
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16
under the Securities Exchange Act of 1934

For the month of May 2024

Commission File Number: 001-41773

Adlai Nortye Ltd.

c/o PO Box 309, Ugland House
Grand Cayman, KY1-1104
Cayman Islands
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F

Form 40-F

EXHIBIT INDEX

| <u>Exhibit No.</u> | <u>Description</u> |
|----------------------|--|
| 99.1 | Press Release: Adlai Nortye Ltd. to Present Encouraging Data of the Combination of AN0025 and Definitive Chemoradiotherapy,(dCRT) at ASCO 2024 |
| 99.2 | Adlai Nortye Ltd. May 2024 Corporate Presentation |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Adlai Nortye Ltd.

By : /s/ Yang Lu
Name : Yang Lu
Title : Chief Executive Officer and Chairman of Board of Directors

Date: May 23, 2024

Adlai Nortye Ltd. to Present Encouraging Data of the Combination of AN0025 and Definitive Chemoradiotherapy (dCRT) at ASCO 2024

SINGAPORE and NORTH BRUNSWICK, N.J. and HANGZHOU, China, May 23, 2024 -- Adlai Nortye Ltd. (NASDAQ: ANL) (the "Company" or "Adlai Nortye"), a clinical-stage biotechnology company focused on the development of innovative cancer therapies, today announced that it will present preliminary data of AN0025 in combination with definitive chemoradiotherapy (dCRT) in unresectable locally advanced or locally recurrent esophageal cancer (EC) at the upcoming American Society of Cancer Oncology (ASCO) Annual Meeting to be held in Chicago from May 31 to June 4, 2024.

AN0025 is a selective EP4 inhibitor that demonstrates antitumor activity by modulating the accumulation and function of macrophages and immunosuppressive myeloid cells in tumor microenvironment. The combination of AN0025 with CRT as neoadjuvant therapy has shown synergistic antitumor efficacy in locally advanced rectal cancer in a prior clinical trial (NCT03152370). The AN0025S0104 study is a single-arm, open-label, multicenter, Phase Ib study comprising a dose escalation phase followed by an expansion phase, aimed at evaluating the safety, tolerability, and feasibility of AN0025 plus dCRT for unresectable locally advanced or locally recurrent EC or esophagogastric junction cancer.

"Our participation in this clinical study underscores our unwavering dedication to pioneering novel cancer therapies with global reach," said Lars Birgerson, President and Chief Medical Officer of Adlai Nortye Ltd. "As we advance oncology research, our commitment remains steadfast in addressing unmet patient needs through innovative drug discovery and strategic partnerships. We look forward to joining the oncology community in Chicago and sharing updates on our cutting-edge pipeline of programs."

Details regarding the Adlai Nortye abstract at ASCO 2024 are as follows:

Abstract title: 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 (AN0025S0104)

Presenting Author: Nan Bi, Department of Radiation Oncology, National Cancer Center/National Clinical Research Center for Cancer/Cancer Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College

Abstract Number: e16076

Link Abstract on ASCO site: <https://meetings.asco.org/abstracts-presentations/235715>

About Adlai Nortye

Adlai Nortye (NASDAQ: ANL) is a global clinical-stage biotechnology company focused on the discovery and development of innovative cancer therapies for patients across the spectrum of tumor types, with global R&D centers established in New Jersey, US, and Hangzhou, China. With a strategic emphasis on oncology, the company has identified and developed a robust pipeline of six drug candidates.

Adlai Nortye has assembled a global management team and a scientific advisory board with industry leaders and influential scientists to provide important strategic guidance to its R&D, business development, and operational organizations. In addition to building its own R&D capabilities, the Company continues to seek and secure partnerships with leading multi-national pharmaceutical companies such as Eisai and Novartis, to fully realize the potential of its pipeline programs. The Company strives to become a global leader in the next wave of oncology therapies employing a combination therapy strategy. Its ultimate goal is to transform deadly cancer into a chronic and eventually curable disease.

Forward-Looking and Cautionary Statements

This announcement contains forward-looking statements. These statements are made under the “safe harbor” provisions of the U.S. Private Securities Litigation Reform Act of 1995. These forward-looking statements can be identified by terminology such as “will,” “expects,” “anticipates,” “future,” “intends,” “plans,” “believes,” “estimates,” “potential,” “continue,” “ongoing,” “targets” and similar statements. Among other things, statements that are not historical facts, including statements about the Company’s beliefs and expectations, the business outlook and quotations from management in this announcement, as well as the Company’s strategic and operational plans, are or contain forward-looking statements.

The Company may also make written or oral forward-looking statements in its periodic reports to the U.S. Securities and Exchange Commission (the “SEC”), in press releases and other written materials and in oral statements made by its officers, directors or employees to third parties. Forward-looking statements involve inherent risks and uncertainties. Factors that could cause the Company’s actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to: the initiation, timing, progress and results of the Company’s preclinical studies, clinical trials and other therapeutic candidate development efforts; the Company’s ability to advance its therapeutic candidates into clinical trials or to successfully complete its preclinical studies or clinical trials; whether the clinical trial results will be predictive of real-world results; the Company’s receipt of regulatory approvals for its therapeutic candidates, and the timing of other regulatory filings and approvals; the clinical development, commercialization and market acceptance of the Company’s therapeutic candidates; the Company’s ability to establish, manage, and maintain corporate collaborations, as well as the ability of its collaborators to execute on their development and commercialization plans; the implementation of the Company’s business model and strategic plans for its business and therapeutic candidates; the scope of protection the Company is able to establish and maintain for intellectual property rights covering its therapeutic candidates and its ability to operate its business without infringing the intellectual property rights of others; estimates of the Company’s expenses, future revenues, capital requirements and its needs for and ability to access sufficient additional financing; risks related to changes in healthcare laws, rules and regulations in the PRC and United States or elsewhere. Further information regarding these and other risks is included in the Company’s filings with the SEC. All information provided in this press release and in the attachments is as of the date of this press release, and the Company does not undertake any obligation to update any forward-looking statement, except as required under applicable law.

Contacts:

Investor Relations:

Charles Zhou

Amanda Kong

Adlai Nortye Ltd.

ir@adlainortye.com



Corporate Prese

May 2024



This presentation is provided solely for informational purposes and has been prepared to assist interested parties in making their own evaluation with respect to a offering of the securities (the "Private Placement") of Adlai Nortye Ltd. (the "Company"). No representations or warranties, express or implied, are given in, or with respect to, the information in this presentation does not contain or purport to contain all of the information that may be relevant to an investor's decision to participate in the Private Placement. It is the responsibility of each investor to make its own evaluation of the Company and the Private Placement and to ask such additional questions and obtain such additional information as the investor deems necessary. The securities to be issued in the Private Placement will not be registered under the Securities Act of 1933, as amended (the "Securities Act") or the securities laws of any other jurisdiction. The Company intends to offer such securities in reliance on exemptions from the registration requirements of the Securities Act and the offer or sale of such securities will only be made to persons that are institutional "accredited investors" within the meaning of Rule 501(a) under the Securities Act and "qualified buyers" within the meaning of Rule 144A under the Securities Act. These securities will not be approved or recommended by any federal, state or foreign securities authorities and these authorities pass upon the merits of the Private Placement. This presentation shall not constitute an offer to sell or the solicitation of an offer to buy these securities in any state or jurisdiction in which such offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities laws of that state or jurisdiction.

This presentation and the information contained herein (the "Confidential Information") constitutes confidential information. By receiving the Confidential Information, you acknowledge the confidentiality of the Confidential Information and that such Confidential Information is subject to any confidentiality obligations you or your affiliates have with respect to the Company, its business, or the Private Placement. Any reproduction or distribution of the Confidential Information without the prior written consent of the Company is prohibited.

All statements contained in this presentation that do not relate to matters of historical fact should be considered forward-looking statements, including statements regarding the Company's financial position and results of operations; the Company's product pipeline, including the timing, conduct and results of preclinical studies and clinical trials, and upcoming milestones. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Except as required by applicable law, the Company has no obligation to update these forward looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in the forward looking statements, if new information becomes available in the future. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause actual results to differ from those contained in the forward looking statements, see the section entitled "Risk Factors" in our most recent annual report on Form 20-F filed with the Securities and Exchange Commission (the "SEC"), as well as discussions of potential risks, uncertainties, and other important factors in our other filings with the SEC. Recipients are cautioned that these forward looking statements, which speak only as of the date such statements are made and should not be construed as statements of fact.

This presentation includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by us and 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 place undue weight to such data. Industry publications and third party research, surveys and studies generally indicate that their information has been obtained from sources that do not guarantee the accuracy or completeness of such information. Our estimates of the potential market opportunities for our product candidates are based on our industry knowledge, industry publications, third party research and other surveys, which may be based on a small sample size and may not represent all market opportunities. While we believe that our internal assumptions are reasonable, and management is responsible for the accuracy of such assumptions and has verified such assumptions.



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 |
|--|--|-----------------------------|--------------------------|--------------------------------|--|
| 6 | 3 | 2 | ~ 90 | 100+ Years | MNCs and |
| 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 | |
| AN2025 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 Strong Proof of Concept ("PoC") Data Laying Concrete Foundation for Potential Registration | | 15+ | | | |
| | | 250+ | | | |
| | | | | | Financial |
| | | | | | Cash, cash marketable securities March 31, 2023 Runway |

Source: Company information.
 Abbreviations: MNC = multinational companies.

Seasoned Management Team of Industry Veterans



Yang (Carsten) Lu, EMBA
CEO & Chairman



Lars E. Birgeron, M.D./Ph.D.
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



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



 Denotes management with extensive global commercialization and regulatory communication experience

Global Pipeline with First-to-Market Drug Candidates

| | Product | MOA | Indication | Discovery | IND Enabling | Phase 1a | Phase 1b | Phase 2 | Phase 3 | Upcoming Milestone | Partner |
|-------------------|----------------------|---------------------------------------|--|-----------|--------------|----------|----------|---------|--------------------------|-------------------------------|---------|
| Clinical Stage | AN2025 (buparlisib) | pan-PI3K | HNSCC 2/3L (+paclitaxel) | | | | | | | OS expected in Q4'24 or Q1'25 | |
| | | | 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 at ASCO 2024 | |
| | | | Neoadj RC (+CRT) | | | | | | | Clinical update in 2025 | |
| 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 | | | | | | | PCC determination | |

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 PI 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 J



AN2025: Market, Clinical and Regulatory Updates

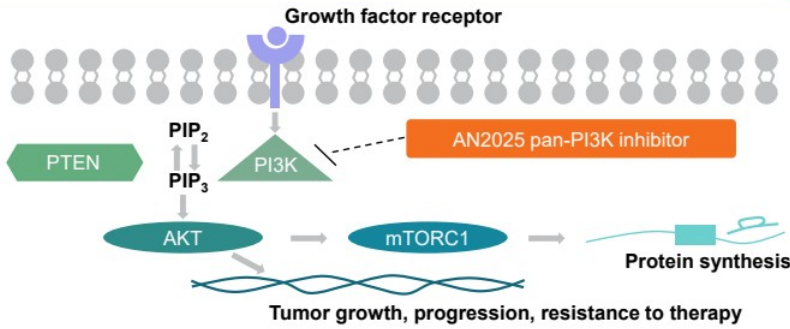




PI3K α and PI3K β in Tumorigenesis

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

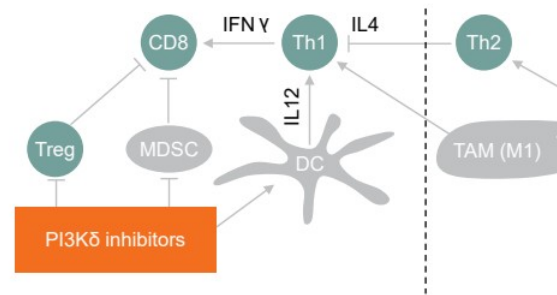
Mechanism of Action



PI3K δ and PI3K γ in Immunity

- Other isoforms of Class I PI3Ks, i.e., PI3K δ and PI3K γ , play roles in immune systems
- PI3K δ is well established to control the function and integrity of T cells
- PI3K γ and PI3K δ help recruit suppressive myeloid cells into microenvironments and strengthen their inhibitory effects on 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 ⁽¹⁾ |
| | 89,000 7MM Incidence ⁽¹⁾ |

| | |
|--|--|
| r/m HNSCC after anti-PD-1 / PD-L1 therapy | 15,000+ U.S. Incidence ⁽¹⁾ |
| | 50,000+ 7MM Incidence ⁽¹⁾ |

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 squamous cell carcinoma

First-line:

- Pembrolizumab/platin (cisplatin or carboplatin)/5-FU
- Pembrolizumab (for tumors that express PD-L1 (category 1))

(NCCN Guidelines)

Keytruda® +/- chemo prevails in 1L HNSCC since 2019. 2 approved therapies currently available for r/m HNSCC in 1L therapy

About 85% patients experience disease progression

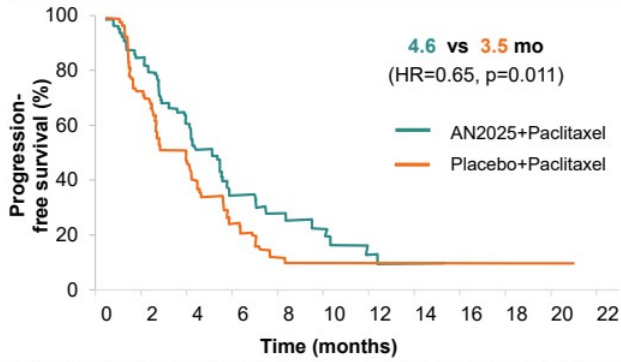
Abbreviation: r/m = refractory and metastatic.

(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).

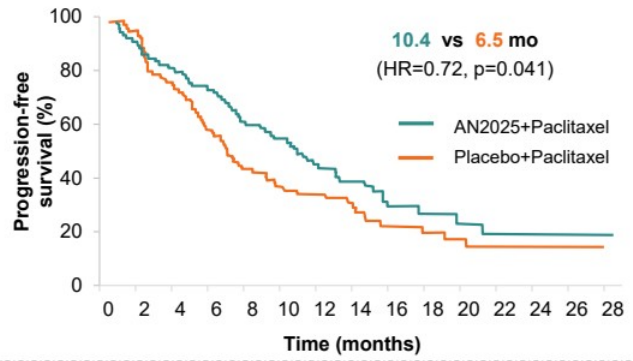
(2) FDA approval on June 10, 2019.

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

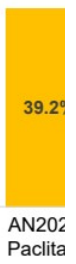
PFS: AN2025 + Paclitaxel vs. Paclitaxel



OS: AN2025 + Paclitaxel vs. Paclitaxel



Overall Re



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 80
28-day treatment cyc**

N=79

**Placebo + Paclitaxel 80mg/m²/we
treatment cycle**

Source: Soulières et al., 2017.

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

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

Source: Soulières et al., 2017.

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

Top 15 Key AEs in the Study

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

AN2025 BURAN Phase 3 Trial in r/m HNSCC After Anti-PD-1/PD-L1 Treatment: Addressing Unmet Medical Need

The BURAN study is a randomized, open-label Phase 3 study assessing the treatment effect of once-daily AN2025 in combination with weekly paclitaxel or 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



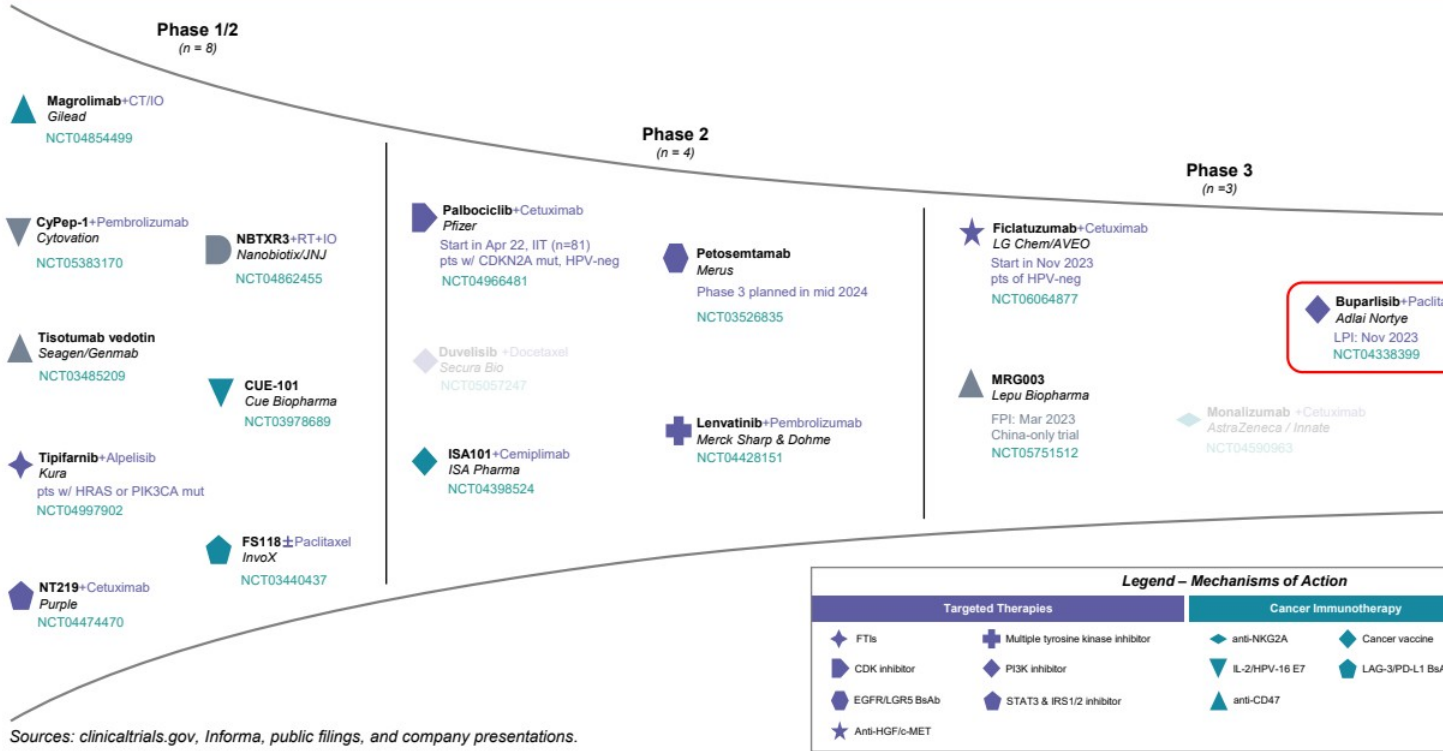
Prof. Barbara

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

Competitive Landscape of Treatment Paradigm in r/m HNSCC after PD-(L)1 therapy

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 w



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

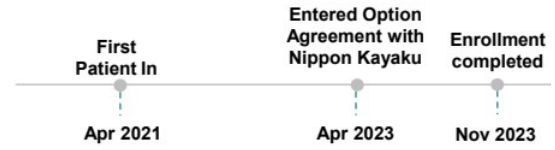
| Clinical Phase | Host | Indication | # of Patients | Trial Status |
|-----------------------|--|---|---------------|------------------------|
| Phase 2 (NCT01852292) |  NOVARTIS | r/m HNSCC (after platinum-based chemotherapy) | 158 | Completed |
| Phase 3 (NCT04338399) |  Adlai Nortye | r/m HNSCC (after 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 clinical trial sites in the U.S., Canada, UK, Spain, Italy, Germany, Hungary, Belgium, Russia, mainland China, Hong Kong, South Korea, Australia, and Argentina



(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 prophylactic and/or diagnostic uses in humans in Japan, pending certain conditions being met. Please refer to the prospectus "Business — License and collaboration agreements — Option agreement section for details.



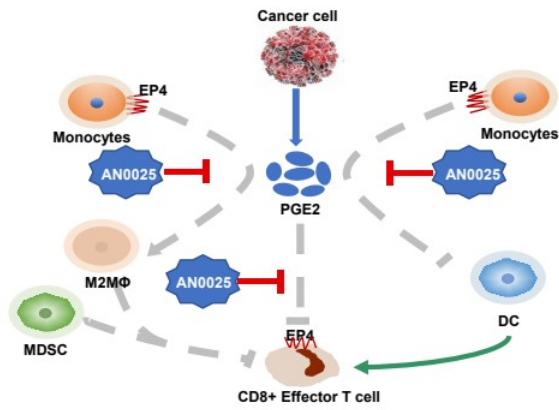
Our Pipeline:

Earlier Stage Clinical Assets

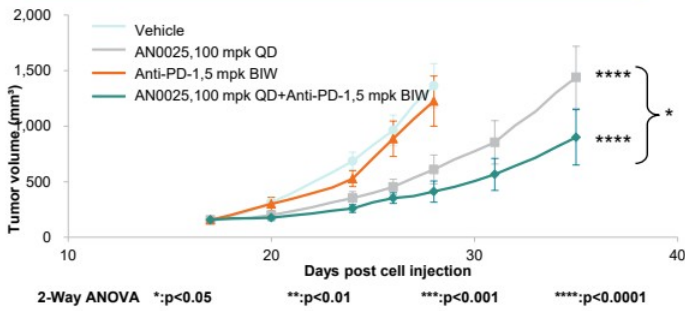


AN0025: Potentially Synergistic Effects in Combination with Checkpoint Inhibitors

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 endpoint

Safety and tolerability

Secondary endpoints

ORR, PFS, DoR, OS



NSCLC



Urothelial Carcinoma



TNBC



Cervical Cancer

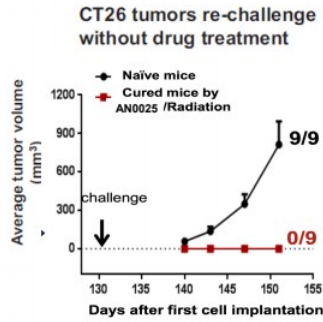
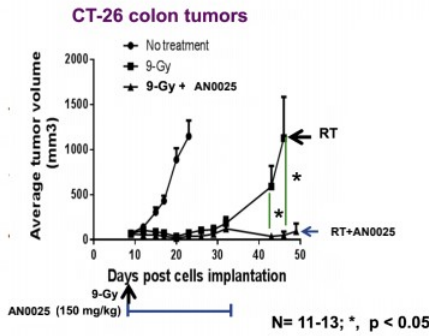
Progressed on anti-PD-1/PD-L1 treatment

Progressed on SoC, no prior L1 treatment

- ✓ All enrolled patients will be treated with AN0025 and Keytruda. If a patient experiences disease progression, unacceptable toxicity, or for a maximum of 35 cycles, they will be withdrawn from the trial.
- ✓ 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:

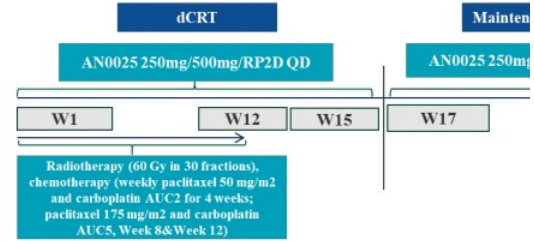
- Locally advanced/locally recurrent EC
- Clinical Stage 2 to 4a (8th AJCC), or Stage 4b
- Unresectable, no prior radiotherapy in the esophageal region

Primary end

- Safety a
- MTD an

Secondary e

- Prelimin: DCR, PF 1.1), OS



- ✓ Currently in cohort expansion phase
- ✓ Clinical results will be presented at ASCO 20

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 enrolled and received the study treatment

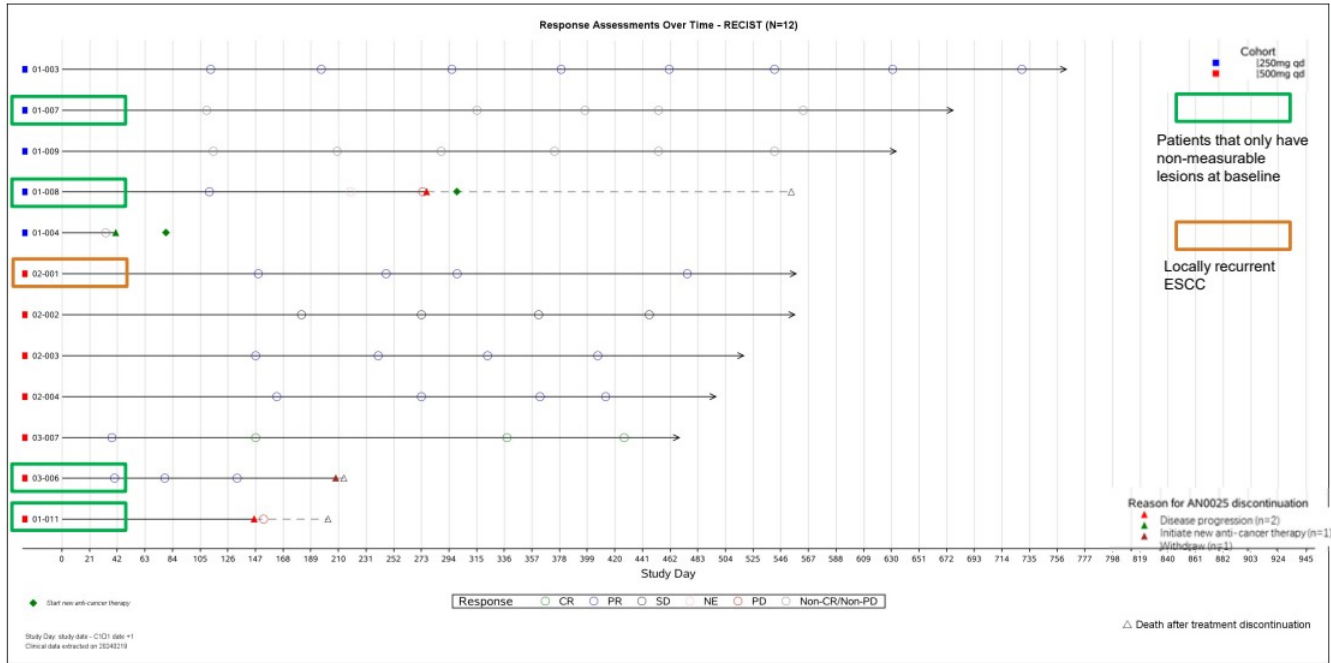
Patient demographics and baseline characteristics

| 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 |

(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 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 + 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

- Overall I
- 15-month
- Patients baseline include
- Patients at baseline (3/4, inc)

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 + 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 ($\geq 30\%$)

| Preferred term | AN0025 250mg QD (N=5) | | AN0025 500mg QD (N=7) | | Total (N=12) | |
|----------------------------------|--------------------------|-------------------------|--------------------------|-------------------------|--------------------|-------------------------|
| | 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 |
| Platelet count decreased | 2 (40.0) | 0 | 2 (28.6) | 0 | 4 (33.3) | 0 |
| Radiation skin damage | 0 | 0 | 4 (57.1) | 0 | 4 (33.3) | 0 |

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

Competitive Landscape in Locally Advanced Esophageal Cancer

| Study name/NCT number | Phase | Sponsor | Study drug | Indication | Sample size | Regimen | Treatment line | Primary endpoint | Start date (FPI) |
|--------------------------------|-------|---------|--|-----------------------|---------------------|---|-----------------------|------------------|------------------|
| BGB-A317-311 (NCT03957590) | III | BeiGene | Tislelizumab (PD-1) | Locally advanced ESCC | 366 (1:1), CN only | Tislelizumab + dCRT vs. placebo + dCRT (concurrent mode) | 1 st -line | PFS | 2019-6-1 |
| SHR-1210-III-323 (NCT04426955) | III | Hengrui | Camrelizumab (PD-1) | Locally advanced ESCC | 390 (1:1), CN only | Camrelizumab + dCRT vs. placebo + dCRT (concurrent mode) | 1 st -line | PFS | 2020-6-3 |
| KUNLUN (NCT04550260) | III | AZ | Durvalumab (PD-L1) | locally advanced ESCC | 600 (2:1), global | Durvalumab + dCRT vs. placebo + dCRT (concurrent mode) | 1 st -line | PFS | 2020-10- |
| KEYNOTE-975 (NCT04210115) | III | MSD | Pembrolizumab (PD-1) | Locally advanced EC | 700 (1:1), global | Pembrolizumab + dCRT vs. placebo + dCRT (concurrent mode) | 1 st -line | EFS, OS | 2022-2-2 |
| SKYSCRAPER-07 (NCT04543617) | III | Roche | Atelizumab (PD-L1) +/- Tiragolumab (TIGIT) | locally advanced ESCC | 760 (1:1:1), global | Atelizumab + Tiragolumab vs. Atelizumab vs. Placebo (consolidation mode following dCRT) | 1 st -line | PFS, OS | 2020-9-2 |

Abbreviation: ESCC = Esophageal Squamous Cell Carcinoma; dCRT = definitive chemoradiation therapy; EFS = event free survival; OS = overall survival

Market Opportunities – Locally Advanced Esophageal Cancer

Locally advanced esophageal cancer in 2028

9,500 U.S. Incidence⁽¹⁾

46,700 7MM Incidence⁽¹⁾

- The concurrent administration of Immune Checkpoint Inhibitors (ICIs) and dCRT can pose challenges or create bottlenecks (KEYNOTE-412⁽²⁾).
- AN0025 + dCRT has the potential to provide novel treatment options beyond ICI in LA EC.

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

(2) <https://www.astrazeneca.com/media-centre/press-releases/2023/update-on-pacific-2-phase-iii-trial-for-imfinzi.html>

(3) *The Lancet Oncology*, doi: [https://doi.org/10.1016/S1470-2045\(24\)00100-1](https://doi.org/10.1016/S1470-2045(24)00100-1)

Preoperative AN0025 + Chemoradiotherapy in Rectal Cancer

An open-label Phase 1b trial:

Main inclusion criteria:

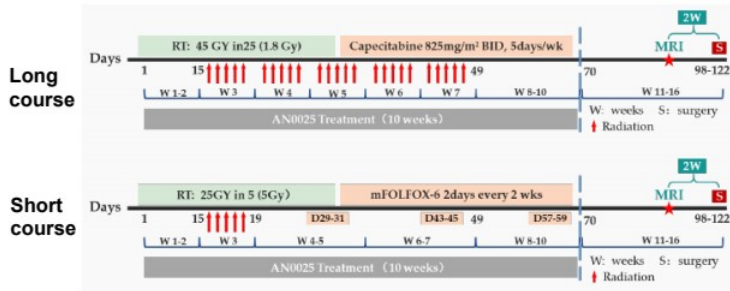
- Locally advanced rectal cancer, no metastatic disease
- Primary resection without CRT is unlikely to achieve clear margins as defined by MRI

Primary endpoints

- Safety and tolerability
- MTD and/or RP2D

Secondary endpoints:

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



Encouraging Preliminary Efficacy

cCR

20%

pCR

16%

- No need for surgery
- Able to avoid proctectomy

- No residual tumor
- Pathological cure

Note: Based on 25 evaluable patients

No DLTs

| TEAE | A |
|--------------------|------|
| Any | 100% |
| Fatigue | 80% |
| Diarrhea | 40% |
| Nausea | 30% |
| Decreased Appetite | 30% |
| Headache | 30% |
| Paresthesia | 30% |

Note: Only listing TEAE patients, N=28

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

Preoperative AN0025 + Chemoradiotherapy in Rectal Cancer

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

Main inclusion criteria:

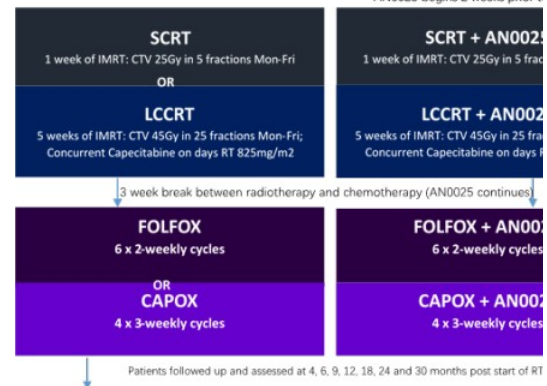
- Biopsy-proven rectal adenocarcinoma; ECOG PS 0-1
- T3b-4a or TanyN1-2 or TanyEMVI+ or with a threatened (<1mm) or involved mesorectal fascia resection margin, or low tumors with involvement of the anal intersphincteric plane or with levator involvement

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 in May 2024
- Collaborated with Leeds University, UK

Market Opportunities – neoadjuvant Rectal Cancer

Neoadjuvant rectal cancer in 2028 **19,000**



50,000

Abbreviation: EMVI = Extramural vascular invasion.

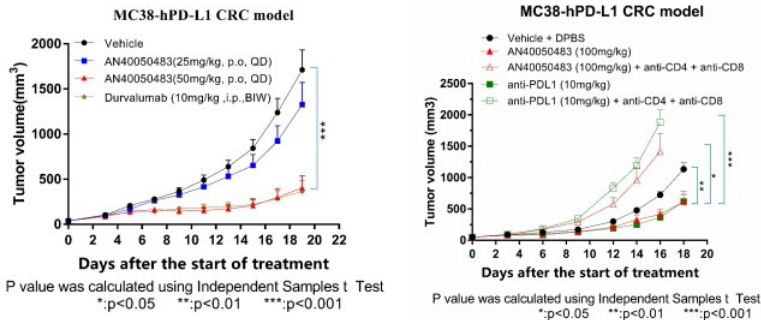
(1) Data from Informa, 2023. 7MM stands for seven major markets (the U.S., the U.K., Germany, France, Italy, Spain, and Japan).

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

AN4005 as a Backbone for Our Future Oral Combination Therapies

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

Robust Activity in Tumor Models



First-in-Human, Dose Escalation study

Main inclusion criteria:

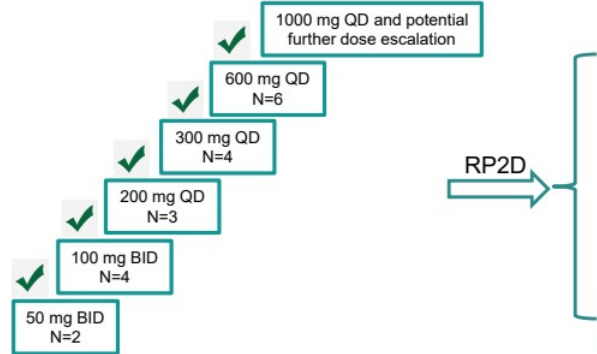
- Advanced unresectable or metastatic solid tumors, or r/r lymphomas
- No standard therapy available
- ECOG 0/1

Primary endpoint

Safety, tolerability

Secondary endpoints

PK, food effect including ORR



- ✓ As of March 2024, 24 eligible patients were enrolled 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

Preliminary Efficacy Summary

- As of March 31st, 2024, 23 patients in U.S. and China were dosed. 74% patients (17/23) had received at least two prior lines of sy
- Overall DCR was 39% (9/23 with 1 CR and 8 SD).
- 43% patients (10/23) have relapsed from immunotherapy; 2 out of these 10 patients showed partial response to prior immunothe (5/10 with 1 CR and 4 SD)
- 57% Patients (13/23) who have not received prior immune checkpoint inhibitors (ICIs) due to specific indications were found not labels. DCR was 31% (4/13 with 4 SD)

26% (6/23) pts dosed with AN4005 among six dose levels reached the TTF (time to failure) \geq 4.2 months.

| Dose Level | Pt ID | Year of birth | Gender | Race | Primary tumor type | PD-(L)1 sensitive? | Prior immunotherapy? | Prior immunotherapy information | AN4005 tr duration |
|------------|----------|---------------|--------|-------|--|--------------------|----------------------|---------------------------------|--------------------|
| 300 mg qd | 20021003 | 1973 | Female | Asian | Colon adenocarcinoma (PD-L1 TPS 30%, MSI-H) | Yes | Yes | BOR was PR | 34 |
| 600 mg qd | 20021005 | 1979 | Male | Asian | Colon adenocarcinoma (EGFR+, pMMR/MSS, PD-L1 TPS<1%) | No | Yes | BOR was PR | 22 |
| 100 mg bid | 10051001 | 1956 | Male | Asian | Thymic cancer | No | Yes | BOR was SD | 39 |
| 200 mg qd | 20031007 | 1956 | Male | Asian | Lung adenocarcinoma | No | No | NA | 18 |
| 600 mg qd | 10031008 | 1952 | Female | White | Uterus endometrial adenocarcinoma | No | Yes | BOR was SD | 16 |
| 300 mg qd | 20021002 | 1972 | Female | Asian | Ovarian cancer | No | No | NA | 14 |

Abbreviation: DCR = disease control rate; CR = complete response; PR = partial response; SD = stable disease; PD = progressive disease; TTF = time to failure; BOR = best of response.
(1) 1 cycle = 28 days

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

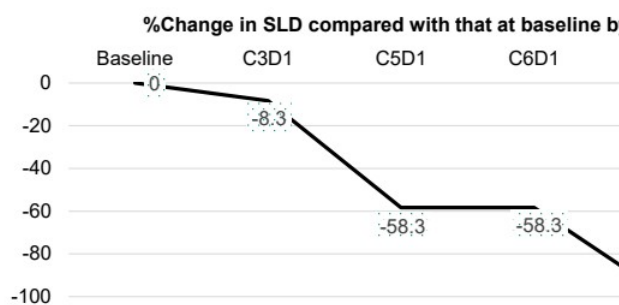
- Prior surgery: Left colon extended radical resection
- Prior systemic therapy:
 - 1) XELOX as adjuvant treatment from Dec 2020 to Apr 2021 followed by one dose of XELOX plus Camrelizumab (an approved PD-1 antibody in China) on 8 May 2021
 - 2) Raltitrexed+Bevacizumab+Camrelizumab/Toripalimab (an approved 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 |
|----------------------------|--------------------------|------------------------------|-----|
| Baseline | 12 | NA | |
| 1 st TA (C3D1) | 11 | Present | |
| 2 nd TA (C5D1) | 5 | Present | |
| 3 rd TA (C6D1) | 5 | Present | |
| 4 th TA (C8D1) | 0 | Present | |
| 5 th TA (C11D1) | 0 | Absent | |



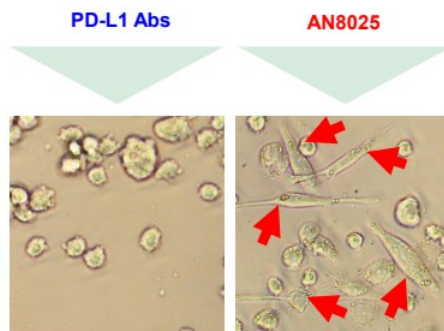
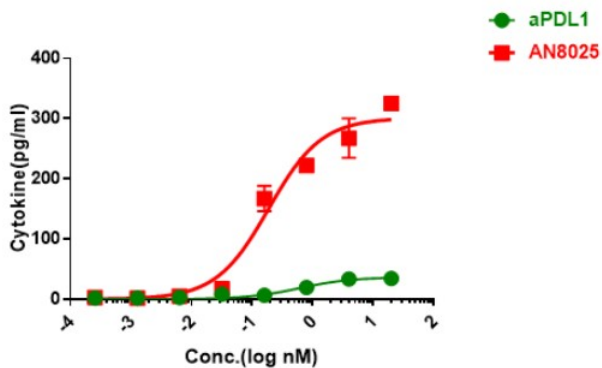
Abbreviations: TA = tumor assessment; SLD = sum of longest diameters of target lesions; RECIST = response evaluation criteria in solid tumors; SD = stable disease; PR = partial response; CR =



Our Pre-clinical Pipeline:

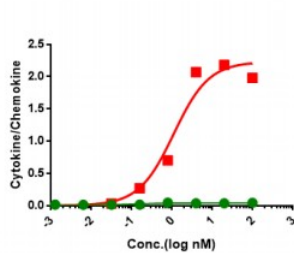
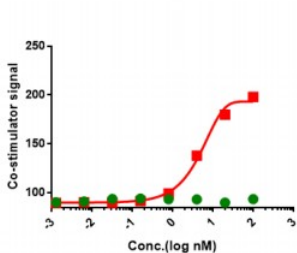
Preclinical Assets with Near-Term INDs

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



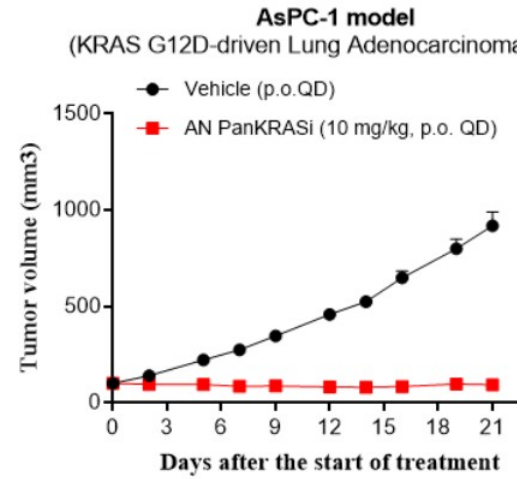
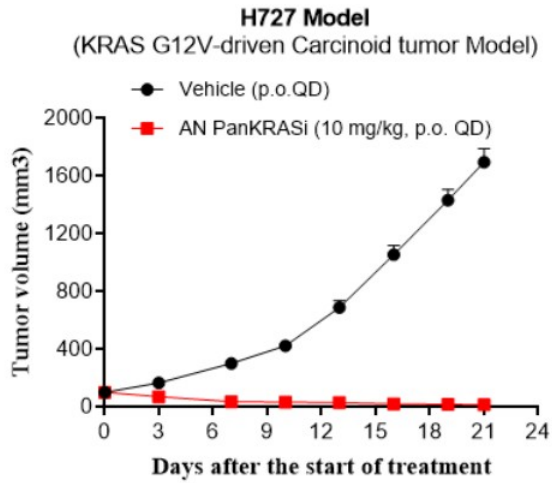
AN8025 imp
and qua
pres

AN8025's Ability to Fully Induce Immune Response in Vitro



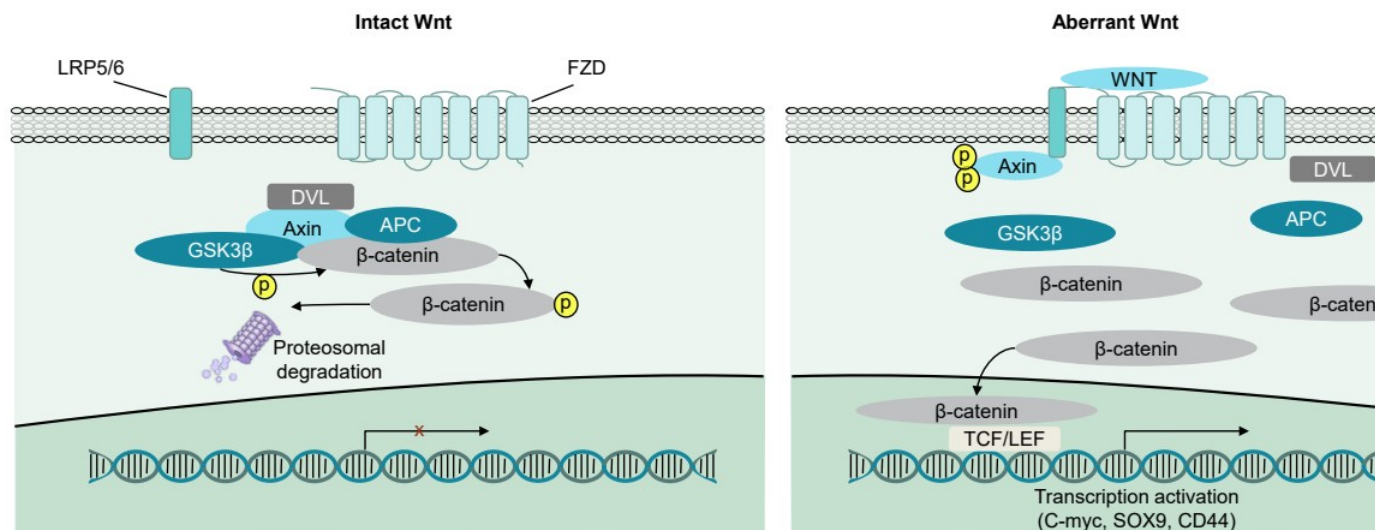
Compared to an anti-PD-L1 mAb, where almost no co-s detected, AN8025 showed significantly stronger co-stim represented enhanced interactions between T c

Currently in IND enabling stage; IND filing expected in H1 2025



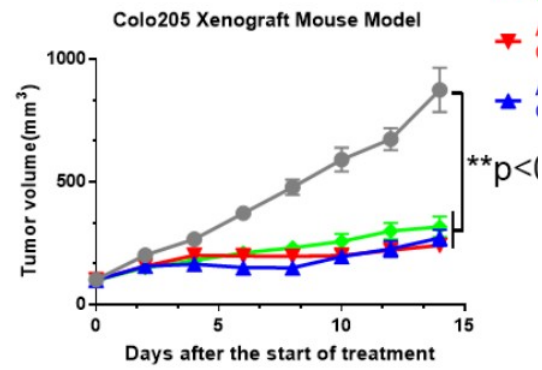
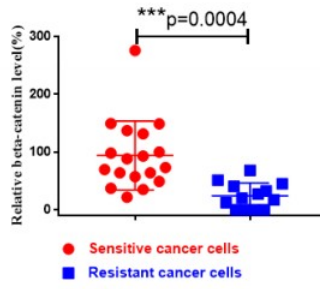
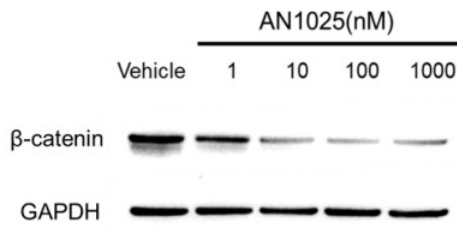
- Addresses broad range of KRAS mutations (one of the most commonly mutated proteins in cancer) in multiple tumor types
- Efficiently inhibited cancer types with KRAS mutations including pancreas adenocarcinoma, lung adenocarcinoma, and colorectal adenocarcinoma. IC₅₀ values
- Shows deep, sustained, and durable anti-tumor efficacy in KRAS-driven xenograft mice models
- Development candidate expected in Q2 2024

Mechanism of Action



- Wnt/ β -catenin pathway is one of the key tumor-promoting signaling cascades that regulate cell cycle progression, epithelial-mesenchymal transition, angiogenesis, 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 intervention

Source: McCord et al., 2017.



- 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 mouse model