

# Økonomisk Ugebrev Investorkonference Søren Bregenholt, CEO 30 Oktober 2024



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## **Investment Case**

01 Phase 2 Biotech company focused on immuno-oncology

Pipeline of best-in-class agonistic monoand bispecific antibodies

02 Best-in-class immunotherapy (CD40 agonist) in pancreatic cancer

Meaningful impact on pancreatic cancer survival with mitazalimab in phase 2

03 Clear path to approval in pancreatic cancer

Regulatory dialogue confirms path forward

04 ) Alligator after mitazalimab

Neo-X-Prime® – the future of CD40 bispecific antibodies

05 Could Alligator be the next M&A target?

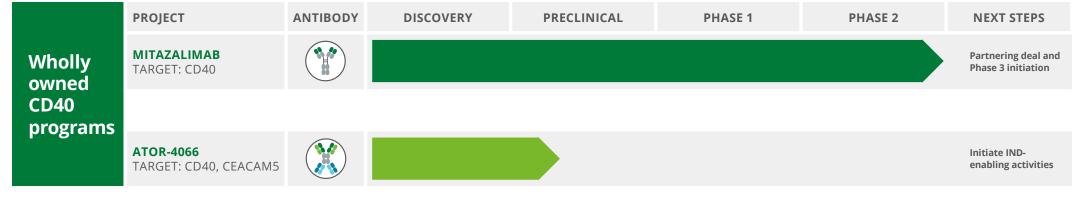
Life sciences deals have rallied back in recent months





## Phase 2 Biotech company focused on immuno-oncology

Robust Immuno-Oncology Pipeline



## **Co-developed program:**



**ALG.APV-527** TARGET: 4-1BB, 5T4



Phase 1 completion H2 2024





## **Mitazalimab**

Best-in-class CD40 agonist in pancreatic cancer

Optimal binding epitope:

Domain 1 on CD40

Optimal Fc:
Wild type IgG1

Anti-CD40

Anti-CD40

CD40

CD40

Domain 1A-4

2A

3A

4A

Cell membrane

## **CD40 Expression:**

 Highly expressed on dendritic cells (DC), macrophages, and B cells.

## **Functional Highlights:**

- Optimal activation of dendritic cells for robust priming of tumor-specific T cells.
- Induces macrophage activation, leading to tumor stromal degradation and improved chemo and immune cell penetration.

### **Ideal Combinations:**

- > With chemotherapies for cold tumors (e.g., pancreatic cancer).
- > With PD-1/PDL-1 for hot tumors (e.g., urothelial cancer).

## **Regulatory Status:**

- > Orphan Drug Designation (FDA and EMA).
- > IND accepted (FDA) for advanced bladder cancer.

## **Clinical Study - OPTIMIZE-1:**

- > Phase 2 study in 1<sup>st</sup> line metastatic pancreatic cancer.
- > Combination with mFOLFIRINOX, with mature primary analysis data.

Futility analysis – 2 Jan 2023
Interim analysis – 26 Jun 2023
Primary analysis – 29 Jan 2024
18-month follow-up – 26 Jun 2024





## Pancreatic cancer

Poorly served by Standard of Care

# Standard of care

Only option is chemotherapy for 80% of patients

- > FOLFIRINOX increasingly used as 1st line regimen in EU and US with ~33% market share
- > Gemzar® gemcitabine holds 60-70% market share in EU and US
- > NALIRIFOX, recently approved combination, offers a small incremental improvement on duration of response but <u>no overall survival benefit</u> over FOLFIRINOX\*
- > Prognosis remains very poor: 5-year survival ~10% and median survival ~6 months

## **Mitazalimab**

- > Nearly <u>doubles duration of response</u> in combination with FOLFIRINOX
- > Unprecedented overall survival data
- > Well-tolerated immunotherapy

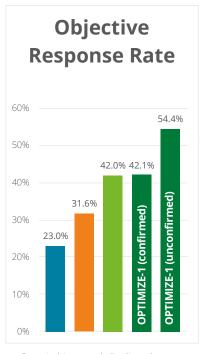


<sup>\*)</sup> Non-contemporaneous comparison

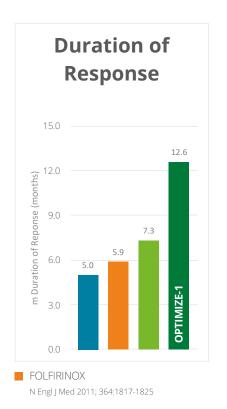


## **OPTIMIZE-1** outcomes in the context of SoC chemotherapy

Unprecedented duration of response: Median 12.6 months







Overall Survival

15.0

12.0

11.1

11.1

11.1

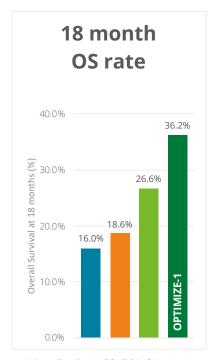
9.0

8.5

NALIRIFOX

Lancet 2023; 402[10409]:1272-1281

Lancet 2023; 402[10409]:1272-1281 Gemcitabine + nab-Paclitaxel DoR values were obtained from this study



■ Mitazalimab + mFOLFIRINOX Lancet Oncology 2024; S1470-2045(24)00263-8

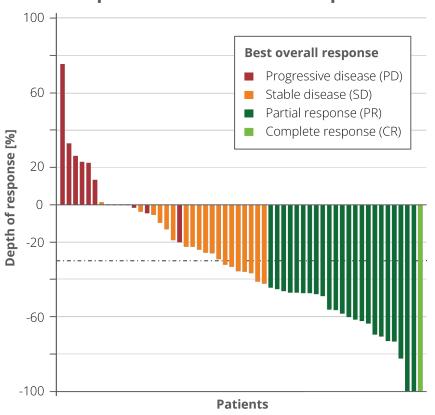




## **OPTIMIZE-1**

Individual patient data (N=57) shows broad efficacy

# Waterfall plot shows best overall response for each individual patient



# Unprecedented clinical benefits in metastatic pancreatic cancer

- > Deep and durable responses
- > 3 patients with complete remission of target lesions
- > 18 months survival nearly doubled versus chemotherapy alone
- > 6 patients remained in study for more than 24 months
- 16 patients still alive in the study 19 months after completed enrollment in March 2023
- > Progression free survival (PFS) at 18 months was over 20%
- > ~80 of patients showed clinical benefit
- > Tolerability similar to mFOLFIRINOX alone



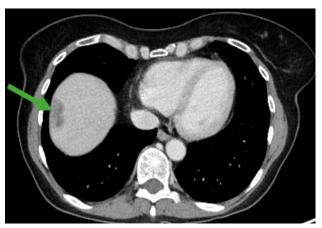


## **Patient case study**

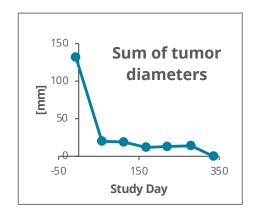
Treatment ongoing as of October 2024

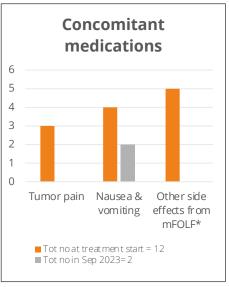
Sep 12, 2022
CT scan before treatment
Liver metastases: 22 + 14 mm

Aug 21, 2023
CT scan after cycle 22
Liver metastases: 0 mm









\*) Dysgeusia; mucositis; constipation; iron deficiency; sensory polyneuropathy

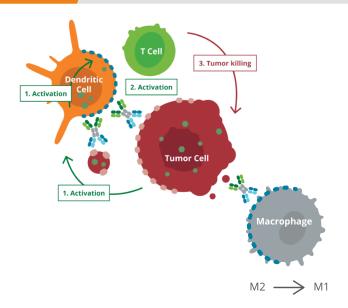




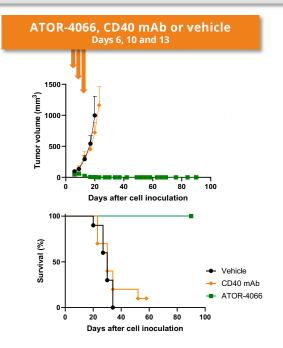
# Alligator beyond mitazalimab Neo-X-Prime® - the future of bispecific antibodies

Neo-X-Prime®

- CD40-binding > stromal disruption and increased tumor penetration
- TAA-binding > uptake of tumor derived material induces broad immunological memory and improved tumor killing



## Superior efficacy vs CD40 mAb







# **Significant news flow over the next 12 months**Clinical and operational updates expected

Mitazalimab	OPTIMIZE-1 top-line readout	Q1 2024	<b>Ø</b>
> ALG.APV-527	Interim Phase 1 readout	H1 2024	
Mitazalimab	OPTIMIZE-1 18-months survival follow-up	Mid 2024	
Mitazalimab	Recruitment of 450 µg/kg cohort completed	Q3 2024	
> ALG.APV-527	Top-line phase 1 data	Q4 2024	
Mitazalimab	US and EU regulatory interactions	Q4 2024	
Mitazalimab	OPTIMIZE-1 24-month follow-up	Q1 2025	
Mitazalimab	Phase 3 initiation	H1 2025	





## **Key Strategic Objectives**

to Deliver Value to All our Stakeholders

2024

## Phase 2 top line read-out in 1st line pancreatic cancer

 OPTIMIZE-1 delivered outstanding mitazalimab data in 1st line pancreatic cancer

### Preferential rights issue

To pursue mitazalimab development and further development of other assets in the pipeline

#### Partner mitazalimab

Find the best global partner to take mitazalimab through Phase 3, and all the way to a commercial success 2025

#### Mitazalimab Phase 3 initiation

Initiate Phase 3 in 1st line Pancreatic Cancer

## Go beyond CD40 with 4-1BB

> Deliver ALG.APV-527 Phase 1 results

### **Deliver on partnerships**

- Deliver clinical data
- > Enter new collaborations

Beyond 2025

# Broaden proprietary and partnered clinical pipeline

- > 3 mid-stage assets by 2030
- > 5 partnered assets by 2030

# Generate first sustainable revenues and reach operating profitability

- > Mitazalimab approval expected in 2030
- Partnership to generate milestones offsetting part of internal R&D



## **Contact information**

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