



# Corporate Presentation

April 2024

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This presentation includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties as well as our own estimates of potential market opportunities. All of the market data used in this presentation involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data. Industry publications and third party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Our estimates of the potential market opportunities for our product candidates include several key assumptions based on our industry knowledge, industry publications, third party research and other surveys, which may be based on a small sample size and may fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, and management is responsible for the accuracy of such assumptions and data, no independent source has verified such assumptions.


















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## Who We Are



*Our Mission is to Transform Deadly Cancer into a Chronic and Eventually Curable Disease*

Synergistic Asset Portfolio		Global Footprint		World Class Management	Strong External Collaboration
6	3	2	~ 90	100+ Years	MNCs and Big Pharma
Drug Candidates	Clinical Assets Including One Phase 3 asset with First-to-Market Potential	R&D Centers in U.S. & China	Dedicated R&D Scientists	Cumulative Industry Experience	<div></div> <div></div> <div></div> <div></div> <div></div>
AN2025	15+	Countries for Trials Led by World-Renowned Principal Investigators (“PI”)		<div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div>	Financial Position
Phase 3 recurrent/metastatic HNSCC after anti-PD-1/PD-L1 therapy: ✓ Potentially first-to-market ✓ Most advanced drug candidate by at least THREE years ✓ Fast Track Designation from FDA	250+	Patents and Patent Applications			Cash, cash equivalents and marketable securities \$112mm as of Mar 31 <sup>st</sup> , 2024
Strong Proof of Concept (“PoC”) Data Laying Concrete Foundation for Potential Registration					Runway into 2H 2025



**Yang (Carsten) Lu, EMBA**  
CEO & Chairman





**Lars E. Birgersson, M.D./Ph.D.**  
U.S. President, CMO & U.S. CEO





**Archie Tse, Ph.D.**  
Head of Research & Development





**Kaiyang (Tom) Tang, M.D., MBA**  
SVP & Global Head of Clinical Operations





**Victoria Demby, Ph.D.**  
SVP & Global Head of Regulatory Affairs





**Wei (Vicky) Zhang, M.Sc.**  
Chief Financial Officer





**Nanhai He, Ph.D.**  
VP of Drug Discovery





**Shifeng Liu, Ph.D.**  
Head of CMC, Preclinical Research





**Zhiyong Yu, Ph.D.**  
VP of Operations







**Alex Ye, Ph.D.**  
VP of Global BD



 Denotes management with extensive global commercialization and regulatory communication experience

	Product	MOA	Indication	Discovery	IND Enabling	Phase 1a	Phase 1b	Phase 2	Phase 3	Upcoming Milestone	Partner	Licensors	Licensee
Clinical Stage	AN2025 (buparlisib)	pan-PI3K	HNSCC 2/3L (+paclitaxel)							OS expected in Q4'24 or Q1'25			   <sup>(1)</sup>
			PIK3CA mutant solid tumors 2/3L (+Tecentriq®+AN0025)							Clinical update in Q2'24			
	AN0025 (palupirant)	EP4	TNBC, NSCLC, UC, CC and MSS CRC 2/3L (+Keytruda®)							Clinical update in Q2'24			
			LA EC (+CRT)							Clinical update in Q2'24			
			Neoadj RC (+CRT)							FPI in Apr 24	 		
			Stage 3 NSCLC (+CRT)							FPI in Q2'24			
	AN4005	Small molecule PD-L1	Advanced tumors							Clinical update in Q2'24			
Preclinical Stage	AN8025	Multi-functional T cell/APC modulator	Advanced tumors							IND expected in H1'25			
	AN9025	pan-KRAS	Advanced tumors							PCC expected in Q2'24			
	AN1025	β-catenin degrader	Advanced tumors										

Abbreviations: MOA = mechanism of action; OS = overall survival; TNBC = Triple Negative Breast Cancer; NSCLC = Non-Small Cell Lung Cancer; MSS CRC = Microsatellite Stable Colorectal Cancer; UC = Urothelial Cancer, CC = Cervical Cancer; RP2D = Recommended Phase 2 Dose; RC = rectal cancer; LA = locally advanced; EC = esophageal cancer; FPI = first patient in; IND = Investigational New Drug; PCC = Pre-Clinical Candidate.

(1) In April 2023, Adlai Nortye entered into an option agreement to grant Nippon Kayaku an exclusive option to enter into a license agreement to further develop and commercialize products containing AN2025 in all therapeutic, prophylactic and/or diagnostic uses in humans in Japan, pending certain conditions being met.



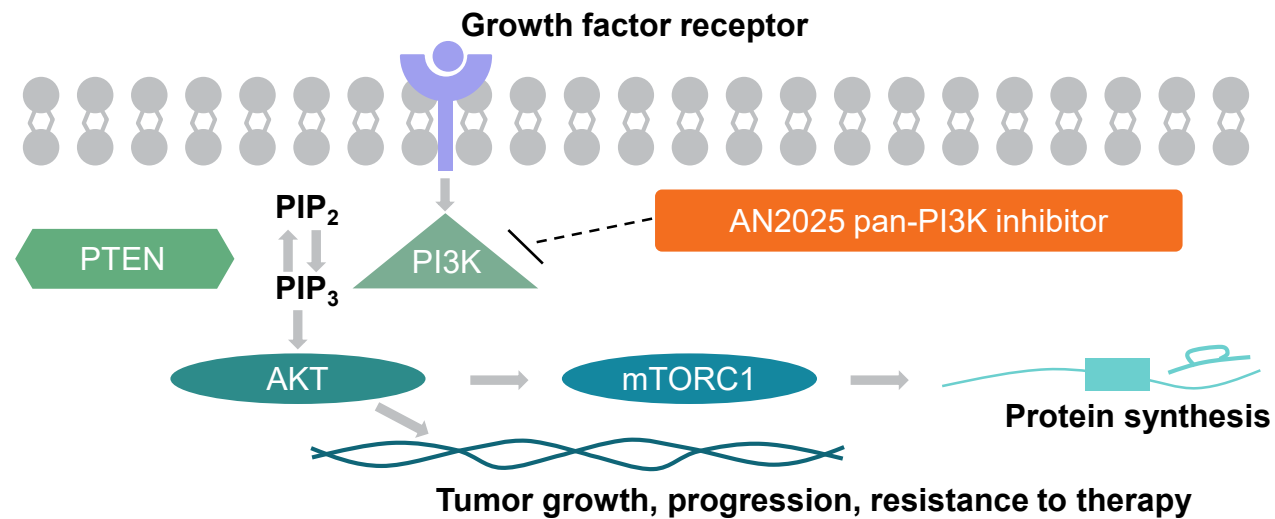
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## **AN2025: Market, Clinical and Regulatory Updates**

## PI3K $\alpha$ and PI3K $\beta$ in Tumorigenesis

- Regulates functions such as cell growth, proliferation, cell migration, and angiogenesis
- Widely implicated in cancer
- Promotes survival, proliferation, and migration of tumor cells

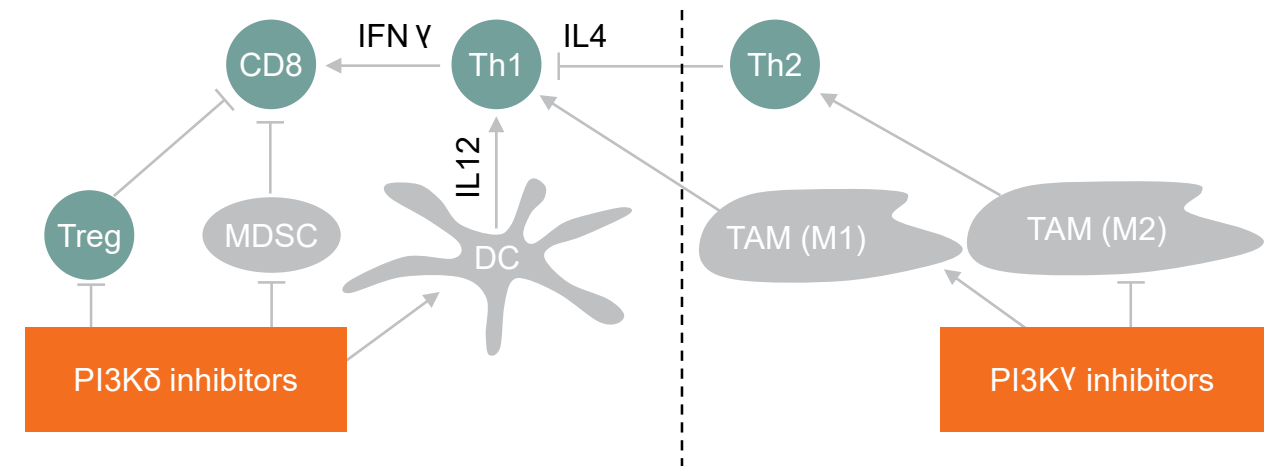
## Mechanism of Action



## PI3K $\delta$ and PI3K $\gamma$ in Immunity

- Other isoforms of Class I PI3Ks, i.e., PI3K $\delta$  and PI3K $\gamma$ , play important roles in immune systems
- PI3K $\delta$  is well established to control the function and integrity of regulation T cells
- PI3K $\gamma$  and PI3K $\delta$  help recruit suppressive myeloid cells into tumor microenvironments and strengthen their inhibitory effects on anti-tumor T cell immune responses

## Mechanism of Action





## Market Opportunities – r/m HNSCC after anti-PD-1 / PD-L1 therapy

### r/m HNSCC in 2028

**32,000** U.S. Incidence<sup>(1)</sup>

**89,000** 7MM Incidence<sup>(1)</sup>

### r/m HNSCC after anti-PD-1 / PD-L1 therapy

**15,000+** U.S. Incidence<sup>(1)</sup>

**50,000+** 7MM Incidence<sup>(1)</sup>

Fast track designation from FDA based on positive data  
from a randomized Phase 2 BERIL-1 study

## Current Treatment Paradigm

Preferred regimens for recurrent or metastatic head and neck cancers

### First-line:

- Pembrolizumab/platin (cisplatin or carboplatin)/5-FU (category 1)
- Pembrolizumab (for tumors that express PD-L1 with CPS $\geq$ 1) (category 1)

*(NCCN Guidelines Version 2.2024)*

Keytruda® +/- chemo prevails in 1L HNSCC since 2019<sup>(2)</sup>, no clinically approved therapies currently available for r/m HNSCC after anti-PD-1/PD-L1 therapy

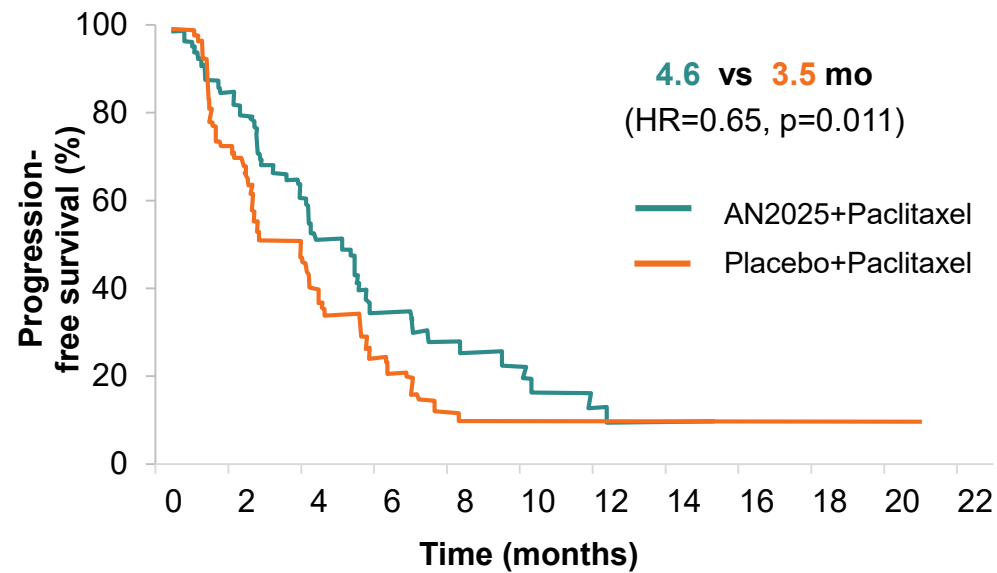
About 85% patients experience disease progression after immunotherapy

Abbreviation: r/m = refractory and metastatic.

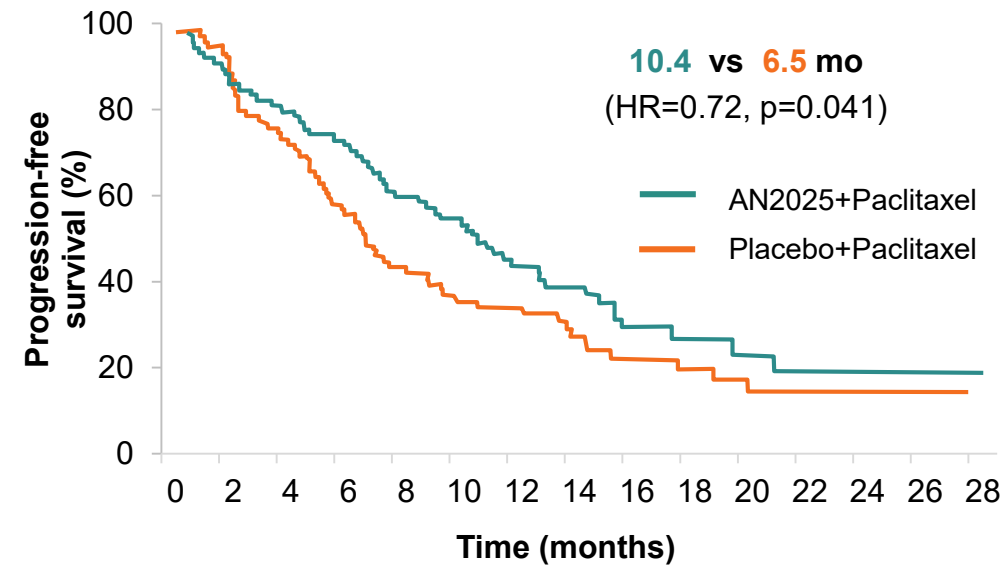
(1) Pharma Intelligence Disease Analysis of HNSCC by Informa, 2022. 7MM stands for seven major markets (the U.S., the U.K., Germany, France, Italy, Spain, and Japan).

(2) FDA approval on June 10, 2019.

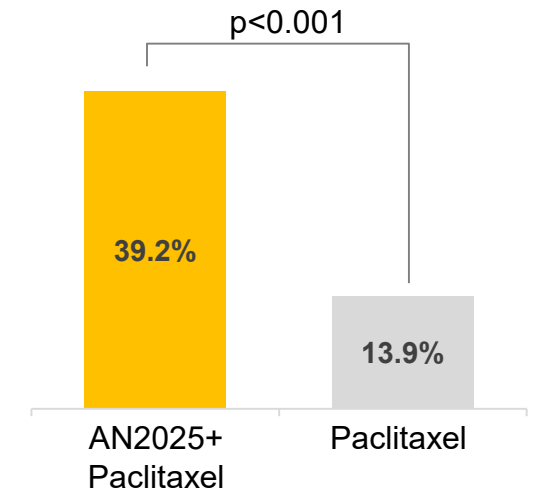
## PFS: AN2025 + Paclitaxel vs. Paclitaxel



## OS: AN2025 + Paclitaxel vs. Paclitaxel



## Overall Response Rate (“ORR”)



## A randomized, double-blind, placebo-controlled Phase 2 trial (BERIL-1)

### Major Inclusion:

- Platinum-pretreated r/m HNSCC
- ECOG 0/1

### Primary Endpoint:

- PFS

### Secondary Endpoints:

- OS ORR, DoR
- TTR, DCR, HRQoL

Randomized

N=79

**AN2025 100mg/day + Paclitaxel 80mg/m<sup>2</sup>/week in a 28-day treatment cycle**

N=79

**Placebo + Paclitaxel 80mg/m<sup>2</sup>/week in a 28-day treatment cycle**

## Key Take-Away Messages

- 1 Similar tolerance of AN2025 plus paclitaxel compared to paclitaxel
- 2 Similar discontinuation rate of AN2025 plus paclitaxel compared to paclitaxel
- 3 The frequency of hyperglycemia was higher with AN2025 plus paclitaxel versus paclitaxel, suggesting effective PI3K pharmacodynamics inhibition
- 4 Known adverse events (“AEs”) associated with AN2025 are manageable

## Top 15 Key AEs in the Study

Key AEs	AN2025 + Paclitaxel N=76			Placebo + Paclitaxel N=78		
	Grade 1-2	Grade 3	Grade 4	Grade 1-2	Grade 3	Grade 4
Hyperglycemia	41%	22%	0	32%	3%	0
Anaemia	22%	18%	0	31%	12%	0
Fatigue	33%	8%	0	12%	10%	0
Diarrhea	37%	1%	0	15%	1%	0
Neutropenia	16%	16%	1%	6%	4%	1%
Alopecia	32%	0	0	19%	0	0
Stomatitis	22%	9%	0	12%	1%	0
Decreased appetite	24%	7%	0	14%	5%	0
Asthenia	20%	8%	0	18%	4%	0
Nausea	24%	3%	0	17%	0	0
Vomiting	22%	4%	0	14%	0	0
Decreased bodyweight	25%	0	0	9%	3%	0
Cough	21%	0	0	23%	0	0
Constipation	18%	0	0	10%	0	0
Headache	17%	1%	0	8%	0	0

Source: Soulières et al., 2017.

Note: For the complete list of AEs observed in the study, please refer to Appendix A.

The BURAN study is a randomized, open-label Phase 3 study assessing the treatment effect of once-daily AN2025 in combination with weekly paclitaxel compared to weekly paclitaxel alone in patients with r/m HNSCC that have progressed after:

1. Prior anti-PD-L1 monotherapy;
2. Prior anti-PD-L1 therapy in combination with platinum-based therapy; or after
3. Sequential treatment of anti-PD-L1 therapy, either prior to or post platinum-based therapy

## Study Design:

### Major Inclusion:

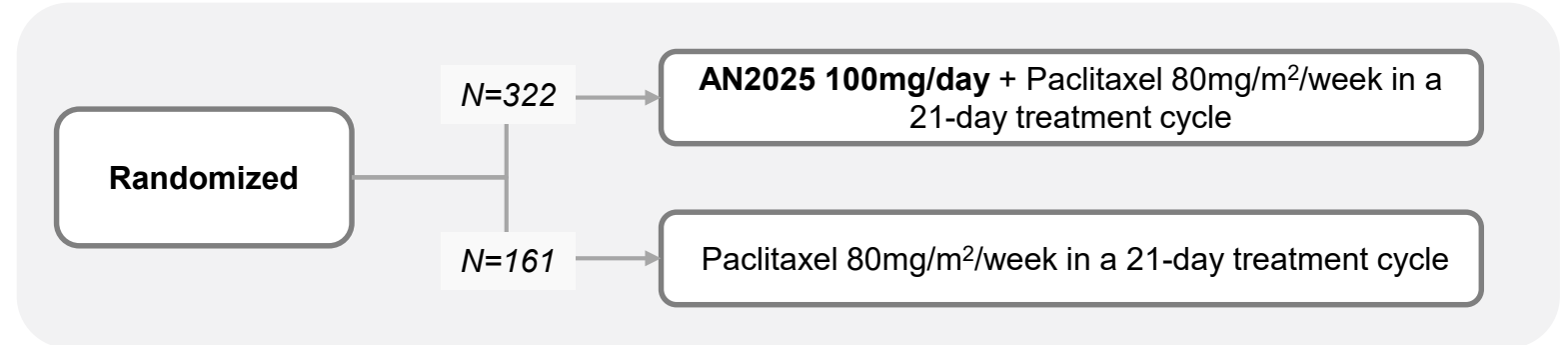
- PD-L1-pretreated r/m HNSCC
- ECOG 0/1

### Primary Endpoint:

- OS

### Secondary Endpoints:

- PFS, ORR
- DoR, HRQoL



## Clinical Trials led by Globally Renowned Principal Investigators (“PIs”)



**Prof. Denis Soulières**

Lead PI of BERIL-1 for AN2025 and KEYNOTE-048 for Pembrolizumab



**Prof. Lisa Licitra**

Lead PI of BERIL-1 for AN2025 and KEYNOTE-048 for Pembrolizumab



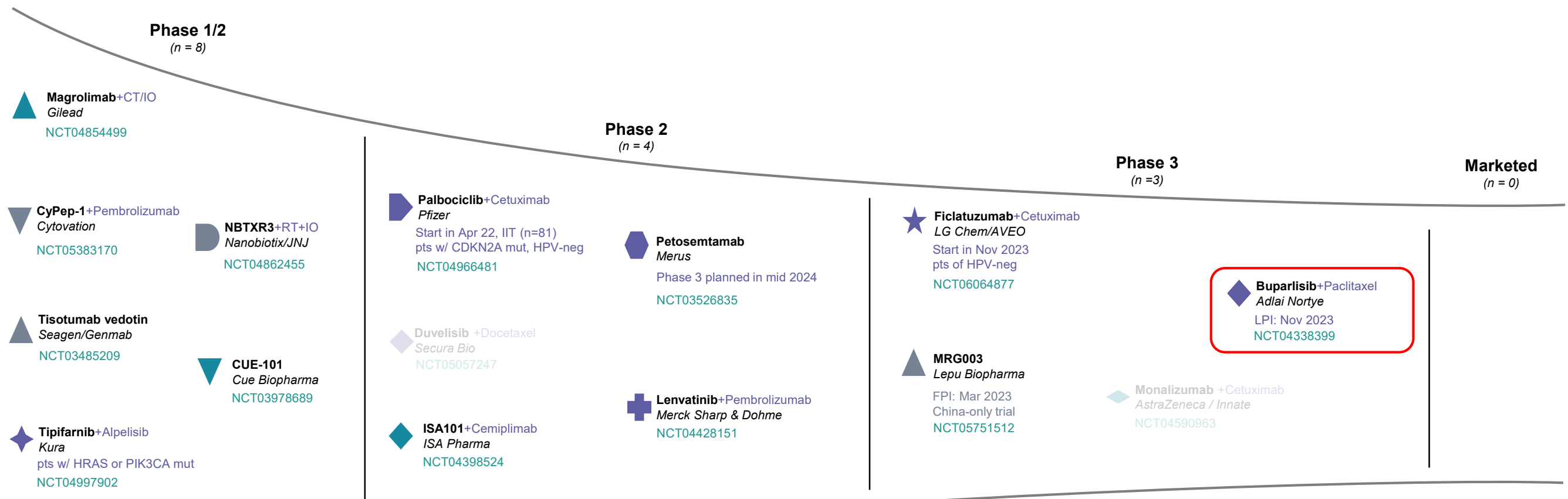
**Prof. Barbara Burtress**

Lead PI of KEYNOTE-048 for Pembrolizumab





AN2025 is the most advanced drug candidate in a Phase 3 trial of r/m HNSCC after PD-1/PD-L1 therapy, an unmet medical need with a sizable market



Legend – Mechanisms of Action				
Targeted Therapies		Cancer Immunotherapy		Other Therapies
◆ FTIs	✚ Multiple tyrosine kinase inhibitor	◆ anti-NKG2A	◆ Cancer vaccine	▲ Antibody-drug conjugate
▮ CDK inhibitor	◆ PI3K inhibitor	▮ IL-2/HPV-16 E7	◆ LAG-3/PD-L1 BsAb	▮ Radio enhancer
▮ EGFR/LGR5 BsAb	▮ STAT3 & IRS1/2 inhibitor	▲ anti-CD47		▮ Membrane destabilizer
★ Anti-HGF/c-MET				

Sources: clinicaltrials.gov, Informa, public filings, and company presentations.  
Note: Faded out molecules are no longer in active clinical development.  
Abbreviations: CT = chemotherapy; RT = radiotherapy; pts = patients; neg = negative, FPI = first patient in; LPI = last patient in.

## AN2025 – Key Highlights

### FIRST-TO-MARKET

- Potentially the first on-label drug globally for r/m HNSCC after anti-PD-1/PD-L1 treatment
- Sizable TAM after anti-PD-1/PD-L1 therapy becoming primary treatment since approval of Keytruda® as first-line therapy for r/m HNSCC in 2019

### CLEAR CLINICAL PATH

- Fast track designation from FDA
- Solid Phase 2 clinical PoC data

## Robust Clinical Development

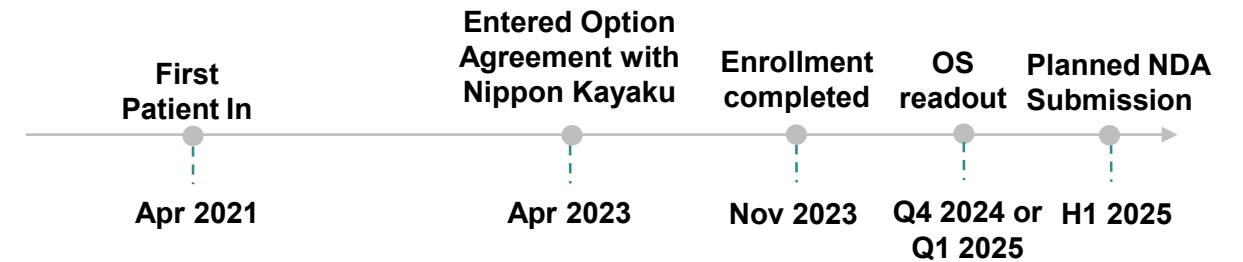
Clinical Phase	Host	Indication	# of Patients	Trial Status
Phase 2 (NCT01852292)	NOVARTIS	r/m HNSCC (after platinum-based chemotherapy)	158	Completed
Phase 3 (NCT04338399)	Adlai Nortye	r/m HNSCC (after anti-PD-1/PD-L1 treatment)	487	Active, not recruiting



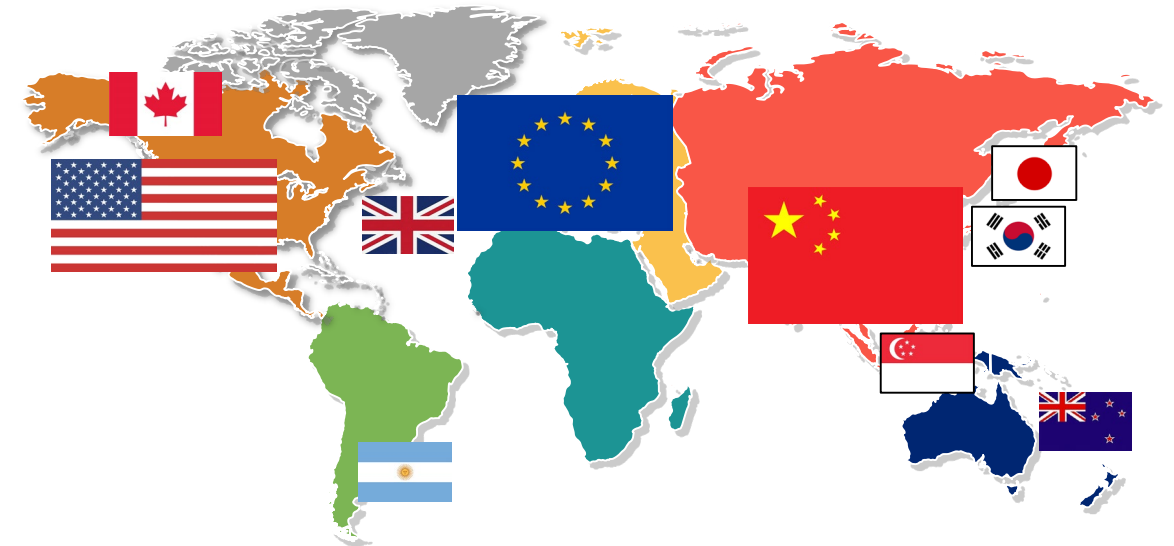
- Clinical trials in Japan will be conducted by Adlai Nortye
- Regulatory pathway in Japan will be managed by Nippon Kayaku



## HNSCC Global Phase 3



Multi-Regional Clinical Setting with patients to be enrolled in approximately 180 clinical trial sites in the U.S., Canada, UK, Spain, Italy, Germany, France, Poland, Hungary, Belgium, Russia, mainland China, Hong Kong, Taiwan, Japan, South Korea, Australia, and Argentina

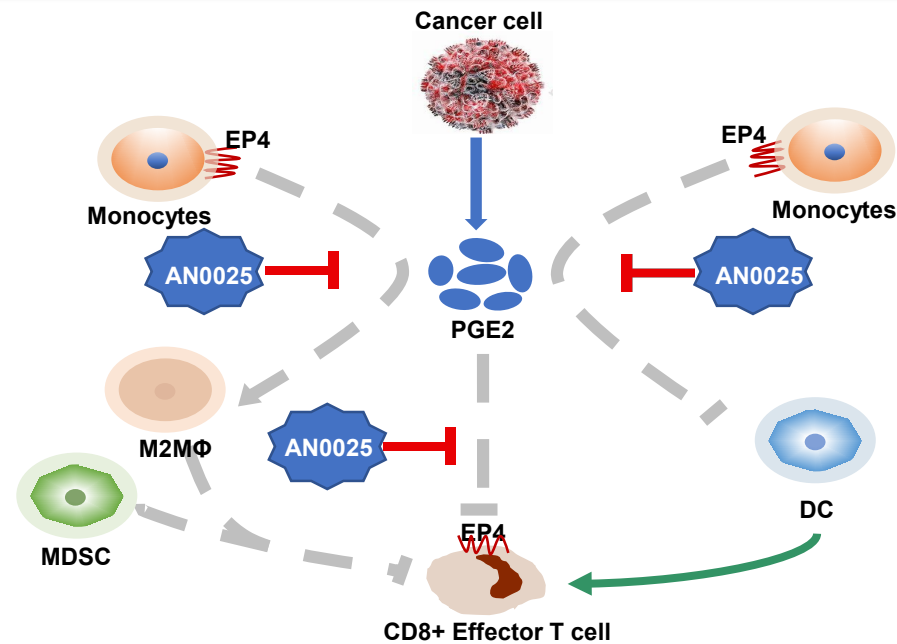




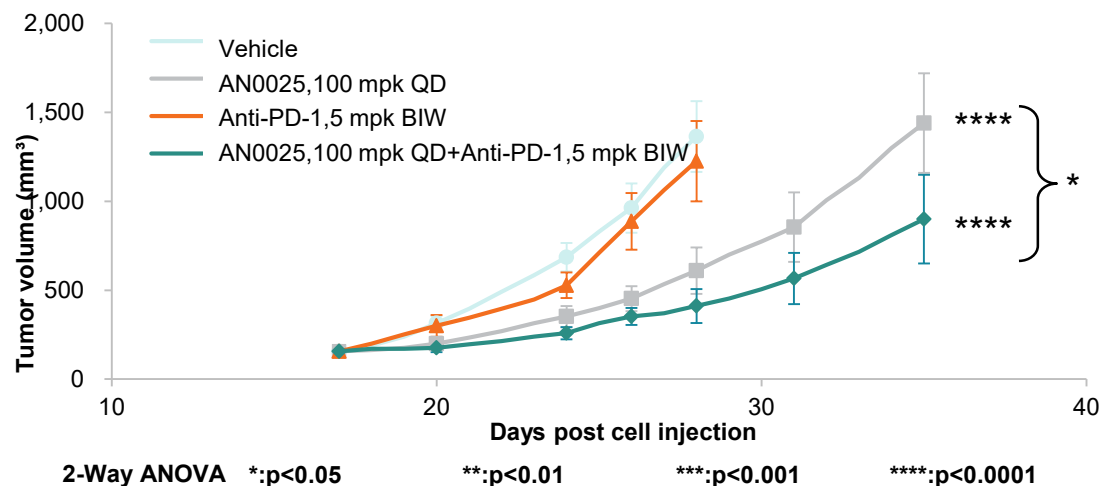
## Our Pipeline:

### Earlier Stage Clinical Assets

## Mechanism of Action



## AN0025 + anti-PD-1 in CT26 model



## AN0025 + anti-PD1 in Advanced Solid Tumors

An open-label basket Phase 1b trial:

### Main inclusion criteria:

- Locally advanced, non-resectable or metastatic
- ECOG 0/1

### Primary endpoints

Safety and tolerability

### Secondary endpoints:

ORR, PFS, DoR, OS



NSCLC



Urothelial Carcinoma



TNBC



Cervical Cancer



MSS CRC

Progressed on anti-PD-1/PD-L1 treatment

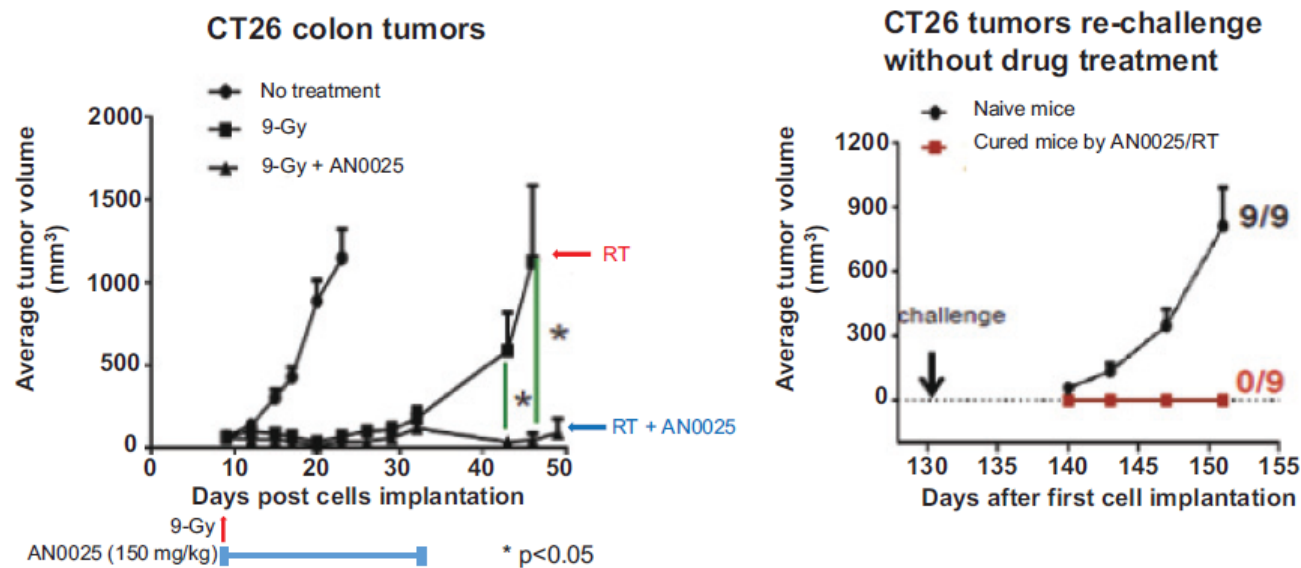
Progressed on SoC, no prior anti-PD-1/PD-L1 treatment

- ✓ All enrolled patients will be treated with AN0025 and Keytruda until the patient experiences disease progression, unacceptable toxicity or withdraws consent, or for a maximum of 35 cycles
- ✓ Currently in cohort expansion stage
- ✓ Clinical results will be presented in Q2 2024



## AN0025 + Chemoradiotherapy (CRT) in locally advanced (LA) esophageal cancer (EC)

### AN0025 + RT in CT26 model



AN0025 combined with Radiotherapy demonstrated improved anti-tumor activity and prolonged survival, compared with each compound alone, and antitumor memory T-cell response in mice

### An open-label Phase 1b trial:

#### Main inclusion criteria:

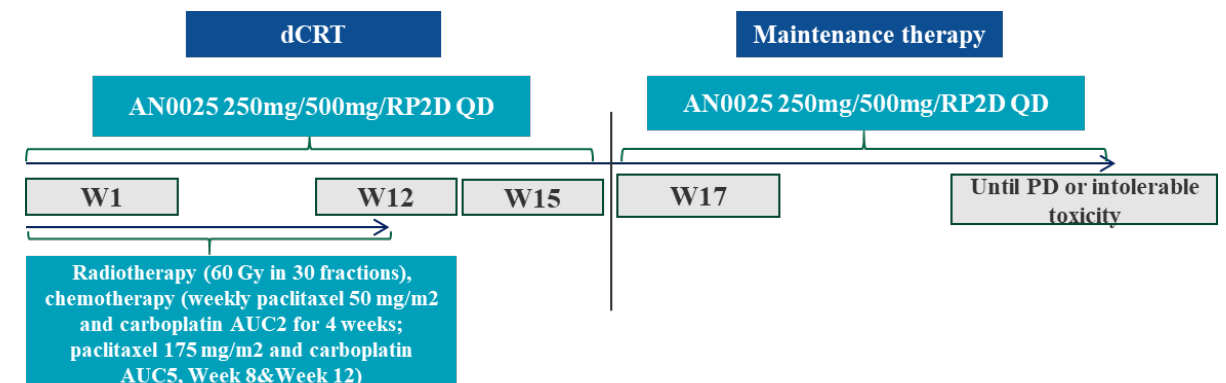
- Locally advanced/locally recurrent EC
- Clinical Stage 2 to 4a (8th AJCC), or Stage 4b
- Unresectable, no prior radiotherapy in the esophageal region

#### Primary endpoints

- Safety and tolerability
- MTD and/or RP2D

#### Secondary endpoints:

- Preliminary efficacy: ORR, DCR, PFS, DOR (RECIST 1.1), OS, PK



- ✓ Currently in cohort expansion phase
- ✓ Clinical results will be presented in Q2 2024

## Preoperative AN0025 + Chemoradiotherapy (CRT) in Rectal Cancer

### An open-label Phase 1b trial:

#### Main inclusion criteria:

- Locally advanced rectal cancer, no metastatic disease
- Primary resection without CRT is unlikely to achieve clear margins as defined by MRI

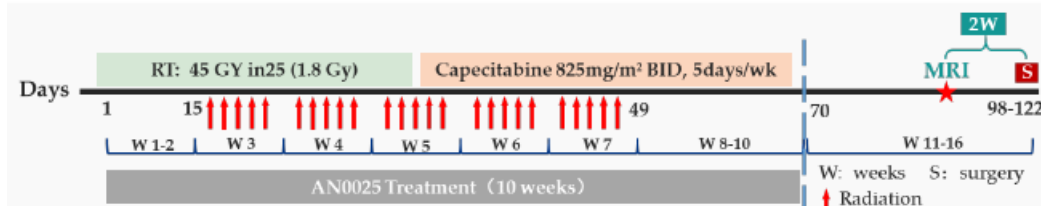
#### Primary endpoints

- Safety and tolerability
- MTD and/or RP2D

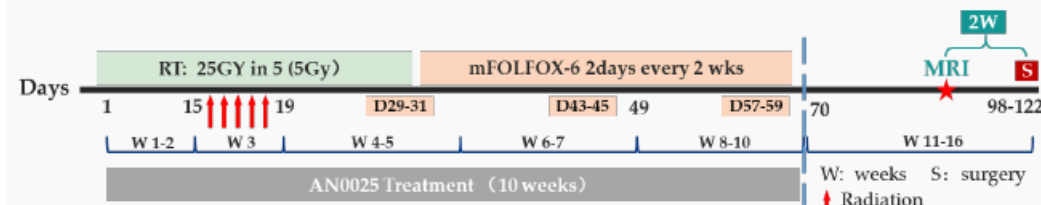
#### Secondary endpoints:

- pCR, CRM, pTRG, MRI-confirmed down staging in T stage, DFS, PK

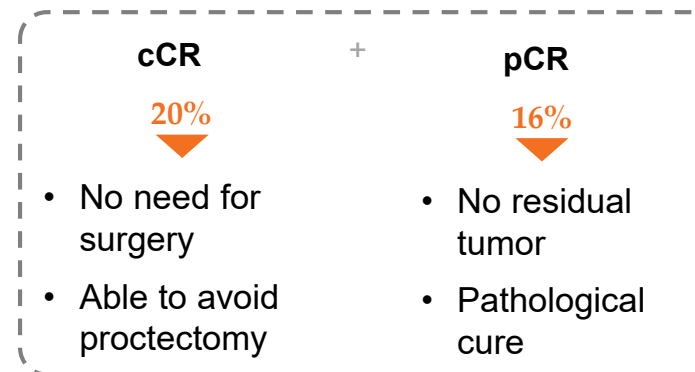
Long  
course



Short  
course



### Encouraging Preliminary Efficacy



Note: Based on 25 evaluable patients

### No DLTs Observed

TEAE	All Grade	≥Grade3
Any	19 (67.9%)	2 (7.1%)
Fatigue	8 (28.6%)	1 (3.6%)
Diarrhea	4 (14.3%)	1 (3.6%)
Nausea	3 (10.7%)	-
Decreased Appetite	3 (10.7%)	-
Headache	3 (10.7%)	-
Paresthesia	3 (10.7%)	-

Note: Only listing TEAEs that occurred in >10% patients, N=28

- AN0025 was well tolerated in combination with CRT
- Preliminary efficacy results are encouraging and support the further development of AN0025 in combination with CRT in this indication

## Preoperative AN0025 + Chemoradiotherapy (CRT) in Rectal Cancer

### A Phase 2, open-label, randomized controlled trial (140 pts)

#### Main inclusion criteria:

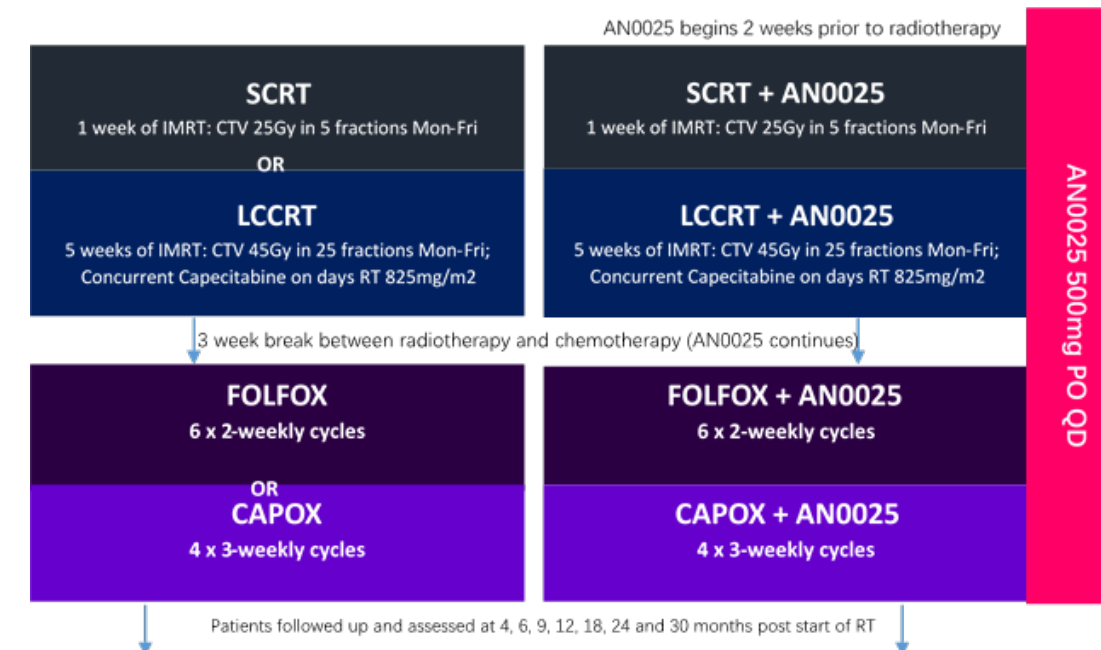
- Biopsy-proven rectal adenocarcinoma; ECOG PS 0-1
- T3b-4a or TanyN1-2 or TanyEMVI+ or with a threatened (<1mm) or involved mesorectal fascia resection margin, or low tumors with involvement of the anal intersphincteric plane or with levator involvement

#### Primary endpoints

- Clinical Complete Response rate at 6 months post start of RT

#### Secondary endpoints:

- Acute and late toxicity, HRQoL, surgical outcomes, response assessment, organ preservation, DFS, OS



LCCRT = long course chemoradiotherapy; SCRT = short course radiotherapy

### Study Information

- FPI expected in April 2024
- Collaborated with Leeds University, UK

### Market Opportunities – neoadjuvant Rectal Cancer

Neoadjuvant rectal cancer in 2028



19,000 U.S. Incidence<sup>(1)</sup>

50,000 7MM Incidence<sup>(1)</sup>

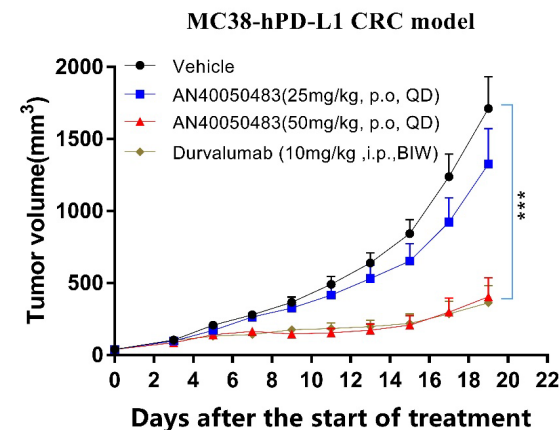
Abbreviation: EMVI = Extramural vascular invasion.

(1) Data from Informa, 2023. 7MM stands for seven major markets (the U.S., the U.K., Germany, France, Italy, Spain, and Japan).

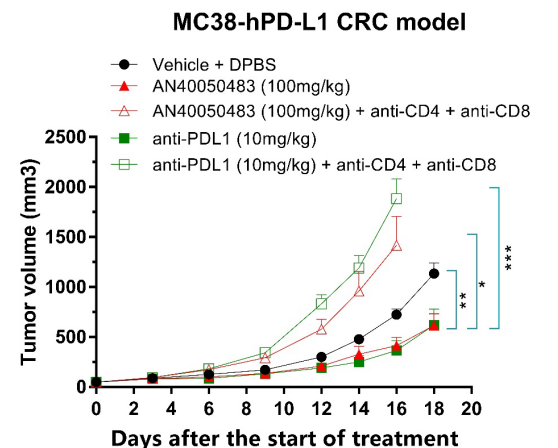
## AN4005 as a Backbone for Our Future Oral Combination Therapies

 <p><b>Market Opportunity</b></p>	<ul style="list-style-type: none"> <li>No small-molecule PD-L1 inhibitor approved in any jurisdiction globally</li> <li>Effectively induce and stabilize PD-L1 dimer formation/dimerization</li> </ul>
 <p><b>Benefits Over Antibodies</b></p>	<ul style="list-style-type: none"> <li>Opportunity for oral administration, improved tumor penetration, and lack of immunogenicity</li> </ul>

## Robust Activity in Tumor Models



P value was calculated using Independent Samples t Test  
\*:p<0.05 \*\*:p<0.01 \*\*\*:p<0.001



P value was calculated using Independent Samples t Test  
\*:p<0.05 \*\*:p<0.01 \*\*\*:p<0.001

## First-in-Human, Dose Escalation study of AN4005

### Main inclusion criteria:

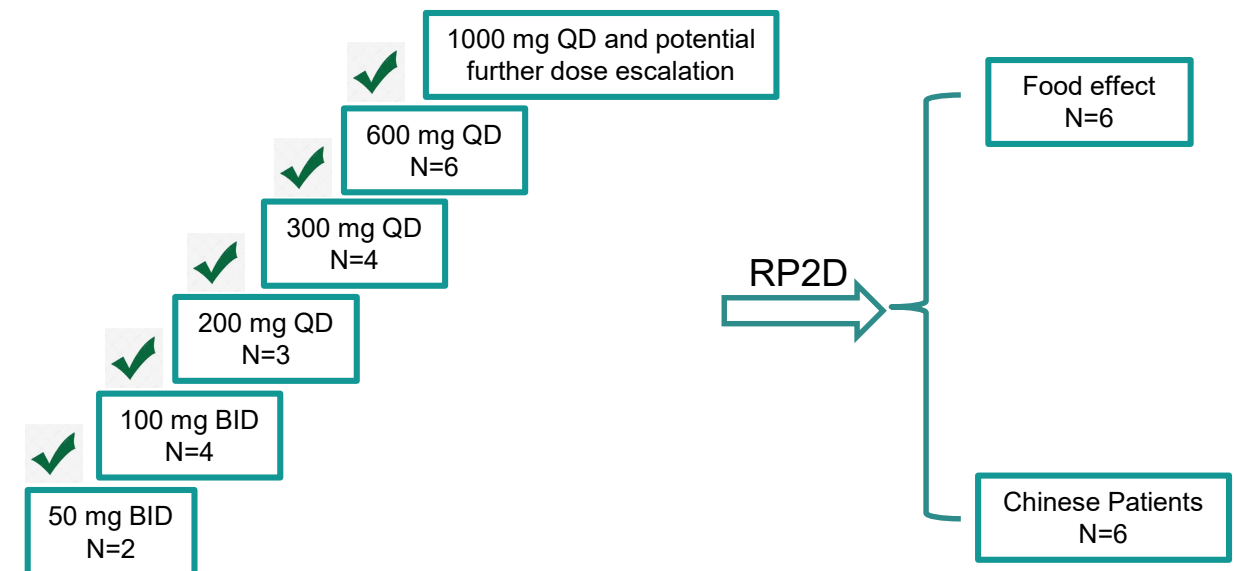
- Advanced unresectable or metastatic solid tumors, or r/r lymphomas
- No standard therapy available
- ECOG 0/1

### Primary endpoints

Safety, tolerability, MTD and/or RP2D

### Secondary endpoints:

PK, food effect, preliminary efficacy including ORR, PFS, DoR, OS



- ✓ As of February 2023, 24 eligible patients were enrolled in 6 dose levels in escalation part in the US and China
- ✓ No DLT observed to date
- ✓ Preliminary clinical efficacy was also observed
- ✓ Clinical update will be presented in Q2 2024



## Demographics and Baseline Characteristics

- 50-yr, Asian, female
- Diagnosed with Stage 4 colon adenocarcinoma with metastasis in peritoneum at baseline
- CPS 30%, MSI-H, KRAS p.G13D mutation, BRAF mutation

## Prior Treatment

- Prior surgery: Left colon extended radical resection
- Prior systemic therapy:
  - 1) XELOX as adjuvant treatment from Dec 2020 to Apr 2021 followed by one dose of XELOX plus Camrelizumab (an approved PD-1 antibody in China) on 8 May 2021
  - 2) Raltitrexed+Bevacizumab+Camrelizumab/Toripalimab (an approved PD-1 antibody in China) from Jun to Nov 2021 with BOR of PR and progressed in Aug 2022
  - 3) Envolimab (an approved PD-L1 antibody in China) from Sep to Nov 2022 with BOR of PR and progressed in Feb 2023

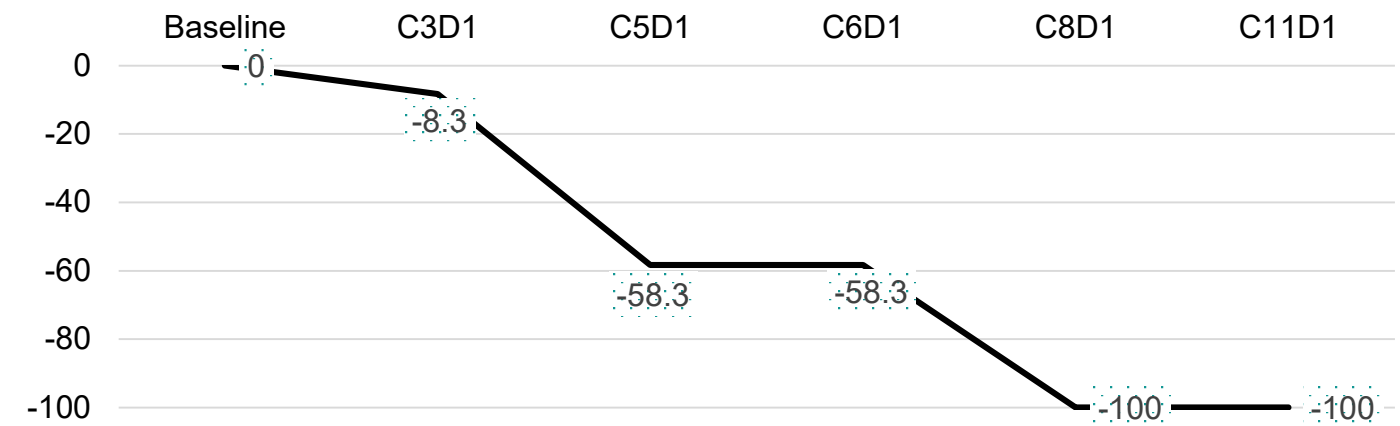
## AN4005 Treatment Course

- Single dose at 300mg on 10 Apr 2023
- Multiple doses at 300mg QD started from 17 Apr 2023, 28 days per cycle, is still on treatment (cycle 13)

## Tumor Assessment

	SLD (mm) (peritoneum)	Non-target lesion (colon)	New lesions	Overall response
Baseline	12	NA	NA	NA
1 <sup>st</sup> TA (C3D1)	11	Present	No	SD
2 <sup>nd</sup> TA (C5D1)	5	Present	No	PR
3 <sup>rd</sup> TA (C6D1)	5	Present	No	PR
4 <sup>th</sup> TA (C8D1)	0	Present	No	PR
5 <sup>th</sup> TA (C11D1)	0	Absent	No	<b>CR</b>

## %Change in SLD compared with that at baseline by RECIST 1.1

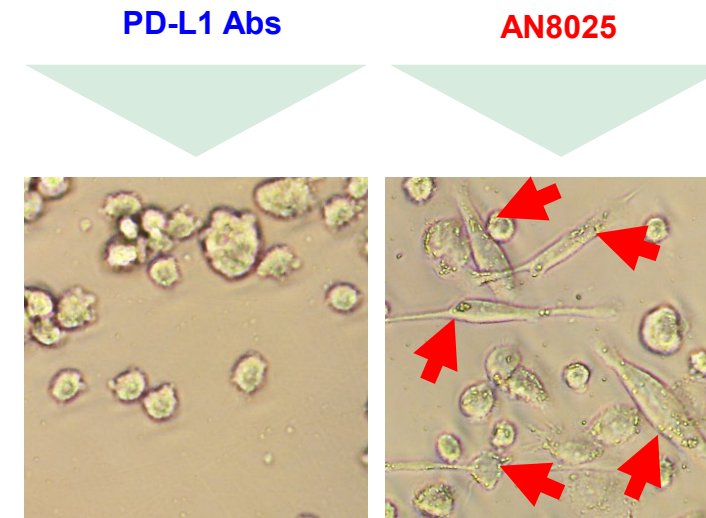
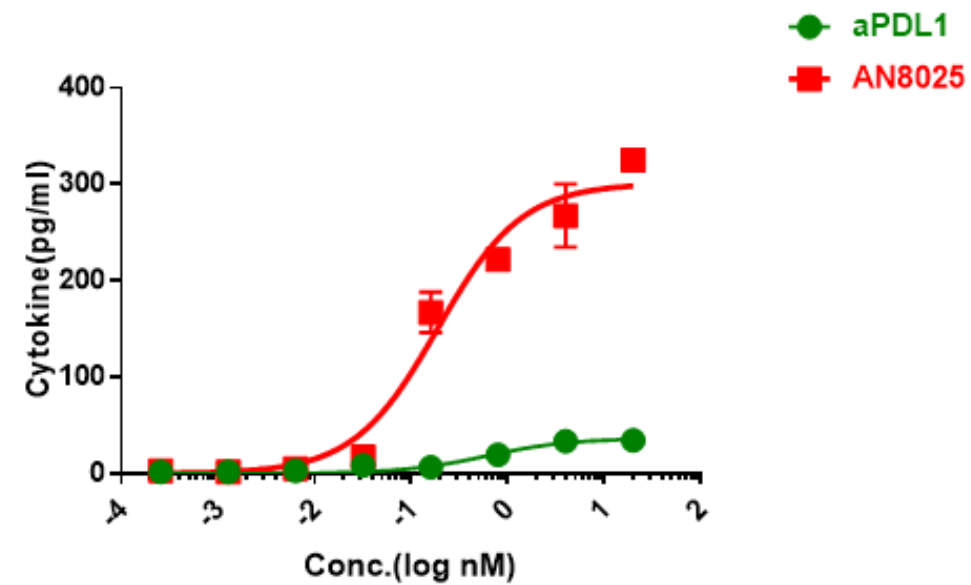




## Our Pre-clinical Pipeline:

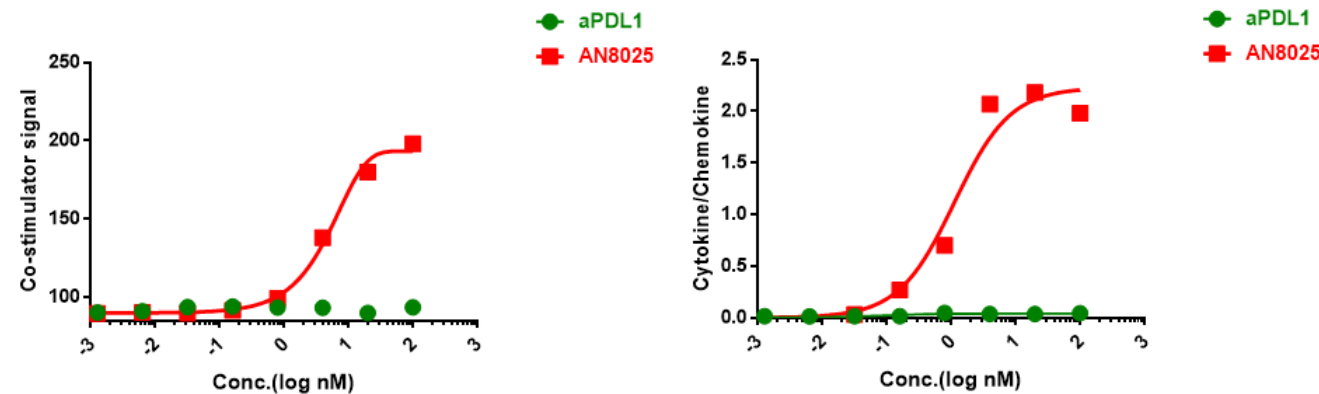
**Preclinical Assets with Near-Term INDs**

## AN8025's Ability to Induce Stronger T Cell Response than PD-L1 Antibody in Vitro

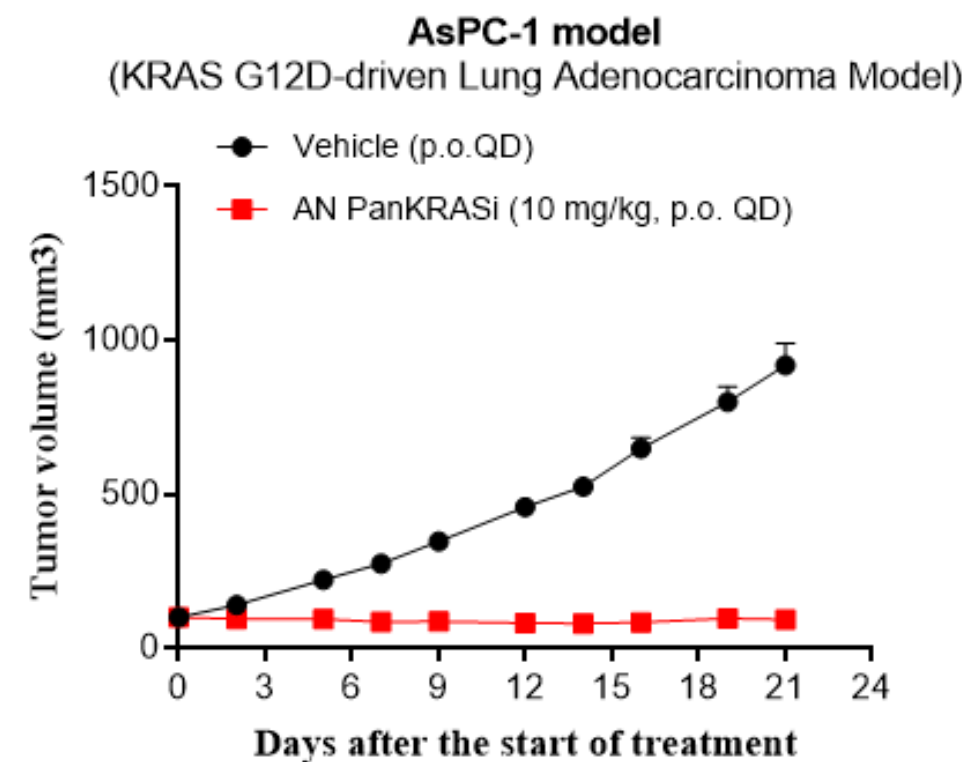
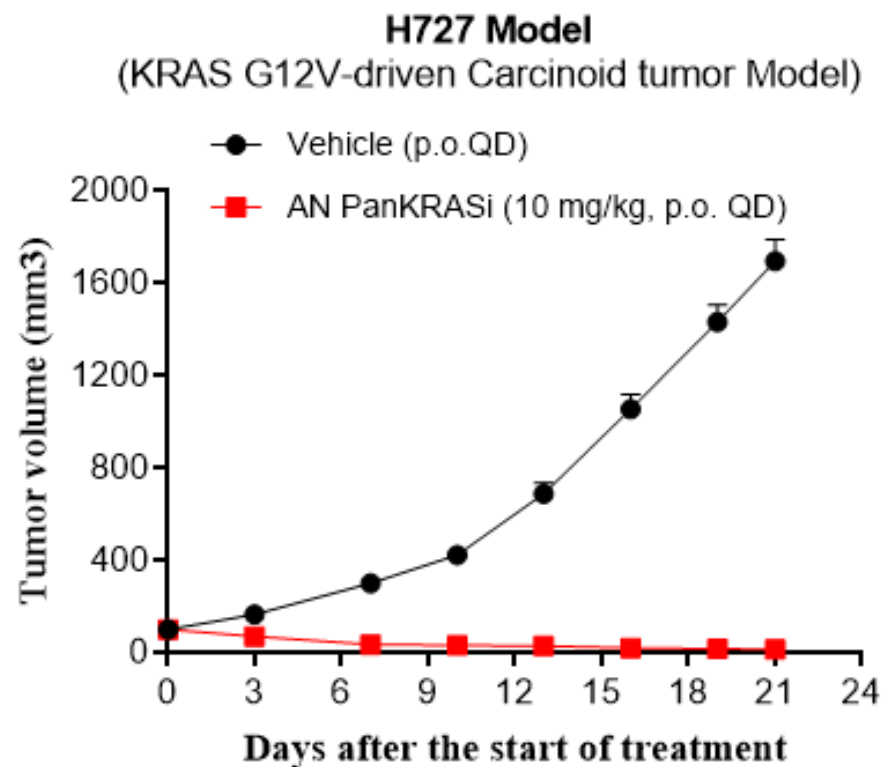


AN8025 improved the quantity and quality of antigen presenting cells

## AN8025's Ability to Fully Induce Immune Response in Vitro



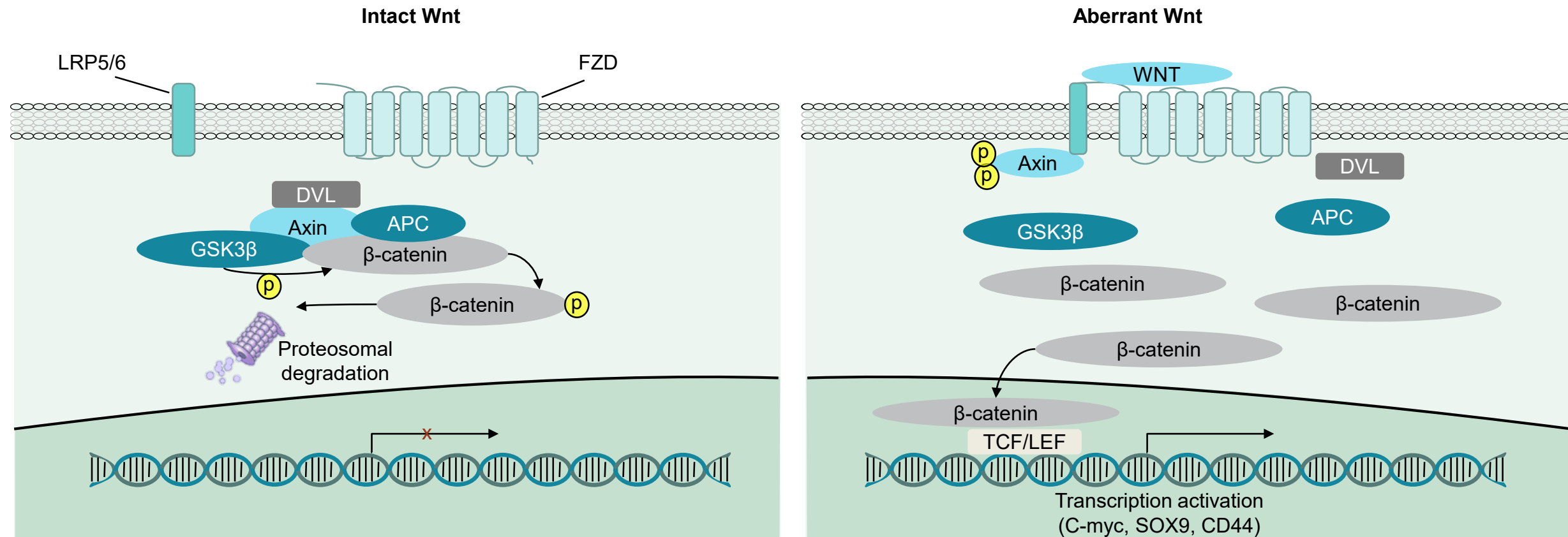
Compared to an anti-PD-L1 mAb, where almost no co-stimulation signals were detected, AN8025 showed significantly stronger co-stimulation signals, which represented enhanced interactions between T cells and APC



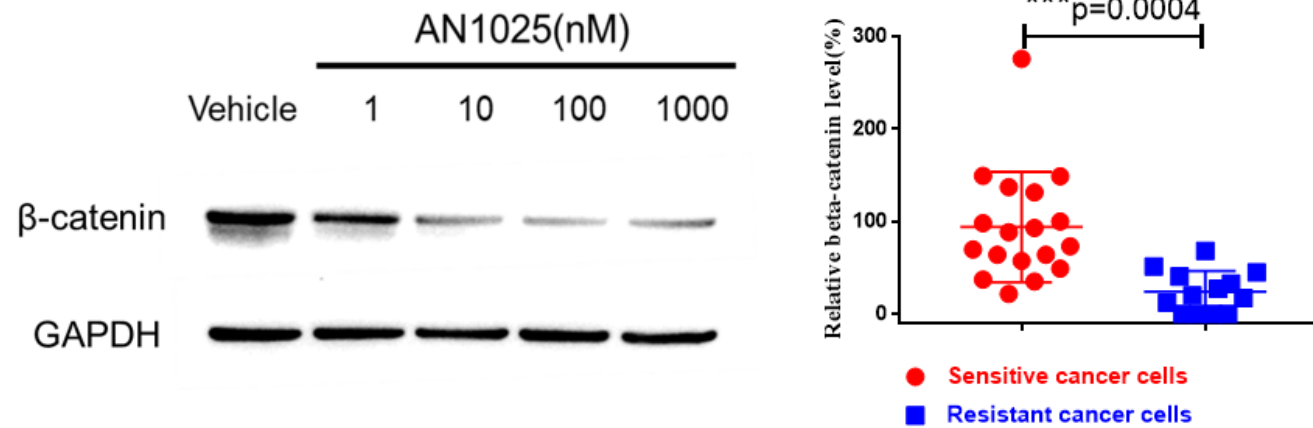
- Addresses broad range of KRAS mutations (one of the most commonly mutated proteins in cancer) in multiple tumor types
- Efficiently inhibited cancer types with KRAS mutations including pancreas adenocarcinoma, lung adenocarcinoma, and colorectal adenocarcinoma with sub-nM IC<sub>50</sub> values
- Shows deep, sustained, and durable anti-tumor efficacy in KRAS-driven xenograft mice models
- Development candidate expected in Q2 2024



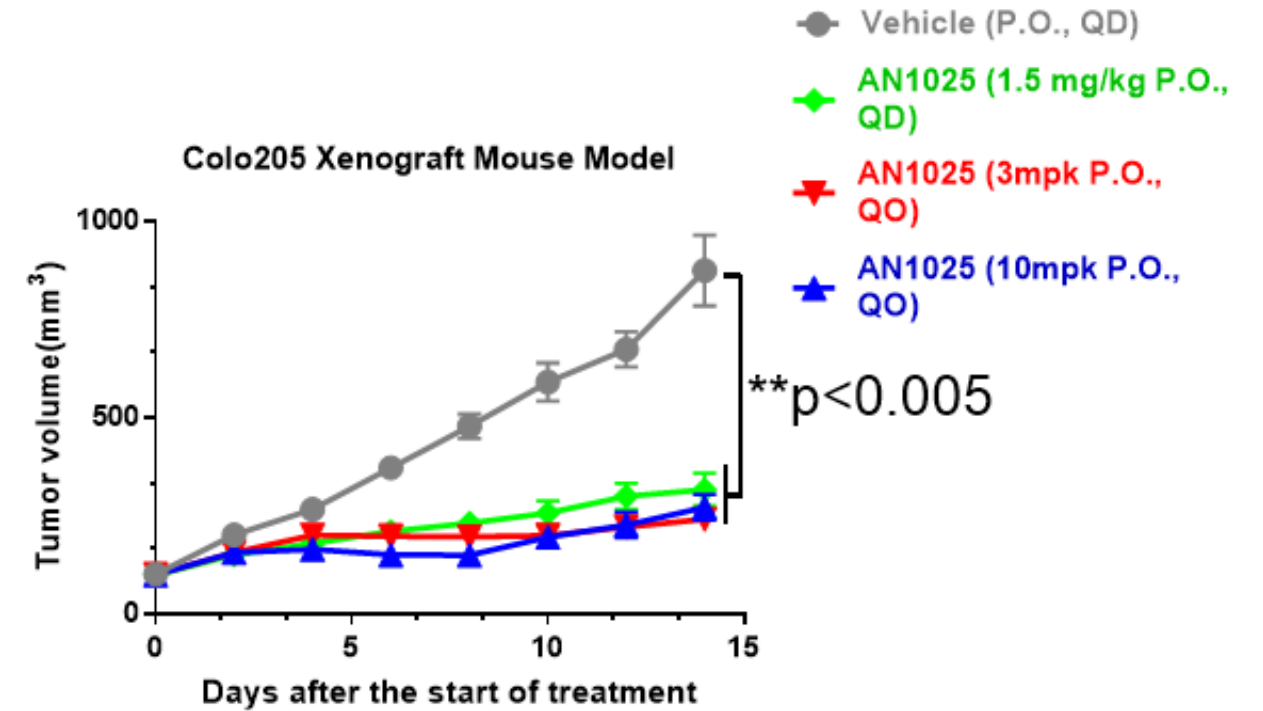
## Mechanism of Action



- Wnt/ $\beta$ -catenin pathway is one of the key tumor-promoting signaling cascades that regulate cell cycle progression, epithelial-mesenchymal transition, angiogenesis, stemness, and tumor immune microenvironment
- Aberrant activation of Wnt signaling as a result of genetic mutation has been linked to different cancers. Therefore, this pathway represents a promising target for therapeutic intervention



- AN1025 treatment led to the reduction of  $\beta$ -catenin level in tumor cells
- $\beta$ -catenin serves as a biomarker of sensitivity to AN1025



- AN1025 showed anti-tumor activities in colo205 xenograft mice models