

# Mitazalimab – a potential gamechanger in pancreatic cancer and beyond

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Clinical stage biotech company fully focused on immuno-oncology

Deep pipeline of best-in-class agonistic mono- and bispecific antibodies

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Novel mono- and bispecific antibody technology platforms

Listed on Nasdaq Stockholm, ATORX

Headquarter: Lund, Sweden



### **Robust Immuno-Oncology Pipeline**





### Mitazalimab - a CD40 Agonist Regulating Key Components of Tumor Specific Immunity



#### Designed with optimal balance of safety/ immune activation

- Binding epitope provides optimal agonistic effect
- FcγR crosslinking-dependent CD40 agonist for tumor-directed effect
- Wildtype IgG1 Fc avoids FcgRIIb-driven exaggerated immune activation

#### Clinical Phase 1 data supports best-in-class profile

- Pharmacokinetics as expected
- Tolerable at high dose levels, 1.2 mg/kg well above target saturation
- Disease control rate 38% as single agent- including pancreatic cancer
- Dose dependent activation of dendritic cells, macrophages and T-cells

#### Phase 2 in 1<sup>st</sup> line pancreatic cancer - OPTIMIZE-1

- Combo with mFOLFIRINOX
- First patient dosed Q3 2021
- ORR of 52.2% announced week 1, 2023
- 2nd interim read-out expected mid-2023
- Topline read-out expected in Q1 2024



### Pancreatic cancer - significant unmedical need

### Pancreatic Cancer

- > 12<sup>th</sup> largest cancer by number of patients
- > 6<sup>th</sup> largest cancer by number of deaths
- > Approximately 200.000 annual cases in US + EU
- > For 80% of patients only option is chemotherapy
- > Chemotherapy offers only marginal benefit
- > 5-year survival ~10% and median survival ~11 months
- > Indication qualified for Orphan Drug Designation
- Global pancreatic cancer market expected to grow at 11.6% CAGR from 2019, to ~\$ 5.4 Bn by 2029
- > FOLFIRINOX preferred for best performing patients
- > US and EU with ~33% market share







### **OPTIMIZE-1: Phase 2 Study of Mitazalimab in 1<sup>st</sup> Line Pancreatic Cancer**

Rationale	Overview
<ul> <li>Leverage mitazalimab efficacy/safety balance:</li> <li>Combine with mFOLFIRINOX in 1<sup>st</sup> line pancreatic cancer</li> <li>Dose higher than peers</li> <li>Dose more frequent that peers</li> </ul>	<ul> <li>1<sup>st</sup> line metastatic pancreatic cancer in combo with mFOLFIRINOX</li> <li>64 patients to be enrolled at 900 µg/kg</li> <li>Ongoing recruitment in FR, BE &amp; SP</li> </ul>



CT: Computed Tomography

EoT: End of Treatment Visit

For each treatment cycle, mFOLFIRINOX is given at day 1 and mitazalimab at day 3 in order for mFOLFIRINOX to induce tumor cell death and release tumor antigens that can be taken up by dendritic cells, then allowing mitazalimab to activate these dendritic cells so that they efficiently present the tumor antigens to the T cells.



Interim phase 2 data show mitazalimab + FOLFIRINOX differentiation from chemo-backbone in 1st line pancreatic cancer



PRODIGE: Conroy et al, N Engl J Med 2011; 364:1817-1825, AVENGER: Agop Philip et al, ASCO 2022 CISPD3: Fu et al, ASCO GI Cancer Symposium 2022, Shigal et al ESMO 2014 and Li et al, Cancer Lett.2017; 406; 22-26

Interim analysis outcome Objective Response Rate: 52% Disease Control Rate: 91% Safety profile with FOLFIRINOX confirmed

2nd Interim analysis mid-2023 ORR and DCR from more patients Maturing Progression Free Survivial data Biomarker data



### **Upcoming mitazalimab Milestones and Priorities**





### Neo-X-Prime<sup>™</sup> a Novel Myeloid Engagers Driving Tumorspecific Immunity

#### Increase priming of tumor specific T cells



Brings together in-house CD40 and immunooncology expertise with proprietary technology platforms and know-how

## CD40 x TAA bsAb inducing powerful patient-specific immune responses:

- Delivering tumor exosomes to dendritic cells
- Inducing T-cell responses to tumor neo-antigens
- Enhancing tumor elimination

#### Technology suitable for multiple CD40 x TAA combinations:

- Applicable across multiple tumor types
- Future proprietary and partnered pipeline
- Growth and transactional catalyst
- Validated by MacroGenics agreement



### Neo-X-Prime<sup>™</sup> conditional T- cell priming and activation



### Neo-X-Prime<sup>™</sup> drive superior in vivo efficacy



#### Neo-X-Prime has superior effect on tumor growth and survival vs. the combination of monotargeting therapies



Human CD40 transgenic (hCD40tg) mice were inoculated with MB49-TAA<sup>+</sup> cells s.c. and administered at equimolar doses with 100 µg CD40 mAb, 167 µg isotype-TAA bsAb, 100 µg CD40 mAb plus 167 µg isotype-TAA bsAb or 167 µg CD40xTAA bsAb.



### ATOR-4066: a First-in-class CEA x CD40 Neo-X-Prime bi-specific Antibody

- > Targets CEA (also known as CEACAM5)
  - GPI linked glycoprotein involved in cell adhesion, migration and invasion
  - > Expressed on tumor debris/exosomes/extracellular vesicles
  - > Highly expressed tumor selective target
  - > Lead candidate identified
- Outstanding functional properties and anti-tumor efficacy
  - > Strong developability profile
  - > Favorable PK profile
  - > Low immunogenicity risk
  - > Surrogate CD40xCEA bsAb well tolerated  ${\leq}37.5 \text{mg/kg}$  in Non-Human Primate
- Opportunities in colorectal, gastric, pancreatic, bladder and breast cancer





### Neo-X-Prime<sup>™</sup> Offers Future Growth Opportunities Across Multiple Indications

### TAA-binding domains



**CD40-binding domains** 



- > Enhance clinical response to radiotherapy and chemotherapies in cold tumors (blue), macrophage dense tumors
- > Enhance clinical response to CPI in hot tumors (red)
- > New treatment options in hemato-oncology



### ALG.APV-527 molecular design and mechanism





#### Non-Confidential Presentation



### ALG.APV-527 clinical plan overview

- Phase 1 study protocol finalized
  - Multicenter, open-label, dose escalation and dose expansion study
  - Dose escalation with modified 3+3 design
  - Intravenous dosing of ALG.APV-527 biweekly
  - Patients with advanced and/or refractory solid malignancies reported to have high 5T4 expression to be included
- FDA issued a "May Proceed" notification for the ALG.APV-527 IND in October 2022,
- First patient dosed February 2023



Non-Confidential Presentation





### **Alligator Investment Summary**

Mid-stage biotech company with core expertise on CD40 pathway and proven ability to deliver partnerships

Best-in-Class mitazalimab CD40 agonist in Phase 2 in Pancreatic cancer with major inflection points mid-2023 and early 2024

Additional long-term opportunities including:

- ATOR-4066 a CD40/CEA boosting dendritic and T-cell activation
- Neo-X-Prime<sup>™</sup> 3<sup>nd</sup> generation CD40 agonists

4 Highly differentiated antibody platforms

Proven track record in licensing with 5 existing partnerships and clinical stage programs ready for out-licensing

Attractive upcoming news flow over the coming 6-24 months

### Upcoming mitazalimab news flow

Mitazalimab interim data at ASCO June 23	June 2023
Mitazalimab interim ORR and PFS data	Mid-2023
Mitazalimab phase 2 topline data	Q1 2024
Initiation of phase 2 study in undisclosed indication	H1 2024







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