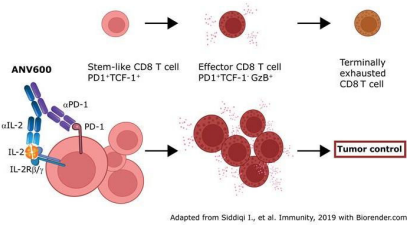


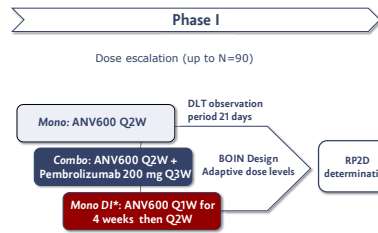
Background

ANV600 is a novel PD-1-targeted IL-2Rβγ agonist that binds PD-1 on a unique non-blocking epitope, distinct from that targeted by pembrolizumab and other PD-1 checkpoint inhibitors. It is designed to preferentially stimulate PD-1⁺ CD8⁺ T cells with a pre-exhausted, cytotoxic phenotype, aiming to activate tumor antigen-experienced T cells within the tumor microenvironment.



This targeted, non-blocking PD-1 approach may reduce IL-2-related toxicities, enhance tumor selectivity, and potentiate responses in checkpoint-refractory tumors without compromising combination therapies.

EXPAND-1 study design and patient characteristics



Key Eligibility Criteria

- ≥ 18 years of age
- ECOG PS 0 or 1
- Measurable disease per RECIST v1.1 criteria
- Adequate organ function
- No IL-2 or IL-2 analogues prior anti-cancer therapy within 18 months
- No known active central nervous system metastases and/or carcinomatous meningitis

Primary Objective:

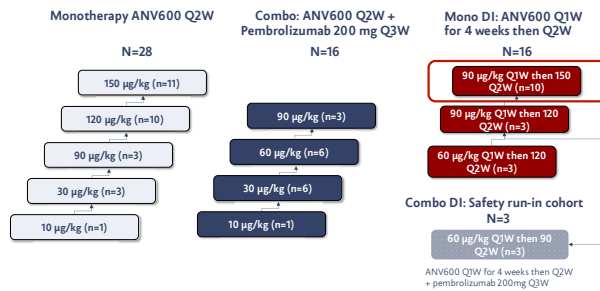
To determine MTD and/or RP2D of ANV600 single agent and in combination with pembrolizumab

Demographic /performance status	Total n=63 (%)
Age (mean; years)	59.8
Male	41
Female	22
ECOG PS 0	27
ECOG PS 1	36
Primary cancer diagnosis	
Anal Cancer	8
Non-small Cell Lung Cancer (NSCLC)	8
Colorectal Cancer (CRC)	7
Ovarian Cancer	4
Renal Cancer (RCC)	4
Cutaneous Melanoma	3
Mucosal Melanoma	3
Gastric cancer	2
Head And Neck Squamous Cell Carcinoma (HNSCC)	2
Other	22

Prior Lines of Therapy and Checkpoint Inhibitor (CPI) Exposure
Monotherapy n=44 (%)
Prior lines of therapy (Range)
4 (1 - 16)
Prior CPI exposure
27 (61%)
Combination n=19 (%)
Prior lines of therapy (Range)
4 (1 - 10)
Prior CPI exposure
9 (47%)

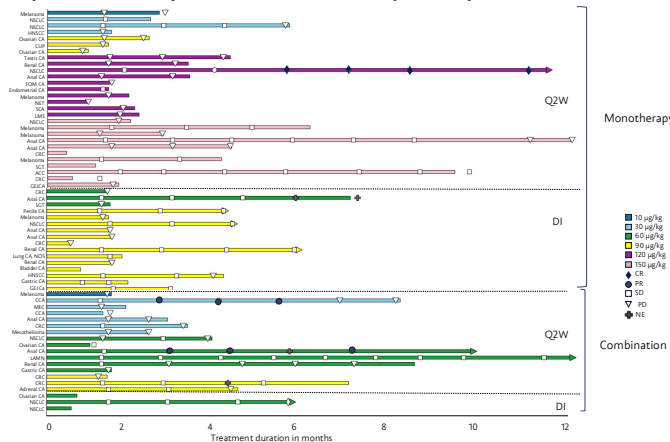
Results

EXPAND-1: Dose escalation cohort status

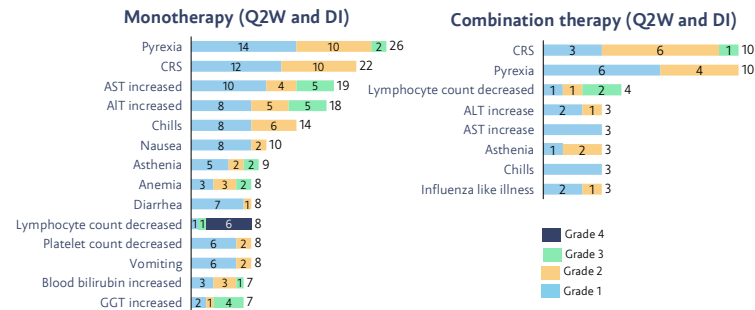


RP2D determined as 90µg/kg Q1W for four weeks followed by a maintenance dose of 150µg/kg Q2W

Exposure: On-study Patients' Duration & Responses by RECIST v1.1

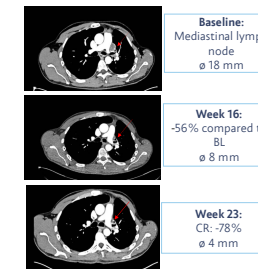


Safety: ANV600 related AEs reported in ≥ 15% of Patients (CTCAE v5.0) (Highest grade per patient)



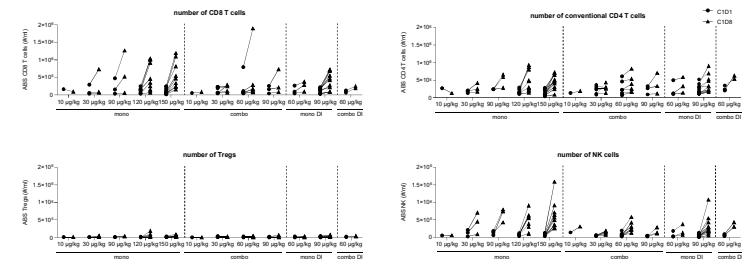
- ANV600 was generally well tolerated
- The safety profile observed is similar across the regimen (monotherapy and combination, Q2W and dose intensification)
- The transaminases elevations reported were transient and self-limiting

Complete response in a NSCLC patient: ANV600 monotherapy (120µg/kg)



- Baseline: Mediastinal lymph node ø 18 mm
- Week 16: -56% compared to BL ø 8 mm
- Week 23: CR: -78% ø 4 mm
- 37 years old male with NSCLC
- TMN staging at trial entry: stage IV, T4, N3, M1
- Bronchial adenocarcinoma with mediastinal metastasis
- Prior systemic therapies: Durvalumab (09/2023 – 05/2024) Carboplatin + Paclitaxel (07/2024 – 11/2024)
- 120 µg/kg ANV600 monotherapy

Pharmacodynamics: absolute numbers of immune cells in peripheral blood



- ANV600 treatment results in higher absolute numbers of CD8⁺ T cells than Tregs in peripheral blood at CID8.
- CD8, conventional CD4, Tregs, and NK cell dynamics were similar between ANV600 monotherapy and combination treatment with pembrolizumab.

Conclusions

- ANV600 is well tolerated as monotherapy and in combination with pembrolizumab.
- CRS, pyrexia and transient increase of liver transaminases were the most frequently reported AEs.
- The RP2D established based on the totality of dose-escalation data (Safety, PK, PD) is ANV600 90µg/kg Q1W for 4 weeks followed by a maintenance dose of 150µg/kg Q2W.
- A CR was observed in a patient with NSCLC previously progressing on CPI, treated with ANV600 monotherapy at 120 µg/kg Q2W.
- PRs were reported for two patients treated respectively with 30 µg/kg and 60 µg/kg ANV600 Q2W in combination with pembrolizumab Q3W.
- Treatment with ANV600 resulted in higher absolute counts of CD8⁺ T cells and NK cells over regulatory T cells.
- These data suggest clinical benefit and warrant additional clinical investigation with larger patient cohorts.

Thank you to all sites and patients in the study!

1 Health Oostvliet (MOCH), Medical Oncology & Hematology, St. Gallen, Switzerland; 2 START Madrid-CCIC, Centro Integral Oncológico Clara Campal, Madrid, Spain; 3 Oncology Institute of Southern Switzerland, Ente Ospedaliero Cantonale, Bellinzona, Switzerland; 4 Institut Universitaire du Cancer de Toulouse Oncopole, Toulouse, France; 5 Institut Bergonié, Bordeaux, France; 6 Krankenhaus Nordwest GmbH, Frankfurt, Germany; 7 Département d'Innovation Thérapeutique et d'Essais Préoces (DITEP), Gustave Roussy, Villejuif, France; 8 University Medical Center of the Johannes Gutenberg University Mainz, Germany; 9 Hospital Clínico Universitario de Valencia, Valencia, Spain; 10 Hospital Universitario Vall d'Hebron, Barcelona, Spain; 11 Netherlands Cancer Institute Amsterdam, the Netherlands; 12 Comprehensive Cancer Center and Dept of Hematology, Oncology and Tumor Immunology, Charité - Universitätsmedizin Berlin, Berlin, Germany; 13 Karmanos Cancer Institute/ Wayne State University, Detroit, MI, USA; 14 University of Texas, MD Anderson Cancer Center, Houston, TX, USA; 15 Clínica Universidad de Navarra, Pamplona, Spain; 16 Cliniques Universitaires Saint-Luc, Brussels, Belgium; 17 Merck & Co., Inc., Rahway, NJ, USA; 18 Anaveon AG, Basel, Switzerland; 19 CEPCM, Hôpital de la Timone, APHM, Marseille France

