



# Enabling the immune system to fight cancer

Ultimovacs Company Presentation

29 September 2023

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# Ultimovacs is developing a universal, off-the-shelf cancer vaccine in a broad clinical program; expecting data from three Phase II studies in a year

## **UV1 is a universal, off-the-shelf cancer vaccine, targeting telomerase (hTERT)**

- hTERT is essential for cancer cell survival and is expressed in 85-90% of cancer types throughout all disease stages; potential use in multiple cancer types
- The vaccine is off-the-shelf, easy to use and does not require sophisticated infrastructure, enabling patient access to therapy also in rural and underserved communities



## **Excellent clinical trial execution and external validation**

- Phase I data showing strong safety profile, efficacy signals, and immune response durability
- Five randomized Phase II trials ongoing in different cancer indications and biologies, whereof three has completed enrollment
- Validation through joint projects with large pharma companies, oncology specialist groups and FDA designations



## **Near term milestones and key value inflection points**

- Results from the NIPU study, a randomized UV1 Phase II study in Malignant Pleural Mesothelioma, will be shared as an oral presentation at ESMO, 21 October 2023
- Data from next two randomized Phase II trials, INITIUM and FOCUS, expected within a year and within current financial runway





# Ultimovacs has a highly skilled team, supported by strong, long-term shareholders, with a cash runway to mid-2024

## Company profile

- Clinical-stage biotech, developing universal cancer vaccines
- Founded in 2011
- Listed at Euronext Oslo Stock Exchange in 2019
- 26 employees in Oslo, Norway and Uppsala, Sweden
- **Market cap**<sup>1</sup>: ~NOK 3.5 bn (~MUSD 330)
- Total cash end of Q2 2023 amounted to MNOK 344 (MUSD 32) providing an **estimated financial runway to H2 2024**

## Management



**Carlos de Sousa**  
**MD, EMBA**  
Chief Executive Officer



**Jens Bjørheim**  
**MD, PhD**  
Chief Medical Officer



**Ingunn H. Westgaard**  
**PhD**  
Head of Research



**Hans V. Eid**  
Chief Financial Officer



**Ton Berkien**  
Chief Business Officer

## Inventors



**Gustav Gaudernack**  
**Inventor, Professor Emeritus**  
Chief Scientific Officer



**Sara Mangsbo**  
**PhD, Ass. Professor**  
Chief Innovation Officer

## Shareholders<sup>2</sup>

Investor	Holding
Gjelsten Holding	18.9%
Canica	7.9%
Sundt Group <sup>3</sup>	7.7%
Watrium	5.2%
Government Pension Fund Norway <sup>4</sup>	4.4%
Radforsk (Biotech fund)	4.4%
Inven2 - University of Oslo TTO	4.1%
Langøya Invest	4.1%
<b>Top 20</b>	<b>67.8%</b>
<b>Other</b>	<b>32.2%</b>

## Capital markets transactions

Date	Transaction	Deal value
Oct '21	Private placement <sup>5</sup>	MNOK 270 (MUSD 28)
May '20	Private placement <sup>5</sup>	MNOK 160 (MUSD 17)
May '19	IPO	MNOK 370 (MUSD 38)

# UV1 Phase II program ongoing: Strong recruitment of > 670 patients across cancer indications in combination with various checkpoint inhibitors (CPI)

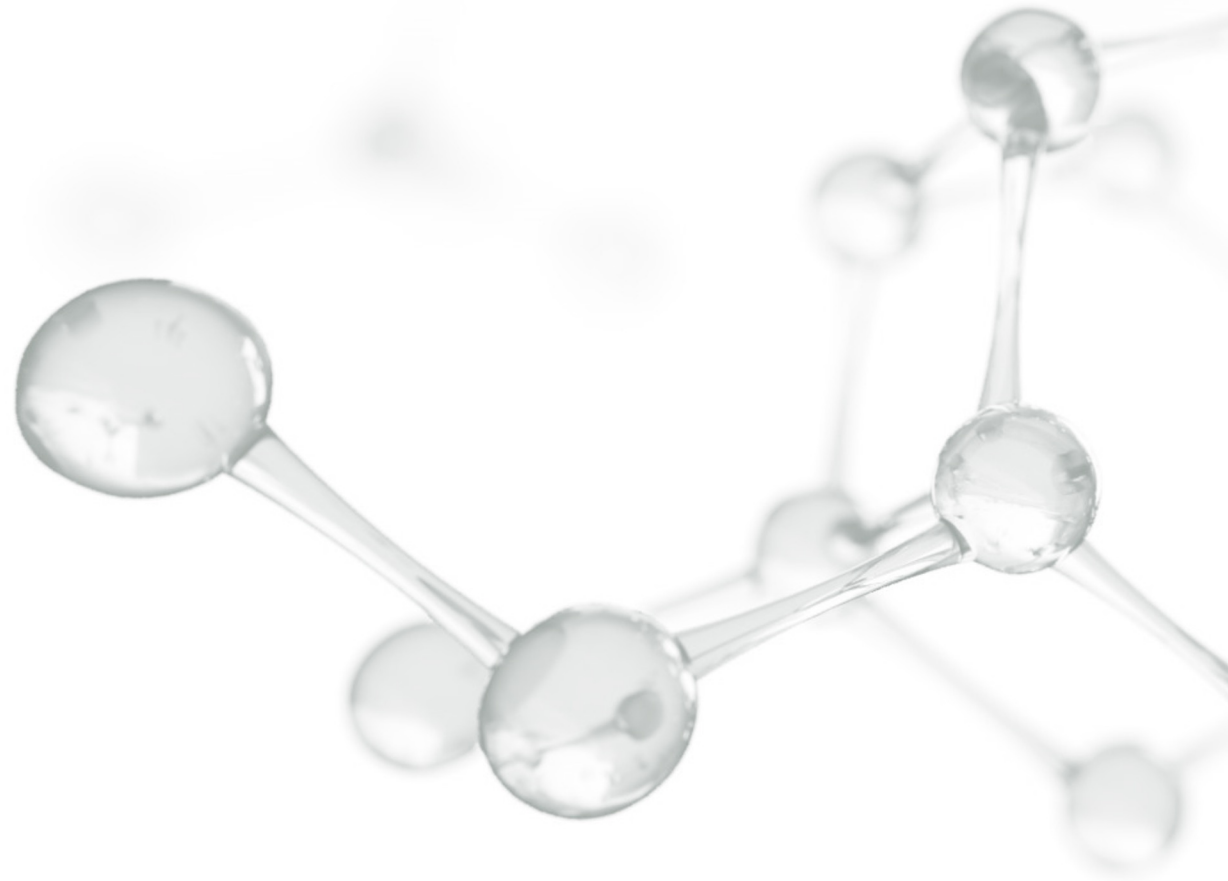
	Cancer indication	Checkpoint inhibitors	Patients (#)	Enrollment status	Expected topline readout	Phase I	Phase II	Investigator-initiated trial contributors
UV1	Malignant melanoma	Ipilimumab	12	✓	✓	UV1-ipi ●		
	Malignant melanoma	Pembrolizumab	30	✓	✓	UV1-103 ●		
	Malignant melanoma	Ipilimumab & nivolumab	156	✓	H1 2024		INITIUM ●	
	Pleural mesothelioma	Ipilimumab & nivolumab	118	✓	Results at ESMO, Oct 2023		NIPU ●	Bristol Myers Squibb <sup>3</sup> Oslo University Hospital
	Head and neck cancer	Pembrolizumab	75	✓	H2 2024		FOCUS ●	MARTIN-LUTHER-UNIVERSITÄT HALLE-WITTENBERG
	Ovarian cancer	Durvalumab & olaparib	184	>20% <sup>1</sup>	H2 2024 <sup>2</sup>		DOVACC ●	NSGO-CTU AstraZeneca <sup>3</sup> ENGOT European Network of Gynaecological Oncological Trial groups
	Non-small cell lung cancer (NSCLC)	Cemiplimab <sup>4</sup>	138	<10% <sup>1</sup>	H2 2025 <sup>2</sup>		LUNGVAC ●	VESTRE VIKEN DRAMMEN HOSPITAL
TET	Prostate cancer	Dose finding, monotherapy	12	✓	Q4 2023	TENDU ●		



**Note:** UV1 Phase II development is further supported by good safety profile and signals of clinical efficacy observed in two other Phase I trials where 40 patients with prostate cancer and lung cancer were included. Patients in these studies have been followed for at least five years.

1: As of Q2 2023 reporting. 2: DOVACC and LUNGVAC: Readout estimates will be updated with the Q4 2023 report.

3: Supply agreements. 4: As per 1 January 2023



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- 1. UV1: A universal cancer vaccine**
2. Phase I trial results
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4. TET platform
5. Market potential and competition

# UV1 enhances antitumor response by activating telomerase-specific T cells

## Current CPI challenges

- Checkpoint Inhibitors (CPI) have transformed cancer therapies, but rely on a pre-existing T cell responses towards the tumor for efficacy
- Only 10-58% patients have a long-term response to CPI treatment, depending on indication<sup>1</sup>
- A universal cancer vaccine could address these challenges and improve the immune response

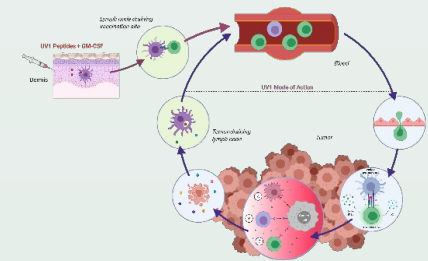
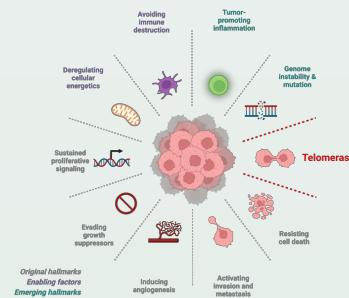
## Approach Ultimovacs

### 1 Telomerase

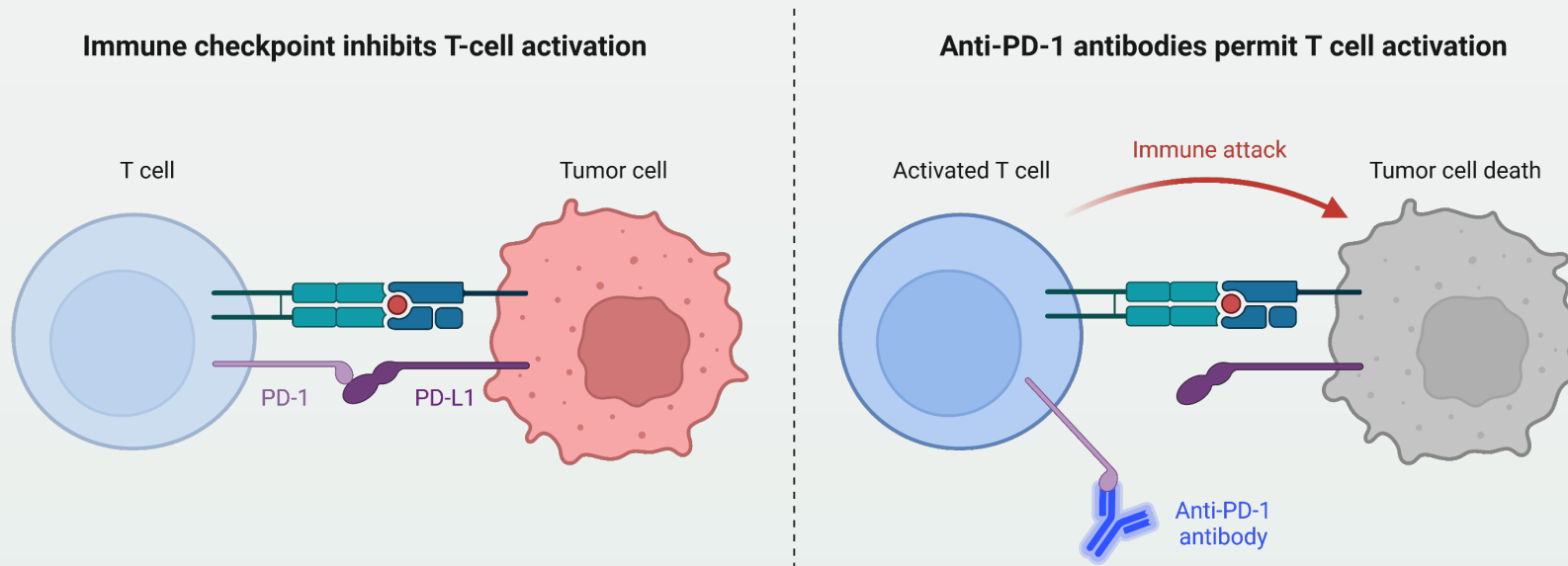
- Lead candidate UV1 targets telomerase (TERT), which plays an essential role in tumor proliferation and immortality
- Telomerase is universally expressed by cancer cells (85-90%) and present throughout all tumor stages

### 2 Mechanism of action

- Telomerase peptides are picked up by antigen-presenting cells and prime T cells
- Telomerase-specific T cells migrate to the tumor site and initiate tumor killing
- Through cytokine secretion, the T cells activate other immune cells, enhancing the immune response against the tumor



# CPIs have transformed cancer therapy, but efficacy can be improved

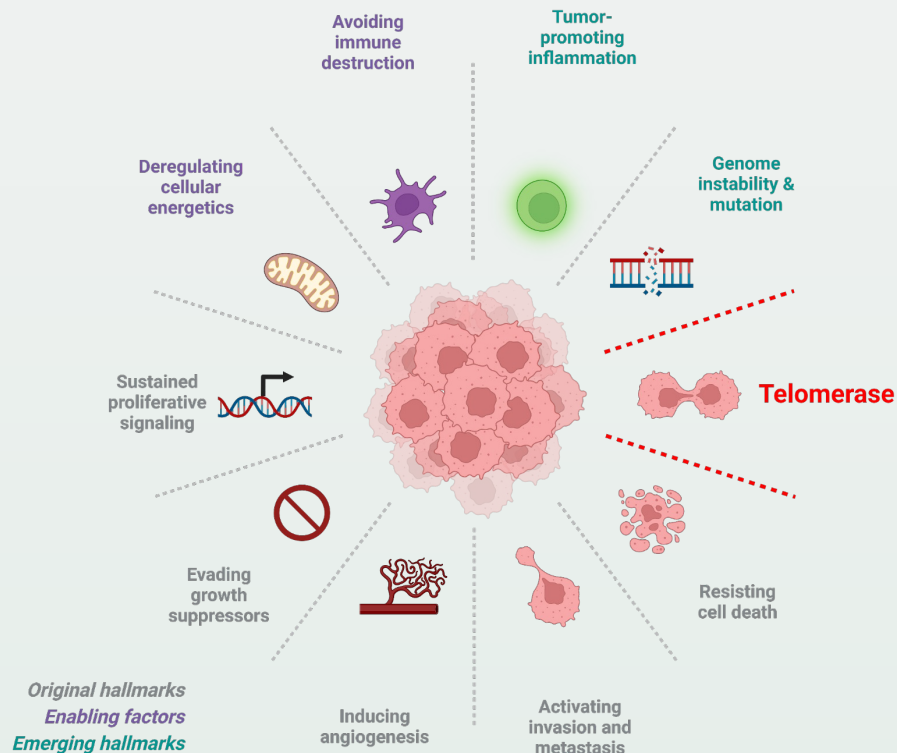


- CPIs rely on **spontaneous** T cell responses against tumors, which remains the biggest bottleneck for broader CPI efficacy<sup>1</sup>
- Most patients do not experience clinical benefit from checkpoint inhibition due to large variability in spontaneous anti-tumor immune responses
- **UV1 is ideally positioned to improve the T cell response** required for broader efficacy



# UV1 induces T cell responses against telomerase: a hallmark of cancer

## Hallmarks of Cancer<sup>1</sup>



### Telomerase Characteristics

### UV1 Vaccine Qualities

#### Universal

85-90% of tumor types express telomerase<sup>2,3</sup>

Applicable to a broad range of cancer types

#### Essential

Tumor cells depend on expressing telomerase

High relevance in heterogenous tumor environments

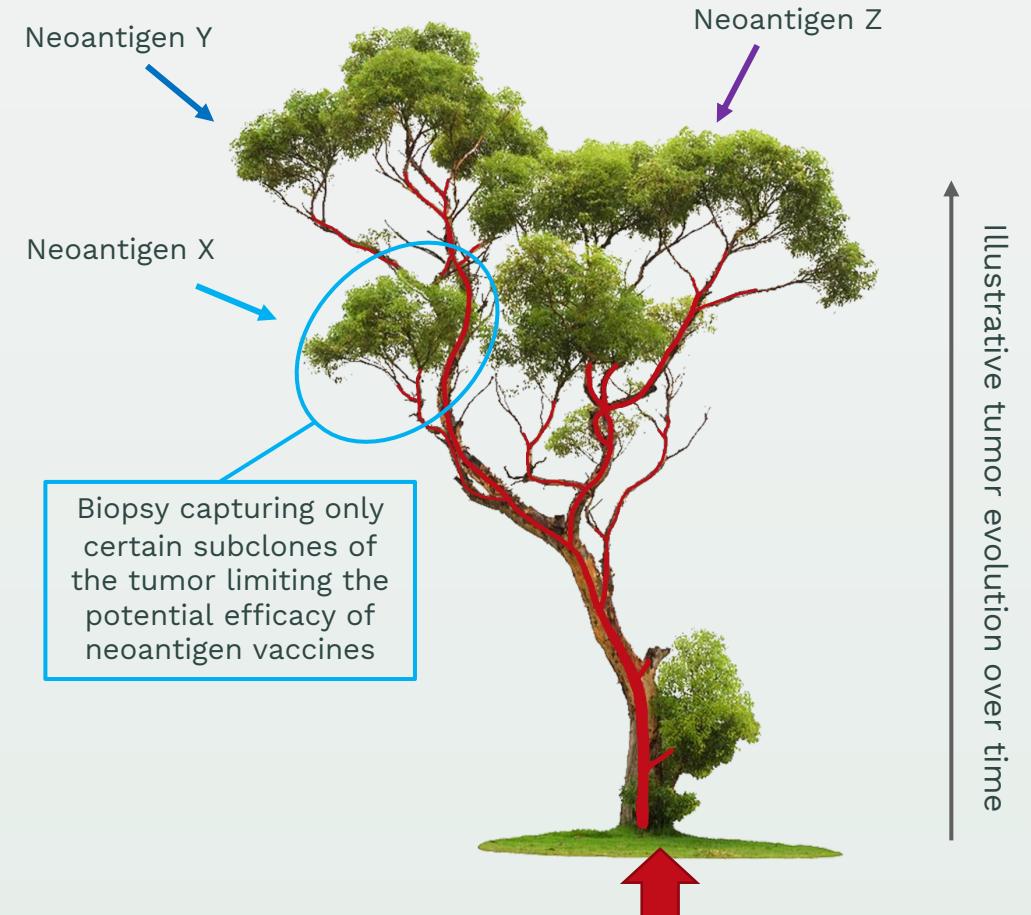
#### Enduring

Present throughout tumor evolution: primary to metastatic cancer

Enduring and relevant immune response over time

# UV1 activates hTERT specific CD4-helper T lymphocytes

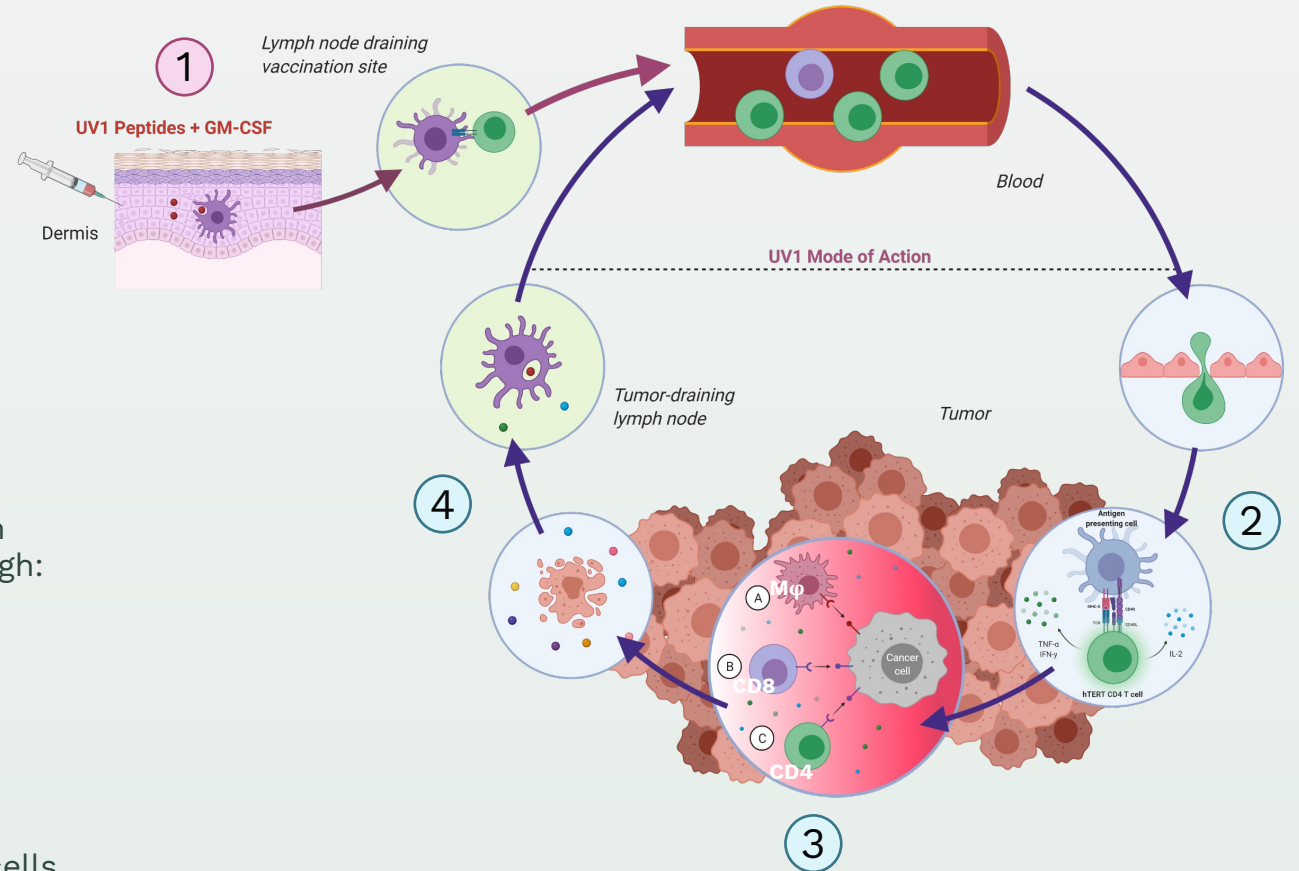
- **Mechanism of action:** Vaccination induces T cell responses, which have pro-inflammatory functions and roles in activation of CTLs and memory T cell formation
- **Vaccine design:** UV1 consists of three synthetic long peptides (one 30-mer, two 15-mers), covering the catalytic site of human telomerase reverse transcriptase – hTERT
- **Easy to use:** Peptides are promiscuous with respect to HLA class I and II alleles – No need for pre-screening of HLA type or other biomarkers
- **Administration:** 8 UV1 intradermal vaccinations over a 14-week period – off the shelf. Local administration of GM-CSF as vaccine adjuvant to attract DCs
- **Safe:** UV1 does not inhibit telomerase activity but generates T cell responses recognizing fragments of telomerase presented in the context of HLA molecules on cells in the tumor. No safety signals seen from healthy tissues expressing telomerase (e.g. stem cells).



hTERT expression is a truncal event for the tumor and a **relevant tumor antigen in space and time**

# UV1 mode of action and downstream mechanisms enhance tumor killing

- 1 **Intradermal injection of UV1 and activation of TERT-specific T cells**
- 2 **Improved priming of anti-tumor immune responses**
  - T cells bind their antigen (TERT) expressed on local APCs and the T cells release cytokines (TNF- $\alpha$ , IFN- $\gamma$  and IL-2) inducing a pro-inflammatory “hot” tumor microenvironment
- 3 **Enhanced intratumoral activation of T cells**
  - T cells activate other cells of the immune system through cytokine secretion, directing killing through:
    - i. Macrophages
    - ii. CD8 T cells
    - iii. CD4 T cells
- 4 **Increased tumor cell killing**
  - Dying tumor cells release antigens
  - These are taken up by APCs and presented to T cells, broadening the immune response against the tumor





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# Strong Phase I efficacy and safety data of UV1 in two combination trials

## Malignant melanoma

Trial design	① UV1 + ipilimumab	② UV1 + pembrolizumab
Nr. of patients	12	30 (cohort 1: 20, cohort 2: 10)
UV1 dose	300 µg	300 µg
GM-CSF dose	75 µg	Cohort 1: 37.5 µg, cohort 2: 75 µg
Primary endpoint	Safety (good)	Safety (good)
Secondary endpoints	PFS, OS, ORR, exploratory biomarkers	PFS, OS, ORR, exploratory biomarkers
Clinical activity	Strong initial signals	Strong initial signals
Publication	Poster presentation at <a href="#">SITC Annual Meeting 2021</a> , publication in <a href="#">Frontiers in Immunology</a> (May 2021)	Data reported at ASCO 2021 and updates presented at the 19th International Conference of the Society for Melanoma Research, 17-20 October 2022 in Edinburgh

### FDA designations

- In Oct 2021, granted **Fast Track designation** for UV1 as add-on therapy to ipilimumab or pembrolizumab in advanced non-resectable and metastatic melanoma
- In Dec 2021, granted **Orphan Drug designation** for UV1 as add-on therapy to ipilimumab and nivolumab in stage IIB-IV malignant melanoma



# UV1 + ipilimumab has shown positive efficacy vs. historical control

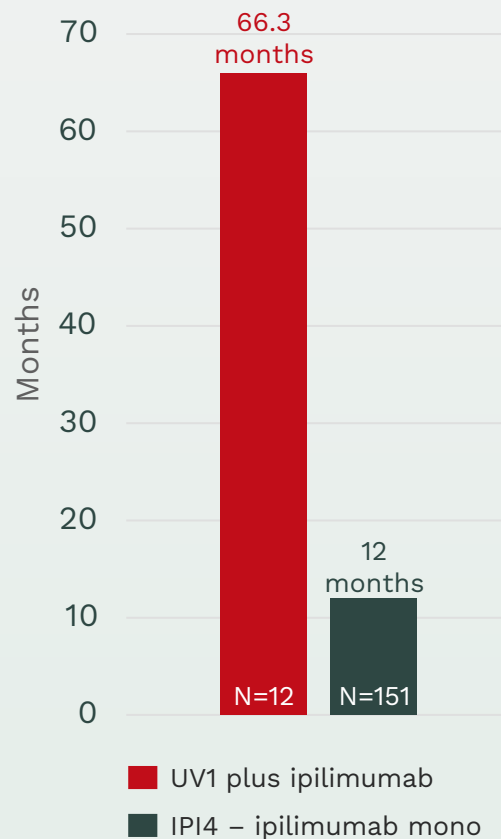
## Malignant melanoma

### Patient characteristics

- All patients had stage IV disease
  - M1c in 50% of patients
- Elevated LDH in 50% of patients
- 33.3% of patients had received prior therapy

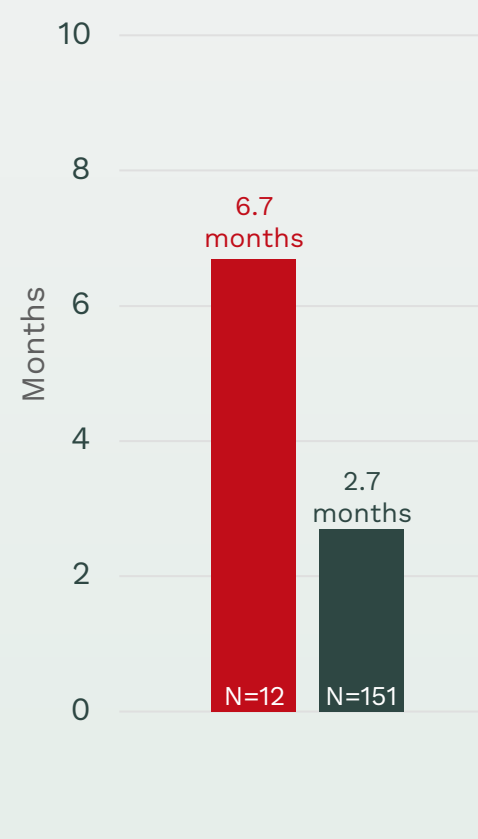
### Median Overall Survival (mOS)

UV1+ipilimumab vs ipilimumab monotherapy (IPI4 study)<sup>1</sup>



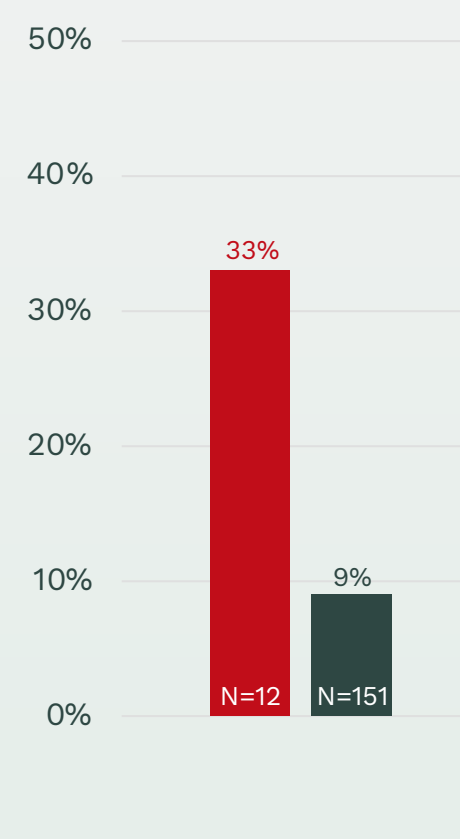
### Median Progression Free Survival (mPFS)

UV1+ipilimumab vs ipilimumab monotherapy (IPI4 study)<sup>1</sup>



### Objective Response Rate (ORR)

UV1+ipilimumab vs ipilimumab monotherapy (IPI4 study)<sup>1</sup>



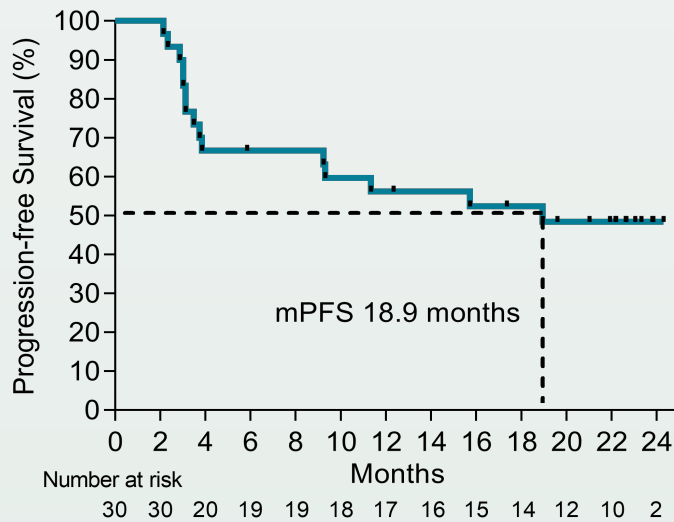
# UV1 + pembrolizumab - promising efficacy in Phase I trial UV1-103

## Malignant melanoma

### Median progression free survival:

- Cohort 1+2 combined is 18.9 months

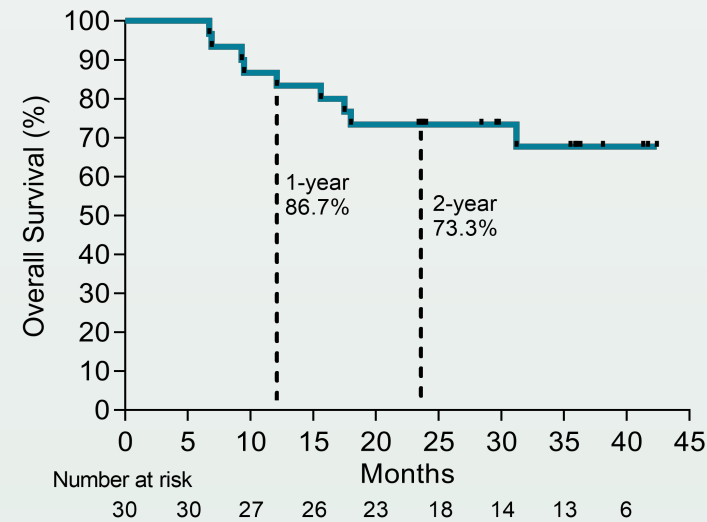
Progression-free Survival (n=30)



### Overall survival:

- Cohort 1+2 combined after 12 months: 87%
- Cohort 1+2 combined after 24 months: 73%
- Cohort 1 +2 combined after 36 months\*: 67%

Overall Survival (n=30)\*

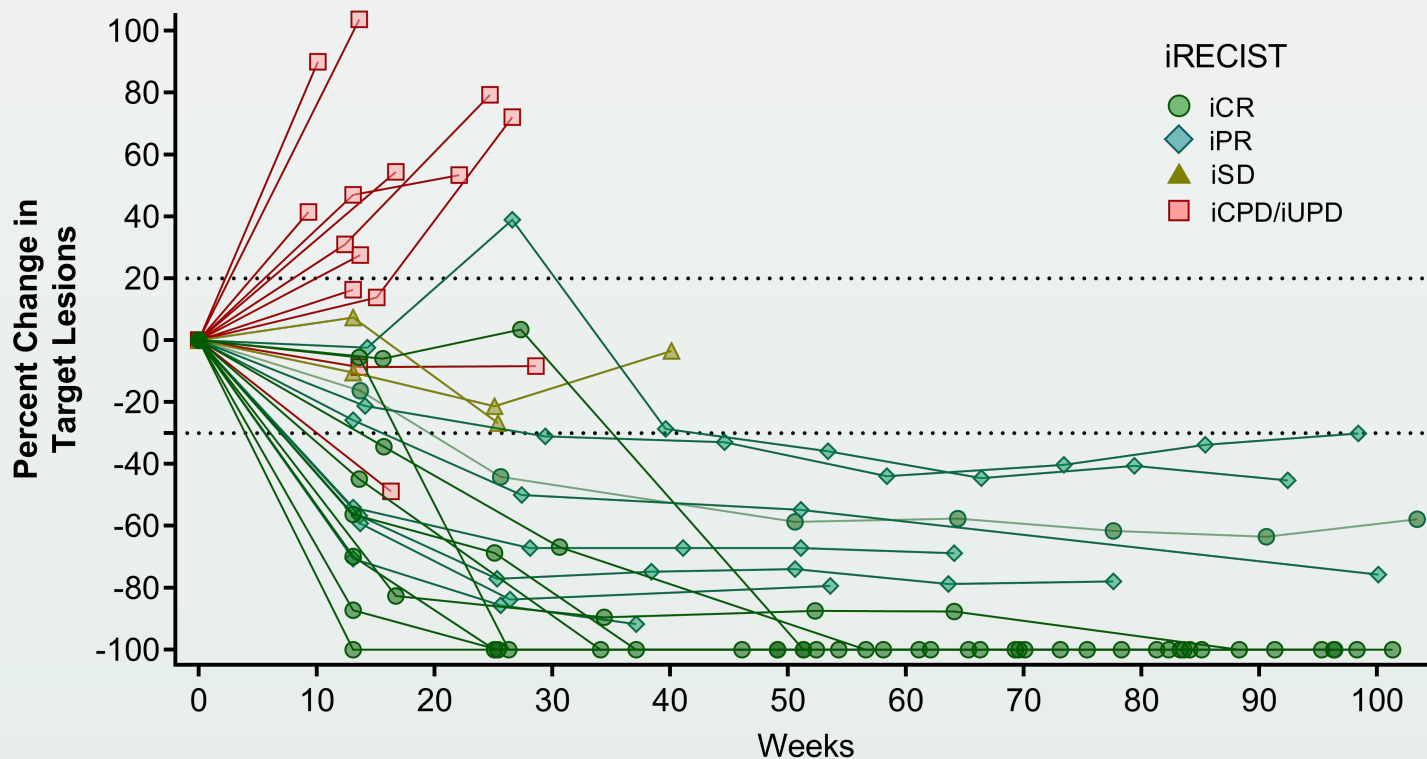


- UV1 has demonstrated a good safety profile; no unexpected safety issues have been observed in the trial
- Patients will continue to be followed for long-term survival

# Deep and durable clinical responses to UV1 + pembrolizumab

## Malignant melanoma

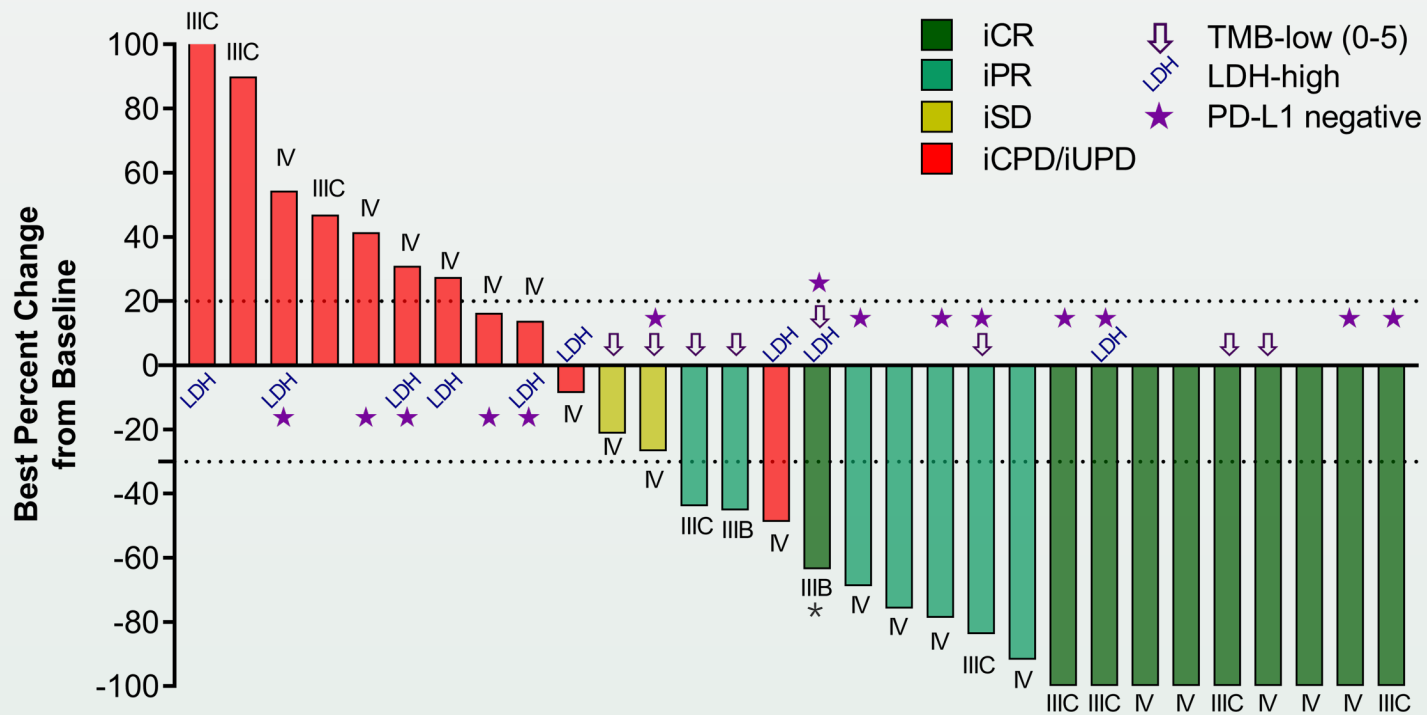
Responses lasting up to 2 years (maximum follow-up)



- Patients were followed with CT scans for up to two years
- 57% of patients achieved an objective response to the treatment (>30% reduction in tumor size)
- 33% of patients achieved complete response (complete disappearance of the tumor)
- 94% of the objective responses lasted more than 1 year

# Robust clinical responses in patients typically obtaining reduced CPI efficacy

Sustained high ORR and CR rate to UV1 + pembrolizumab combo in PD-L1 negative tumors



Best Overall Response (iRECIST)	n	%
<b>ORR (n=30)</b>	17	56.7
Complete Response	10	33.3
Partial Response	7	23.3
Stable Disease	2	6.7
Progressive Disease	11	36.7
<b>ORR in PD-L1 negative patients (n=14)**</b>	8	57.1
Complete Response	5	35.7
Partial Response	3	21.4

Historical reference study: KEYNOTE-006 (FDA Package insert; Robert C, 2019; Carlino MS, 2018)

**ORR:** 34-42%

**CR:** 5-14%

**ORR PD-L1 neg:** 24.3% (95% CI, 16.4%–33.7%)

**CR PD-L1 neg:** 5.8%

\* Lymph node target lesion was reduced from 17.2 mm to 6.3 mm (-63% change). A lymph node size of <10 mm is considered normal, and a PET/CT-scan later confirmed no malignant activity. The patient is therefore considered an iCR according to iRECIST

\*\* PD-L1 staining with 22C3 pharmDx for Autostainer Link 48. PD-L1 positive defined as ≥1% of tumor cells








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# UV1 clinical program consists of five comparative, randomized Phase II trials in different cancer types, biologies, and CPI combinations

Trial design	 <b>1 INITIUM</b>	 <b>2 NIPU</b>	 <b>3 FOCUS</b>	 <b>4 DOVACC</b>	 <b>5 LUNGVAC</b>
<b>CPI combination</b>	Ipilimumab + nivolumab	Ipilimumab + nivolumab	Pembrolizumab	Durvalumab + olaparib	Cemiplimab
<b>Indication</b>	First line malignant melanoma	Second line mesothelioma	First line head and neck cancer	Second line ovarian cancer	First line non-small cell lung cancer
<b>Timeline</b>	2020 – 2023	2020 – 2023	2021 – 2023	2021 – 2023	2022 – 2024
<b>Expected topline results</b>	<b>H1 2024</b>	<b>Results at ESMO 21 October 2023</b>	<b>H2 2024</b>	H2 2024 <sup>1</sup>	H2 2025 <sup>1</sup>
<b>No. of patients</b>	N=156	N=118	N=75	N=184	N=138
<b>Enrollment status<sup>2</sup></b>	<b>100% recruited</b>	<b>100% recruited</b>	<b>100% recruited</b>	<b>&gt; 20% recruited</b>	<b>&lt; 10% recruited</b>
<b>Sites &amp; countries</b>	40 sites in US, NO, BE, UK	6 sites in NO, SE, DK, ES, AU,	10 sites in DE	>40 sites in NO, SE, DK, FI, BE, NL, DE, AT, LT, EE, GR	8-10 sites in NO

**Primary endpoint: Progression Free Survival (PFS)**

**Secondary endpoints: Overall Survival (OS) + Objective Response Rate (ORR) + Duration of Response (DOR) + safety**

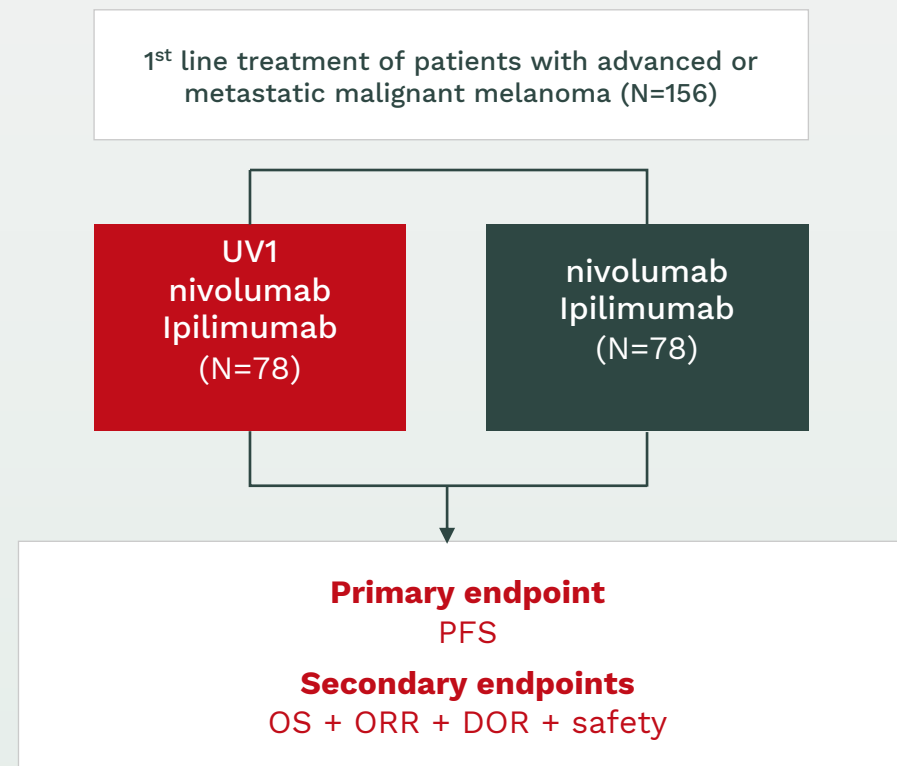
# INITIUM UV1 Phase II trial

## INITIUM: First line advanced or metastatic malignant melanoma

- **Combination:** nivolumab, ipilimumab
- **Contributors:** Sponsored by Ultimovacs
- **Patients:** 156 patients\* from 39 sites in 4 countries: US, UK, Belgium and Norway
- **Recruitment: 100%**
- First patient enrolled June 2020
- Randomized and statistically powered trial
- Patient enrollment completed July 2022
- **Milestones:** Topline results expected **H1 2024**



## INITIUM

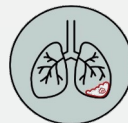


PFS = progression-free survival; OS = overall survival; ORR = overall response rate; DOR = duration of response

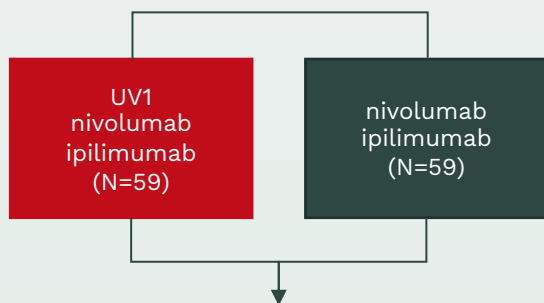
\* A supplementary study was initiated after enrollment of the 154 (156 in total) patients was completed. The objective is to further support that an immune response specific to the UV1 vaccine transfers into anti-tumor activity and clinical benefit for the patients. 20 additional patients will receive experimental treatment, i.e. the triple combination of UV1, ipilimumab and nivolumab.

# NIPU & FOCUS UV1 Phase II Trials

## NIPU: Second line malignant metastatic pleural mesothelioma (MPM)



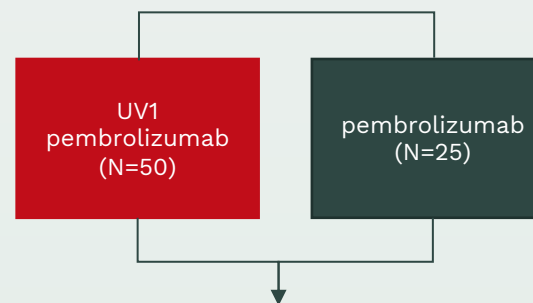
- **Combination:** nivolumab, ipilimumab
- **Contributors:** Oslo University Hospital (sponsor), BMS
- **Patients:** 118 from 6 sites in Norway, Sweden, Denmark, Spain and Australia
- **Recruitment: 100%**
- First patient enrolled June 2020
- Patient enrollment completed January 2023
- Topline readout June 2023: PFS not met
- **Milestones:** Detailed and updated data will be presented at **ESMO, 21 October 2023**



## FOCUS: Metastatic or recurrent head and neck squamous cell carcinoma



- **Combination:** pembrolizumab
- **Contributors :** Sponsored by Halle University Hospital network
- **Patients:** 75 from 10 sites in Germany
- **Recruitment: 100%**
- First patient enrolled August 2021
- Patient enrollment completed August 2023
- **Milestones:** Topline results is expected **H2 2024**



**Primary endpoint: PFS**

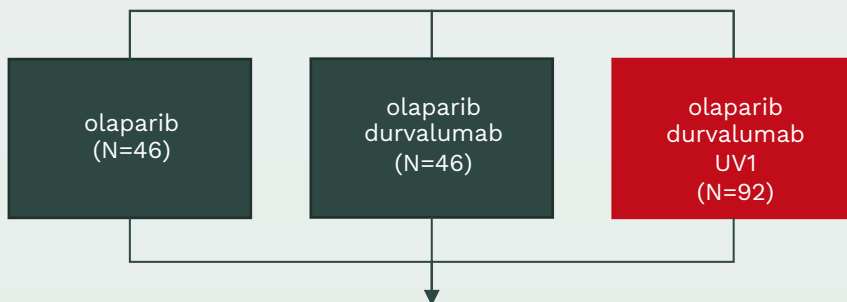
**Secondary endpoints: OS + ORR + DOR + safety**

# DOVACC and LUNGVAC UV1 Phase II Trials

## DOVACC: High-grade BRCA negative ovarian cancer, second line maintenance



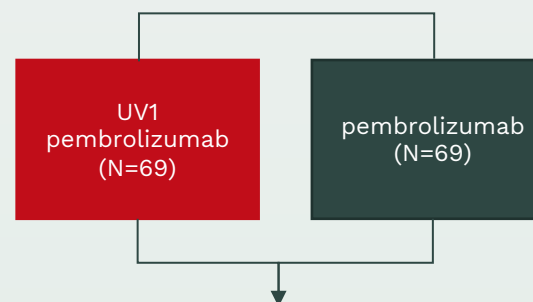
- **Combination:** olaparib, durvalumab
- **Contributors:** NSGO/ENGOT (sponsor), AstraZeneca
- **Patients:** 184 from more than 40 sites in more than 10 European countries
- **Recruitment:** >20%
- First patient enrolled December 2021
- 37 patients enrolled as of 21 August 2023 (Q2 2023 reporting)
- **Milestones:** Topline results expected H2 2024 (to be updated in Q4 reporting)



## LUNGVAC: Advanced or metastatic non-small cell lung cancer (NSCLC)



- **Combination:** cemiplimab
- **Contributors:** Sponsored by Drammen Hospital
- **Patients:** 138 patients from 8-10 hospitals in Norway
- **Recruitment:** <10%
- First patient enrolled October 2022
- 11 patients\* enrolled as of 21 August 2023 (Q2 2023 reporting)
- **Milestones:** Topline results expected H2 2025 (to be updated in Q4 reporting)



**Primary endpoint: PFS**

**Secondary endpoints: OS + ORR + DOR + safety**



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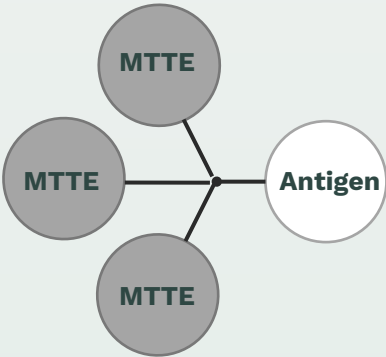


# The TET (Tetanus-Epitope Targeting) adjuvant platform technology

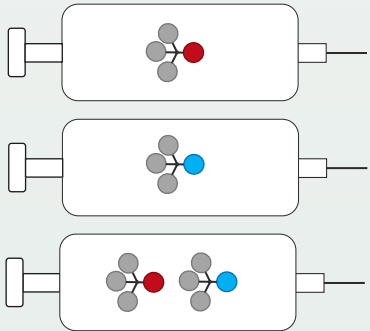
- Ultimovacs' proprietary TET technology combines the two key components of a vaccine in one molecule: The disease specific antigen and the immune response strengthening adjuvant.
- The adjuvanting effect is facilitated by sequences from tetanus toxin (Minimal Tetanus Toxin Epitope - MTTE). The MTTEs are B cell epitopes.

- An innovative technology provides the flexibility to incorporate a variety of antigens to tailor vaccines to different cancer types or infectious disease.

### Adjuvant component



**Disease specific antigen:**  
Directs the immune response towards the target

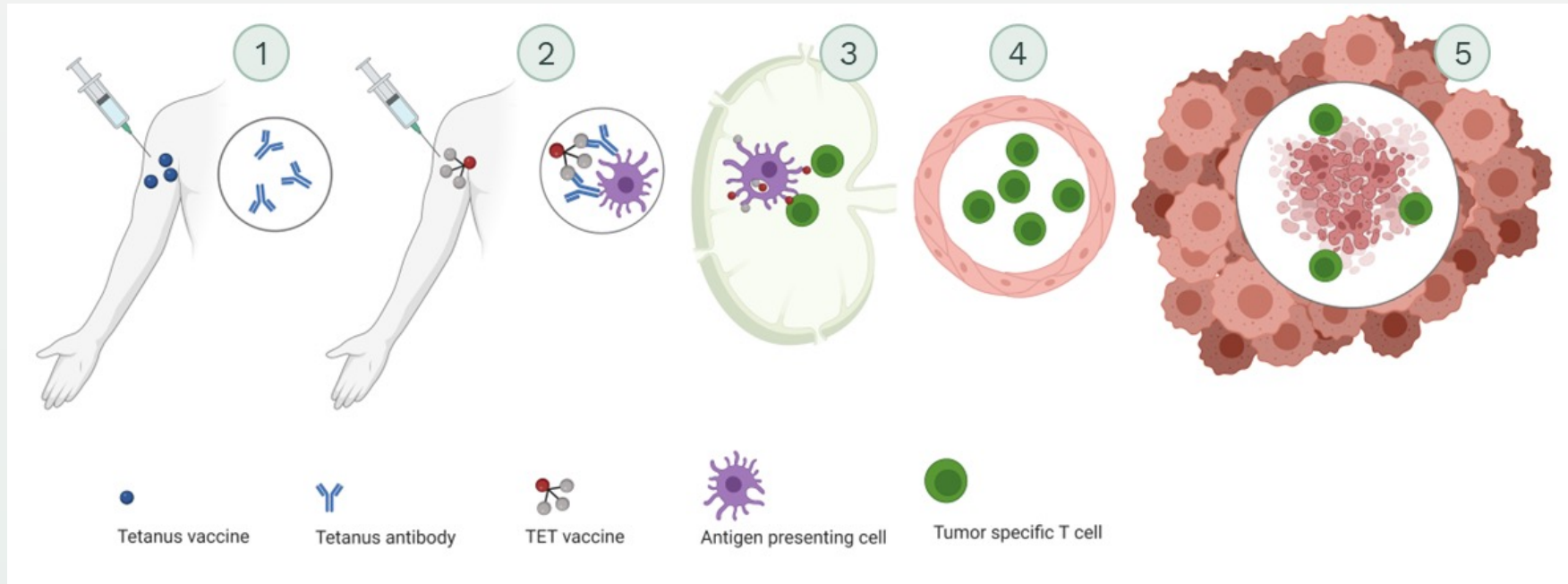


● Fixed adjuvant component

● ● Flexible disease specific antigen components

Several antigens may be combined in a single administration

## TET adjuvant technology platform takes advantage of pre-existing immunity to elicit a strong and antigen specific immune response



### **TET cancer vaccine mode of action:**

#### **Vaccination and immune response: Active and targeted delivery of the vaccine to antigen presenting cells**

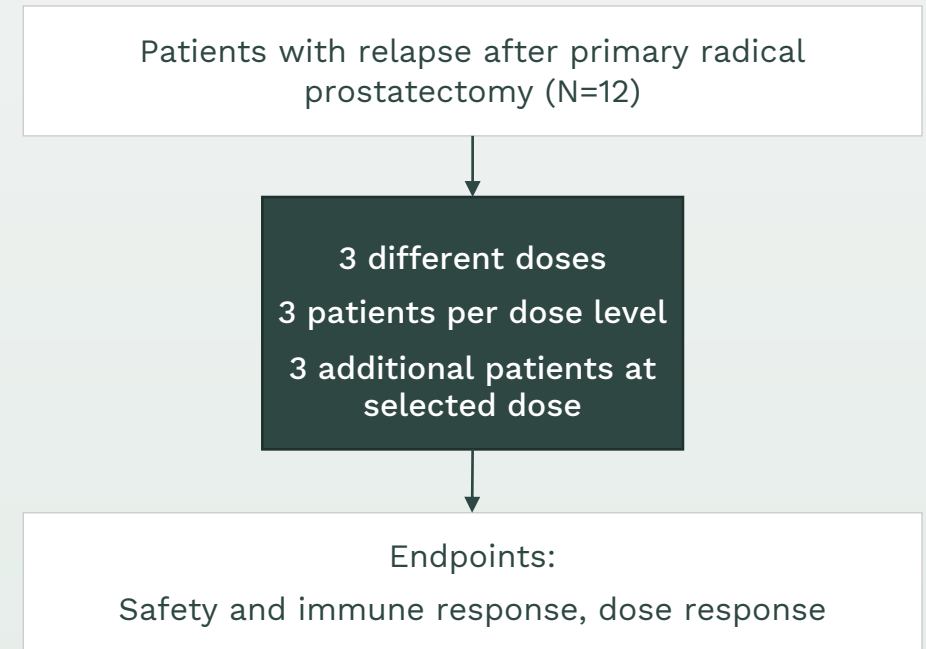
1. Standard tetanus vaccination induces production of anti-tetanus antibodies.
2. The tetanus antibodies bind to the TET vaccine and form an immune complex, which is taken up by an antigen presenting cell. Immune complex formation is known to facilitate immunogenicity.
3. The antigen presenting cell migrates to the lymph node, and tumor specific T cells are made.

#### **Killing of the tumor**

4. T cells enter blood circulation and travel to the tumor.
5. T cells infiltrate the tumor and activate a series of steps that lead to tumor cell killing.

## The TENDU phase 1 trial: First clinical evaluation of a TET vaccine

- The TENDU trial investigates a prostate cancer specific vaccine that is based on the TET technology
- The trial is expected to provide valuable information on dose, safety and immune activation towards the further development of new vaccine solutions utilizing the TET technology
- Primary objective: Evaluate safety and tolerability of different doses of the vaccine in patients with progressive disease after prostatectomy
- Conducted at Oslo University Hospital
- All 12 patients enrolled – enrollment completed
- Study results expected during H2 2023
- No safety concerns to date





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- 5. Market potential and competition**

# UV1 is poised to tap into a large market due to its combination with CPIs

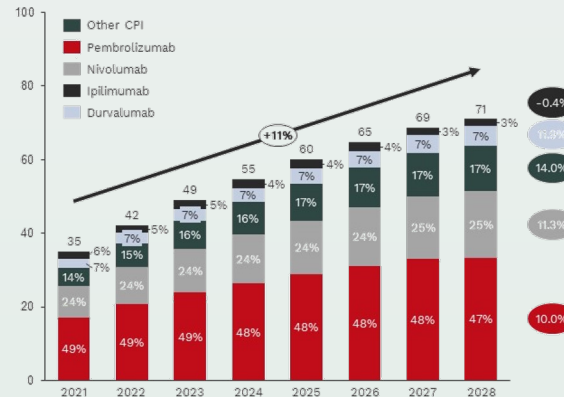
## 1 Combination with CPIs

- UV1 can be combined with the (standard-of-care) CPI in a broad range of cancer types
- Use of UV1 as an add-on therapy is currently evaluated in 5 different cancer indications
- Large opportunity to expand to other cancer types

Cancer indication	UV1	Keytruda	Opdivo	Ultibro	Jemperli	Imfinzi	Tecentriq	Rochevivo	Yervey	Injelo	Opdivo
		pembrolizumab	nivolumab	cemiplimab	dostarlimab	bamlanivab	atezolizumab	avelumab	cemiplimab	tislelizumab	relatlimab
Malignant melanoma	+	with Tenney							with Opdivo	with Tenney	
Lung (NSCLC/PLC)	+	with Tenney							with Opdivo	with Tenney	
HNCC	+	with Tenney							with Opdivo	with Tenney	
Neurofibroma	+	with Tenney							with Opdivo	with Tenney	
Ovarian	+	with Tenney							with Opdivo	with Tenney	
Prostate	+	with Tenney							with Opdivo	with Tenney	
Bladder	+	with Tenney							with Opdivo	with Tenney	
Urothelial/Bladder	+	with Tenney							with Opdivo	with Tenney	
MSI-High	+	with Tenney							with Opdivo	with Tenney	
Gastric	+	with Tenney							with Opdivo	with Tenney	
Cervical	+	with Tenney							with Opdivo	with Tenney	
Uterine	+	with Tenney							with Opdivo	with Tenney	
Mucosal and	+	with Tenney							with Opdivo	with Tenney	
Head&Neck	+	with Tenney							with Opdivo	with Tenney	
Breast	+	with Tenney							with Opdivo	with Tenney	
Pancreatic	+	with Tenney							with Opdivo	with Tenney	
Esophageal	+	with Tenney							with Opdivo	with Tenney	
Endometrial	+	with Tenney							with Opdivo	with Tenney	
Ovarian	+	with Tenney							with Opdivo	with Tenney	

## 2 Substantial market potential

- The target population and market potential is large and growing: the US CPI market is expected to grow by 15% p.a. until 2028
- CPIs most relevant to UV1 currently represent appr. 85% of the market



## 3 Competitive advantage

- UV1 is well positioned in the overall cancer vaccine landscape
- Competitive advantages are related to patient eligibility, production and administration

Vaccine	Eligible patients	Production	Administration
UV1	• No HLA screening or tumor type restriction	• Off-the-shelf / Low cost	• Intradermal
Neoantigen vaccines	• Sequencing of biopsies for prediction of neoantigens	• Long lead-time / High cost	• Intradermal • Sub-Cutaneous • Intra-Muscular
Intratumoral vaccines	• Patients with lesion available for intratumoral injection	• Depending on platform	• Intratumoral
Other tumor-associated antigen (TAA) vaccines	• HLA and biomarker screening for selection of patients	• Depending on platform	• Intradermal • Sub-Cutaneous • Intra-Muscular

# Broad combination potential for UV1 with checkpoint inhibitors in multiple cancer types

Clinical data opens the door to future combination therapy opportunities



Cancer indication	(Neo-) adjuvant	UV1	Keytruda	Opdivo	Libtayo	Jemperli	Imfinzi	Tecentriq	Bavencio	Yervoy	Imjudo	Opdualag
			pembrolizumab	ipilimumab	cemiplimab	dostarlimab	durvalumab	atezolizumab	avelumab	nivolumab	tremelimumab	relatlimab
			PD1				PD-L1			CTLA-4		LAG3
Malignant melanoma		✓		with Yervoy						with Opdivo		with Yervoy
				with Yervoy						with Opdivo		
Lung (NSCLC/SCLC)		✓		with Yervoy			with Imjudo			with Opdivo	with Imfinzi	
HNSCC		✓		with Yervoy						with Opdivo		
Mesothelioma		✓		with Yervoy						with Opdivo		
Ovarian		✓										
Prostate		✓										
Renal				with Yervoy						with Opdivo		
Urothelia/Bladder				with Yervoy						with Opdivo		
MSI-high				with Yervoy						with Opdivo		
Gastric				with Yervoy						with Opdivo		
Cervical				with Yervoy						with Opdivo		
Liver				with Yervoy			with Imjudo			with Opdivo	with Imfinzi	
Merkel cell												
Hodgin Lymphoma				with Yervoy						with Opdivo		
Breast												
Pancreatic												
Esophageal				with Yervoy						with Opdivo		
Endometrial												
Colon				with Yervoy						with Opdivo		

Source: Global Data, 2023, Product package inserts Q2 2023, Company websites



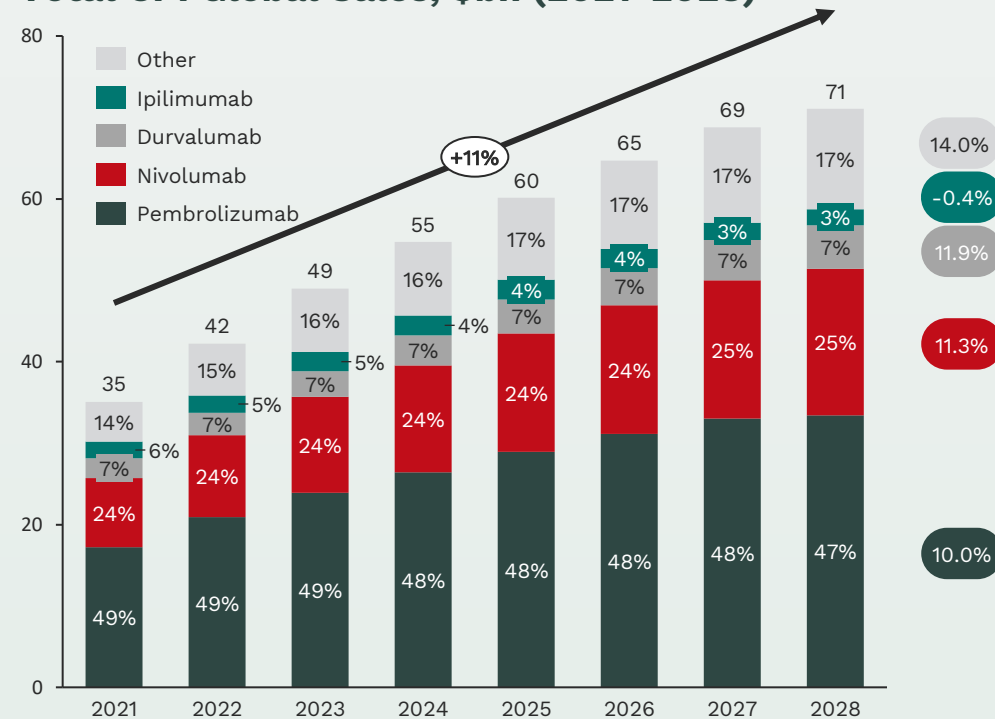
Checkpoint inhibitor approved indication
 ✓ UV1 clinical trials

**Note:** The number of indications included in the table is limited. CPI product approval may include additional indications  
 Incyte's PD-1 program (Zynys) approved for Merkel cell carcinoma (US) not included  
 CPI program approved in China, not included

# UV1 is uniquely positioned in Phase II trials with 5 out of the top 6 CPIs

- UV1 is to be **combined with CPI therapy** to improve treatment outcomes: currently around one third of cancer patients is **eligible to receive CPI<sup>1</sup>**
- UV1 is under investigation with **5 out of the top 6 CPIs**, which together account for **~85% of the CPI market**

**Total CPI Global Sales, \$bn (2021-2028)**



Marketed CPIs	UV1 trial	Indication
1. Pembrolizumab (Keytruda®)	FOCUS	Head & neck cancer
2. Nivolumab (Opdivo®)	INITIUM, NIPU	Malignant melanoma, mesothelioma
3. Atezolizumab (Tecentriq®)		
4. Ipilimumab (Yervoy®)	INITIUM, NIPU	Malignant melanoma, mesothelioma
5. Durvalumab (Imfinzi®)	DOVACC	Ovarian cancer
6. Cemiplimab (Libtayo®)	LUNGVAC	Non-small cell lung cancer




14.0%  
-0.4%  
11.9%  
11.3%  
10.0%



1. Haslam A, Gill J, Prasad V. Estimation of the Percentage of US Patients With Cancer Who Are Eligible for Immune Checkpoint Inhibitor Drugs. JAMA Netw Open. 2020;3(3):e200423. doi:10.1001/jamanetworkopen.2020.0423  
 2. Non small cell lung cancer  
 Source: GlobalData, December 2022



## UV1 competitive profile vs. other cancer vaccines approaches

Vaccine	Eligible patients	Production	Administration
UV1	 No HLA screening or tumor type restriction	 Off-the-shelf / Low cost	 Intradermal
Neoantigen vaccines	Sequencing of biopsies for prediction of neoantigens	Long lead-time / High cost	Intradermal Sub-Cutaneous Intra-Muscular
Intratumoral vaccines	Patients with lesion available for intratumoral injection	Depending on platform	Intratumoral
Other tumor-associated antigen (TAA) vaccines	HLA and biomarker screening for selection of patients	Depending on platform	Intradermal Sub-Cutaneous Intra-Muscular

# UV1 is an easy-to-use product with low production costs and simple logistics

## 1 Easy to use

- UV1 is an **off-the-shelf** product, i.e. can be administered locally, facilitating broad access
- 8 **intra**dermal injections, no complex infrastructure required
- **No need for pre-screening** of HLA type or other biomarkers. UV1 peptides are functional with both HLA class I and II alleles: it can be used in the general population



## 2 Low cost production

- **Low manufacturing cost**
- Straight forward manufacturing process by **standard peptide synthesis**

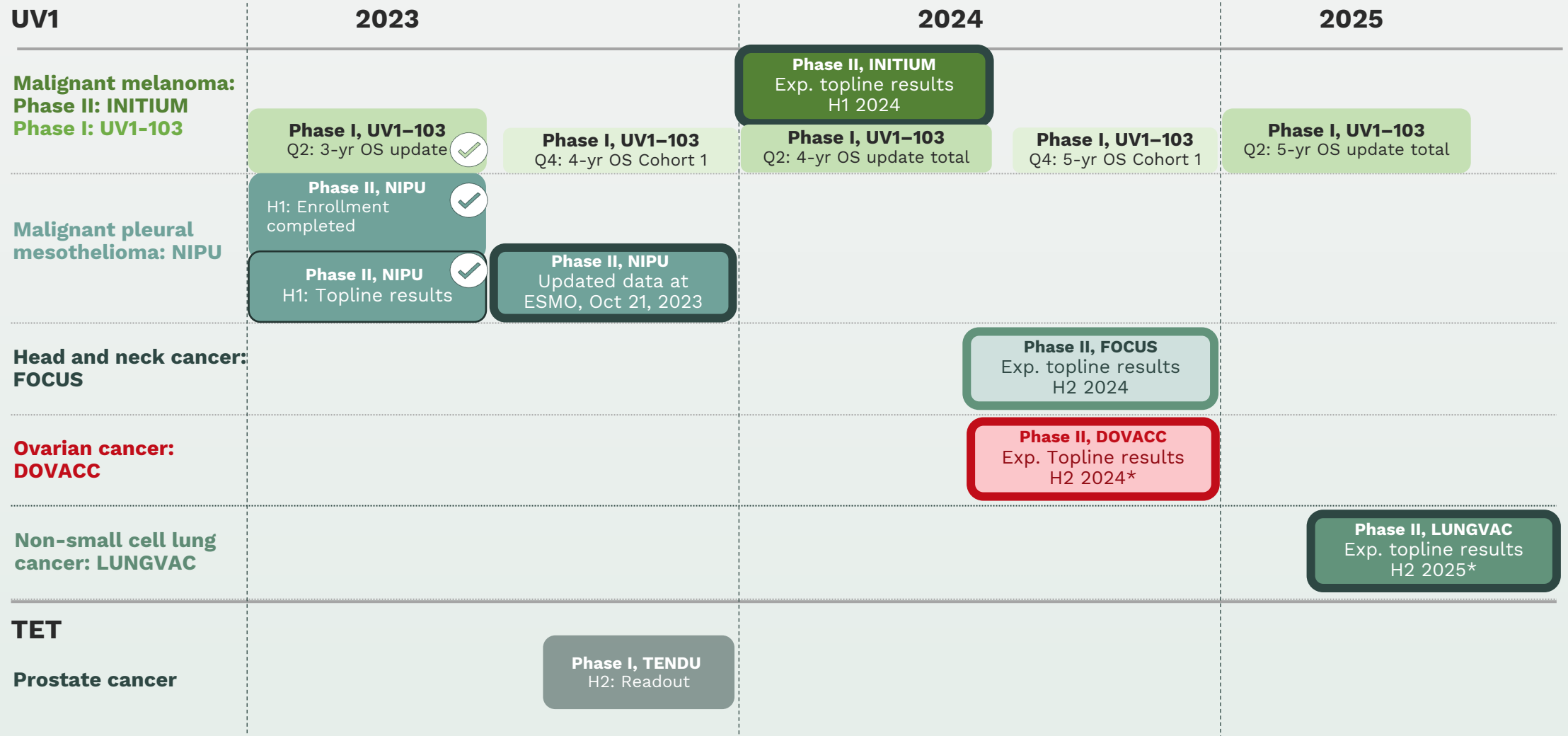


## 3 Simple logistics

- Stable product with **3 years shelf life** at 5°C
- Standard shipping and **simple on-site preparation**, i.e., reconstitution with water
- **Low handling costs** (manpower) for hospitals and community centers



# Newsflow & milestones: Key value inflection points during the next year



## Key takeaways

- Developing universal cancer vaccines to enhance the efficacy and durability of immunotherapies
  - Broadly applicable as backbone therapy in different cancer types and immunotherapy combinations
  - Off-the-shelf and easy to use
- UV1: Good safety profile and clear signals of clinical efficacy inducing immune response durability (>9.5 years)
  - Broad Phase II development program highlights significant commercial potential
  - Near-term key value inflection points from randomized Phase II trials INITIUM, NIPU & FOCUS
  - External validation
    - FDA Fast Track designation and Orphan Drug designation in metastatic melanoma
    - Joint projects with large pharma companies and oncology specialist groups
- TET: Innovative adjuvant technology platform in Phase I, broad potential
- Experienced team, strong long-term shareholders, expected financial runway to H2 2024
- **Near term key value inflection points; readouts from three randomized Phase II clinical trials within a year**



# Appendix

# Patient baseline demographics of Phase I UV1 + ipilimumab

## Malignant melanoma

### Patient characteristics

- All patients had stage IV disease
  - M1c in 50% of patients
- Elevated LDH in 50% of patients
- 33.3% of patients had received prior therapy

Patient	N (%)
<b>Age (years)</b> median, range	57 (44-74)
<b>Sex</b>	
female	5 (42%)
male	7 (58%)
<b>ECOG</b>	
0	11 (91.7%)
1	1 (8.3%)
≥2	0 (0%)
<b>Stage</b>	
M1a	3 (25%)
M1b	2 (16.7%)
M1c	6 (50%)
M1d	1 (8.3%)
<b>BRAF status</b>	
Mut	3 (25%)
wt	9 (75%)

Patient	N (%)
<b>Liver metastases</b>	
Yes	3 (25%)
No	9 (75%)
<b>LDH</b>	
above ULN	6 (50%)
below ULN	6 (50%)
<b>Prior therapy</b>	
Chemotherapy	2 (16.7%)
BRAF/MEK inhibitor	2 (16.7%)
ipilimumab	0 (0%)
<b>Prior lines of therapy</b>	
0	8 (66.7%)
1	4 (33.3%)
≥2	0 (0%)

# Patient baseline demographics of Phase I UV1 + pembrolizumab

## Malignant melanoma

### Key Eligibility Criteria

- Advanced histologically confirmed malignant melanoma (stage IIIB-C, IV)
- Measurable and evaluable disease according to iRECIST
- Previously untreated and eligible for pembrolizumab (prior BRAF and MEK inhibitors permitted)
- ECOG 0-1
- Active brain metastases, and uveal or ocular melanoma not permitted

Characteristic	N=30
<b>Median age</b> (range) - years	70.5 (30-87)
<b>Male sex</b> - no. (%)	21 (70)
<b>ECOG performance status</b> - no. (%)	
0	19 (63)
1	11 (37)
<b>Elevated baseline LDH</b> - no. (%) *	9 (31)
<b>Stage</b> (8 <sup>th</sup> edition AJCC) - no. (%)	
IIIB	2 (7)
IIIC	9 (30)
IV	19 (63)
M1a	5 (17)
M1b	5 (17)
M1c	8 (27)
M1d	1 (3)

Characteristic	N=30
<b>Liver metastasis</b> - no. (%)	4 (13)
<b>BRAF V600E status</b> - no. (%) †	
Mutated	10 (37)
<b>PD-L1 status</b> - no. (%) ¶	
Positive (≥1%)	8 (36)
<b>Tumor mutation burden</b> - no. (%) £	
High (≥20 mutations/Mb)	3 (18)
Intermediate (6-19 mut/Mb)	6 (35)
Low (1-5 mutations/Mb)	8 (47)



## Favorable safety profile of Phase I UV1 + pembrolizumab

### Malignant melanoma

#### Safety of UV1 vaccination

- Safety profile of UV1 in combination with pembrolizumab comparable to that of pembrolizumab alone
- Grade 3 adverse events in 20% of patients – **no grade 4 or 5 events**
- Adverse event type and frequency similar to that of pembrolizumab alone
- Mild grade 1-2 injection site reactions attributable to UV1

Adverse Event	N=30	
	Any grade	Grade 3
<b>Related to treatment*</b>		
Any	21 (70.0)	6 (20.0)
Occurring in more than one patient or grade $\geq 3$		
Fatigue	10 (33.3)	0
Injection site reaction	6 (20.0)	0
Hypothyroidism	6 (20.0)	0
Colitis	5 (16.7)	2 (6.7)
Diarrhea	5 (16.7)	0
Pruritus	4 (13.3)	0
Hyperthyroidism	4 (13.3)	1 (3.3)
Rash	3 (10.0)	0
Arthritis	2 (6.7)	2 (6.7)
Dyspnoea	2 (6.7)	0
Chorioretinitis	1 (3.3)	1 (3.3)
Diabetes mellitus	1 (3.3)	1 (3.3)

Historical reference study: KEYNOTE-006 (Robert C, 2019)

**Any treatment-related adverse event:** 79%

**Grade 3-5 adverse events:** 18%

# Fast track and orphan drug designation confirms our confidence in the therapeutic potential of UV1











## Ultimovacs is granted Fast Track designation from the FDA

- UV1 as add-on therapy to pembrolizumab for the treatment of malignant melanoma
- UV1 as add-on therapy to ipilimumab for the treatment of malignant melanoma
- Fast track is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need  
The purpose is to get important new drugs to the patient earlier

## Ultimovacs is granted Orphan Drug designation from the FDA

- UV1 in the treatment of patients with malignant melanoma
- A status given to certain drugs which show promise in the treatment, prevention, or diagnosis of orphan diseases; a rare disease or condition that affects fewer than 200,000 people with unmet medical needs in the US. The intention of the program is to support and advance the development and evaluation of new treatments.

# Experienced Board of Directors

 <p><b>Jonas Einarsson</b> Chairman of the board</p>	<ul style="list-style-type: none"> <li>CEO of the Norwegian Radium Hospital Research Foundation</li> <li>Board member of several biotech companies</li> <li>One of the initiators behind the Norwegian Center of Expertise, Oslo Cancer Cluster</li> </ul>	 <p><b>Henrik Schüssler</b> Board member</p>	<ul style="list-style-type: none"> <li>CEO and board member of Gjelsten Holding AS</li> <li>Previously CFO and CEO of Norway Seafood</li> <li>Accounting/consulting experience from Ernst &amp; Young</li> </ul>	 <p><b>Haakon Stenrød</b> Board member</p>	<ul style="list-style-type: none"> <li>Senior Investment Manager at Watrium</li> <li>Previously 12 years in the Investment Banking at ABG Sundal Collier, focusing on M&amp;A, restructurings and capital markets advisory</li> <li>Board member of DF Capital, a UK challenger bank listed on AIM London</li> </ul>
 <p><b>Leiv Askvig</b> Board member</p>	<ul style="list-style-type: none"> <li>Investment Advisor at Sundt AS, a Norwegian family owned investment company</li> <li>Board member of Padox AB, Eiendomsspar, Oncoinvent AS and Civita</li> <li>Previously Chairman of the Board of Oslo Stock Exchange and CEO of Sundal Collier &amp; Co</li> </ul>	 <p><b>Kari Grønås</b> Board member</p>	<ul style="list-style-type: none"> <li>Extensive experience in drug development and commercialization within the pharmaceutical industry of new breakthrough products securing regulatory approvals, i.e. Xofigo, Hexvix</li> <li>Board positions in Spago Nanomedical AB, SoftOx AS and The Norwegian Lung Cancer Society</li> </ul>	 <p><b>Aitana Peire</b> Board member</p>	<ul style="list-style-type: none"> <li>Investment Manager of Canica's Future of Health assets. Board member in EXACT-Tx AS</li> <li>Previously senior consultant in Venture Valuation, Pharma equity research analyst at Kepler Cheuvreux and PMA consultant for Stratas Partners in Basel and investment analyst for London-based hedge fund Carval Investors</li> </ul>
 <p><b>Ketil Fjerdings</b> Board member</p>	<ul style="list-style-type: none"> <li>25+ years experience from board and management positions in different companies and industries</li> <li>Ultimovacs' Chairman of the board from '11-'17</li> </ul>	 <p><b>Eva S. Dugstad</b> Board member</p>	<ul style="list-style-type: none"> <li>Manager for Business and Community Relations at Faculty of Mathematics and Natural Sciences, University of Oslo</li> <li>Previously Director for Business Development at Radforsk and President and EVP at the Institute for Energy Technology (IFE)</li> <li>Has been involved in various boards in both public and private sector and in several public expert panels</li> </ul>		

# Management Team with proven execution capabilities



**Carlos de Sousa**

MD, EMBA  
CEO



**Jens Bjørheim**

MD, PhD  
CMO



**Ingunn H. Westgaard**

PhD  
Head of Research



**Hans Vassgård Eid**

MSc Business  
CFO



**Gudrun Trøite**

PhD  
Head of Project  
Coordination



**Audun Tornes**

MSc  
CTO



**Orla Mc Callion**

PhD  
Head of Regulatory &  
QA



**Øivind Foss**

Dr.Scient  
Head of Clinical  
Operations



**Ton Berkien**

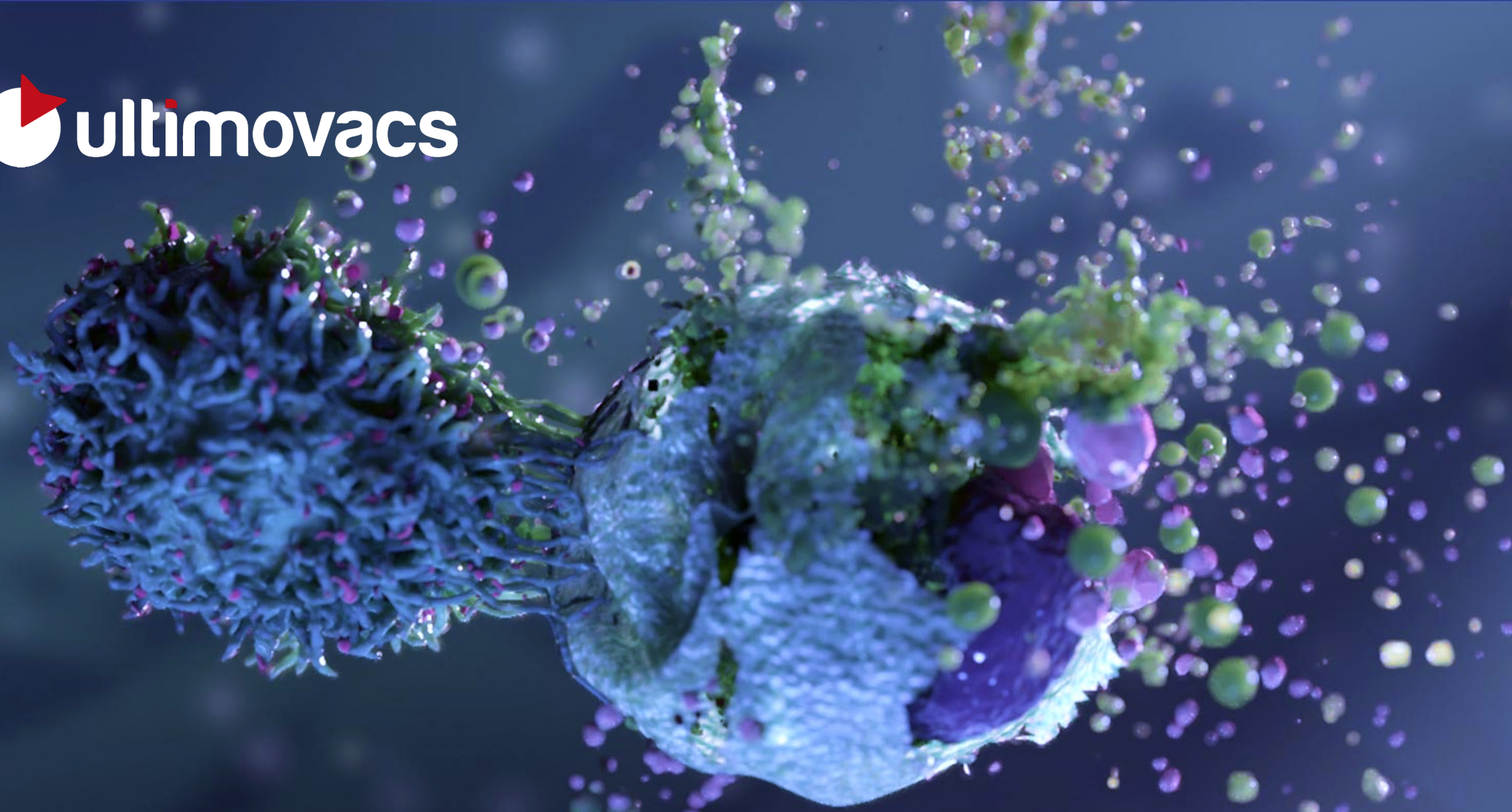
BA Econ, LSid  
CBO



**Anne Worsøe**

MSc Business  
Head of IR





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