

Empower the Immune System to Fight Cancer

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INTRODUCTION

UV1: An off-the-shelf cancer vaccine in a broad clinical program

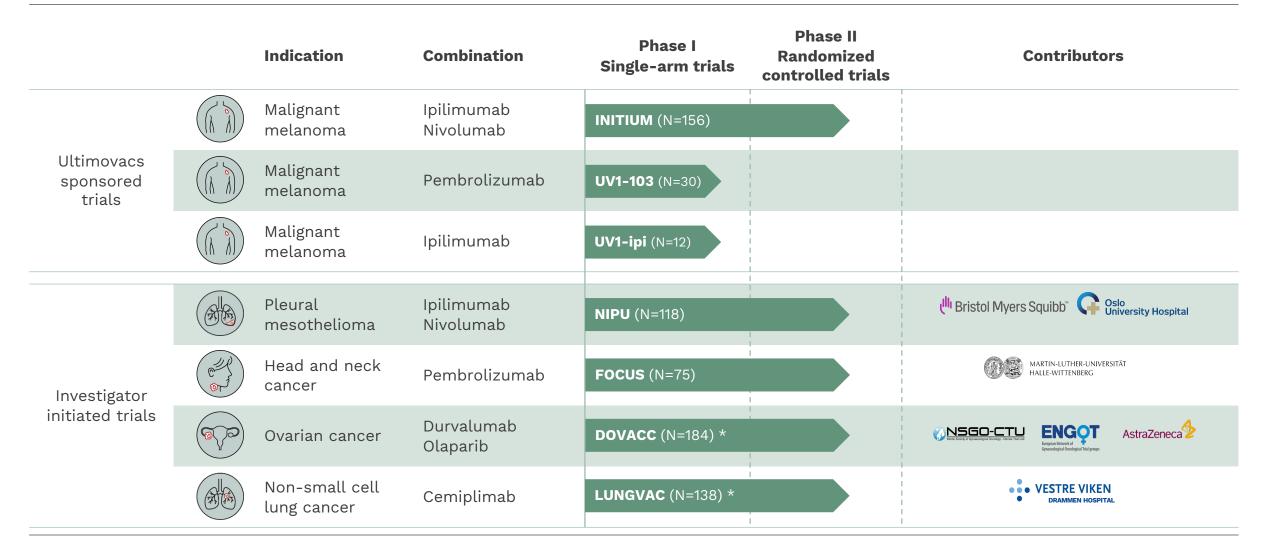
- Immune checkpoint inhibitors (CPI) have transformed cancer treatment, but the success rate varies
 - Cancer vaccines can enhance the activation and infiltration of T cells into the tumor
 - UV1 target telomerase is expressed in 85-90% of cancer types across stages; represent a potential add-on treatment to CPI in multiple solid tumors
- Clinical strategy objective: Assessing UV1 efficacy across different types of cancers expressing telomerase, and where CPI therapy are (or likely to be) approved as standard-of-care
- Phase I studies with UV1 showed good safety profile and promising long-term overall survival
- UV1 + pembrolizumab in advanced melanoma: 33% complete response, ~ 70% overall survival after 4 years; similar results for PD-L1 +/- tumors
- Phase II program: Data-driven approach with five randomized controlled trials (RCT) in various indications First randomized Phase II data in advanced mesothelioma and melanoma
 - NIPU: ipi/nivo +/- UV1 in second-line treatment of malignant mesothelioma: Primary endpoint PSF not met, clinically meaningful survival improvement
 - INITIUM: ipi/nivo +/- UV1, in first-line treatment of advanced melanoma: Primary/secondary endpoint not met

Near-term topline results expected from Phase II trials

- FOCUS: pembro +/- UV1 in head and neck squamous cell carcinoma: Enrollment complete, readout expected Q3 2024
- DOVACC: Second-line treatment of ovarian cancer with UV1 added to olaparib/durvalumab: Enrolling, readout expected H1 2025

INTRODUCTION

Investigating UV1 across cancer indications and combinations

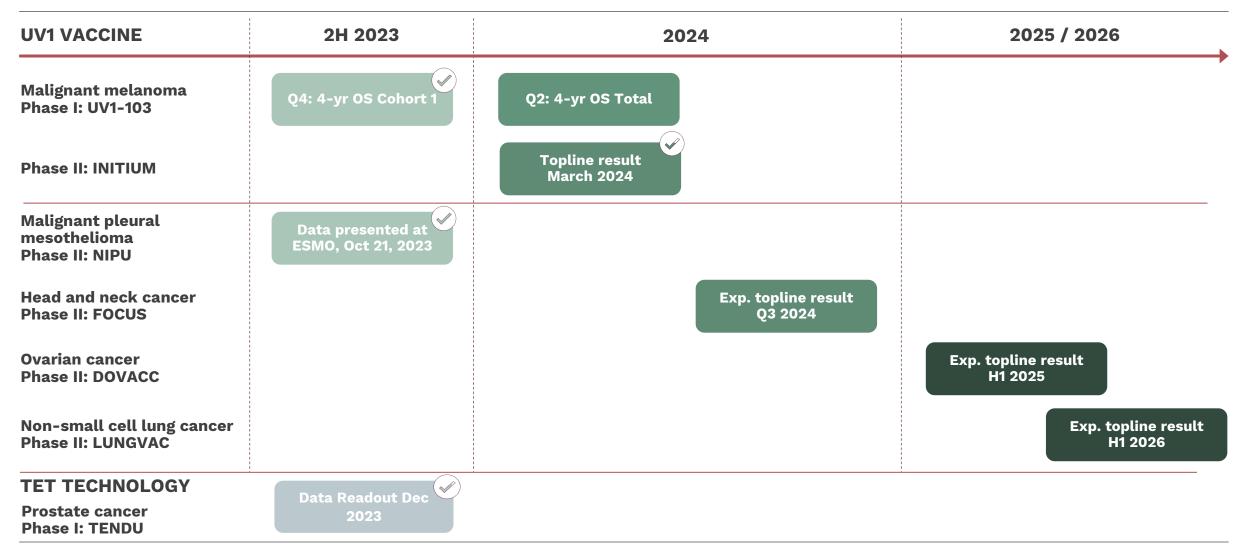




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INTRODUCTION

Newsflow and milestones



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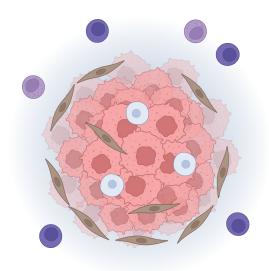
01 UV1 therapeutic cancer vaccine

Checkpoint inhibitor (CPI) efficacy relies on spontaneous T cell responses against cancer¹

Vaccinate to increase the

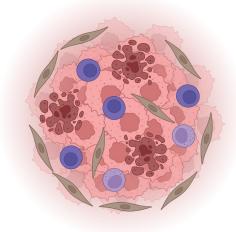
magnitude and durability of

relevant T cell responses



Non-responding (cold) tumors

Scarce anti-tumor T cell responses **Responding (hot) tumors**



High PD-L1 Many TILs High IFNy

Abundant anti-tumor T cell responses



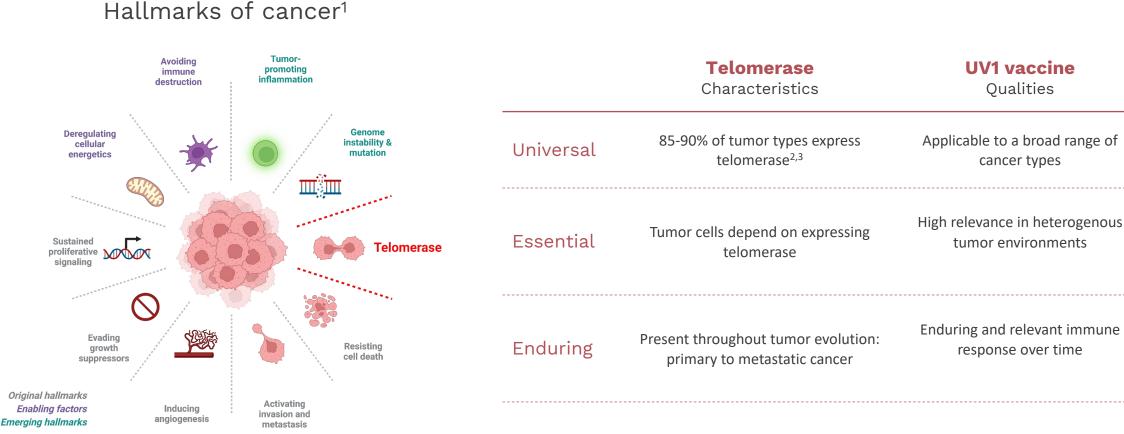
Low PD-L1

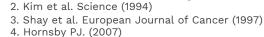
Few TILs

Low IFNv

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The UV1 vaccine induces T cell responses against telomerase





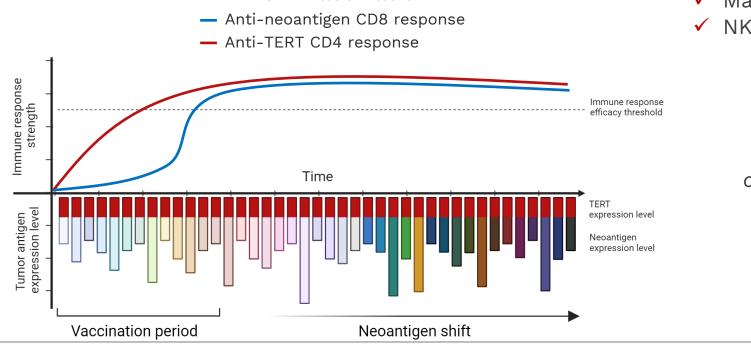
1. Hanahan D et al. Cell (2011) - Figure created with Biorender.

Non-Confidential 9

UV1 leverages the unique features of CD4 T cells

CD8 T cells

- "Soldiers" of the immune response
- Identifies target antigen on HLA class I
- Directly kill cancer cells



UV1 vaccination

CD4 T cells

- "Orchestrators" of the immune response
- Identifies target antigen on HLA class II
- Promotes anti-tumor immune response through activation of:
 - ✓ CD8 T cells
 - ✓ Macrophages
 - ✓ NK cells

CD4+ T cell response towards a continuously present target maintains anti-tumor immune responses over time

UV1

Mode of action & 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-α, IFN-γ and IL-2) inducing a proinflammatory "hot" tumor microenvironment

3

Enhanced intratumoral activation of T cells

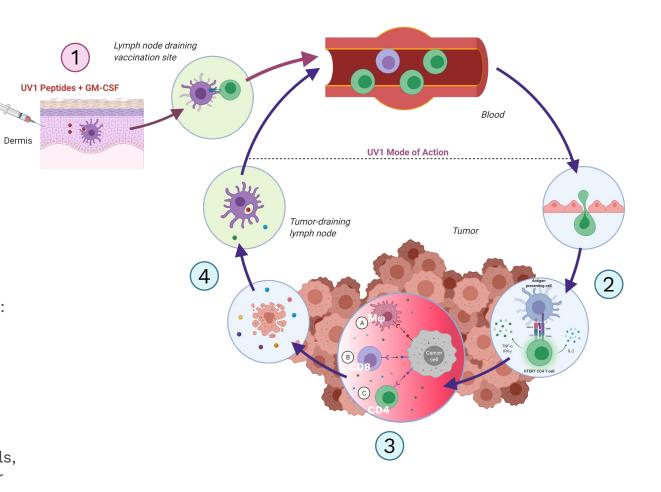
- T cells activate other cells of the immune system through cytokine secretion, directing killing through:
 - i. Macrophages
 - ii. CD8 T cells
 - iii. CD4 T cells



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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



Anti-CTLA-4 and PD-1

INITIUM and NIPU trials

- Most effective SoC immunotherapy in immunogenic solid tumors
 - Represents an opportunity to improve on best-in-class CPIs thereby setting a new efficacy standard
 - Higher hurdle to improve efficacy (already a high bar)
- Mechanistically, anti-CTLA-4 is hypothesized to generate stronger vaccine-induced T cell responses
- The CPI combination comes with significant toxicities and current indications are limited

Anti-PD-1/L1

FOCUS, DOVACC, and LUNGVAC trials

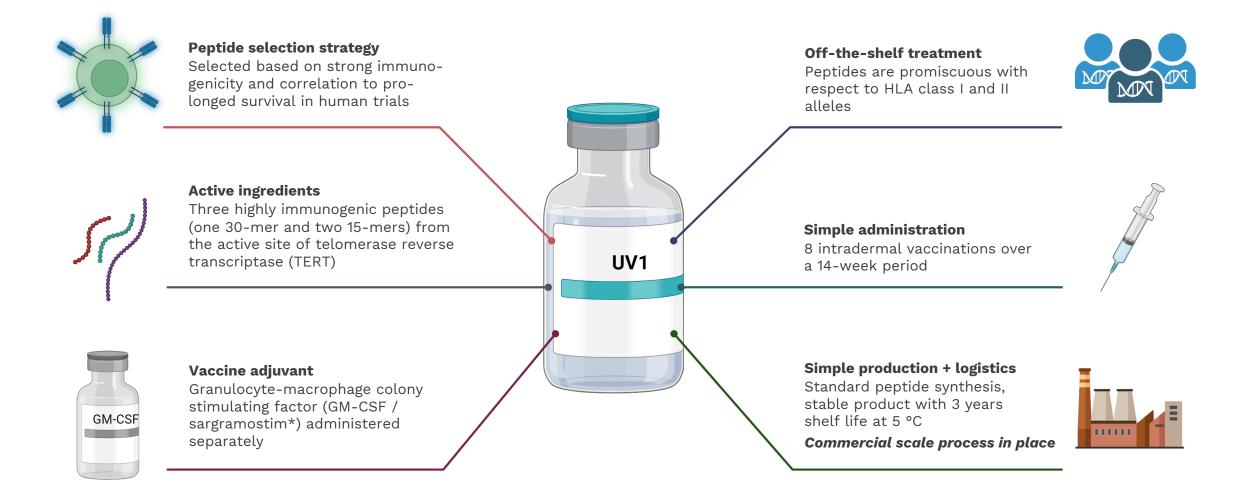
- Widely established SoC in multiple indications (>35)
- Lack of anti-tumor T cell responses firmly established as an efficacy bottleneck
 - Strong rationale for adding UV1 to strengthen and extend efficacy to more patients (e.g. PD-L1 negative as in the 103 trial)
- Additional treatments on top of PD-1/L1 have been shown to improve outcomes for patients as compared to PD-1/L1 alone
- Lower hurdle to improve efficacy
- Competitive space with multiple agents being tested in combination with PD-1 vs. PD-1 alone

Demonstrated good safety across the trials

- 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)
- More than 300 cancer patients have received treatment with UV1 in clinical trials. To date, no safety concerns
 have been reported
- UV1 maintains an excellent safety profile in the randomized Phase II NIPU trial
 - The addition of UV1 to ipilimumab + nivolumab was safe and did not noticeably increase occurrences of serious adverse events
 - The percentage of patients with serious adverse events was similar in both arms



The UV1 vaccine is off-the-shelf and easy to administer







16.12.2 Biokimy

02 Phase I results

PHASE 1 UV1-103 TRIAL

UV1 plus pembrolizumab in advanced melanoma

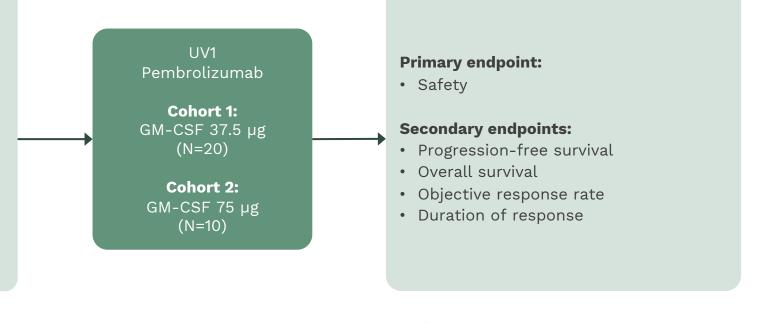
Sponsor: Ultimovacs **Country:** USA



1L treatment of advanced melanoma

N=30

- 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



Status:

Enrollment completed Patients are in long-term follow-up

Results: Published in Clinical Cancer Research (2023)

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Sustained long-term overall survival after 48 months

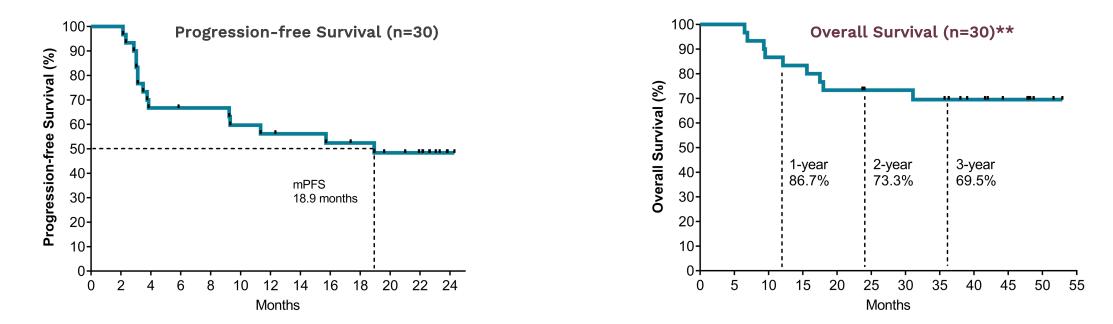
Progression free survival:

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• Median PFS 18.9 months (95% CI, 3.5-NR)

Overall survival:

- Median follow-up 47.8 months
- Median OS not reached (95% CI, 31.2-NR)



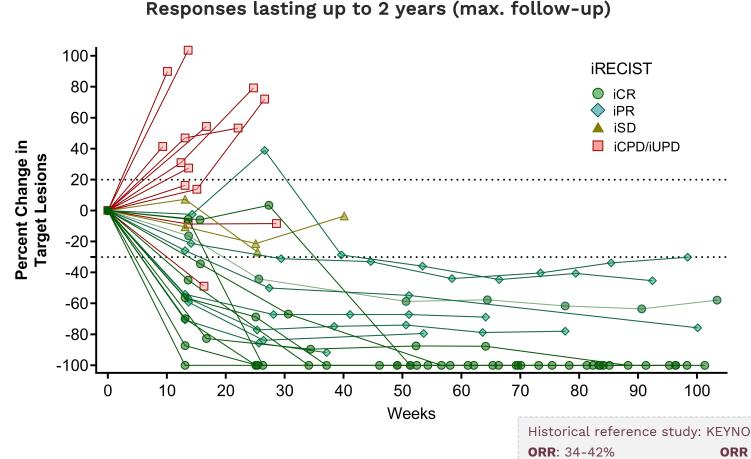
• UV1 has demonstrated a good safety profile; no unexpected safety issues have been observed in the trial

• Patients will continue to be followed for long-term survival

*4-year follow-up of Cohort 1: No confirmed deaths between 3-year and 4-year follow-up. 4-year follow-up of cohort 1+2 combined will be reported Q2 2024. ** Published in Ellingsen et al, Clinical Cancer Research (2023)

PHASE 1 UV1-103 TRIAL IN ADVANCED MELANOMA

Sustained high ORR and CR rate also in PD-L1 negative tumors



Best overall response (iRECIST)	n	%
ORR (n=30)	17	56.7
Complete response	10	33.3
Partial response	7	23.3
Stable disease	2	6.7
Progressive disease	11	36.7
ORR in PD-L1 negative patients (n=14)*	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%	ORR PD-L1 neg:	24.3% (95% CI, 16.4%-33.7%)		
CR : 5-14%	CR PD-L1 neg:	5.8%		

Each line represent one patient, color- and symbol-coded according to best objective response achieved per iRECIST Each symbol represents a CT measurement of the tumor size relative to baseline

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

Published in Ellingsen et al, Clinical Cancer Research (2023)

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03 Phase II strategy and clinical trials

Wide-ranging randomized controlled Phase II clinical program

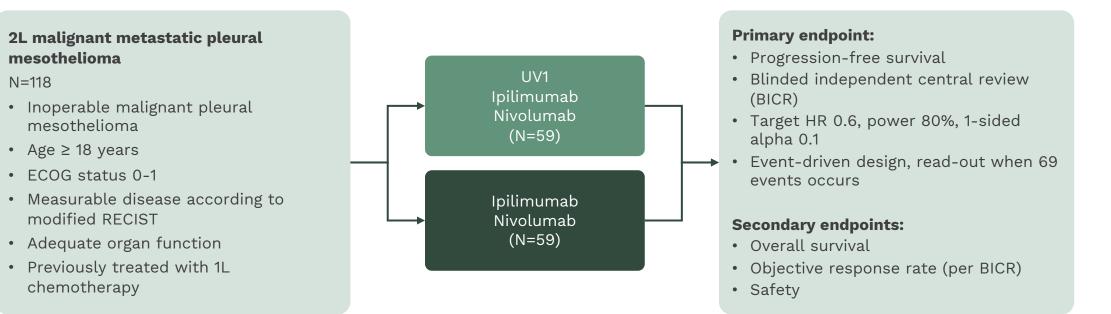
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	NIPU	INITIUM	FOCUS	DOVACC	LUNGVAC
Indication	Second line mesothelioma	First line malignant melanoma	First line head and neck cancer	Second line ovarian cancer	First line non-small cell lung cancer
Immunotherapy combination +/- UV1	Ipilimumab Nivolumab	Ipilimumab Nivolumab	Pembrolizumab	Durvalumab Olaparib	Cemiplimab
Study conduct	118 patients 6 sites 5 countries Europe, Australia	156 patients 39 sites 4 countries Europe, US	75 patients 10 sites Germany	184 patients 35 sites 10 countries Europe	138 patients 9 sites Norway
Enrollment status	\bigcirc	\bigcirc	\bigcirc	>40%	>15%
Topline results	Announced October 2023	Announced March 2024	Q3 2024	H1 2025	H1 2026
	Primary endpoint: Pr	ogression-free survival			

Secondary endpoints: Overall survival, objective response rate, duration of response, safety

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NIPU: Second-line malignant pleural mesothelioma

Sponsor: Oslo University Hospital **Contributors:** BMS, Ultimovacs **Sites and countries:** Six hospitals in Norway, Sweden, Denmark, Spain and Australia <u>NCT04300244</u>



Status:

Enrollment completed between June 2020 and January 2023

Milestones:

Results presented at the ESMO Congress in Madrid, October 2023



Encouraging survival results presented at ESMO 2023

No added toxicity compared to ipi + nivo alone

• Safety profile of UV1 in combination with ipi + nivo is comparable to that of ipi + nivo alone

Primary endpoint progression-free survival not met

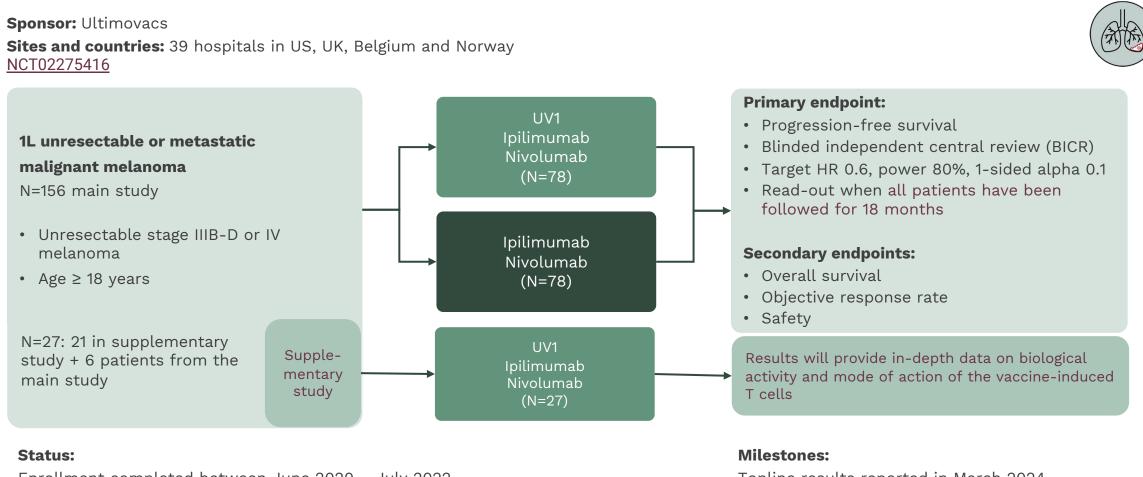
• Main analysis of progression-free survival failed to demonstrate statistical significance

Clinically relevant improvements on secondary endpoints:

- Improved survival: The combination UV1 + ipi + nivo improved overall survival, reducing the risk of death by 27%
- Reduced tumor burden: The combination UV1 + ipi + nivo gave an objective response rate of 31%, as compared to 16% with ipi + nivo alone



INITIUM: First-line advanced melanoma



Enrollment completed between June 2020 – July 2022

Topline results reported in March 2024

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Topline results reported after 18 months follow-up

No added toxicity compared to ipi + nivo alone

• Safety profile of UV1 in combination with ipi + nivo is comparable to that of ipi + nivo alone

Primary and secondary endpoints not met

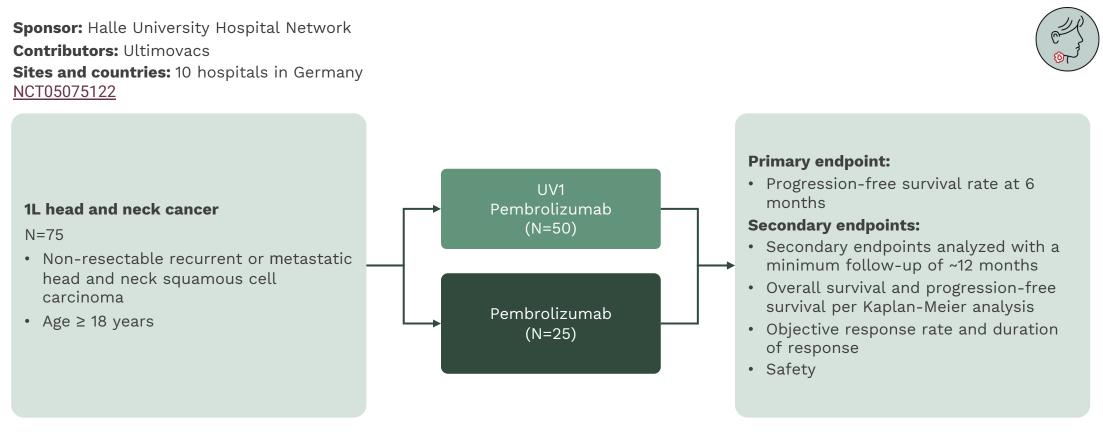
- Main analysis of progression-free survival, overall survival and objective response rate failed to demonstrate statistically significant improvement with the addition of UV1 to the ipi/nivo combination which performed much better than expected based on historical data
- Full dataset is currently being analyzed for subgroup effects and biological activity

Median PFS was not reached in either arm

• Hazard ratio (HR) between the arms for PFS was 0.95



FOCUS: First-line head and neck cancer



Status:

Enrollment completed between August 2021 – August 2023

Milestones:

Topline results expected Q3 2024 Includes readout of all endpoints up to 12 months and primary endpoint at 6 months

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DOVACC: Relapsed ovarian cancer

Sponsor: NSGO/ENGOT **Contributors:** AstraZeneca, Ultimovacs Sites and countries: 35 hospitals, 10 countries in Europe NCT04742075



UV1 High-grade BRCA negative ovarian Olaparib cancer, 2L maintenance Durvalumab **Primary endpoint:** (N=92) Progression-free survival • Histologically diagnosed epithelial ovarian, fallopian tube or primary Olaparib Secondary endpoints: peritoneal cancer Durvalumab • Overall survival • Confirmation of relapse disease ≥ 6 (N=46) • Objective response rate month after last chemotherapy • Duration of response Non-gBRCAmut or tBRCAwt • Safety Olaparib • Age \geq 18 years (N=46)

Status:

N=184

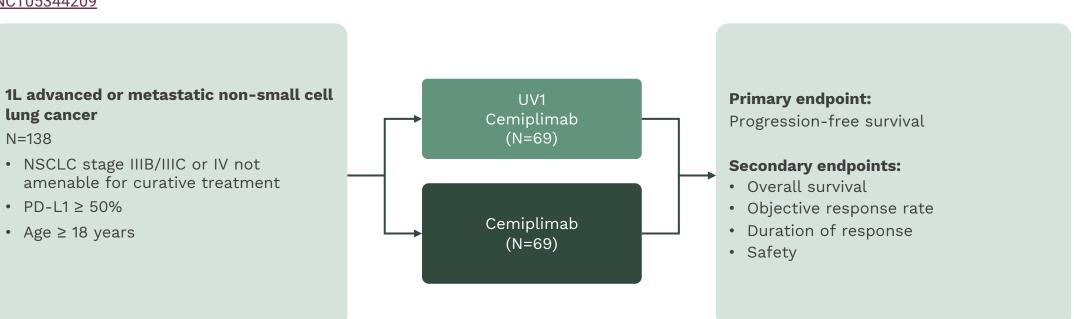
First patient enrolled in December 2021 Enrollment per Q1 2024 reporting: 99 patients (>50%) **Milestones:**

Topline results expected H1 2025

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LUNGVAC: First-line non-small cell lung cancer

Sponsor: Drammen Hospital **Contributors:** Ultimovacs **Sites and countries:** 9 hospitals in Norway <u>NCT05344209</u>



Status:

First patient enrolled in October 2022 Enrollment per Q1 2024 reporting: 27 patients (>15%)

Milestones:

Topline results expected H1 2026



04 Discovery: TET technology



The TET vaccine technology

TET (Tetanus-Epitope Targeting) is Ultimovacs' patent protected vaccine adjuvant technology.

TET ensures targeted delivery of both antigen and adjuvant signals to antigen presenting cells.

TET is a novel strategy to effectively activate tumor specific T cells.

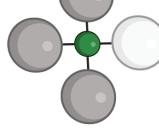
The units delivering the adjuvant and the antigen signals are linked by use of an innovative conjugation technology.

This conjugation technology allows for flexibility to incorporate a variety of antigens, and thereby tailoring vaccines to different types of cancer.

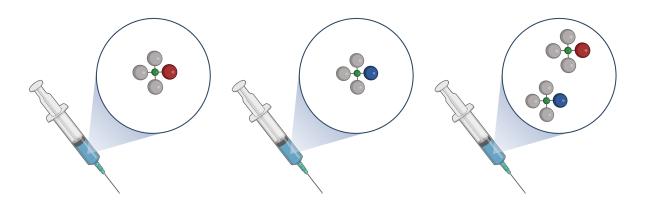
The TET vaccine adjuvant technology and the conjugation technology may be basis for new, first-in-class therapeutic cancer vaccines.

ADJUVANT:

Tetanus-derived sequences facilitating the adjuvant function

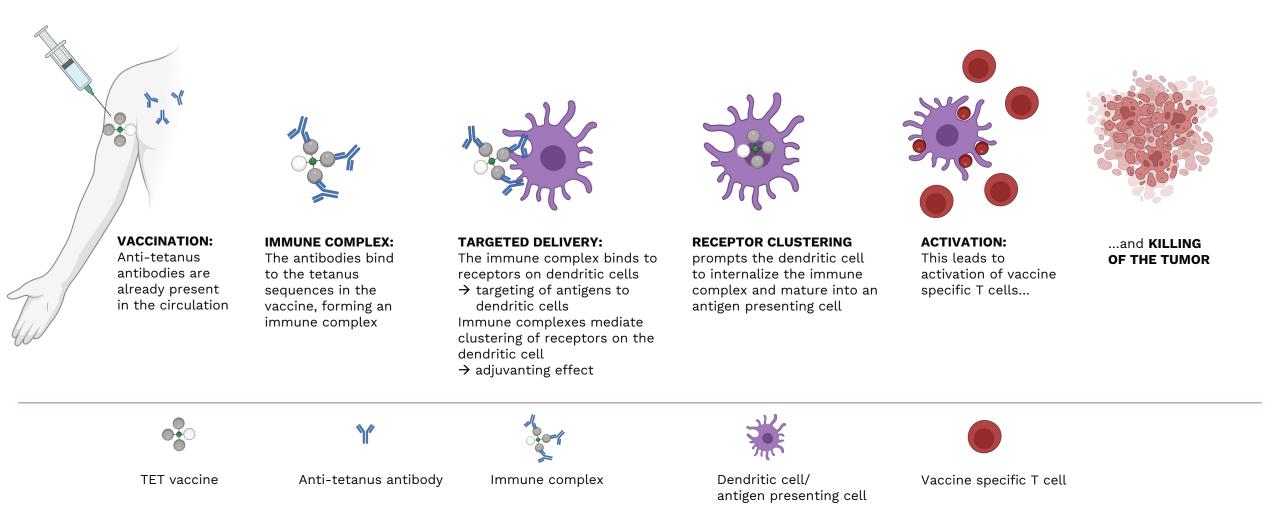


ANTIGEN that directs the immune response towards the intended goal



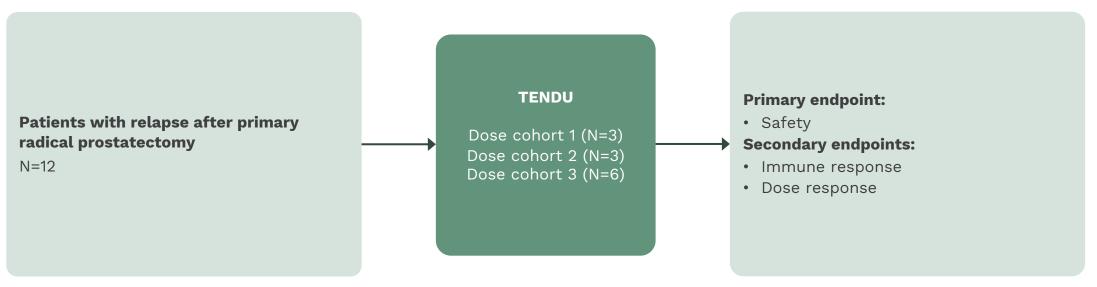


Targeted delivery of the vaccine to antigen presenting cells



TENDU: First clinical evaluation of a TET vaccine

Sponsor: Ultimovacs **Sites and countries:** Oslo University Hospital, Norway <u>NCT04701021</u>



Status: Enrollment completed

Milestones:

Results reported December 2023: Good safety and tolerability across all dose cohorts Observations of immune activation with vaccine specific T cell responses

Other CMC and preclinical development

- Ultimovacs is conducting a series of activities to further develop and explore the potential of TET and the conjugation technology
- Preclinical experiments support the TET strategy of targeted delivery of antigens and adjuvant signals to antigen presenting cells
- The combination of exploratory research using Ultimovacs' conjugation technology, significant progress made in the manufacturing process, and the clinical data, provide a valuable basis for potential expansion of Ultimovacs' pipeline
- Ultimovacs will continue the ongoing TET nonclinical activities
- Future development of TET based vaccine candidates will take into consideration the evolution of the therapeutic landscape and medical needs in different tumor types





04 Outlook and opportunities



OPPORTUNITIES

Investigating UV1 with the leading immune checkpoint inhibitors

- Immune checkpoint inhibitors (CPI) have transformed cancer treatment the last decade, but the success rates varies
- Currently around one third of cancer patients is eligible to receive CPI¹
- Cancer vaccines may enhance the activation and infiltration of T cells into the tumor and improve treatment outcomes from immunotherapy
- In current Phase II program, UV1 is under investigation with 5 out of the top 6 CPIs, accounting for ~85% of the CPI market
- Multiple combination opportunities in solid tumors remains, and across stages

Cancer indication	CPI use %	US market	UV1	Approved CPIs
Melanoma	80%	\$3.8 bn		Pembrolizumab, ipilimumab, nivolumab, opdualag
Lung cancer	48%	\$12.8 bn		Pembrolizumab, ipilimumab, nivolumab, atezolizumab
Head and neck	58%	\$1 bn		Pembrolizumab, nivolumab
Ovarian	-	\$2.2 bn		
Mesothelioma	40%	\$0.2 bn		ipilimumab, nivolumab
Renal cell carcinoma	40%	\$3.4 bn	\bigcirc	Pembrolizumab, ipilimumab, nivolumab
Bladder cancer	45%	\$1.5 bn	\bigcirc	Pembrolizumab, nivolumab, atezolizumab
Gastric/Gastro	50%	\$0.8 bn	\bigcirc	Pembrolizumab, ipilimumab, nivolumab
Liver	39%	\$1.1 bn	\bigcirc	Pembrolizumab, ipilimumab, nivolumab, atezolizumab
B-cell lymphoma	4%	\$10.5 bn	\bigcirc	Pembrolizumab, nivolumab
Colorectal	24%	\$4.4 bn	\bigcirc	Pembrolizumab, ipilimumab, nivolumab
				Source: Global Data (Febr 2024)



The benefit of off-the-shelf vs. individualized vaccines

	Off-the-shelf	Individualized
Vaccine modality	Shared antigen	Individualized
Patient screening (biopsy)	Not required	Required
Specialized hospital infrastructure	Not required	Required
Time to treatment	Immediate	~6 weeks
Possibility to expand to neoadjuvant or metastatic setting	Yes	Limited due to long lead time
Manufacturing costs	Low	High
Resistance potential	No	Yes



UV1 regulatory designations in the U.S. and the EU

MelanomaFDA Orphan Drug Designation has been granted to UV1 for treatment of stage IIB-IV
melanoma (December 2021)

FDA Fast Track Designation has been granted for UV1 as add-on therapy to ipilimumab or pembrolizumab for treatment of unresectable or metastatic melanoma (October 2021)

Mesothelioma EMA Orphan Drug Designation has been granted to UV1 for treatment of mesothelioma (February 2024)

FDA Fast Track Designation has been granted for UV1 as add-on therapy to ipilimumab and nivolumab for treatment of malignant pleural mesothelioma (February 2024)

FDA Orphan Drug Designation has been granted to UV1 for treatment of mesothelioma (October 2023)



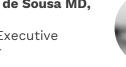
Corporate overview

Company profile

- Founded in 2011 based on more than 30 years of research
- Listed at Euronext Oslo Stock Exchange in 2019
- 26 employees from 7 nationalities
- Located in Oslo, Norway and Uppsala, Sweden
- Total cash end of Q1 2024 amounted to MNOK 220 (MUSD 20)
- Estimated financial runway towards the end of 2025

Management







Ingunn H. Westgaard PhD Head of Research



Largest shareholders²

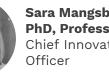
Investor	Holding
Gjelsten Holding	18.9%
Radforsk (Biotech/oncology fund)	4.4%
Inven2 (University of Oslo TTO)	3.7%
Folketrygdfondet (Gov. pension fund)	2.7%
Тор 20	46.3%

Capital markets transactions

Date	Transaction	Deal value
Oct '21	Private placement ²	MNOK 270 (MUSD 28)
May '20	Private placement ²	MNOK 160 (MUSD 17)
May '19	IPO	MNOK 370 (MUSD 38)



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



Sara Mangsbo PhD. Professor Chief Innovation



Key takeaways

Ultimovacs is dedicated to investigate the potential of UV1 to enhance the efficacy of cancer therapies:

- UV1 has shown promising benefits in several clinical studies, inducing robust, durable, and dynamic T cell responses against telomerase a 'Hallmark of cancer'
- Significant indication expansion potential; vaccine antigen is nearly universally expressed in cancer
- UV1 addresses a bottleneck for CPI efficacy and may extend efficacy to a broader population, e.g. PD-L1 negative patients
- Excellent safety profile from phase I and randomized phase II trials
- 'Off-the-shelf & easy to use' promotes broad access for patients to cancer treatment, also in rural areas; potentially well positioned in the emerging cancer vaccine landscape

Ultimovacs remains committed to support the ongoing broad randomized controlled Phase II development program. Readouts began in 2023 and will guide the future development of UV1:

- Five Phase II CPI combination trials ongoing across different cancer types, enrolling > 670 patients in 15 countries
- Phase II data in malignant mesothelioma: Near doubling of ORR and clinically meaningful survival improvement
- Key value inflection points near term and over the next 18 months: Randomized results from the FOCUS and DOVACC trials

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Empower the Immune System to Fight Cancer

Contact: ir@ultimovacs.com