Adlai Nortye

NASDAQ: ANL

Corporate Presentation

August 2024

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Adlai Nortye at a Glance:

- Phase 3 OS data for buparlisib (pan-PI3Ki) in r/m HNSCC patients after anti-PD-(L)1 therapy expected in Q1 2025
- Oral anti-PD-L1 in development with potential to shift treatment paradigm; Phase 1a data expected by 2024YE
- Multiple potential first and best-in-class preclinical assets with great potential to address significant unmet medical needs: AN8025 (multi-functional IO), AN9025 (pan-RAS)
- Global footprint with R&D centers in the U.S. and China; and clinical trial operations globally
- Strong balance sheet – cash, cash equivalents and marketable securities of $98 million as of June 30, 2024, funding its operational into 2H 2025

Pipeline Chart:

Product	MOA	Indication	Discovery	IND Enabling	Phase 1a	Phase 1b	Phase 2	Phase 3	Upcoming Milestone
AN2025 (buparlisib)	**pan-PI3K**	HNSCC 2/3L (+paclitaxel)							OS expected in 1Q 2025
AN4005	**Small molecule PD-L1**	Advanced tumors							Target clinical update at 2H 2024 medical conference
AN8025	**Multi-functional T cell/APC modulator**	Advanced tumors							IND expected in mid-2025
AN9025	**pan-RAS**	RAS-addicted solid tumors							IND expected in 2H 2025
AN1025	**β-catenin suppressor**	WNT/β-catenin driven solid tumors							PCC determination
Investigator Initiated Trials									
AN0025 (palupiprant)	**EP4**	LA EC (+CRT)							Target clinical update at 2H 2024 medical conference
		Neoadj RC (+CRT)							Ph2 update in 2H 2025
		Stage 3 NSCLC (+CRT)							Ph1b update in 2H 2025

Abbreviations: MOA = mechanism of action; OS = overall survival; RP2D = Recommended Phase 2 Dose; LA = locally advanced; EC = esophageal cancer; RC = rectal cancer; NSCLC = non-small cell lung cancer; CRT = chemoradiation therapy; IND = Investigational New Drug; PCC = Pre-Clinical Candidate.

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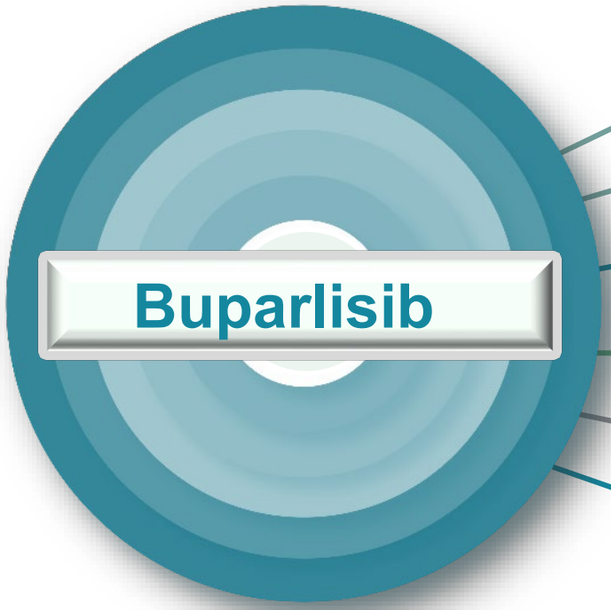
Buparlisib (AN2025): Market, Clinical and Regulatory Updates

Buparlisib (AN2025) – Addressing Large Unmet Medical Needs with Near-term Catalysts



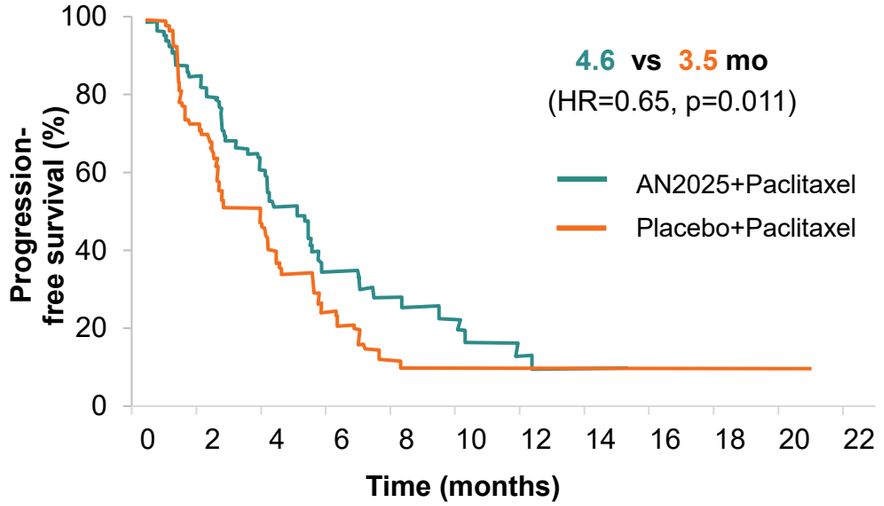
- Well-tolerated safety profile in r/m HNSCC with compelling efficacy shown in Phase 2 trial run by Novartis
- Fast Track Designation granted by US FDA
- Potential to be first-to-market approved therapy globally including the US, EU, UK, Japan and China
- Potential to address over 15,000 and 50,000 r/m HNSCC patients after anti-PD-(L)1 therapy in the US and 7MM, respectively
- Global market of r/m HNSCC after anti-PD-(L)1 therapy is expected to exceed $2.0B
- Ongoing evaluation of partnership to prepare for potential commercialization

Abbreviation: r/m = refractory and metastatic; HNSCC = Head and neck squamous cell carcinoma

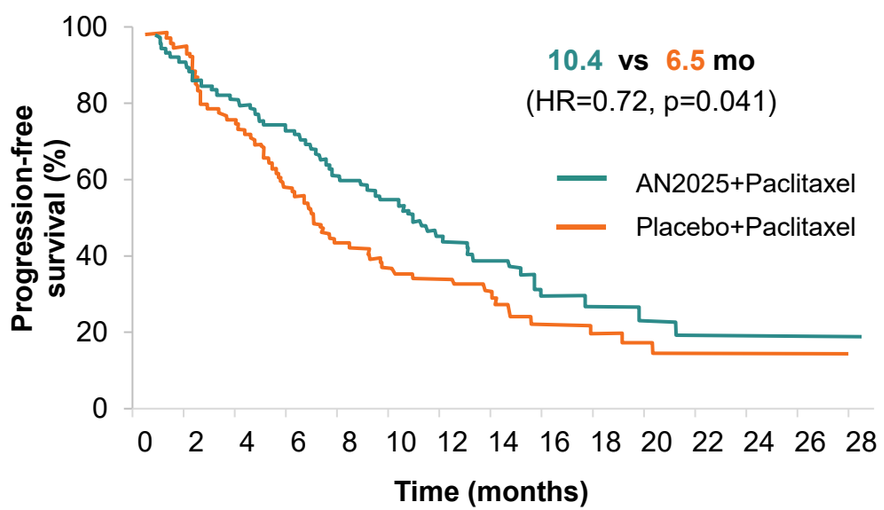
(1) Pharma Intelligence Disease Analysis of HNSCC by Informa, 2022. 7MM stands for seven major markets (the U.S., the U.K., Germany, France, Italy, Spain, and Japan).

BERIL-1 Phase 2 Study for r/m HNSCC with Compelling Efficacy

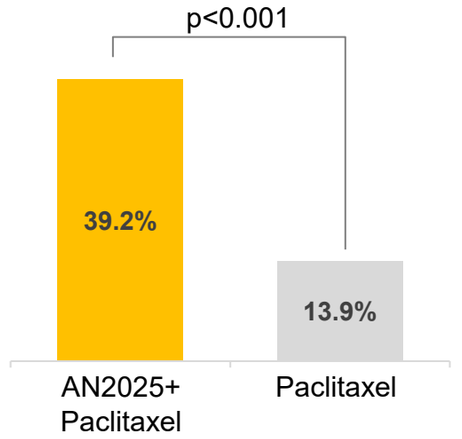
PFS: AN2025 + Paclitaxel vs. Paclitaxel



OS: AN2025 + Paclitaxel vs. Paclitaxel



Overall Response Rate ("ORR")



A Randomized, Double-blind, Placebo-Controlled Phase 2 Trial (BERIL-1)

Major Inclusion:

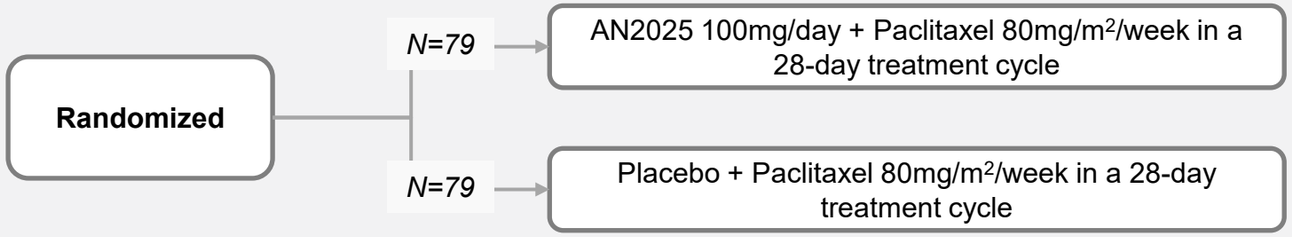
- Platinum-pretreated r/m HNSCC
- ECOG 0/1

Primary Endpoint:

- PFS

Secondary Endpoints:

- OS ORR, DoR
- TTR, DCR, HRQoL



Source: Soulières et al., 2017.

Abbreviations: TCR: Time-to-Response; DCR: Disease Control Rate.

BERIL-1 Phase 2 Study for r/m HNSCC with Manageable Safety Profile

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.

Addressing Unmet Medical Need in r/m HNSCC After Anti-PD-(L)1 Therapy: BURAN Phase 3 Trial

The BURAN study is a randomized, open-label Phase 3 study assessing the treatment effect of once-daily buparlisib (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-(L)1 monotherapy;
2. Prior anti-PD-(L)1 therapy in combination with platinum-based therapy; or after
3. Sequential treatment of anti-PD-(L)1 therapy, either prior to or post platinum-based therapy

Study Design:

Major Inclusion:

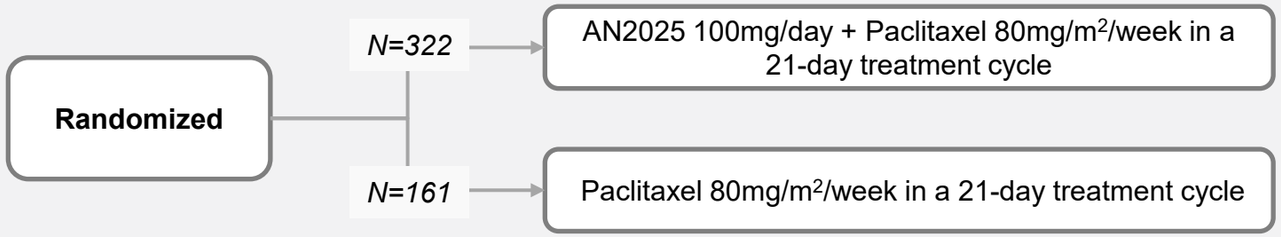
- PD-(L)1-pretreated r/m HNSCC
- ECOG 0/1

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 Burtness

Lead PI of KEYNOTE-048 for Pembrolizumab

Abbreviations: ECOG: Eastern Cooperative Oncology Group Performance Status Scale; OS: Overall Survival; PFS: Progression-Free Survivor; DoR: Duration of Response; HRQoL: Health-Related Quality of Life.

Buparlisib Could Be the Potential First-to-Market Globally

Buparlisib is the most advanced drug candidate in a Phase 3 trial of r/m HNSCC after anti-PD-(L)1 therapy

	Buparlisib	Ficlatuzumab	Petosemtamab	Ozuriftamab vedotin	Tisotumab vedotin
Current status	**Fully enrolled in Ph3; NCT04338399**	FPI of Ph3 in Jan 24; HPV negative; NCT06064877	FPI of Ph3 in Jul 24; NCT03526835	Received BTD from FDA; plan for registrational trial	HNSCC cohort of innovaTV 207 Part C completed

Summary of the Proof-of-Concept Trials

Study design	**buparlisib + paclitaxel vs. paclitaxel**	ficlatuzumab + erbitux	Petosemtamab monotherapy	Ozuriftamab vedotin monotherapy	Tisotumab vedotin monotherapy
Patient background	**chemo-refractory**	anti–PD-1 mAb and platinum refractory	anti–PD-1 mAb and platinum refractory	anti–PD-1 mAb	anti–PD-1 mAb
Sample size	**79 each arm, total 158 patients**	33 patients	49 patients	29 patients	40 patients
ORR	**39.2% vs. 13.9%**	19%	37.2%	19%	32.5%
mPFS (months)	**4.6 vs. 3.5**	3.7	5.3	-	-
mOS (months)	**10.4 vs. 6.5**	-	11.5	-	-

Note: 1) These data are derived from different clinical trials at different points in time, with differences in trial design and patient populations. No head-to-head clinical trials have been conducted; 2) these data are extracted from company websites

AN4005 oral PD-L1 in early clinical stage

AN4005: Orally Available, Small-Molecule PD-L1 Inhibitor

AN4005 as a Backbone for Our Future Oral Combination Therapies

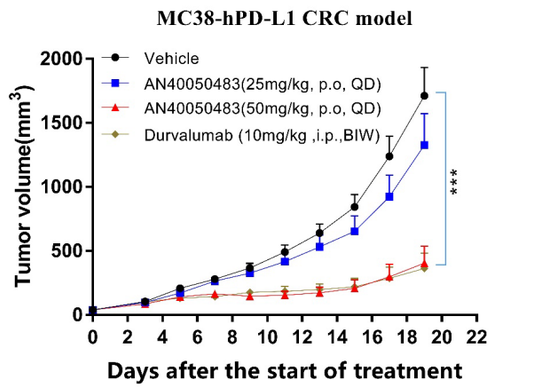
Market Opportunity

- No small-molecule PD-L1 inhibitor approved in any jurisdiction globally
- Effectively disrupt the interaction between PD-1 and PD-L1

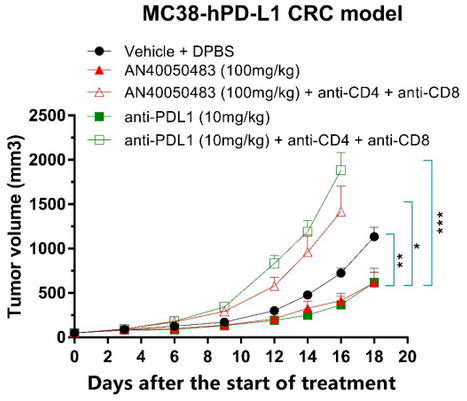
Benefits Over Antibodies

- Opportunity for oral administration, improved tumor penetration, and lack of immunogenicity

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

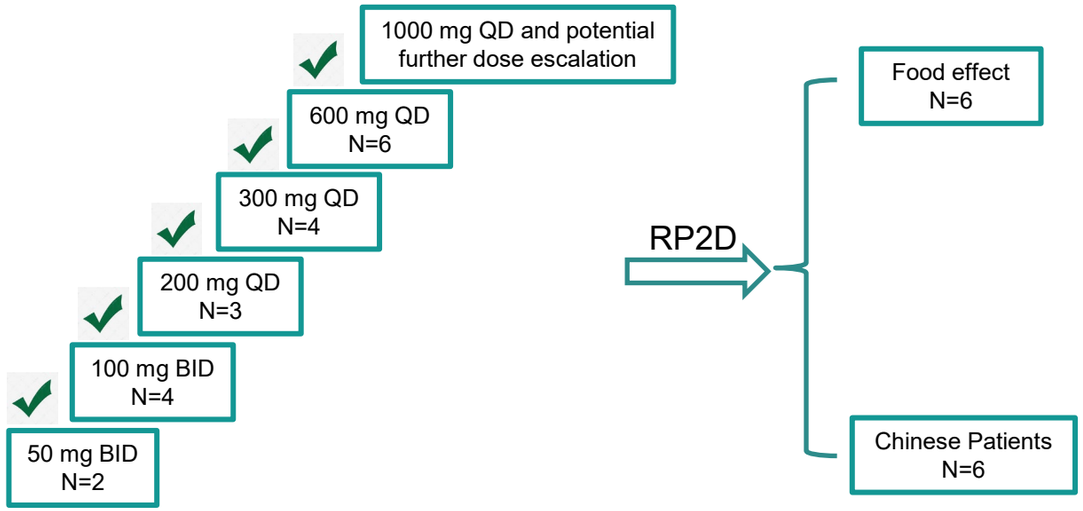
First-in-Human, Dose Escalation study of AN4005

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 March 2024, 23 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
- ✓ Expansion cohorts for IO treatment-naïve patients will be initiated in H2’24

AN4005: Complete Response Observed in Late-stage Patient with Prior Systemic Therapy

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

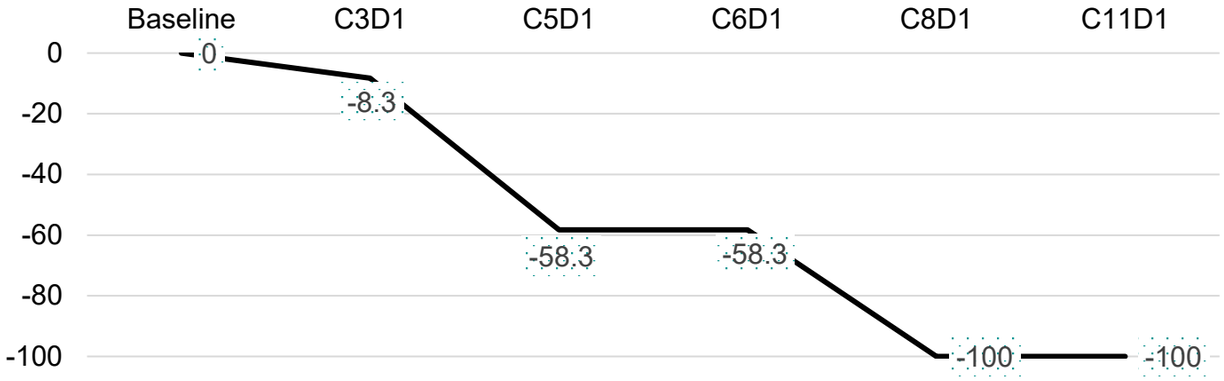
AN4005 Treatment Course

- 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
1st TA (C3D1)	11	Present	No	SD
2nd TA (C5D1)	5	Present	No	PR
3rd TA (C6D1)	5	Present	No	PR
4th TA (C8D1)	0	Present	No	PR
5th TA (C11D1)	**0**	Absent	No	**CR**

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



Abbreviations: TA = tumor assessment; SLD = sum of longest diameters of target lesions; RECIST = response evaluation criteria in solid tumors; SD = stable disease; PR = partial response; CR = complete response.

AN4005: Development Strategy

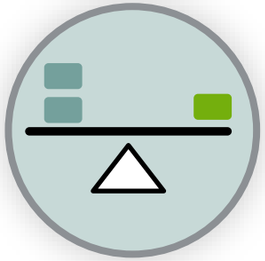
Differentiated Approach for AN4005

Expansion cohort aims to further evaluate the efficacy and safety of AN4005, benchmarking against those of aPD(L)1 mABs

- Evaluate anti-PD(L)1 naïve patients with indications fit for anti-PD(L)1 monotherapy
- Address geographical regions where insurance does not provide full coverage for approved indications (e.g. Hong Kong, Taiwan, Thailand)

Improved Patient Convenience

- Monotherapy or in combination (e.g. cancer vaccine) in maintenance or adjuvant settings



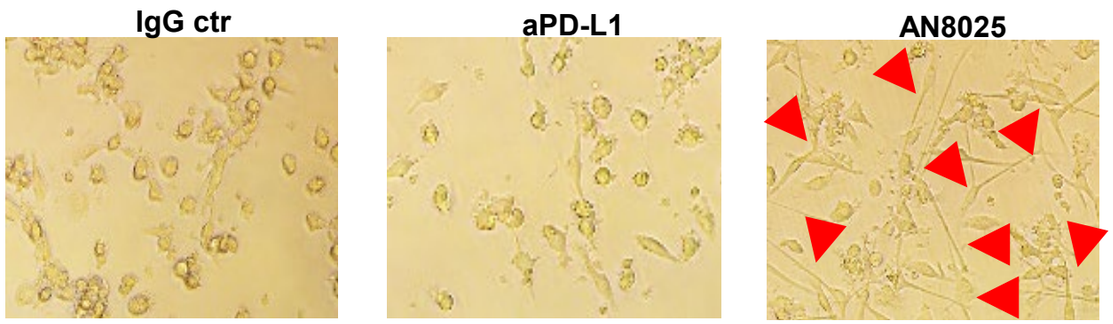
Improved Safety Management

- AN4005 in combination with other small molecules, e.g. Ras inhibitor (AN9025)

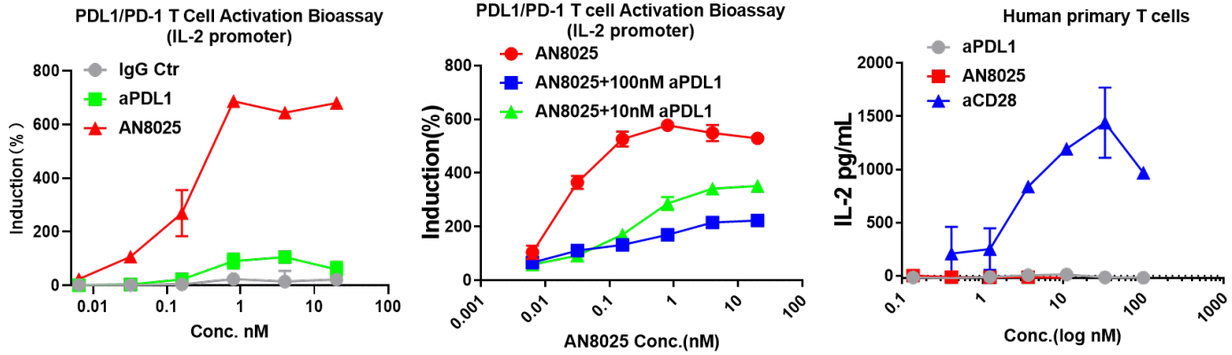
Pre-clinical assets

AN8025: A Multi-Functional T cell/APC modulator

AN8025: improve the quality and quantity of antigen presenting cells

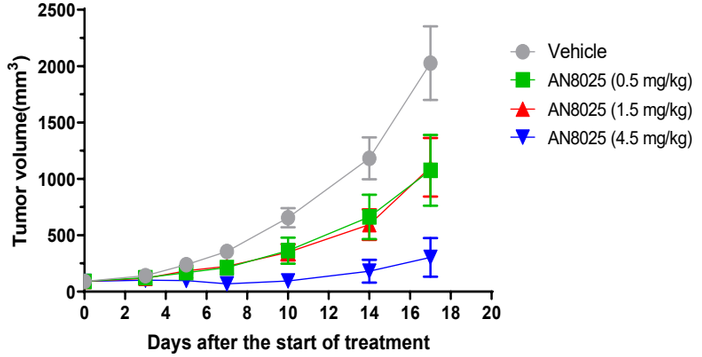


AN8025:induce stronger T Cell response than aPD-L1 and displays PD-L1-dependent T-cell activation

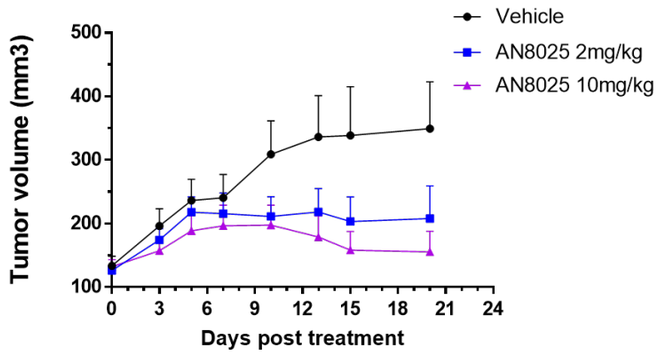


AN8025 displays potent antitumor efficacy in syngeneic and humanized mouse tumor models

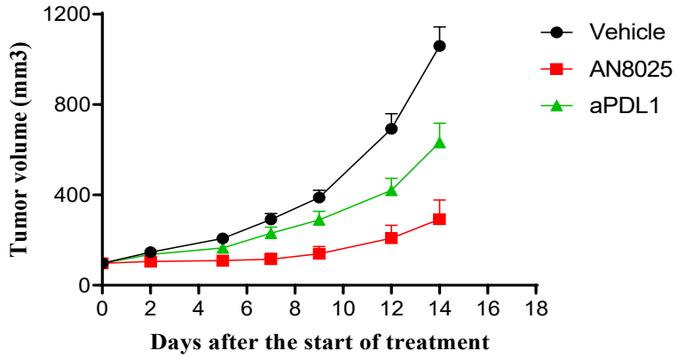
MC38-hPDL1



MDA-MB-231/hPBMC Model

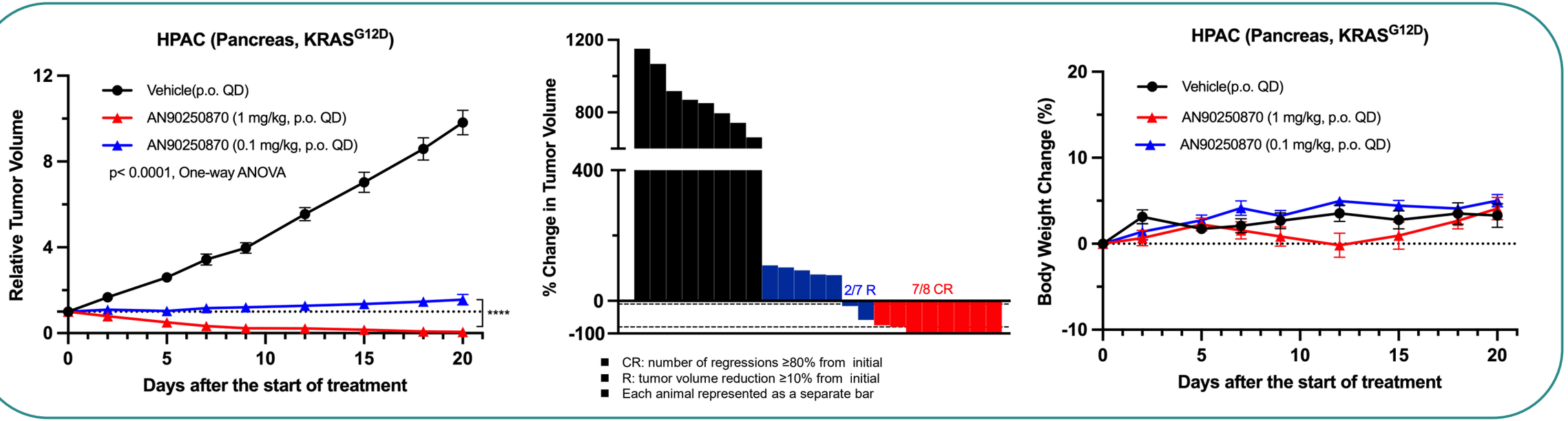


MC38-hPDL1



Currently in IND enabling stage; IND filing expected in mid-2025

AN9025: An Oral Small-Molecule Pan-RAS Inhibitor



- Addresses broad range of RAS mutations (one of the most commonly mutated proteins in cancer) in multiple tumor types
- Efficiently inhibited cancer types with RAS mutations including pancreas adenocarcinoma, lung adenocarcinoma, and colorectal adenocarcinoma with pM IC_{50} values
- Shows deep, sustained, and durable anti-tumor efficacy in RAS-driven xenograft mice models
- IND filing expected in 2H 2025

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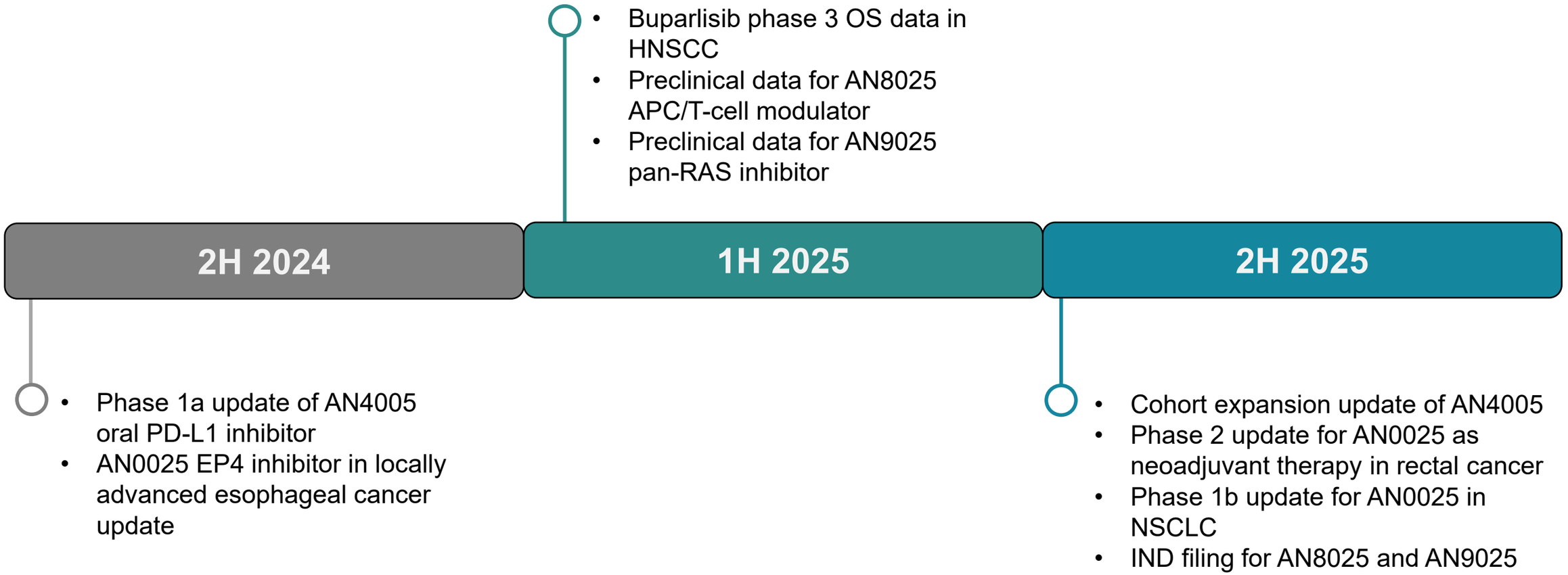
Upcoming Milestones

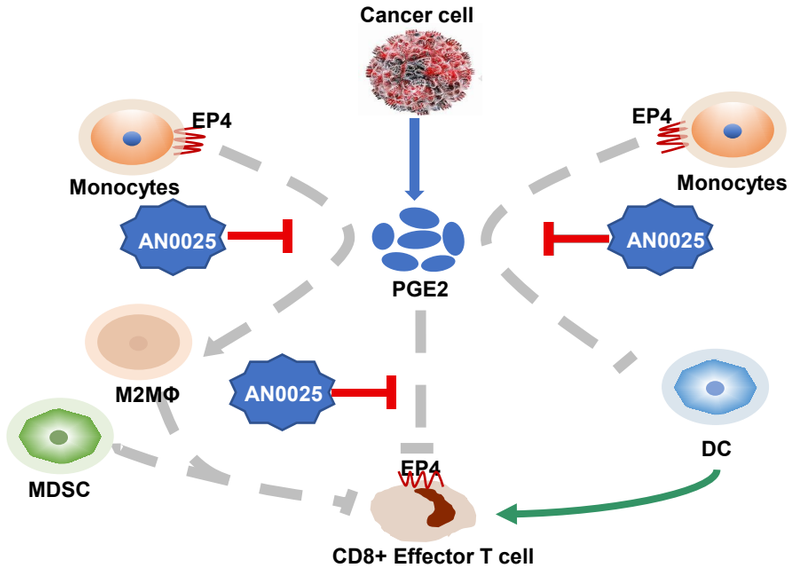
Near-Term Milestones



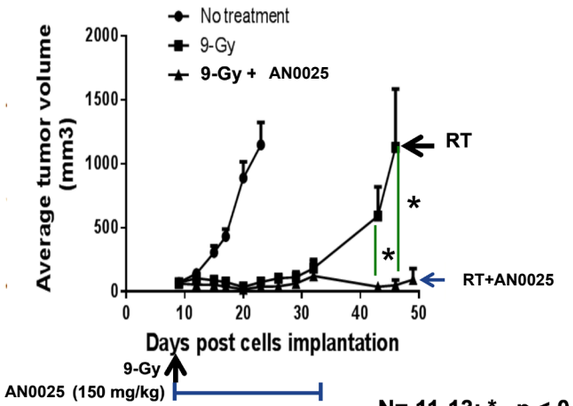
Other Assets

AN0025: A Potential Enhancer of Radiotherapy

Mechanism of Action

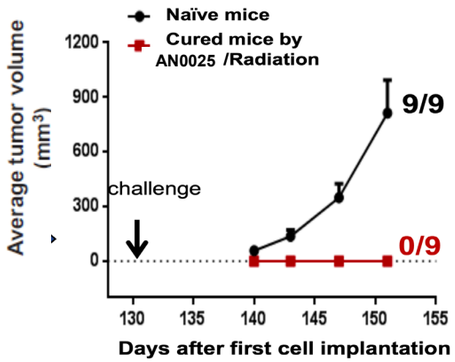


CT-26 colon tumors



N= 11-13; *, $p < 0.05$

CT26 tumors re-challenge without drug treatment



AN0025 + Chemoradiotherapy (CRT) in Locally Advanced (LA) Esophageal Cancer (EC)

An open-label Phase 1b trial:

Main inclusion criteria:

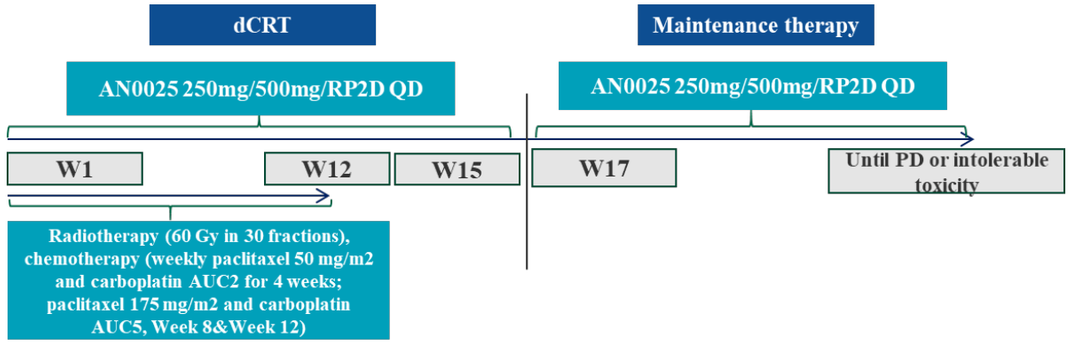
- Locally advanced/locally recurrent EC
- Clinical Stage 2 to 4a (8th AJCC), or Stage 4b
- Unresectable, no prior radiotherapy in the esophageal region

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 was presented at ASCO 2024

AN0025: A Potential Enhancer of Chemoradiotherapy (Cont'd)

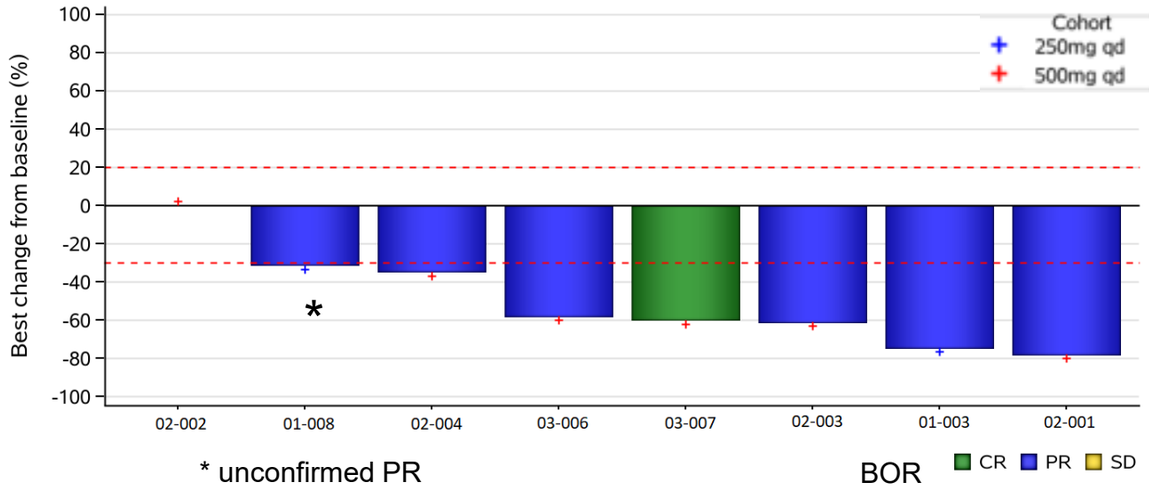
AN0025 + Chemoradiotherapy in Locally Advanced Esophageal Cancer

12 Chinese patients (11 males and 1 female, median age 62) with histologically confirmed esophageal squamous cell carcinoma (ESCC) were enrolled and received the study treatment

Patient demographics and baseline characteristics

Patient Number	Age	Gender	Dose level	T	N	M	Clinical stage
01-003	62	M	250mg qd	T4b	N3	M0	IVA
01-004	52	M	250mg qd	T4b	N1	M0	IVA
01-007	64	M	250mg qd	T2	N1	M0	II
01-008	61	M	250mg qd	T3	N1	M0	III
01-009	58	M	250mg qd	T3	N1	M0	III
01-011	70	F	500mg qd	T3	N2	M0	III
02-001(1)	56	M	500mg qd	T3	N1	M0	III
02-002	61	M	500mg qd	T2	N2	M0	III
02-003	60	M	500mg qd	T3	N3	M0	IVA
02-004	65	M	500mg qd	T3	N2	M1	IVB
03-006	64	M	500mg qd	T3	N2	M0	III
03-007	69	M	500mg qd	T3	N2	M0	III

Best % Change in SLD of Target Lesions



* unconfirmed PR

Clinical data extract date: 19 Feb 2024

Source: ASCO 2024 abstract (AN0025 in combination with definitive chemoradiotherapy (dCRT) in unresectable locally advanced or locally recurrent esophageal cancer (EC): A single-arm, open-label, multicenter, phase Ib study. | Journal of Clinical Oncology (ascopubs.org))

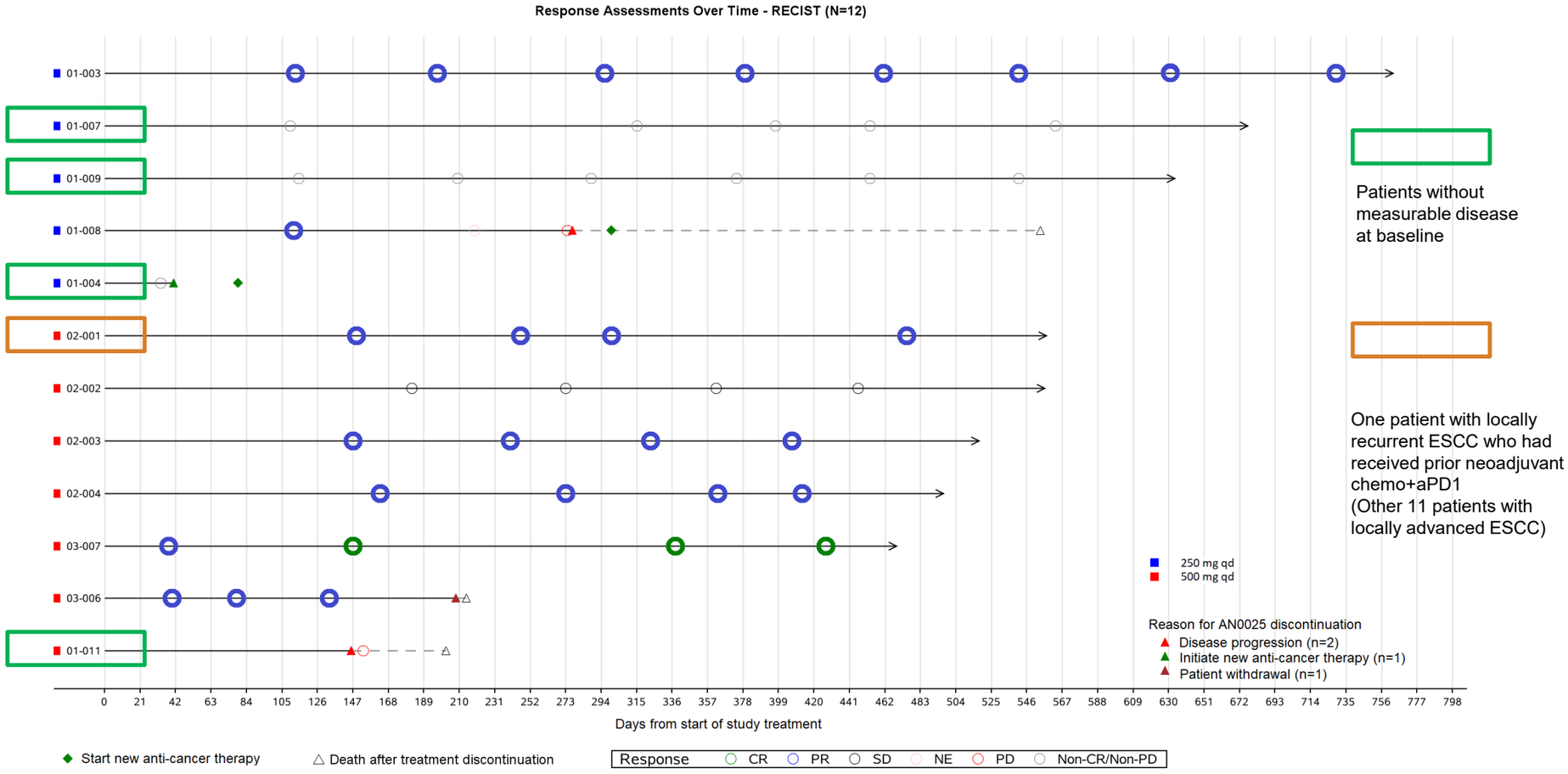
Abbreviation: SLD = sum of longest diameters. BOR = best overall response; PR = partial response; CR = complete response; SD = stable disease

(1) 02-001: locally recurrent esophageal cancer. Prior anti-cancer therapies include: neoadjuvant therapy (Tislelizumab, a PD-1 antibody approved in China + Nab- paclitaxel + Nedaplatin), May 20, 2021 to Jun 10, 2021; esophagectomy, Jul 12, 2021; adjuvant therapy (Sintilimab, a PD-1 antibody approved in China + Nab- paclitaxel + Nedaplatin), Sep 9, 2021 to Oct 22, 2021.

AN0025: A Potential Enhancer of Chemoradiotherapy (Cont'd)

AN0025 + Chemoradiotherapy in Locally Advanced Esophageal Cancer

As of February 19, 2024 (median follow-up is 15.4 months), the tumor response and treatment duration are:



Encouraging Preliminary Efficacy

- Overall DCR = 92% (11/12)
- 15-month PFS rate = 73% (8/11[(1)])
- Patients with measurable disease at baseline (N=8): ORR = 87.5% (7/8, including 1 CR), DCR = 100%
- Patients without measurable disease at baseline (N=4): DCR = 75% (3/4, including 1 pCR[(1)])

Source: ASCO 2024 abstract (AN0025 in combination with definitive chemoradiotherapy (dCRT) in unresectable locally advanced or locally recurrent esophageal cancer (EC): A single-arm, open-label, multicenter, phase Ib study. | Journal of Clinical Oncology (ascopubs.org))

Abbreviation: DCR = disease control rate; PFS = progression-free survival; ORR = objective response rate; pCR = pathologic complete response; CR = complete response; PR = partial response; SD = stable disease; NE = not evaluable; PD = progressive disease

(1) Patient 01-004 was censored because the patient underwent surgery after the treatment and was confirmed as pCR.

AN0025: A Potential Enhancer of Chemoradiotherapy (Cont'd)

Adlai Nortye

AN0025 + Chemoradiotherapy in Locally Advanced Esophageal Cancer

- No dose-limiting toxicity occurred at either dose level, and the maximum tolerated dose was not reached
- As of 19 Feb 2024, most frequent TEAEs by preferred term and maximum CTCAE Grade (>=30%)

	AN0025 250mg QD (N=5)		AN0025 500mg QD (N=7)		Total (N=12)	
Preferred term	All grade n (%)	Grade≥3 n (%)	All grade n (%)	Grade≥3 n (%)	All grade n (%)	Grade≥3 n (%)
Total	5 (100.0)	5 (100.0)	7 (100.0)	5 (71.4)	12 (100.0)	10 (83.3)
Anemia	5 (100.0)	0	7 (100.0)	1 (14.3)	12 (100.0)	1 (8.3)
Lymphocyte count decreased	5 (100.0)	5 (100.0)	6 (85.7)	5 (71.4)	11 (91.7)	10 (83.3)
White blood cell count decreased	5 (100.0)	2 (40.0)	6 (85.7)	1 (14.3)	11 (91.7)	3 (25.0)
Weight decreased	3 (60.0)	1 (20.0)	6 (85.7)	0	9 (75.0)	1 (8.3)
Hypoalbuminaemia	4 (80.0)	0	4 (57.1)	0	8 (66.7)	0
Radiation oesophagitis	3 (60.0)	0	5 (71.4)	0	8 (66.7)	0
Neutrophil count decreased	5 (100.0)	2 (40.0)	2 (28.6)	1 (14.3)	7 (58.3)	3 (25.0)
COVID-19	1 (20.0)	1 (20.0)	6 (85.7)	0	7 (58.3)	1 (8.3)
Hypokalaemia	3 (60.0)	1 (20.0)	2 (28.6)	1 (14.3)	5 (41.7)	2 (16.7)
Asthenia	1 (20.0)	0	3 (42.9)	1 (14.3)	4 (33.3)	1 (8.3)
Vomiting	2 (40.0)	0	2 (28.6)	1 (14.3)	4 (33.3)	1 (8.3)
Hypocalcaemia	3 (60.0)	0	1 (14.3)	0	4 (33.3)	0
Pyrexia	4 (80.0)	0	0	0	4 (33.3)	0
Diarrhoea	2 (40.0)	0	2 (28.6)	0	4 (33.3)	0
Insomnia	1 (20.0)	0	3 (42.9)	0	4 (33.3)	0
Platelet count decreased	2 (40.0)	0	2 (28.6)	0	4 (33.3)	0
Hyponatremia	1 (20.0)	0	3 (42.9)	0	4 (33.3)	0
Radiation skin damage	0	0	4 (57.1)	0	4 (33.3)	0

Source: ASCO 2024 abstract (AN0025 in combination with definitive chemoradiotherapy (dCRT) in unresectable locally advanced or locally recurrent esophageal cancer (EC): A single-arm, open-label, multicenter, phase Ib study. | Journal of Clinical Oncology (ascopubs.org))

Abbreviation: TEAEs = treatment emergent adverse events; CTCAE = common terminology criteria for adverse events.

AN0025: A Potential Enhancer of Chemoradiotherapy (Cont'd)

Preoperative AN0025 + Chemoradiotherapy 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

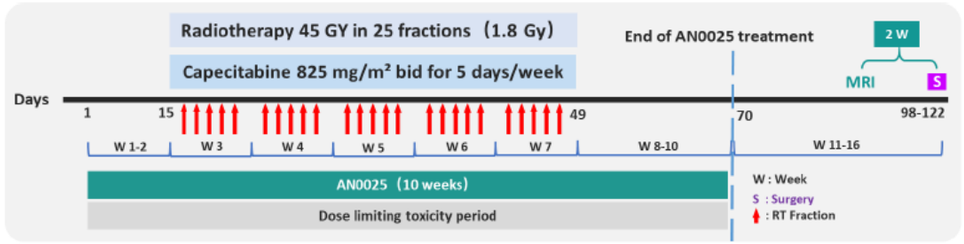
Primary endpoints

- Safety and tolerability
- MTD and/or RP2D

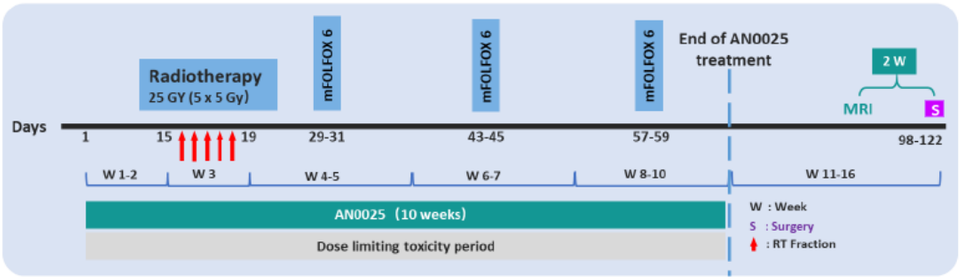
Secondary endpoints:

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

Long course



Short course



Encouraging Preliminary Efficacy

cCR	+	pCR
20%		16%
• No need for surgery • Able to avoid proctectomy		• No residual tumor • Pathological cure

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

AN0025: A Potential Enhancer of Chemoradiotherapy (Cont'd)

Preoperative AN0025 + Chemoradiotherapy in Rectal Cancer

ARTEMIS (Augmenting RadioTherapy in REctal Cancer to Minimise Invasive Surgery)

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

Main inclusion criteria:

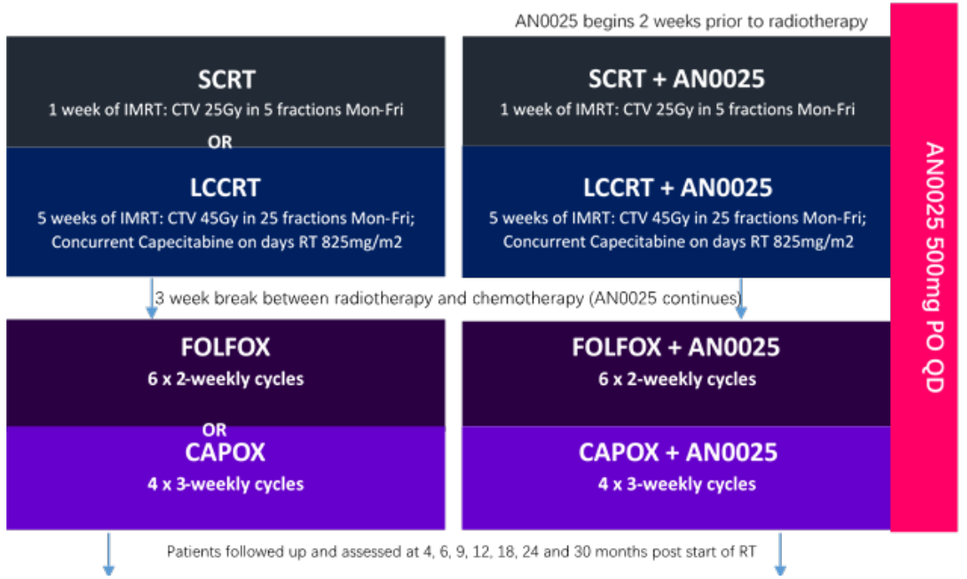
- Biopsy-proven rectal adenocarcinoma; ECOG PS 0-1
- T3b-4a or TanyN1-2 or TanyEMVI+ or with a threatened (<1mm) or involved mesorectal fascia resection margin, or low tumors with involvement of the anal intersphincteric plane or with levator involvement

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 in May 2024
- Collaborated with Leeds University, UK

Market Opportunities – neoadjuvant Rectal Cancer

Neoadjuvant rectal cancer in 2028

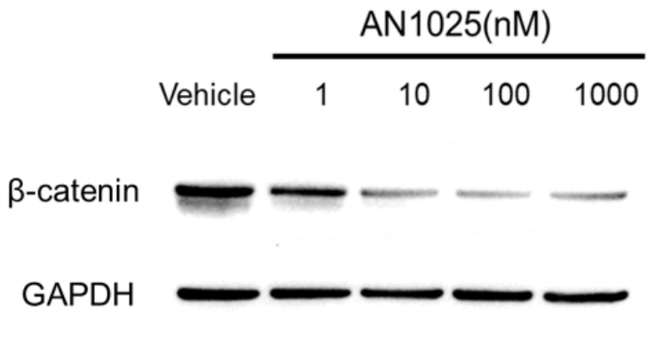
19,000 U.S. Incidence[(1)]

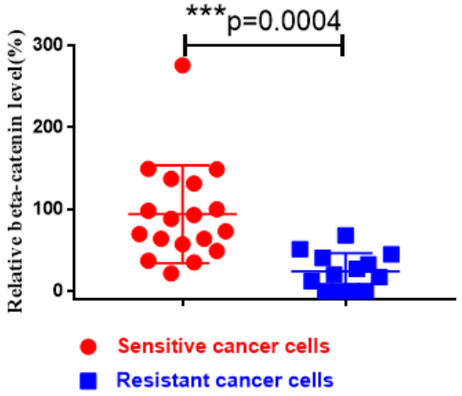
50,000 7MM Incidence[(1)]

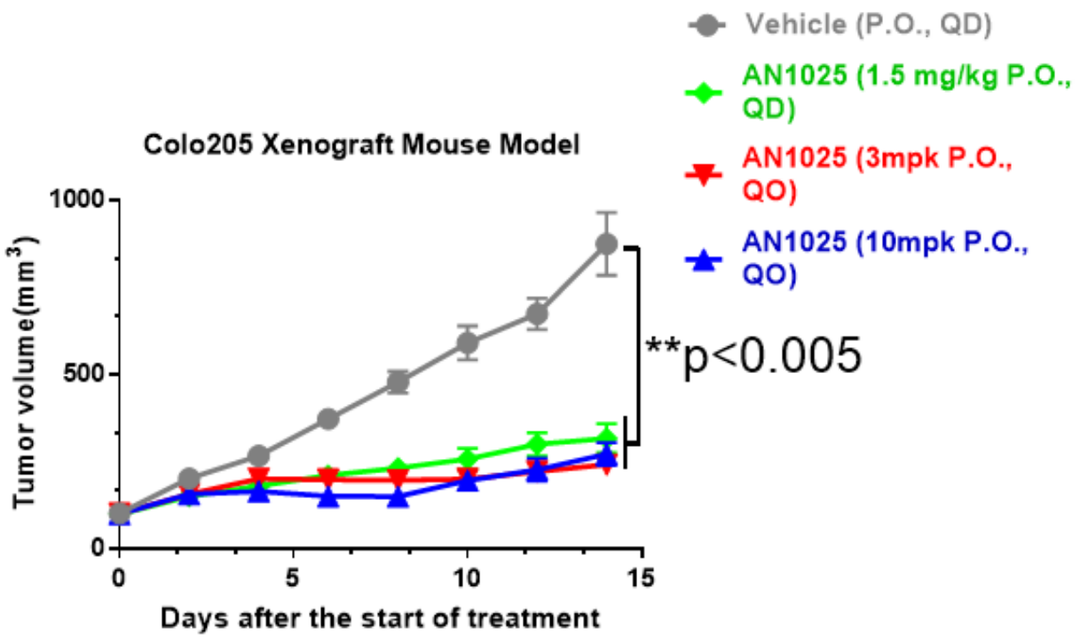
Abbreviation: EMVI = Extramural vascular invasion.

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

AN1025: An Oral Small-Molecule Suppressor of β-catenin







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

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