical	Phase I	Phase II	Phase III	
KN026	HER2/HER2	Global ⁽¹⁾	HER2-positive/low mGC/GEJ, late line	NCT03925974	China → Phase II				
			HER2-positive, 1L (<i>KN026+ docetaxel</i>) /HER2 low mBC	NCT04165993	China → Phase II				4Q 2022
			HER2-positive mBC, mGC/GEJ, late line	NCT03847168	U.S. → Phase I				
KN046+ KN026 combo	PD-L1/ CTLA4 + HER2/ HER2	Global ⁽¹⁾	HER2-low mBC ⁽²⁾	NCT04165993	China → Phase II				
			HER2-positive/low solid tumors	NCT04521179	China → Phase II				H2 2022

Notes:

1. No licensing partner as of the Latest Practicable Date.
2. Patients with HER2 low expressing, HR negative MBC are enrolled in KN026-201 HER2-low cohort

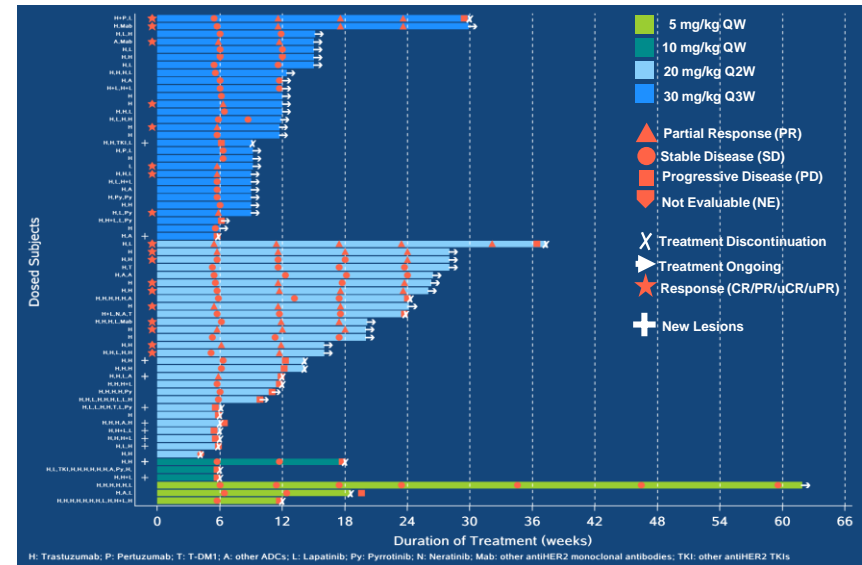
Clinical data : KN026-CHN-001

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



As of Jan.22, 2020	5 mg/kg QW (n=3)	10 mg/kg QW (n=3)	20 mg/kg Q2W (n=28)	30 mg/kg Q3W (n=28)	Total (n=62)	Pooling 20 mg/kg Q2W & 30 mg/kg Q3W (n=56)
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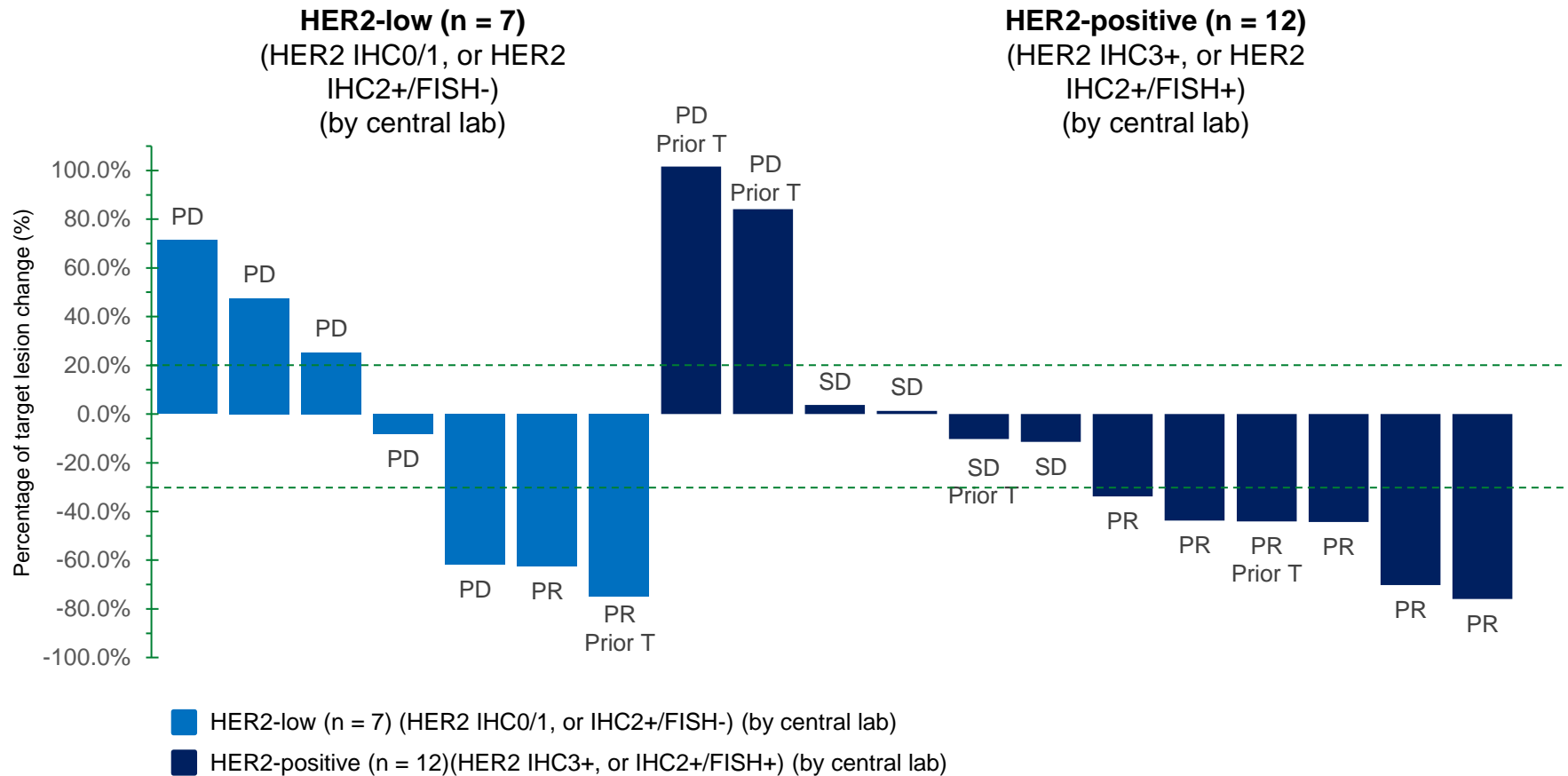
CR	0	0	0	0	0	0
PR	0	0	10 (35.7%)	8 (28.6%)	18 (29.0%)	18 (32.14%)
SD	2 (66.7%)	1 (33.3%)	8 (28.6%)	17 (60.7%)	28 (45.2%)	25 (44.64%)
PD	1 (33.3%)	2 (66.7%)	9 (32.1%)	3 (10.7%)	15 (24.2%)	12 (21.43%)
NE	0	0	1 (3.6%)	0	1 (1.6%)	1 (1.79%)
ORR (%)	0	0	10 (35.7%)	8 (28.6%)	18 (29.0%)	18 (32.14%)
DCR (%)	2 (66.7%)	1 (33.3%)	18 (64.3%)	25 (89.3%)	46 (74.2%)	43 (76.79%)



- HER2 positive breast cancer
- Median age: 54 (range: 31~69)
- Median exposure duration: 12 weeks (range: 4~62)
- Median prior lines of HER2 target therapies: 2 (range: 1~12)

Clinical data : KN026-202

KN026 monotherapy activity in HER2-low and HER2-positive GC/GEJ



Notes:

1. As of 21-Aug-2020. Trial ongoing
2. HER2-positive according to ASCO/CAP 2018
3. Prior T : received Herceptin treatment previously

KN035 update

KN035

Subcutaneous
PD-L1

KN046

Dual blockade of PD-L1 and CTLA-4

KN026

Dual blockade of HER2 domain II and IV

KN019

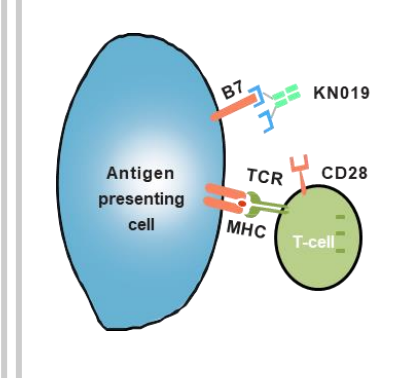
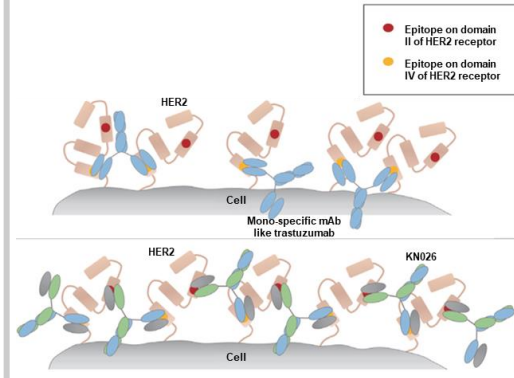
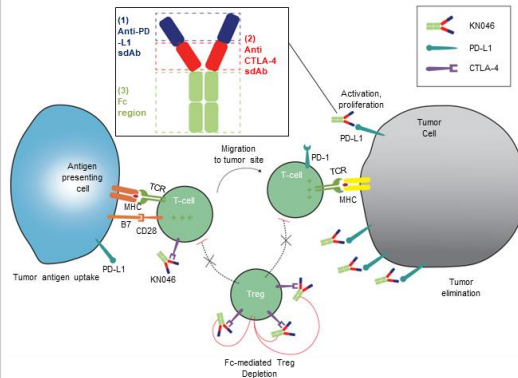
A safe option for autoimmune
diseases

Subcutaneous
PD-L1 for
maintenance
therapy

Enable earlier lines of therapies for
improved efficacy and safety

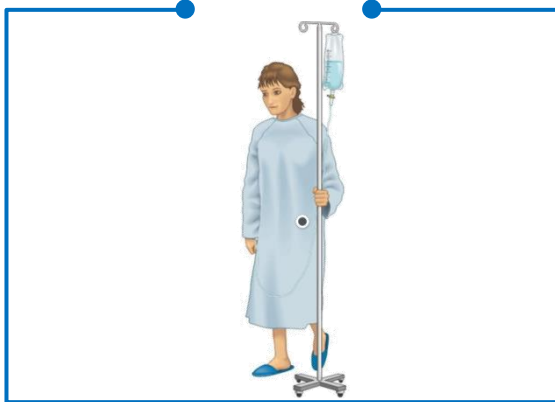
Potential for all settings of HER2
aberration
Synergy with KN046 through
immune modulation

Supplement to
immunotherapies
for AE
management



KN035 – Potential First-global SC PD-L1 for Near-term Commercialization

Intravenous Infusion vs. Subcutaneous Injection



Intravenous Infusion



Subcutaneous Injection

Favorable Partnership Term

- 3DMed to pay for all clinical and commercialization expenses
- Alphamab, Simcere and 3DMed partner for the commercialization of KN035's oncology indication in China

Advantages



Better/quicker administration



Prolonged half-life to support a less frequent dosing schedule



Preferred for patients with limited vein access



Precedent for strong competitiveness: 4 years after launch, SC Herceptin represents **~50%** of Herceptin sales in European market



Lower medical cost

Efficacy Results in Subjects Who Had Completed ≥ 2 On-Study Tumor Assessments

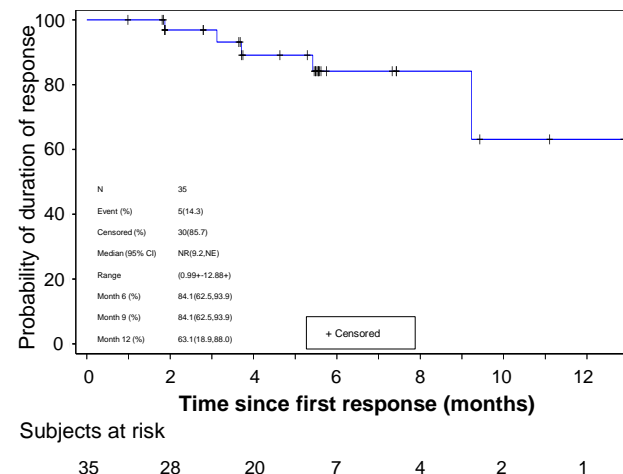
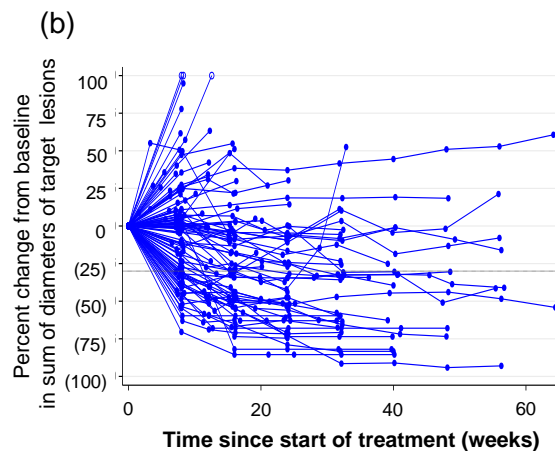
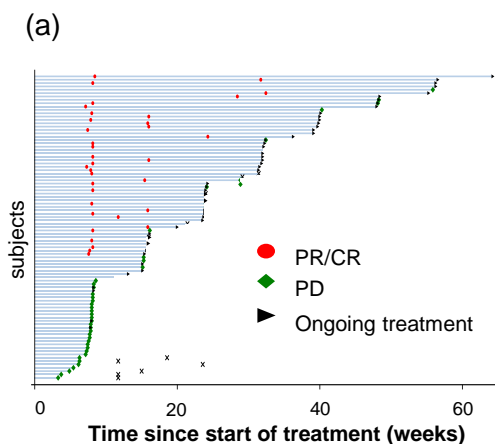
Drug Candidate	PEP ⁽¹⁾			CRC failed F and O or I (n=24)	Other tumors (n=20)
	CRC (n=39)	GC (n=11)	Total (n=50)		
Confirmed ORR (BIRC)	28.2%	36.4%	30.0%	54.2%	35.0%
DCR (BIRC)	59.0%	72.7%	62.0%	66.7%	65.0%
6-month DoR (BIRC)	63.0%	100.0%	71.9%	88.9%	100%
Median PFS (BIRC), months	4.9	11.1	6.6	11.1	5.6
Median OS, months	Not reached				
12-month OS rate	61.5%	68.2%	63.7%	90.5%	76.8%

Tumor response over time in overall population

DoR in subjects with a confirmed response per BIRC in overall population

Swimmer plot of disease status over time (a)

Spider plot of change in sum of diameters of target lesions by subjects over time (b)



- Safety profile was similar to other PD-(L)1 antibodies but without infusion reactions. No colitis or pneumonitis case was reported in the study.

Notes:

1. PEPⁱ refers to the primary efficacy population for interim analysis, patients in the PEP who had at least two post-baseline tumor assessments

KN019 update

KN035

Subcutaneous PD-L1

KN046

Dual blockade of PD-L1 and CTLA-4

KN026

Dual blockade of HER2 domain II and IV

KN019

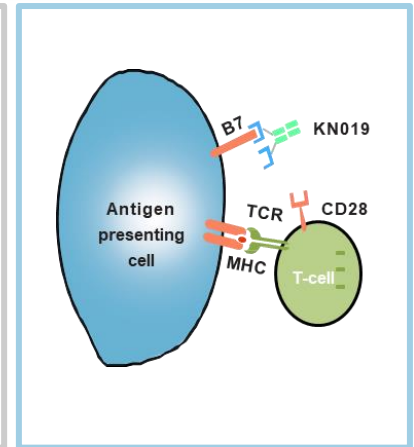
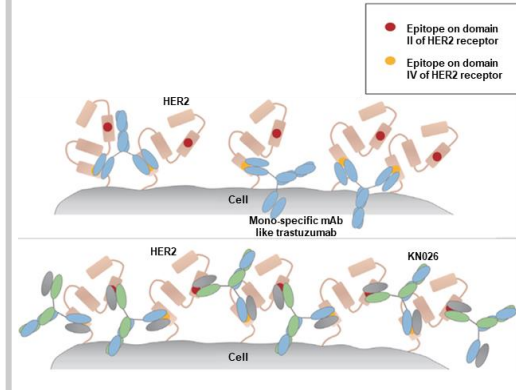
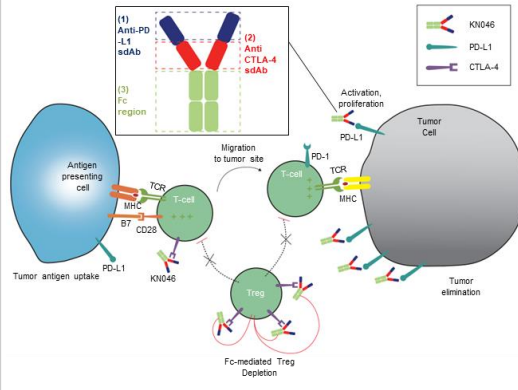
A safe option for autoimmune diseases

Subcutaneous PD-L1 for maintenance therapy

Enable earlier lines of therapies for improved efficacy and safety

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

Supplement to immunotherapies for AE management

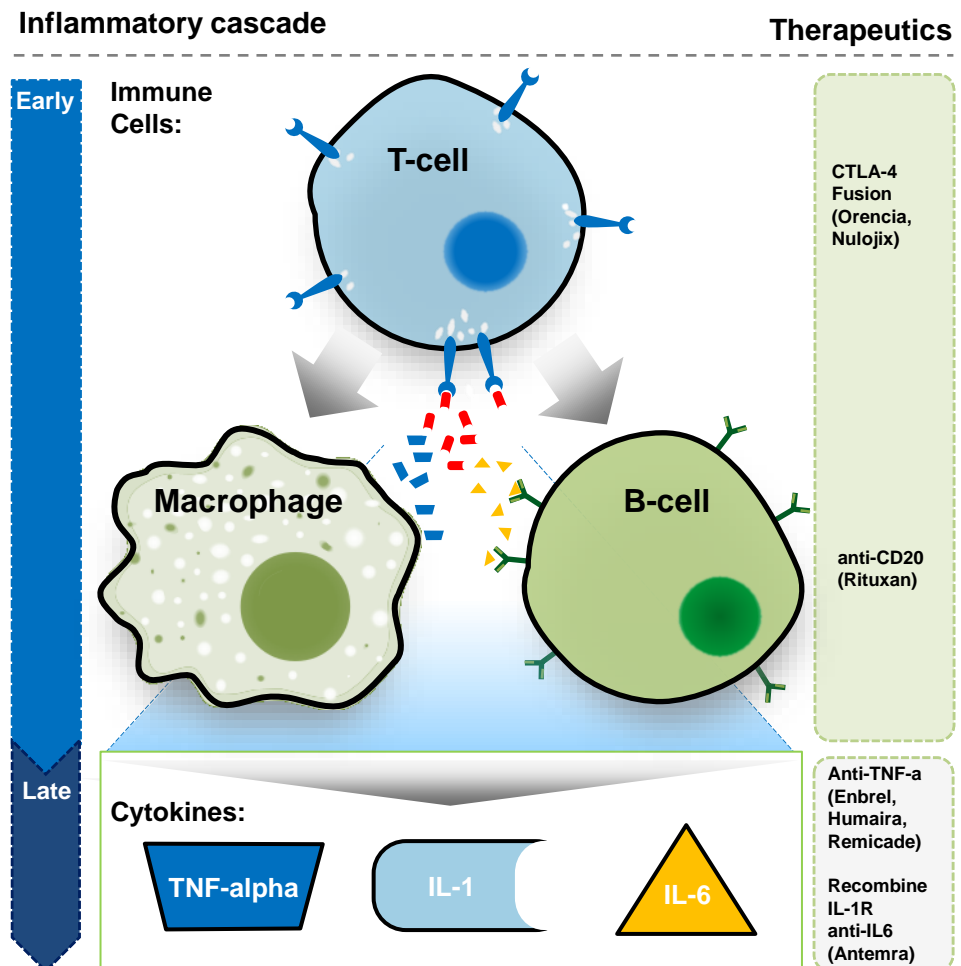


CTLA-4-Fusion Proteins : Immunosuppressant Drugs

Overview of CTLA-4-Fusion Proteins

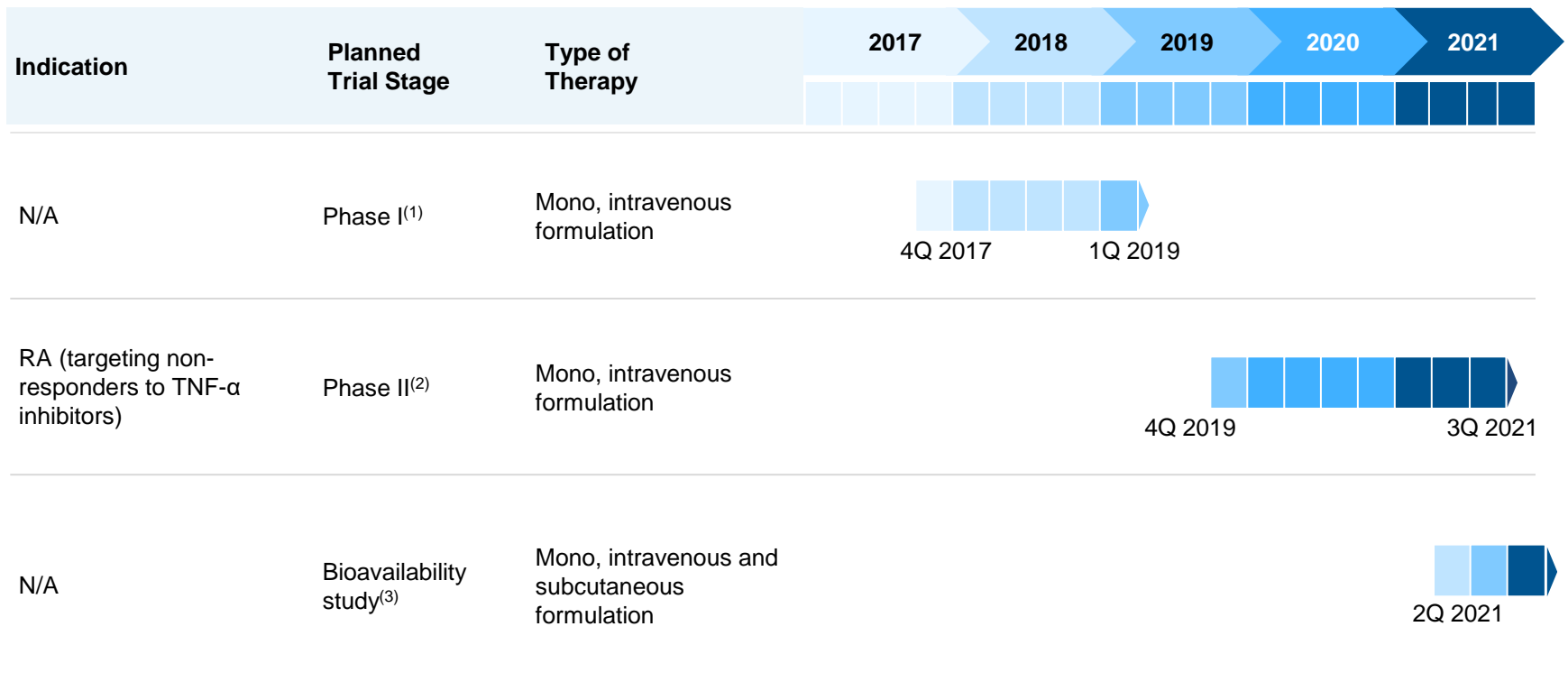
- Function in the early stage of T-cell activation and may achieve efficient global downregulation of unwanted immune responses
- Clinically-validated for treatment of RA, idiopathic arthritis, psoriatic arthritis and prophylaxis of organ rejection after kidney transplant outside China
- Potentials to become a **supportive therapy for o mitigate IO treatment–induced immune disorders** (*N Engl J Med* 2019; 380:2377-2379)
- Approx. **100,000 patients** suffering below immune disorders in China without effective treatment
 - IrAEs in patients treated with immune checkpoint inhibitor therapy
 - Severe cytokine release syndrome (CRS) due to massive cytokine release by certain cell therapies (CAR-T and TCR-T) and CD3 agonists
 - Graft-versus-host diseases during leukemia treatment

Major Lymphocytes and Signals for Activation & Maintenance of Immune Response



KN019 – Targeted Clinical Strategy

Clinical Development Plan (China)



Notes:

1. A double-blinded, placebo-controlled dose-escalation trial in healthy subjects
2. A multi-center, open-label, single arm clinical trial
3. Abbreviations: mono = monotherapy
4. A bioavailability study in healthy subjects to switch the administration of KN019 from intravenous formulation to subcutaneous formulation

Preliminary Plan for Medical Conferences

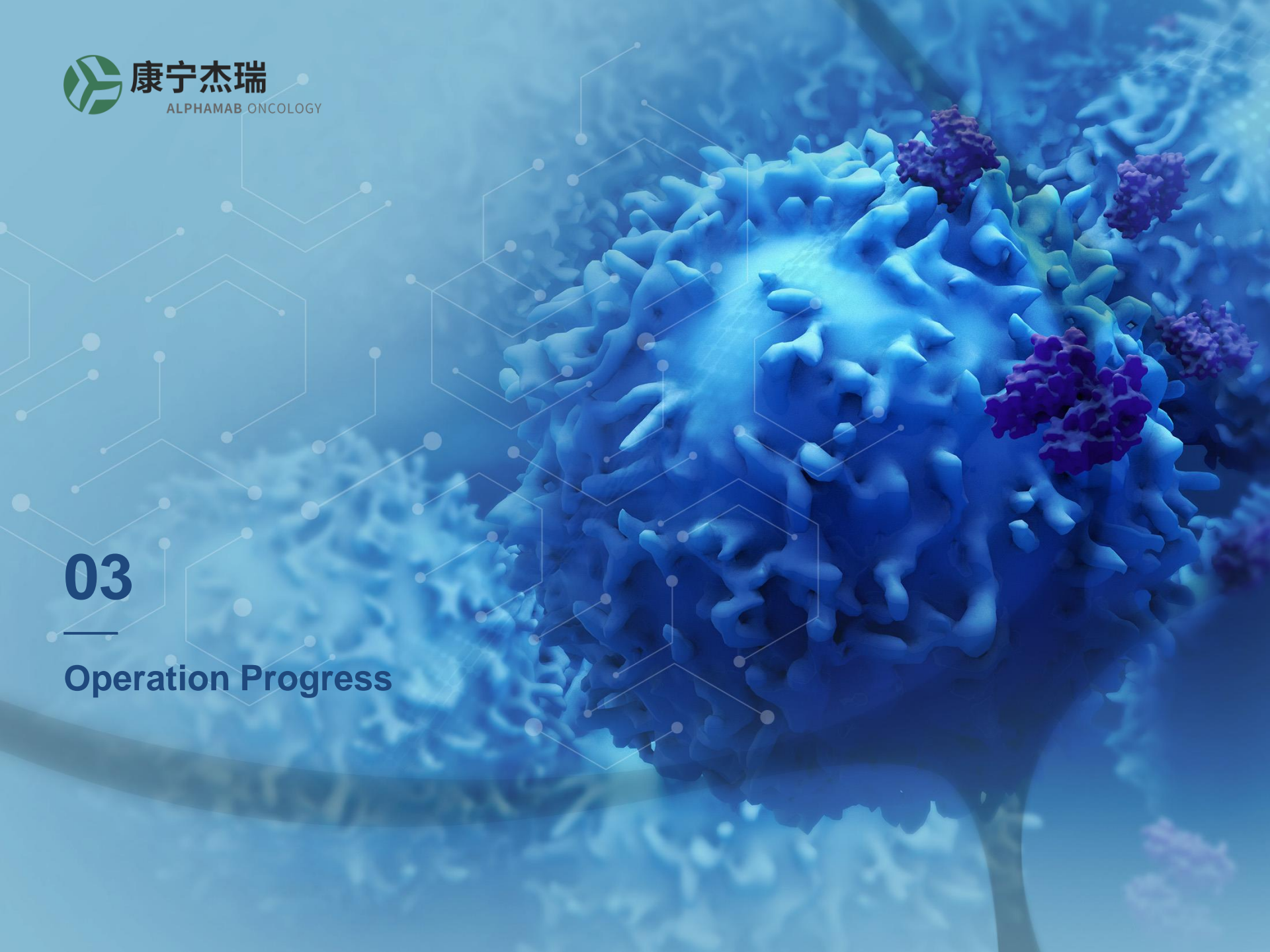
Year	Month	Conference	Title
2021	January	 Gastrointestinal Cancers Symposium	KN046-IST-01 ESCC (CRT)
2021	January	 2020 World Conference on Lung Cancer Singapore	KN046-201 2L NSCLC
			KN046-AUS-001 Thymic cancer
2021	April	 American Association for Cancer Research	KN046-203 TNBC
2021	June		KN046-202 1L NSCLC
			KN026-202 GC
			KN026-203 KN046+KN026 in HER2-positive solid tumors
2021	September		KN046-204 ESCC

Note:

1. Essay must be accepted for submission
2. The results of clinical trials can not be predicted
3. 2020 WCLC conference is postponed to 2021, January
4. The preliminary plan for medical conferences is potentially subject to change

03

Operation Progress




Business Development : comprehensive combo strategy

..to unlock KN046's full potential

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

Business Development : strong potential MNC interest in KN026

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

Target	Combo Drug	Partner
CDK4/6	Ibrance® (palbociclib)	
Microtubule inhibitor	Taxotere® ⁽³⁾ (Docetaxel)	

Notes:

1. Herceptin's label only covers Her-2 High, about 25% of breast cancer patients. While total Her-2 High, Midium and Low is about 80% of patients
2. Herceptin's label only covers Her-2 High, about 10-18% of gastric cancer patients. While total Her-2 High, Midium and Low is about 40% of patients
3. Sanofi has an exclusive option agreement for the strategic collaboration to advance clinical studies investigating KN026

Further expansion of management team



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

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



Further expansion of management team (cont'd)



Vice President, Quality Weidong Ma

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



Further expansion of management team (cont'd)

Vice President, Business Development, Kathy Yu, MD, MBA



- Over fifteen years of industry experience in business development and strategic planning
- Served various positions in a number of pharmaceutical companies including Merck Serono, Pfizer, UCB and Novartis
- Led important licensing, co-development and co-commercialization projects, and also has experience in managing Joint Venture collaboration and post-acquisition integration
- Doctor degree in Clinical Medicine from Peking Union Medical College, Master degree in Business Administration from Rutgers University



Further progress in manufacturing

Jiangsu Alphamab's New Manufacturing Facilities' Phase I production lines Have Received "Drug Production License"

Alphamab Oncology announced the Phase I (2x2,000L) production lines of its new manufacturing facilities has obtained "Drug Production License" by Jiangsu Provincial Drug Administration.

The new manufacturing facility has a designed total capacity over 30,000L



05

Q&A

