



Empower the Immune System to *Fight Cancer*

Ultimovacs Company Presentation

March 23, 2024



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- 02 Phase I results
- 03 Phase II strategy and clinical trials
- 04 Discovery: TET technology
- 05 Outlook and opportunities

















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**

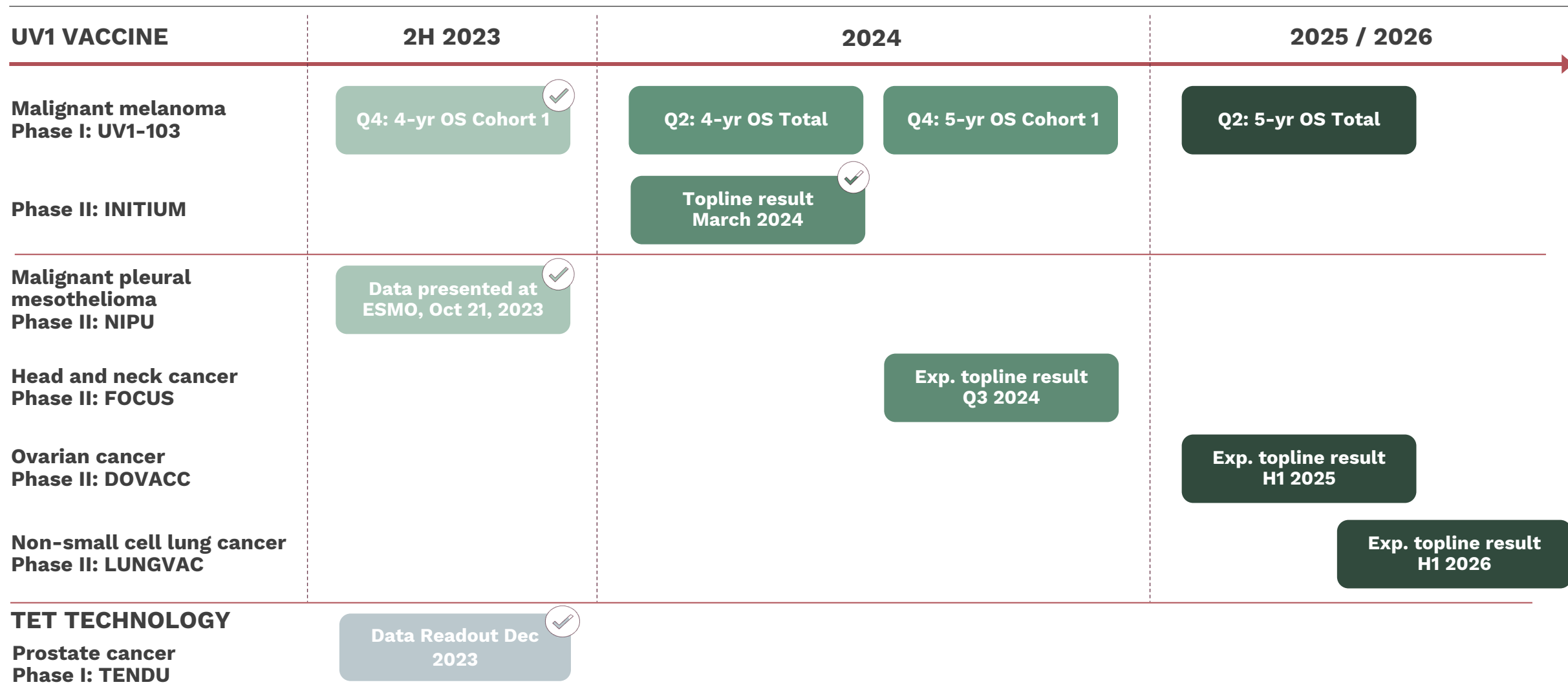
INTRODUCTION

Investigating UV1 across cancer indications and combinations

	Indication	Combination	Phase I Single-arm trials	Phase II Randomized controlled trials	Contributors
Ultimovacs sponsored trials	 Malignant melanoma	Ipilimumab Nivolumab	INITIUM (N=156)		
	 Malignant melanoma	Pembrolizumab	UV1-103 (N=30)		
	 Malignant melanoma	Ipilimumab	UV1-ipi (N=12)		
Investigator initiated trials	 Pleural mesothelioma	Ipilimumab Nivolumab	NIPU (N=118)		 Bristol Myers Squibb™  Oslo University Hospital
	 Head and neck cancer	Pembrolizumab	FOCUS (N=75)		 MARTIN-LUTHER-UNIVERSITÄT HALLE-WITTENBERG
	 Ovarian cancer	Durvalumab Olaparib	DOVACC (N=184) *		 NSGO-CTU  ENGOT  AstraZeneca
	 Non-small cell lung cancer	Cemiplimab	LUNGVAC (N=138) *		 VESTRE VIKEN DRAMMEN HOSPITAL

INTRODUCTION

Newsflow and milestones



01

UV1 therapeutic cancer vaccine

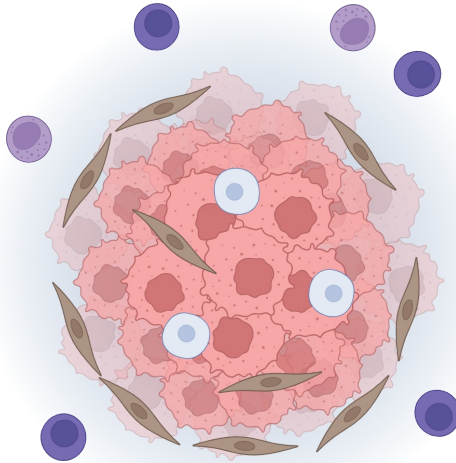


The rationale for therapeutic cancer vaccination

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

Non-responding (cold) tumors

Low PD-L1
Few TILs
Low IFN γ

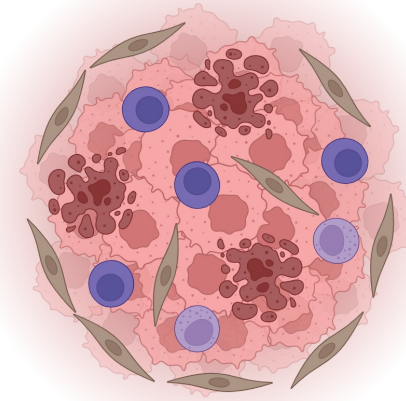


**Scarce anti-tumor
T cell responses**

Vaccinate to increase the
magnitude and durability of
relevant T cell responses

Responding (hot) tumors

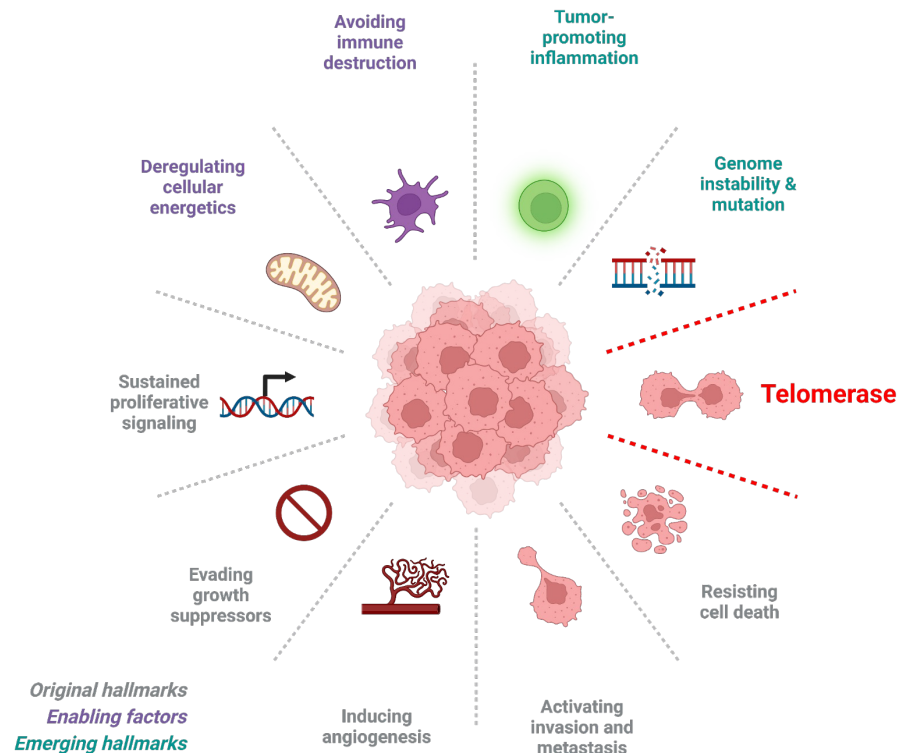
High PD-L1
Many TILs
High IFN γ



**Abundant anti-tumor
T cell responses**

The UV1 vaccine induces T cell responses against telomerase

Hallmarks of cancer¹



Telomerase Characteristics

UV1 vaccine Qualities

Universal

85-90% of tumor types express telomerase^{2,3}

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 leverages the unique features of CD4 T cells

CD8 T cells

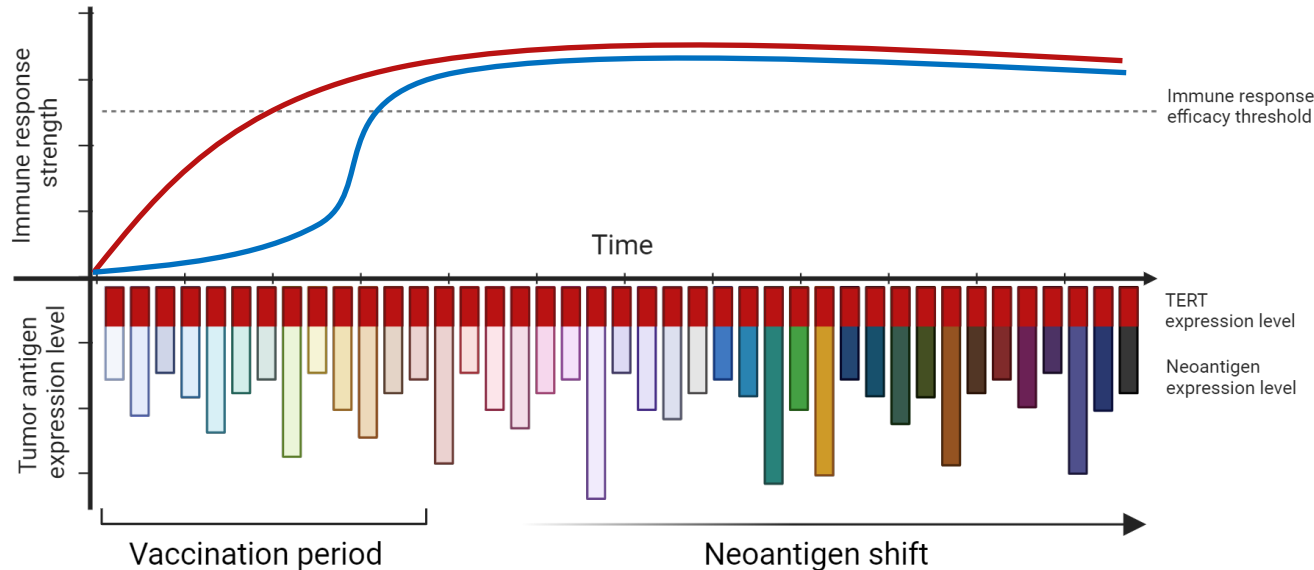
- “Soldiers” of the immune response
- Identifies target antigen on HLA class I
- Directly kill cancer cells

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

UV1 vaccination

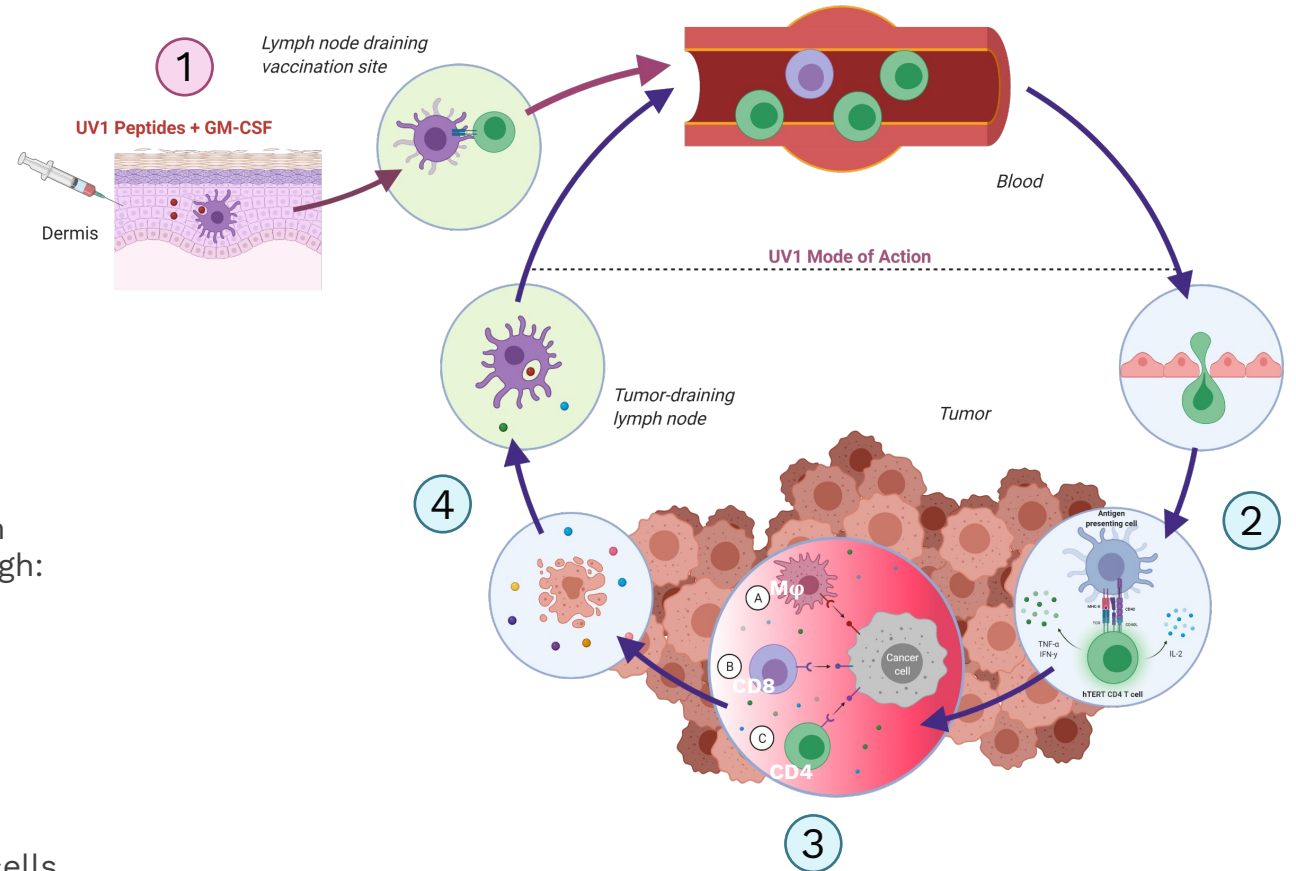
- Anti-neoantigen CD8 response
- Anti-TERT CD4 response



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

Mode of action & downstream mechanisms enhance tumor killing

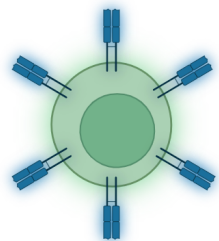
- 1 Intradermal injection of UV1 and **activation of TERT-specific T cells**
- 2 **Improved priming of anti-tumor immune responses**
 - T cells bind their antigen (TERT) expressed on local APCs and the T cells release cytokines (TNF- α , IFN- γ and IL-2) inducing a pro-inflammatory “hot” tumor microenvironment
- 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



Demonstrated good safety across the trials

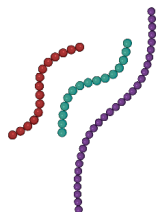
- UV1 does not inhibit telomerase activity but generates T cell responses recognizing fragments of telomerase presented in the context of HLA molecules on cells in the tumor
- No safety signals seen from healthy tissues expressing telomerase (e.g. stem cells)
- More than 300 cancer patients have received 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



Peptide selection strategy

Selected based on strong immunogenicity and correlation to prolonged survival in human trials



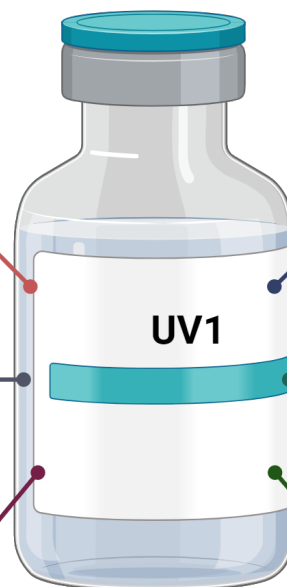
Active ingredients

Three highly immunogenic peptides (one 30-mer and two 15-mers) from the active site of telomerase reverse transcriptase (TERT)



Vaccine adjuvant

Granulocyte-macrophage colony stimulating factor (GM-CSF / sargramostim*) administered separately



Off-the-shelf treatment

Peptides are promiscuous with respect to HLA class I and II alleles



Simple administration

8 intradermal vaccinations over a 14-week period



Simple production + logistics

Standard peptide synthesis, stable product with 3 years shelf life at 5 °C

Commercial scale process in place



02

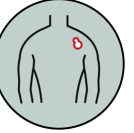
Phase I results



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

UV1
Pembrolizumab

Cohort 1:
GM-CSF 37.5 µg
(N=20)

Cohort 2:
GM-CSF 75 µg
(N=10)

Primary endpoint:

- Safety

Secondary endpoints:

- Progression-free survival
- Overall survival
- Objective response rate
- Duration of response

Status:

Enrollment completed

Patients are in long-term follow-up

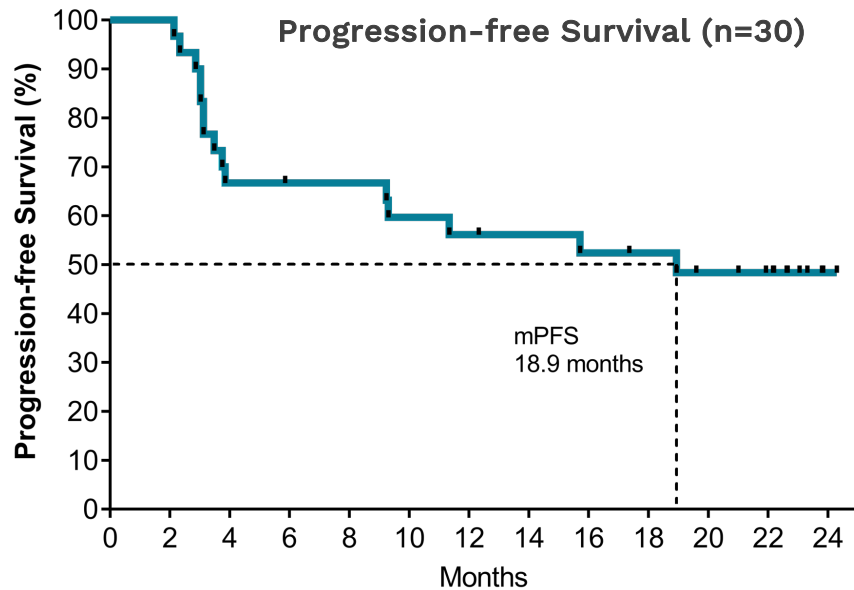
Results:

Published in Clinical Cancer Research (2023)

Sustained long-term overall survival after 48 months

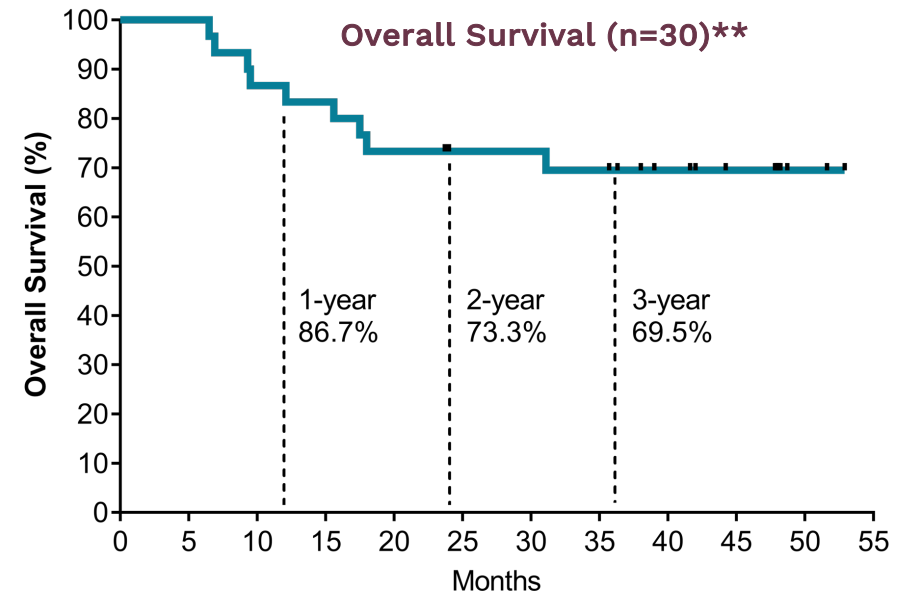
Progression free survival:

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



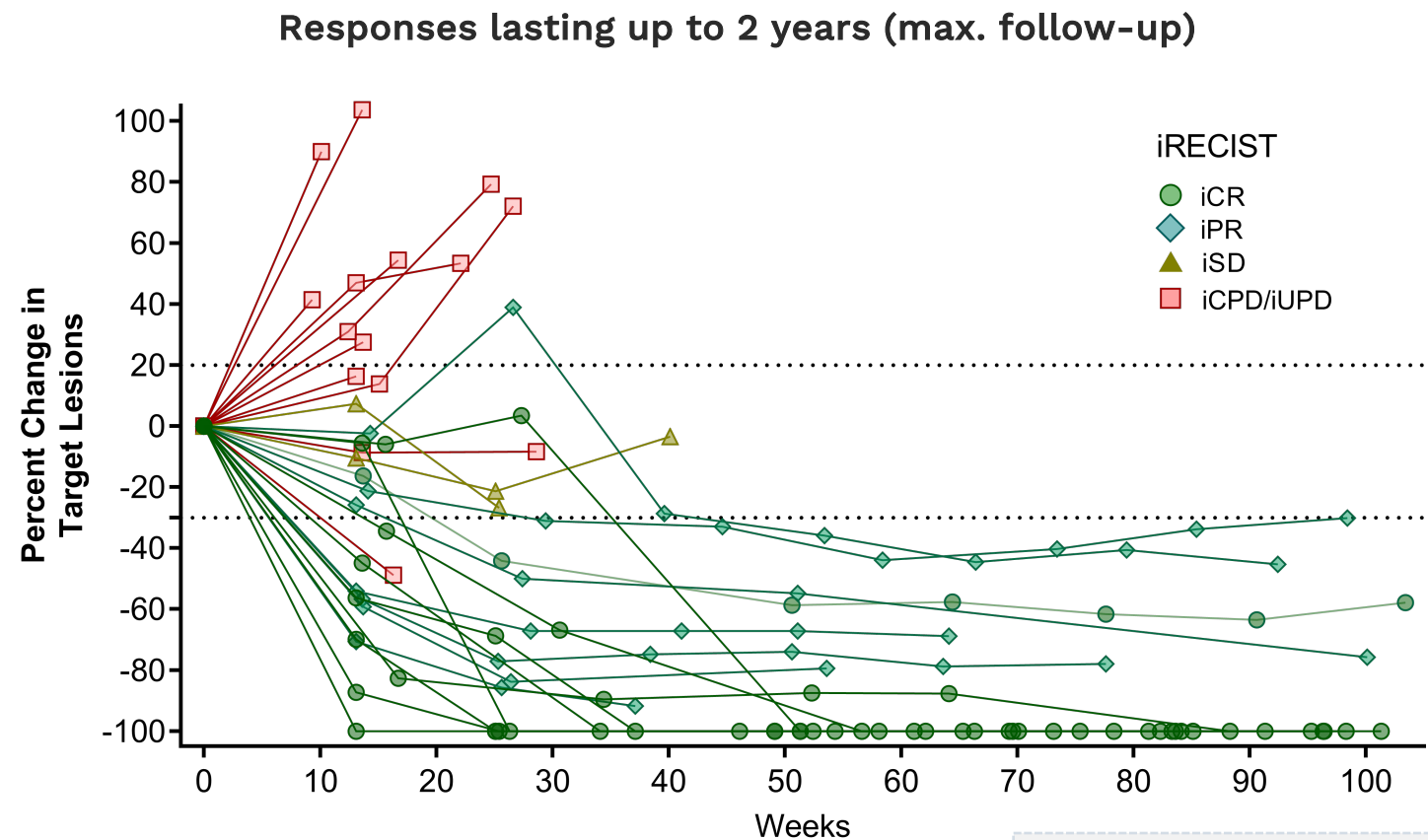
Overall survival:

- 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

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

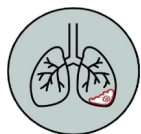
- PD-L1 staining with 22C3 pharmDx for Autostainer Link 48. PD-L1 positive defined as ≥1% of tumor cells

03

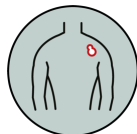
Phase II strategy and clinical trials



Wide-ranging randomized controlled Phase II clinical program



NIPU



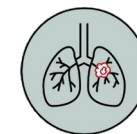
INITIUM



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



>40%

>15%

Topline results

Announced
October 2023

Announced
March 2024

Q3 2024

H1 2025

H1 2026

Primary endpoint: Progression-free survival

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

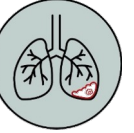
NIPU: Second-line malignant pleural mesothelioma

Sponsor: Oslo University Hospital

Contributors: BMS, Ultimovacs

Sites and countries: Six hospitals in Norway, Sweden, Denmark, Spain and Australia

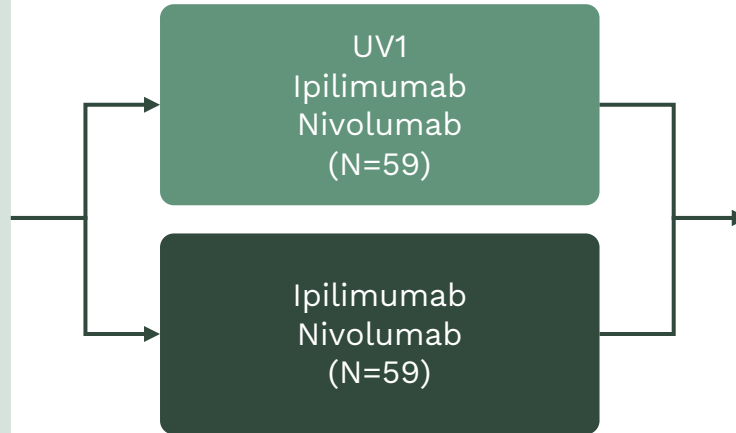
[NCT04300244](#)



2L malignant metastatic pleural mesothelioma

N=118

- Inoperable malignant pleural mesothelioma
- Age ≥ 18 years
- ECOG status 0-1
- Measurable disease according to modified RECIST
- Adequate organ function
- Previously treated with 1L chemotherapy



Status:

Enrollment completed between June 2020 and January 2023

Primary endpoint:

- Progression-free survival
- Blinded independent central review (BICR)
- Target HR 0.6, power 80%, 1-sided alpha 0.1
- Event-driven design, read-out when 69 events occurs

Secondary endpoints:

- Overall survival
- Objective response rate (per BICR)
- Safety

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

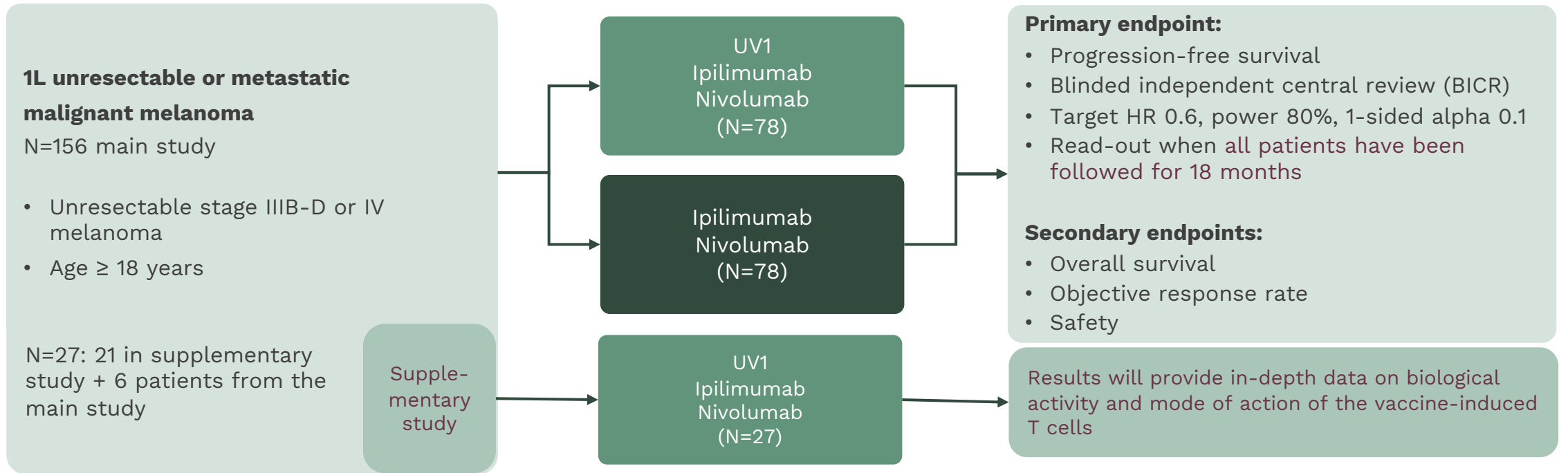
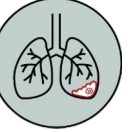
Clinically relevant improvements on secondary endpoints:

- 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

Sponsor: Ultimovacs

Sites and countries: 39 hospitals in US, UK, Belgium and Norway
[NCT02275416](#)



Status:

Enrollment completed between June 2020 – July 2022

Milestones:

Topline results reported in March 2024

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

Sponsor: Halle University Hospital Network

Contributors: Ultimovacs

Sites and countries: 10 hospitals in Germany

[NCT05075122](#)



1L head and neck cancer

N=75

- Non-resectable recurrent or metastatic head and neck squamous cell carcinoma
- Age \geq 18 years

UV1
Pembrolizumab
(N=50)

Pembrolizumab
(N=25)

Primary endpoint:

- Progression-free survival rate at 6 months

Secondary endpoints:

- Secondary endpoints analyzed with a minimum follow-up of ~12 months
- Overall survival and progression-free survival per Kaplan-Meier analysis
- Objective response rate and duration of response
- Safety

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

DOVACC: Relapsed ovarian cancer



Sponsor: NSGO/ENGOT

Contributors: AstraZeneca, Ultimovacs

Sites and countries: 35 hospitals, 10 countries in Europe

[NCT04742075](https://clinicaltrials.gov/ct2/show/study/NCT04742075)

High-grade BRCA negative ovarian cancer, 2L maintenance

N=184

- Histologically diagnosed epithelial ovarian, fallopian tube or primary peritoneal cancer
- Confirmation of relapse disease ≥ 6 month after last chemotherapy
- Non-gBRCAmut or tBRCAwt
- Age ≥ 18 years

UV1
Olaparib
Durvalumab
(N=92)

Olaparib
Durvalumab
(N=46)

Olaparib
(N=46)

Primary endpoint:

- Progression-free survival

Secondary endpoints:

- Overall survival
- Objective response rate
- Duration of response
- Safety

Status:

First patient enrolled in December 2021

Enrollment per Q4 2023 reporting: 75 patients (>40%)

Milestones:

Topline results expected **H1 2025**

LUNGVAC: First-line non-small cell lung cancer

Sponsor: Drammen Hospital

Contributors: Ultimovacs

Sites and countries: 9 hospitals in Norway

[NCT05344209](#)



1L advanced or metastatic non-small cell lung cancer

N=138

- NSCLC stage IIIB/IIIC or IV not amenable for curative treatment
- PD-L1 $\geq 50\%$
- Age ≥ 18 years

UV1
Cemiplimab
(N=69)

Cemiplimab
(N=69)

Primary endpoint:

Progression-free survival

Secondary endpoints:

- Overall survival
- Objective response rate
- Duration of response
- Safety

Status:

First patient enrolled in October 2022

Enrollment per Q4 2023 reporting: 23 patients (>15%)

Milestones:

Topline results expected **H1 2026**



04

Discovery: TET technology

The TET vaccine technology

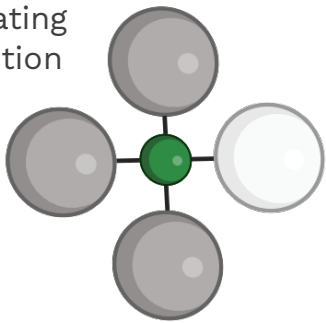
TET (Tetanus-Epitope Targeting) is Ultimovacs' patent protected vaccine adjuvant technology.

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

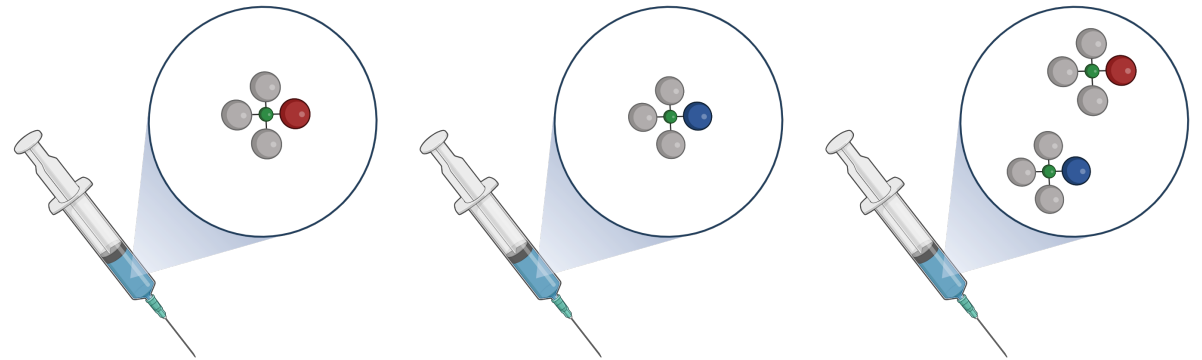
TET is a novel strategy to effectively activate tumor specific T cells.

ADJUVANT:

Tetanus-derived sequences facilitating the adjuvant function



ANTIGEN that directs the immune response towards the intended goal

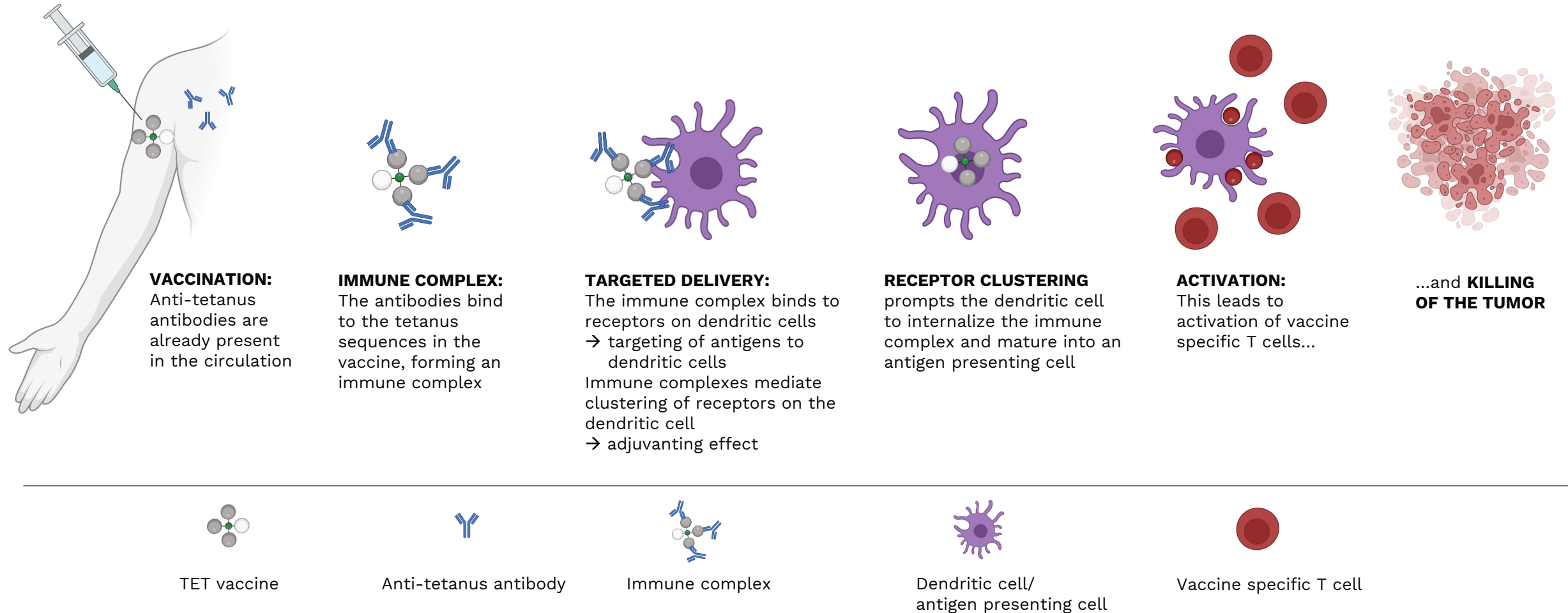


The units delivering the adjuvant and the antigen signals are linked by use of an innovative conjugation technology.

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.

Targeted delivery of the vaccine to antigen presenting cells

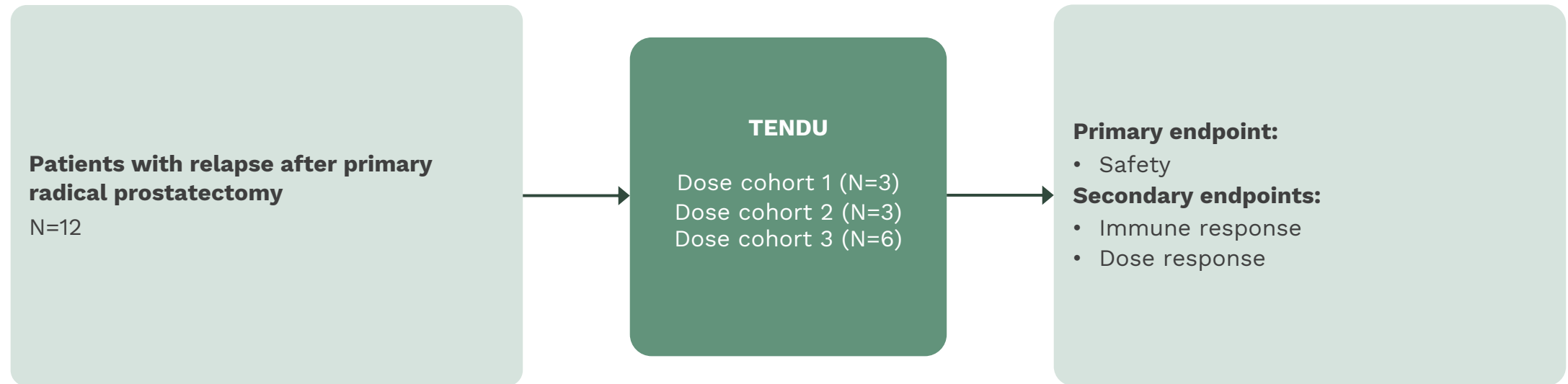


TENDU: First clinical evaluation of a TET vaccine

Sponsor: Ultimovacs

Sites and countries: Oslo University Hospital, Norway

[NCT04701021](#)



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		Pembrolizumab, ipilimumab, nivolumab
Bladder cancer	45%	\$1.5 bn		Pembrolizumab, nivolumab, atezolizumab
Gastric/Gastro	50%	\$0.8 bn		Pembrolizumab, ipilimumab, nivolumab
Liver	39%	\$1.1 bn		Pembrolizumab, ipilimumab, nivolumab, atezolizumab
B-cell lymphoma	4%	\$10.5 bn		Pembrolizumab, nivolumab
Colorectal	24%	\$4.4 bn		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

Melanoma

FDA 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)

Thirty years of research – proven execution capabilities

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 Q4 2023 amounted to MNOK 267 (MUSD 25)
- Estimated financial runway into 2025

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, Professor
Chief Innovation Officer

Shareholders²

Investor	Holding
Gjelsten Holding	18.9%
Radforsk (Biotech/oncology fund)	4.4%
Inven2 (University of Oslo TTO)	3.7%
J.P. Morgan Securities PLC	1.9%
Nordnet Livsforsikring (pension fund)	1.8%
Prieta (Gustav Gaudernack)	1.6%
Top 20	46.0%

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)

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



Empower the Immune System to *Fight Cancer*

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