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SEMIA



## An Next-Generation Personalised Immunotherapy Platform based on Artificial Intelligence and Synthetic DNA

Jean-Marc Limacher, MD



## ODI-2001 a solution for unmet medical needs

*Medical Need*



Immune Checkpoint Inhibitors' (ICIs) efficacy is limited to 20% of patients

*Our Solution*



Personalized double adjuvanted immunization platform based on Synthetic DNA and AI

*Expected benefit*



- ✓ Improved results of ICIs (anti-PD1) in their current indications
- ✓ anti-PD1 activity in not yet addressed indications

*Technology advantages*



Powerful immunization  
Short turn-around time  
Low COGs (Cost of Goods)

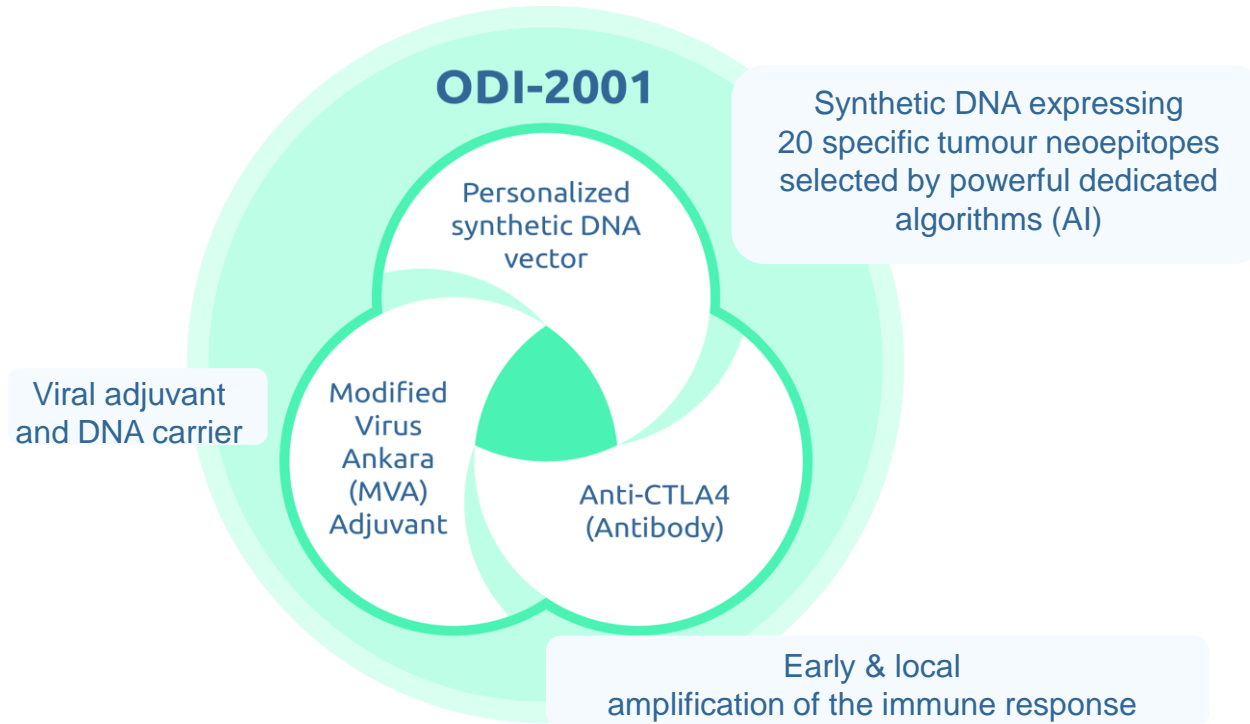
*Clinical trial ready to go*



GMP product ready  
Investigation center ready to go

# ODI-2001: Odinma's proprietary synthetic DNA based personalized immunotherapy

ODI-2001 product is Classified by EMA as Gene Therapy (ATMP)



- ✓ Proprietary formulation (WO2017060650)
- ✓ Two additional patents filed
- ✓ Neoepitope selection by AI (myNEO®)
- ✓ Manufacturing ready and supply chain in place
- ✓ Limited production cost for synthetic DNA
- ✓ No bacterial residues, no antibiotic resistance genes, no antibiotics
- ✓ MVA and anti-CTLA4 of produced in advance
- ✓ 7 weeks manufacturing process

DNA adsorption on MVA, double promoter allowing DNA expression both from nucleus and cytoplasm of MVA infected cells



# ODI-2001 production process

## 2 Sequencing & Mapping

Sequencing and mapping of the mutations present in the tumor DNA

## 1 Collection

Collection of individual patient samples from blood and tumor in order to extract DNA

## 6 Delivery & subcutaneous administration of the solution

## 3 Neoantigens prediction by AI myNEO® prediction algorithm

## 4 Tailored synthetic DNA production

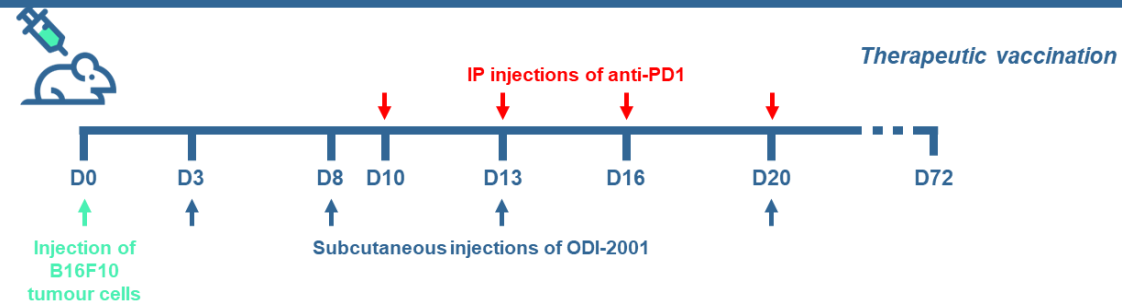
## 5 Packaging and shipping



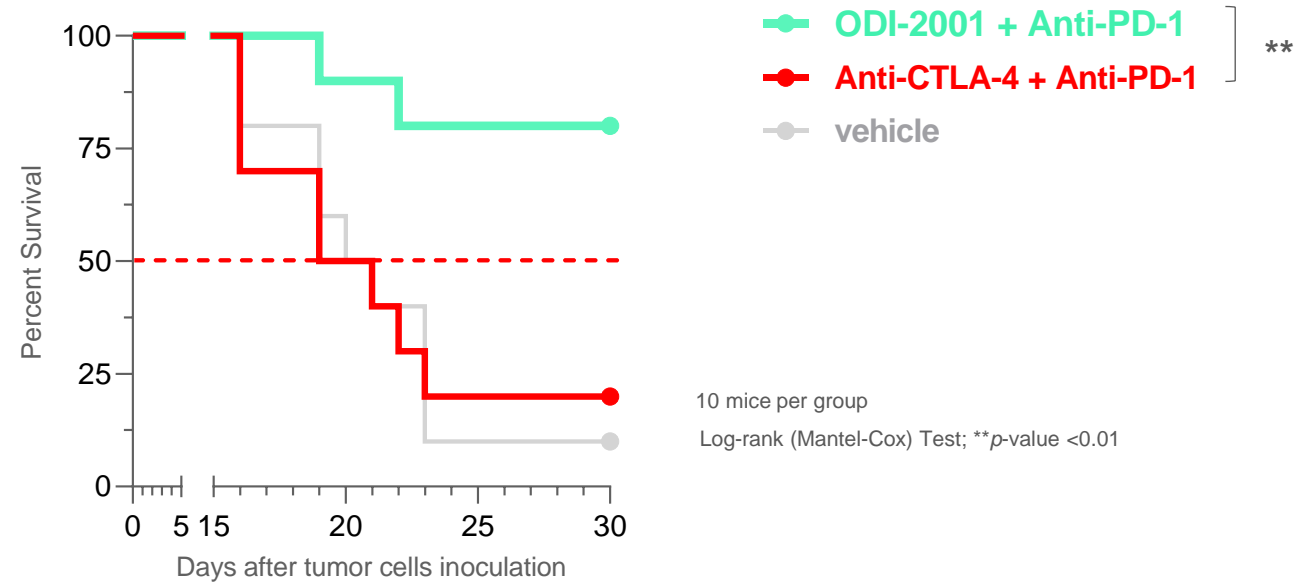
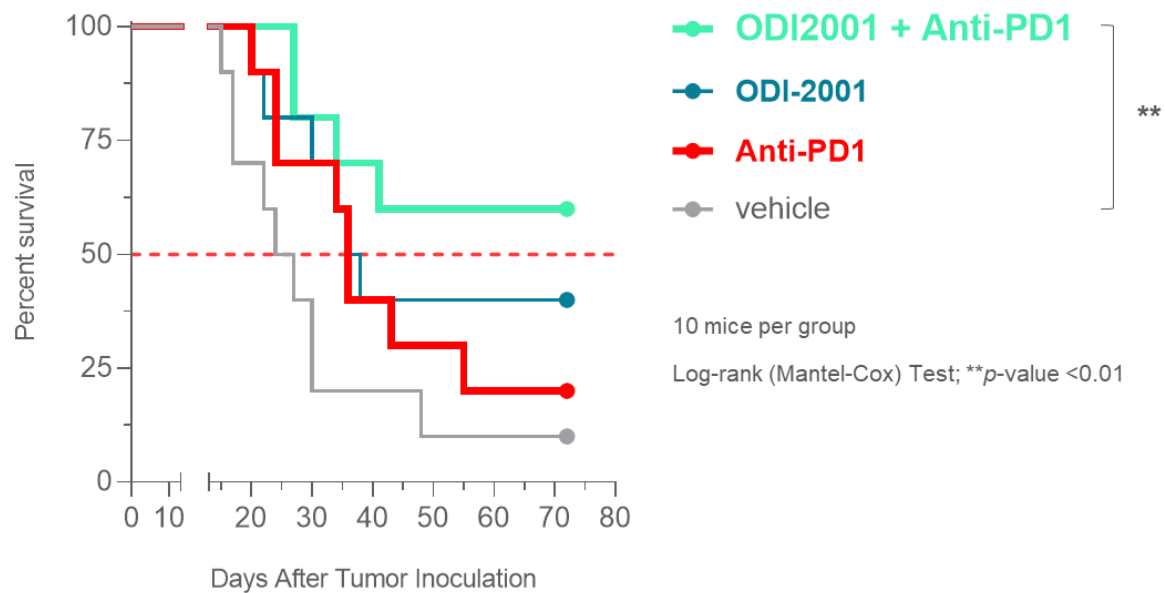
Through an only 6 to 8 week process, Odemma is able to offer each patient an innovative and powerful personalized immunotherapy



# ODI-2001 potentiates the most used immunotherapy (Anti-PD1)



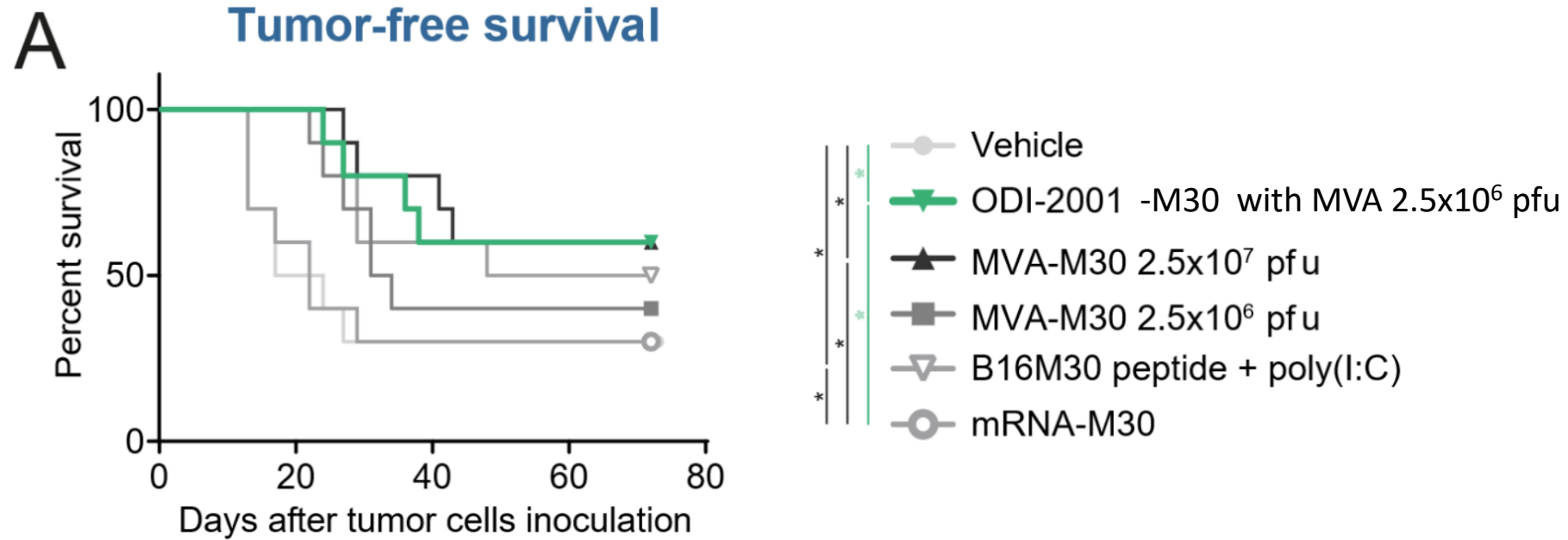
Survival in mice melanoma model



ODI-2001 combined to anti-PD1 performs significantly better than anti-PD1 +/- anti-CTLA4 in an aggressive mice melanoma model  
Significant activity in monotherapy



## ODI-2001 performs better than competitive immunization technics including lipoplexed mRNA

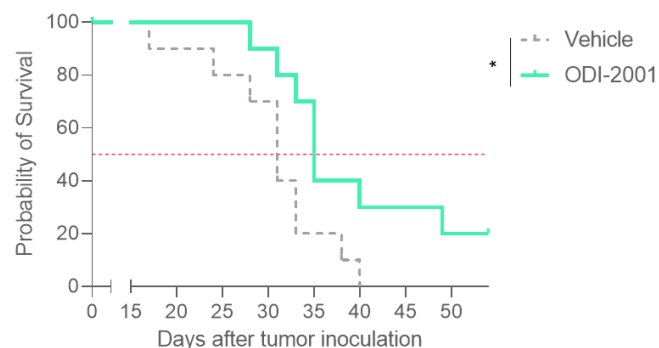
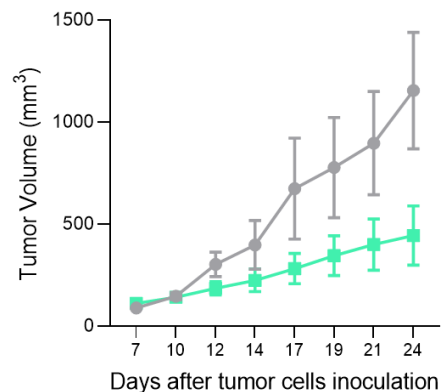


B16F10 mice melanoma model, M30 neoepitope, monotherapy



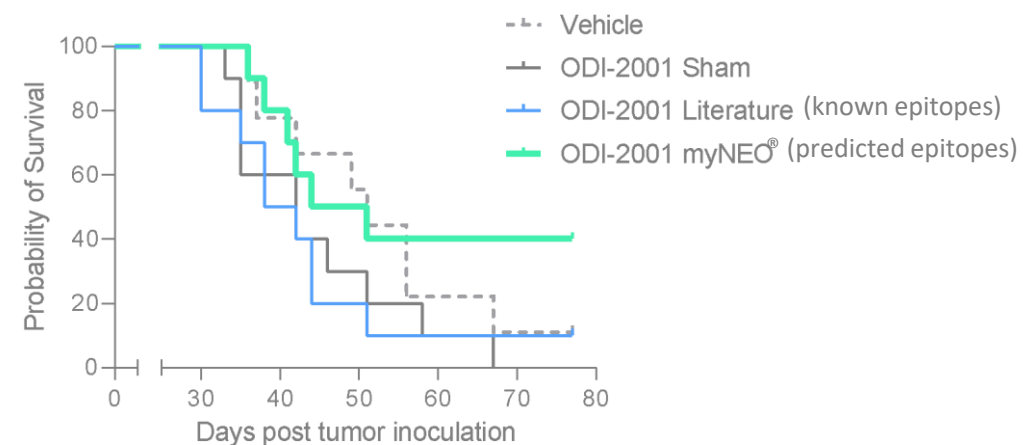
## ODI-2001: robust activity accross different aggressive cancer models

### Metastatic colo-rectal carcinoma



ODI-2001 treatment increases the survival in advanced stage CT26 model

### Triple negative breast cancer



ODI-2001 treatment increases mice survival in 4T1 model, the myNEO<sup>®</sup> prediction algorithm is key



## Phase I/II in colorectal cancer

### *Indication*



Advanced stage colorectal cancer

### *Investigator centers*



Principal Investigator : Pr F. Ghiringhelli,  
Centre Georges François Leclerc, INSERM, Dijon, France  
Additional centers under investigation

### *Rationale*



- ✓ ICIs approved only in 15% of CRC (those with DNA instability)
- ✓ Personalized immunotherapy with ODI-2001 aims to induce similar immunity in CRC patients with stable DNA (85% of cases)
- ✓ Preclinical activity of ODI-2001 in CT26 colon cancer model
- ✓ Phase I in 15 patients in 2025

### *Study extension with additional patient cohorts*



Other settings, combination with ICIs (anti-PD1)

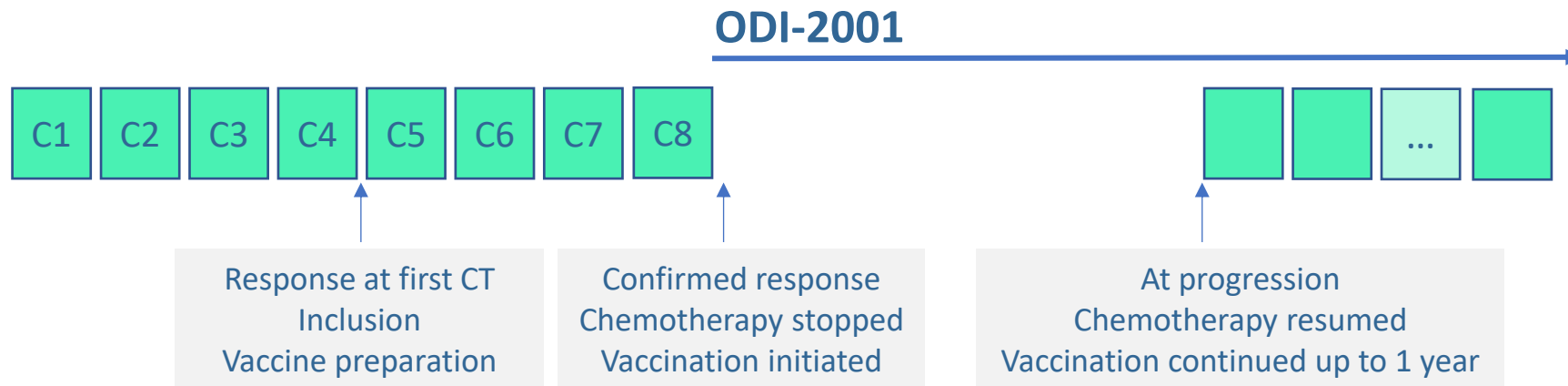




## Phase I/II in colorectal cancer – Synopsis

- **Study population**
  - Patients with metastatic or locally advanced non-operable colo-rectal cancer or pancreatic cancer
  - Responding to first-line chemotherapy (FOLFOX or FOLFIRINOX)

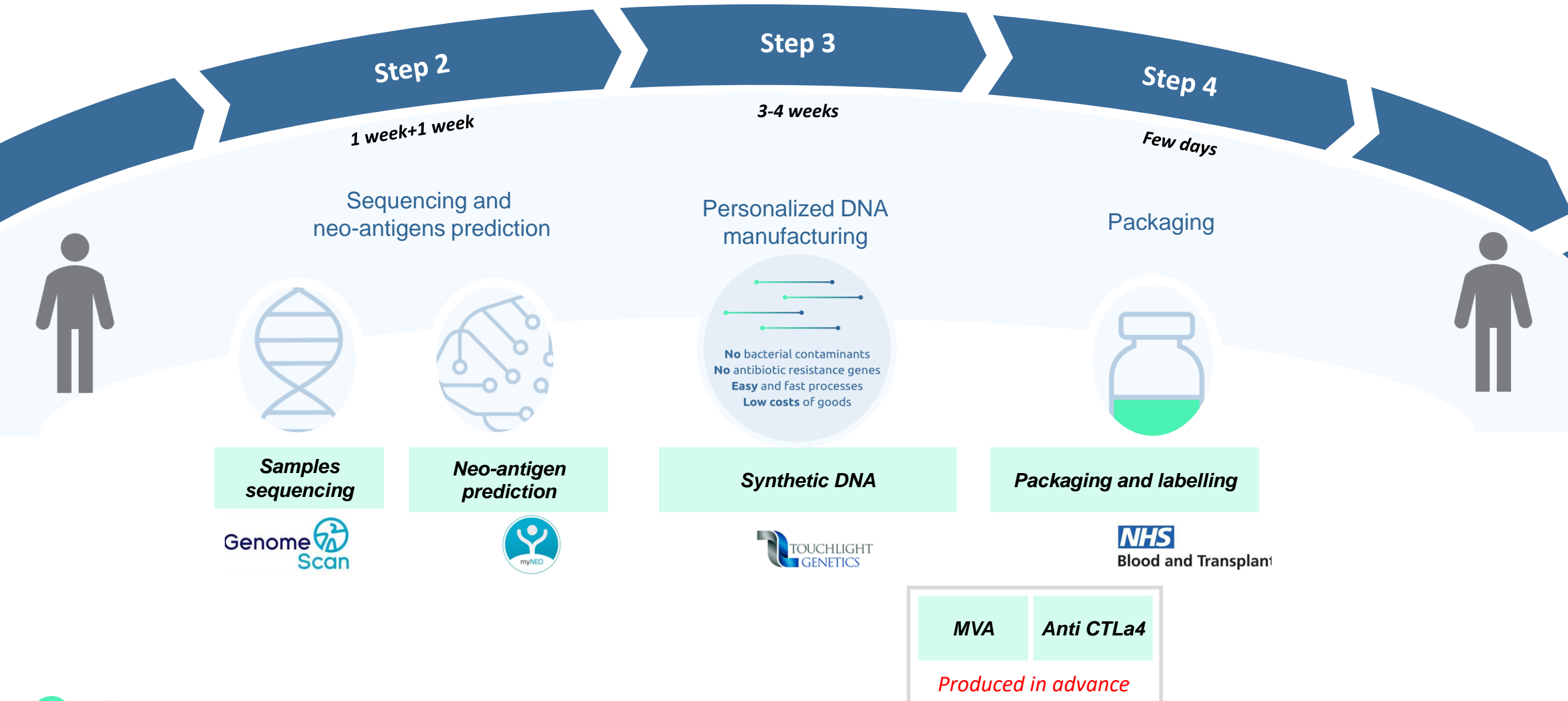
- **Intervention**



- ODI 2001 given weekly for 6 weeks and then every 3 weeks up to 1 year or intolerance
- **Outcomes :**
  - **Primary : Safety and Feasibility (CTC-AE 5.0)**
  - **Secondary : Progression free survival during chemotherapy holiday, duration of response, response under immunotherapy, duration of response under immunotherapy, response at chemo re-introduction, second PFS, overall survival, cellular immune response against neoepitopes, change in ctDNA**



## Manufacturing : We make the complexity simple



# A Team with Strong Experience in Science, Product Development & Business

**Jean-Marc Limacher, MD,**  
**Co-Founder, President, CMO**  
Medical Oncologist & Cancer Geneticist



**Pascale Balducchi, DVM, MBA,**  
**Partner, CEO, CBO**  
Strategy & Business Partnering



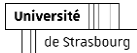
**Ronald Rooke, PhD,**  
**Scientific Affairs**  
Immunologist



**Rémi Gloeckler, PhD,**  
**Pharmaceutical Development**  
Biologist



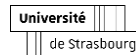
**Célia Matta, PhD,**  
**Scientist**  
Biologist



**Jérémy Amzallag, PharmD,**  
**Qualified Person,**  
**Head of Quality**



**Nicolas Ferry, MD,**  
**Regulatory Affairs**  
Immunologist



**Cécile Hugel,**  
**Project Engineer**  
Biologist & Immunologist



## Company Profile

Odimma Therapeutics was founded in 2017.

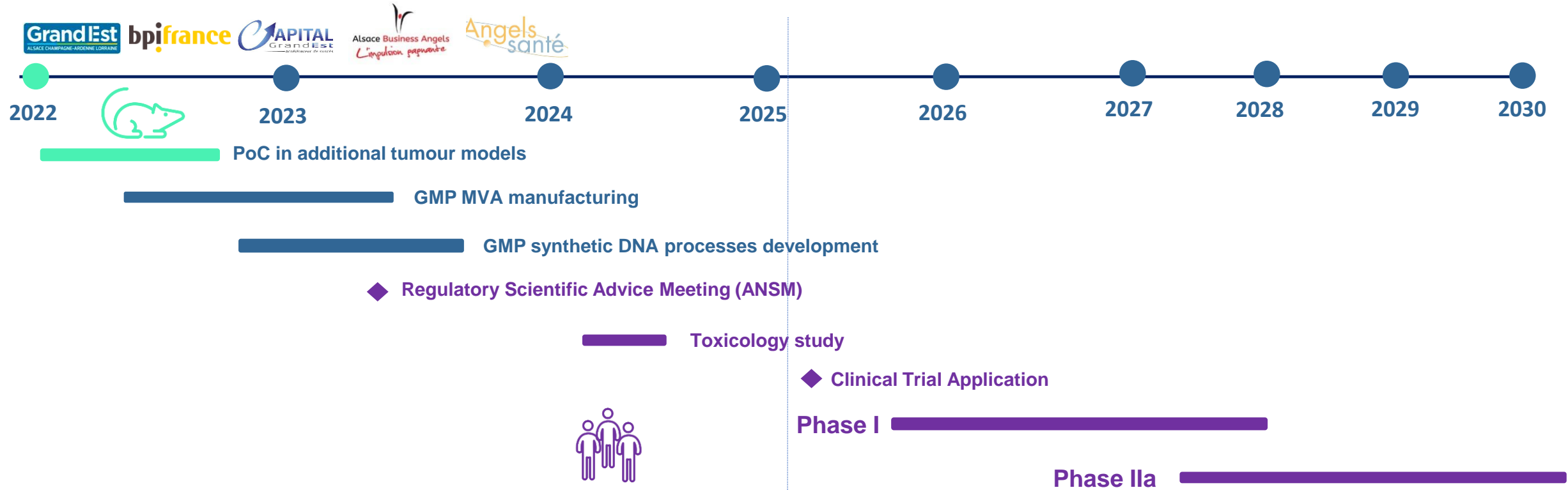
Based in Strasbourg and Supported by Key Regional and National Players

Has been granted a Seal of Excellence by European Commission in 2024

Backed-up by an international advisory board



# Timelines





### Competitive advantages on different levels: Science and Pharmaceutical Modalities



#### **Effective**

Improved preclinical activity over main competitors including RNA



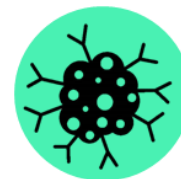
#### **Safe**

Excellent expected safety profile



#### **Cost-effective**

Fast and affordable manufacturing for greater economic value



#### **Versatile**

Effective in multiple types of cancers, both in mono- and combination therapy



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