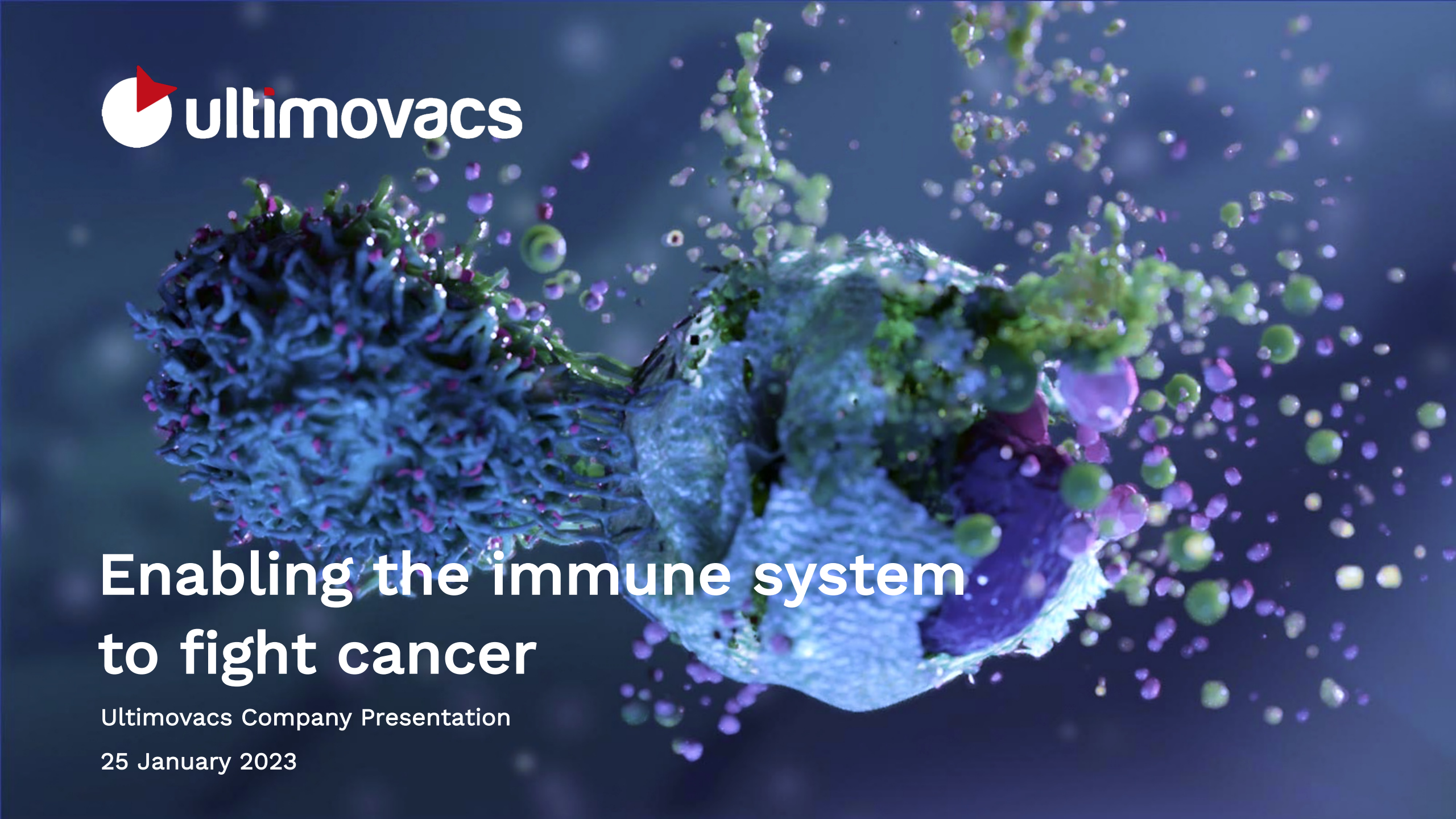

ultimovacs

Enabling the immune system to fight cancer

Ultimovacs Company Presentation

25 January 2023

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Ultimovacs is a clinical-stage biotech developing a universal, off-the-shelf cancer vaccine in a broad clinical program

Universal, off-the-shelf cancer vaccine, targeting telomerase

- Telomerase is expressed in 85-90% of cancer types throughout all disease stages
- Target essential for cancer cell survival, difficult for the tumor to escape immune response
- The vaccine is easy to use and has the potential to be used in multiple cancer types

Excellent clinical trial execution

- Currently one Phase I and five Phase II trials ongoing. Multiple phase I in long term follow-up
- Strong safety profile, efficacy signals, and immune response durability
- 5 key value inflection points in the next 6-24 months

Strong external validation

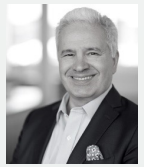
- Fast Track designation and Orphan Drug designation in metastatic melanoma provides FDA validation
- Validation through joint projects with large pharma companies and oncology specialist groups

Ultimovacs has a strong financial position, experienced management team, supported by long-term shareholders, with a cash runway into 2024

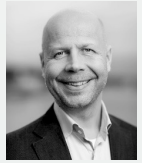
Company profile

- 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**[1]: NOK 3.75bn ($380m)
- **Estimated cash runway** to the first part of 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[2]

Investor	Holding
Gjelsten Holding	18.89%
Canica	7.87%
Sundt Group[3]	7.71%
Watrium	5.18%
Inven2 - University of Oslo's TTO	4.52%
Radforsk (biotech fund)	4.40%
Government Pension Fund Norway[4]	4.39%
Langøya Invest	4.04%
Top 20	**68.89%**
Other	**31.11%**

Capital markets transactions

Date	Transaction	Deal value
Oct '21	Private placement[5]	NOK 270m ($28m)
May '20	Private placement[5]	NOK 160m ($17m)
May '19	IPO	NOK 370 ($38m)

1. As of January 24, 2023
2. As of December 6, 2022
3. Comprises Helene Sundt, CGS Holding, Sundt
4. Folketrygdfondet
5. Oversubscribed

Broad Phase II program ongoing for UV1: strong recruitment of >650 patients

	Indication	Checkpoint inhibitor(s)	Patients (#)	Recruited	Expected topline readout	Phase I	Phase II	Phase III	Contributors
UV1	**Malignant melanoma**	Ipilimumab	12	Completed	Completed	**UV1-ipi**			
	Malignant melanoma	Pembrolizumab	30	Completed	Completed	**UV1-103**			
	Malignant melanoma	Ipilimumab & nivolumab	156	**Completed**	**H1 2023**		**INITIUM**		
	Pleural mesothelioma	Ipilimumab & nivolumab	118	**Completed**	**H1 2023**		**NIPU**		Bristol Myers Squibb[3]; Oslo University Hospital
	Head and neck cancer	Pembrolizumab	75	**>50%[1]**	End of 2023[2]		**FOCUS**		NSGO-CTU; AstraZeneca[3]; ENGOT
	Ovarian cancer	Durvalumab & olaparib	184	**<10%[1]**	End of 2023[2]		**DOVACC**		MARTIN-LUTHER-UNIVERSITÄT HALLE-WITTENBERG
	Non-small cell lung cancer (NSCLC)	Cemiplumab[4]	138	**<10%[1]**	End of 2024[2]		**LUNGVAC**		VESTRE VIKEN DRAMMEN HOSPITAL
TET	**Prostate cancer**	Dose finding trial, monotherapy	12	**Completed**	H2 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 Q3 2022 reporting. 2: FOCUS, DOVACC and LUNGVAC: Readout estimates will be updated with the Q4 2022 report
3: Supply agreements. 4: As per 1 January 2023

Contents

UV1 enhances antitumor response by activating telomerase-specific T cells

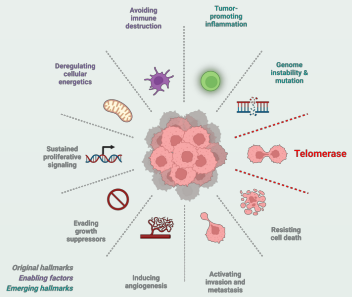
Current CPI challenges

- 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[1]
- A universal cancer vaccine could address these challenges and improve the immune response

Approach Ultimovacs

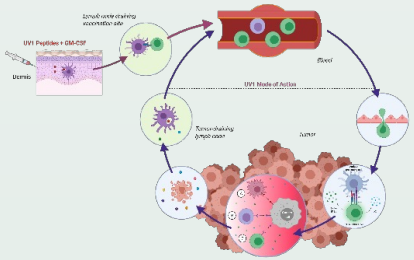
1 Telomerase

- 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



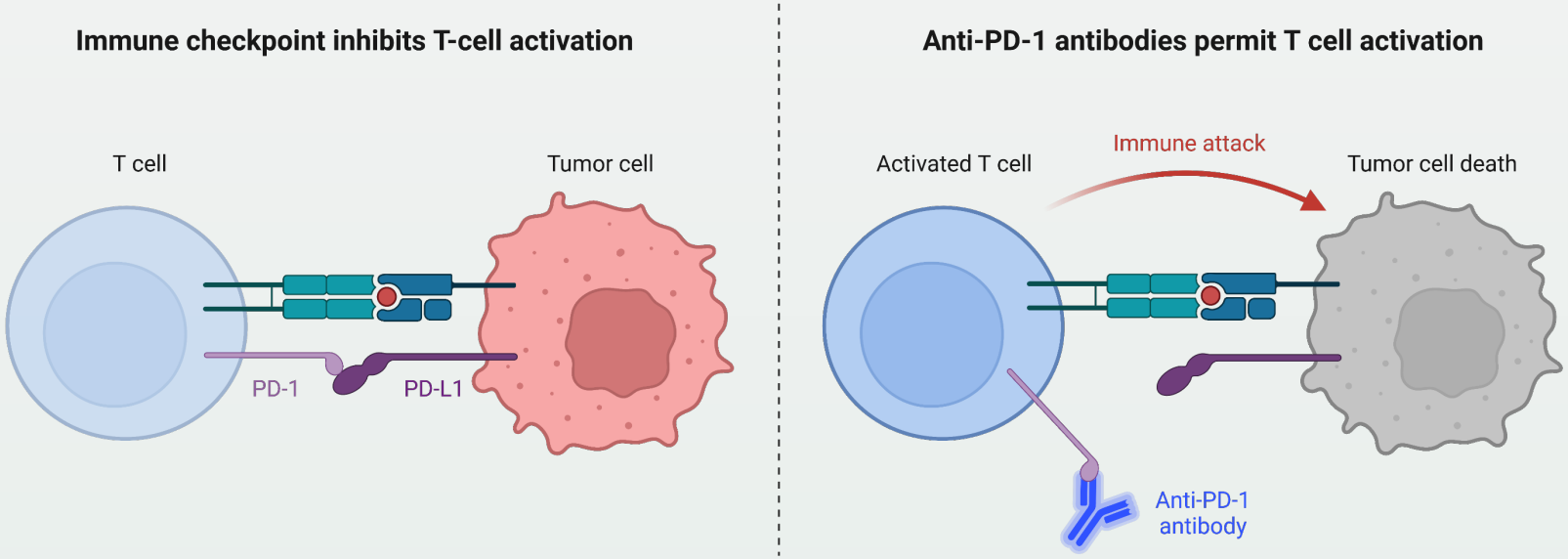
2 Mechanism of action

- 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



1. 10% - 58% response for indications in development. Compugen Corporate Overview 2021/FDA Label (PD-1 monotherapy/combination activity across indication) *Netw Open.* 2019;2(5):e192535. doi:10.1001/jamanetworkopen.2019.2535

CPIs have transformed cancer therapy, but efficacy can be improved

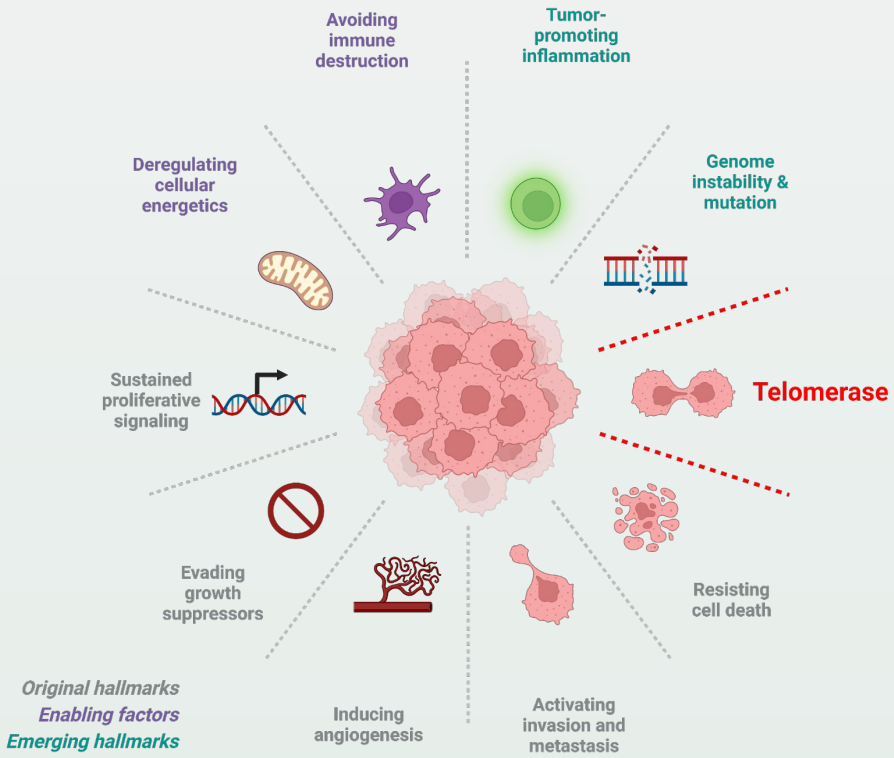


- CPIs rely on **spontaneous** T cell responses against tumors, which remains the biggest bottleneck for broader CPI efficacy[1]
- Most patients do not experience clinical benefit from checkpoint inhibition due to large variability in spontaneous anti-tumor immune responses
- **UV1 is ideally positioned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

1. Tumeh, P., Harview, C., Yearley, J. *et al.* PD-1 blockade induces responses by inhibiting adaptive immune resistance. *Nature* **515**, 568–571 (2014).
Figure: Jenkins, R., Barbie, D. & Flaherty, K. Mechanisms of resistance to immune checkpoint inhibitors. Br J Cancer (2018) Created with Biorender

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

Hallmarks of Cancer[1]

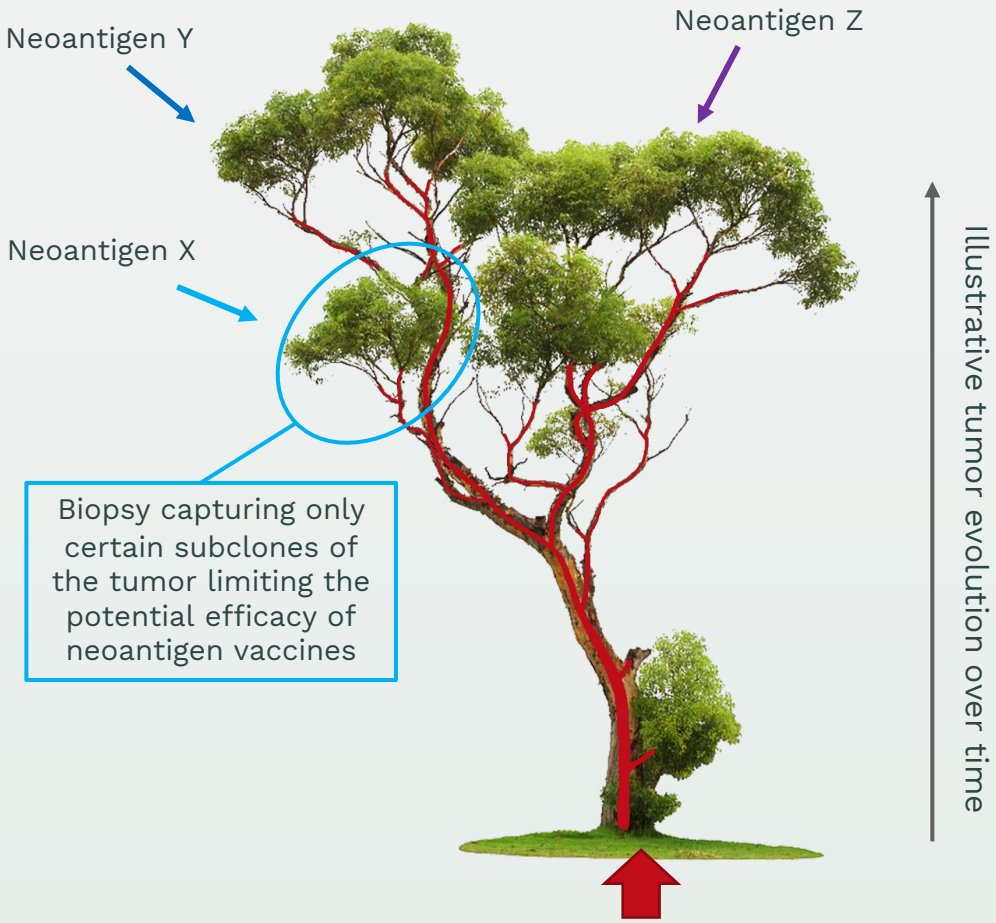


	Telomerase Characteristics	**UV1 Vaccine** Qualities
Universal	85-90% of tumor types express telomerase[2,3]	Applicable to a broad range of cancer types
Essential	Tumor cells depend on expressing telomerase	High relevance in heterogenous tumor environments
Enduring	Present throughout tumor evolution: primary to metastatic cancer	Enduring and relevant immune response over time

1. Hanahan D et al. Cell (2011) - Figure created with Biorender.
2. Kim et al. Science (1994)
3. Shay et al. European Journal of Cancer (1997)
4. Hornsby PJ. (2007)

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**

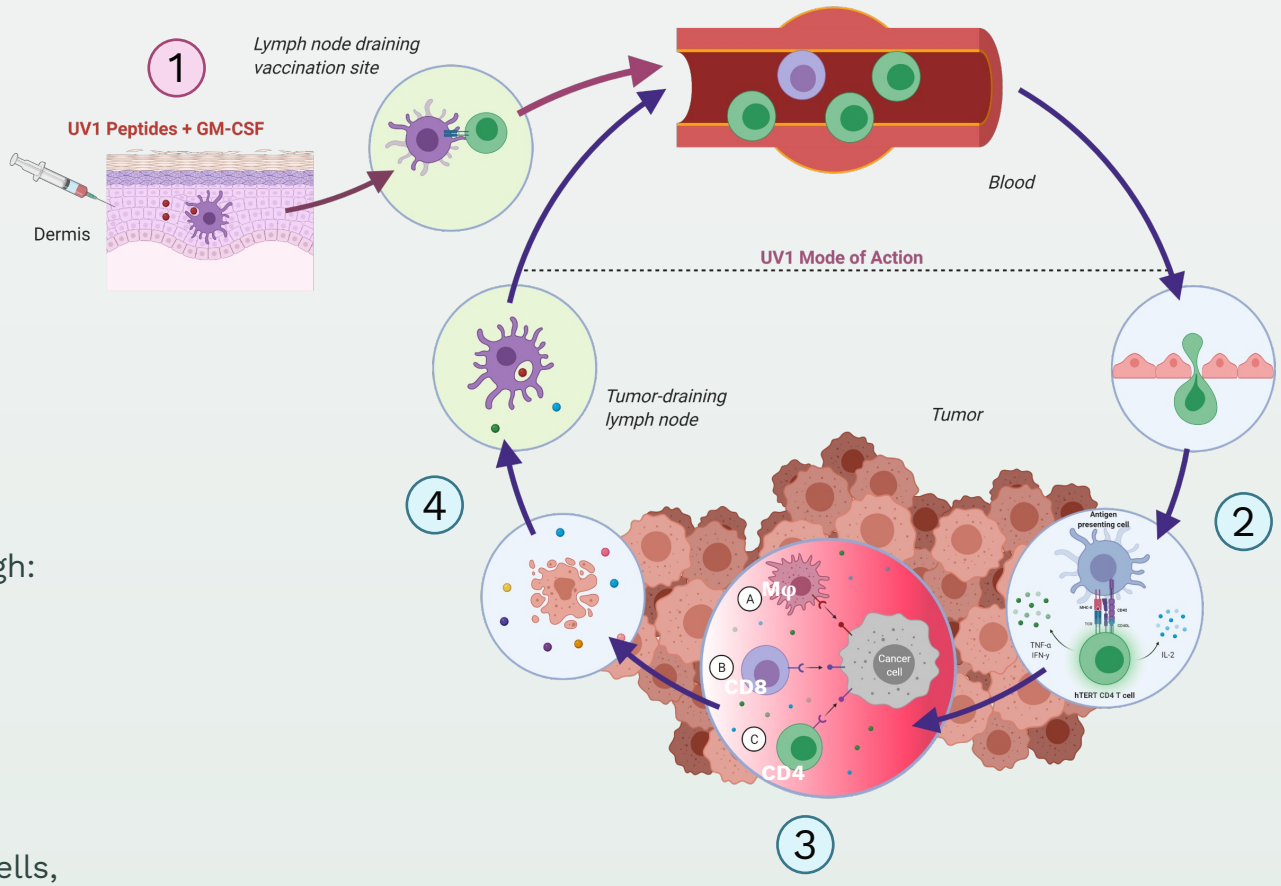
UV1 mode of action and downstream mechanisms enhance tumor killing

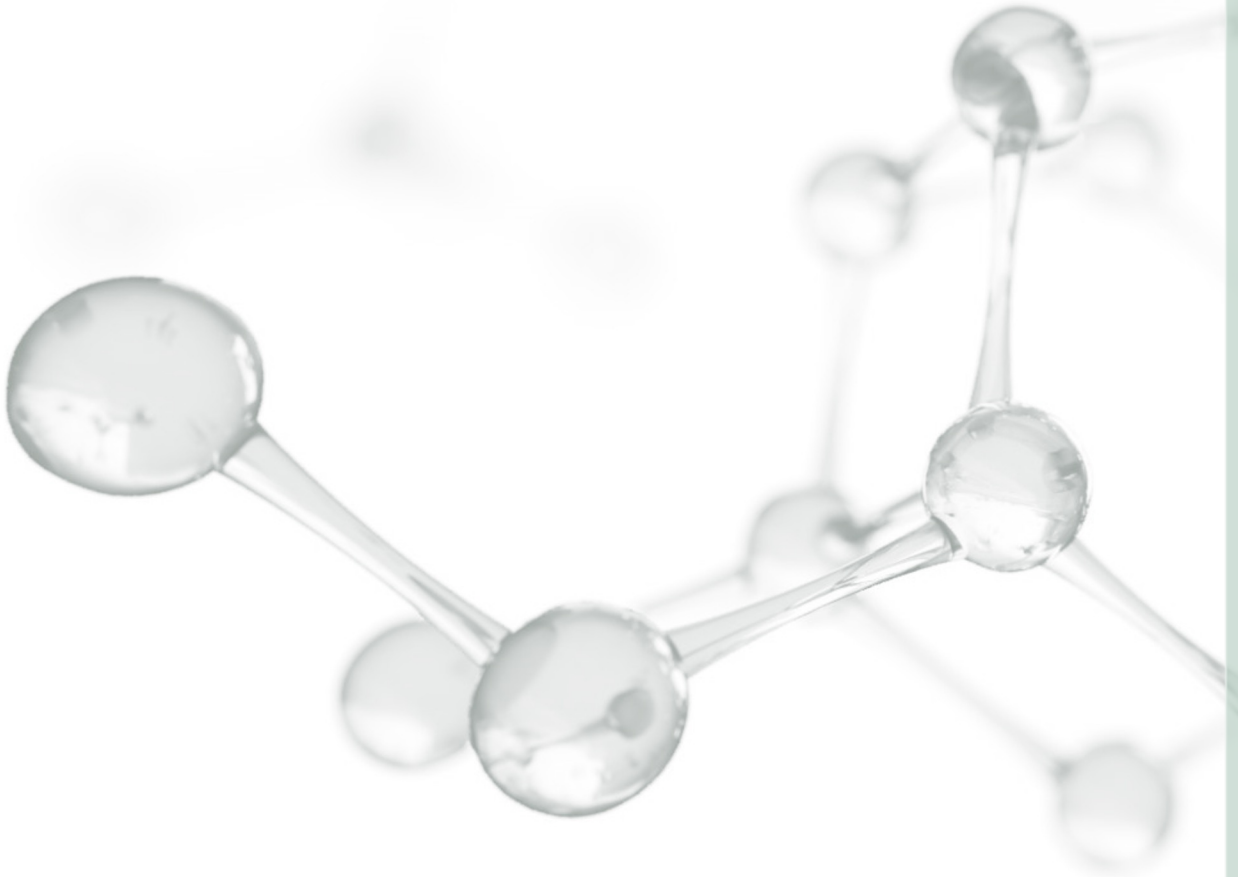
1 Intradermal injection of UV1 and **activation of TERT-specific T cells**

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-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





Contents

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 SITC Annual Meeting 2021, publication in Frontiers in Immunology (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

Consistently favorable efficacy and safety signals vs. historical controls

Malignant melanoma

Regimen	n	ORR (%)	CR (%)	mPFS (months)	mOS (months)	Grade 3-5 TRAE (%)	Reference
Nivolumab + ipilimumab	314	58	22	11.5	72.1	59	*CheckMate-067 Wolchok JD et al. 2022 Larkin et al. 2019*
Nivolumab + relatlimab	355	43	16	10.2	Not reached (2-year OS 64%)	21	*RELATIVITY-047 Long GV et al. 2022*
Pembrolizumab	556	34-42	5-14	5.5-11.6	38.7	18	*KEYNOTE-006 FDA Package Insert Robert C et al 2019**
UV1 + Pembrolizumab	30	57	33	18.9	Not reached (2-year OS 73%)	20	*Zakharia et al. SMR oral pres. 2022*
Ipilimumab	151	9	2	2.7	12.1	28	*IPI4 Aamdal E et al. 2022*
UV1 + Ipilimumab	12	33	8	6.7	66.3	42	*Ellingsen EB et al. 2022*

*mPFS and mOS in subgroup receiving pembrolizumab as first-line treatment (Robert C et al, 2019)
TRAE: Treatment-related adverse event

Not a head-to-head comparison – for reference only

UV1 + ipilimumab has shown positive efficacy vs. historical control

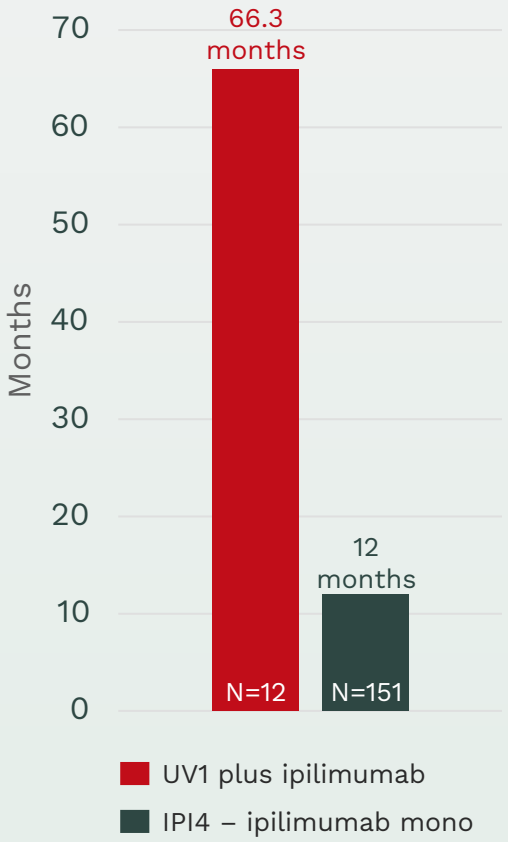
Malignant melanoma

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

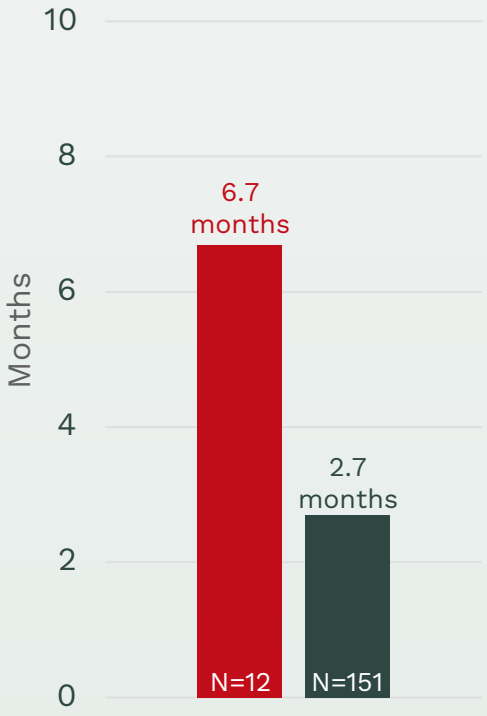
Median Overall Survival (mOS)

UV1+ipilimumab vs ipilimumab monotherapy (IPI4 study)[1]



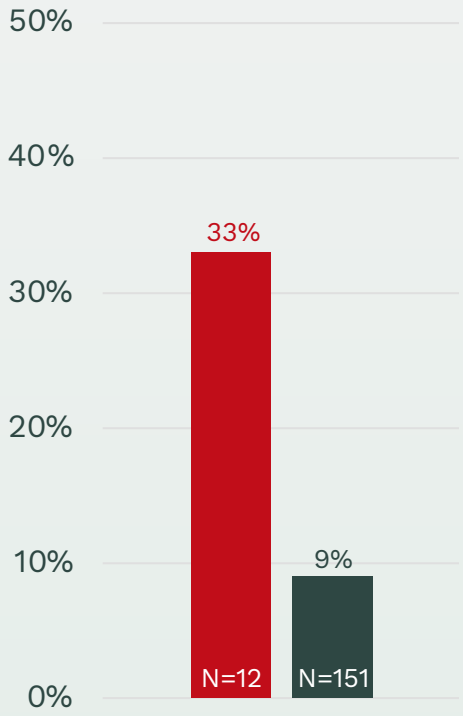
Median Progression Free Survival (mPFS)

UV1+ipilimumab vs ipilimumab monotherapy (IPI4 study)[1]



Objective Response Rate (ORR)

UV1+ipilimumab vs ipilimumab monotherapy (IPI4 study)[1]



1. Historical control for the melanoma study: Aamdal, E. et al (2021) Ipilimumab in a real-world population: A prospective Phase IV trial with long-term follow-up. Int. J. Cancer. https://doi.org/10.1002/ijc.33768 Measurement: RECIST 1.1 in the UV1 + ipilimumab trial

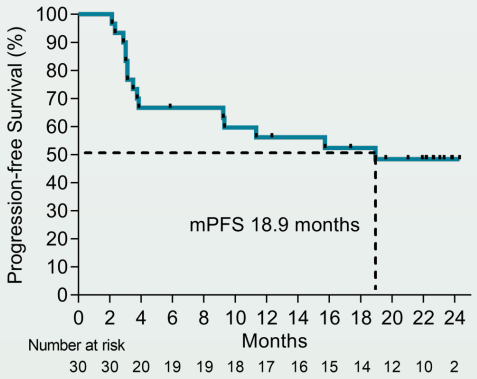
UV1 + pembrolizumab - promising efficacy in Phase I trial

Malignant melanoma

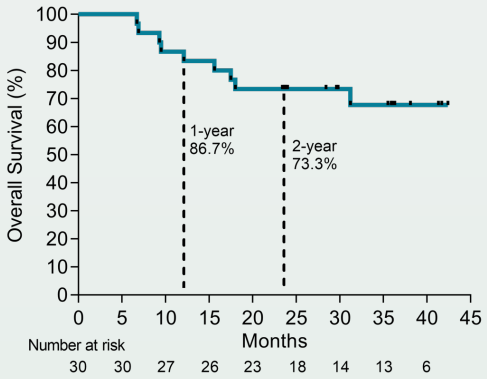
The **survival rates** for the 30 patients in cohort 1 and cohort 2 combined

- **Median progression free survival**: Cohort 1+2 combined is 18.9 months
- **Overall survival**
  - Cohort 1+2 combined after 12 months: 87%
  - Cohort 1+2 combined after 24 months: 73%
  - Cohort 1 after 36 months: 71%

Progression-free Survival (n=30)



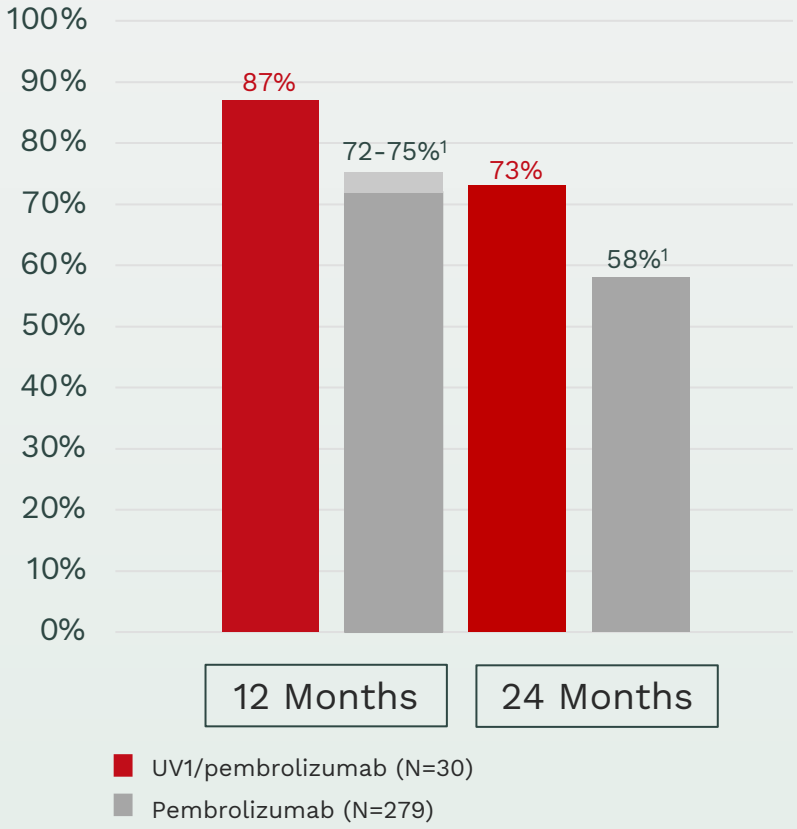
Overall Survival (n=30)



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

Overall survival at 12 and 24 months

Topline readout from Phase I trial in malignant melanoma compared to historical pembrolizumab data[1]

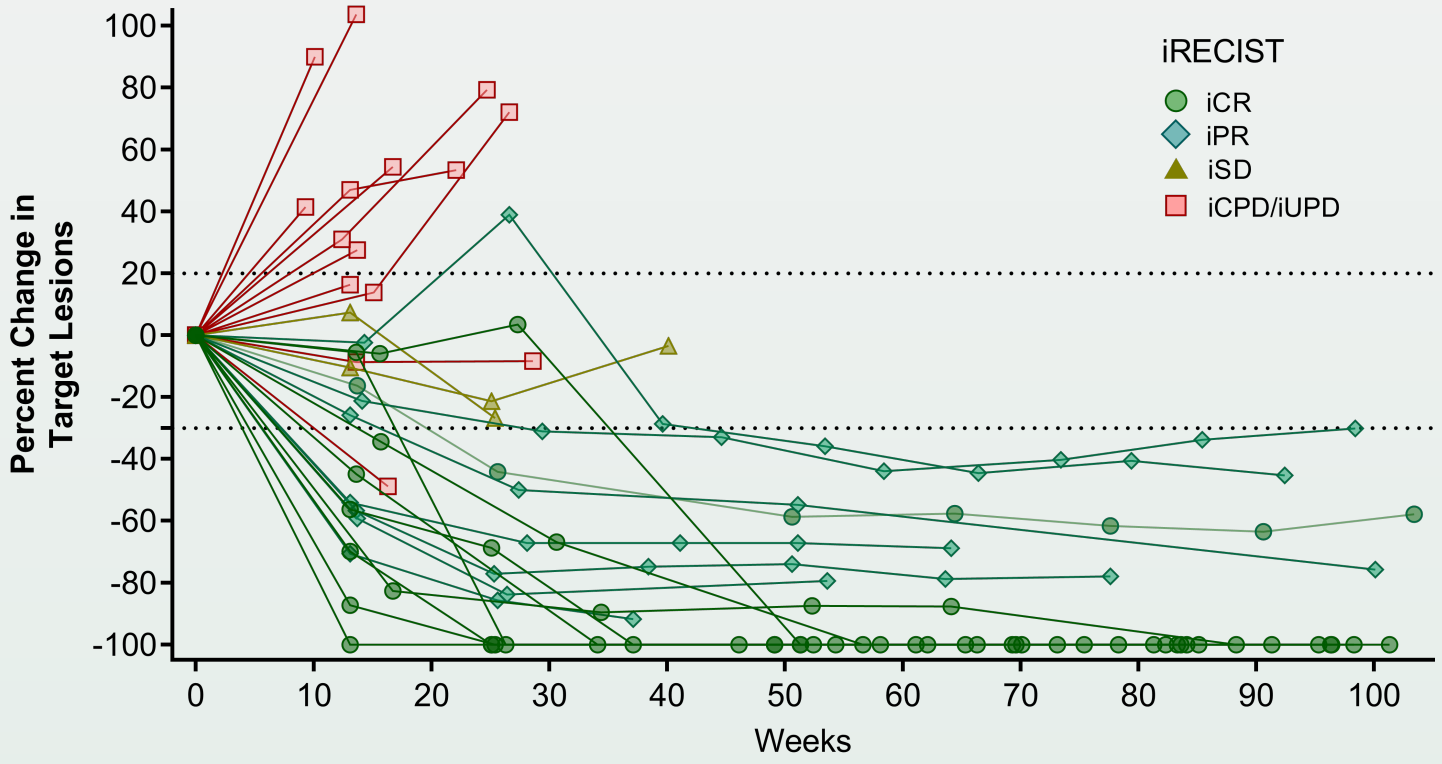


1. Not a head-to-head comparison, for reference only. Data from KEYNOTE-006 sub-set of patients is the reference trial for pembrolizumab in melanoma
2. Data from KEYNOTE-006 (Robert C, 2019), the pivotal study referred to in the Keytruda (pembrolizumab) package inserts

Deep and durable clinical responses to UV1 + pembrolizumab

Malignant melanoma

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

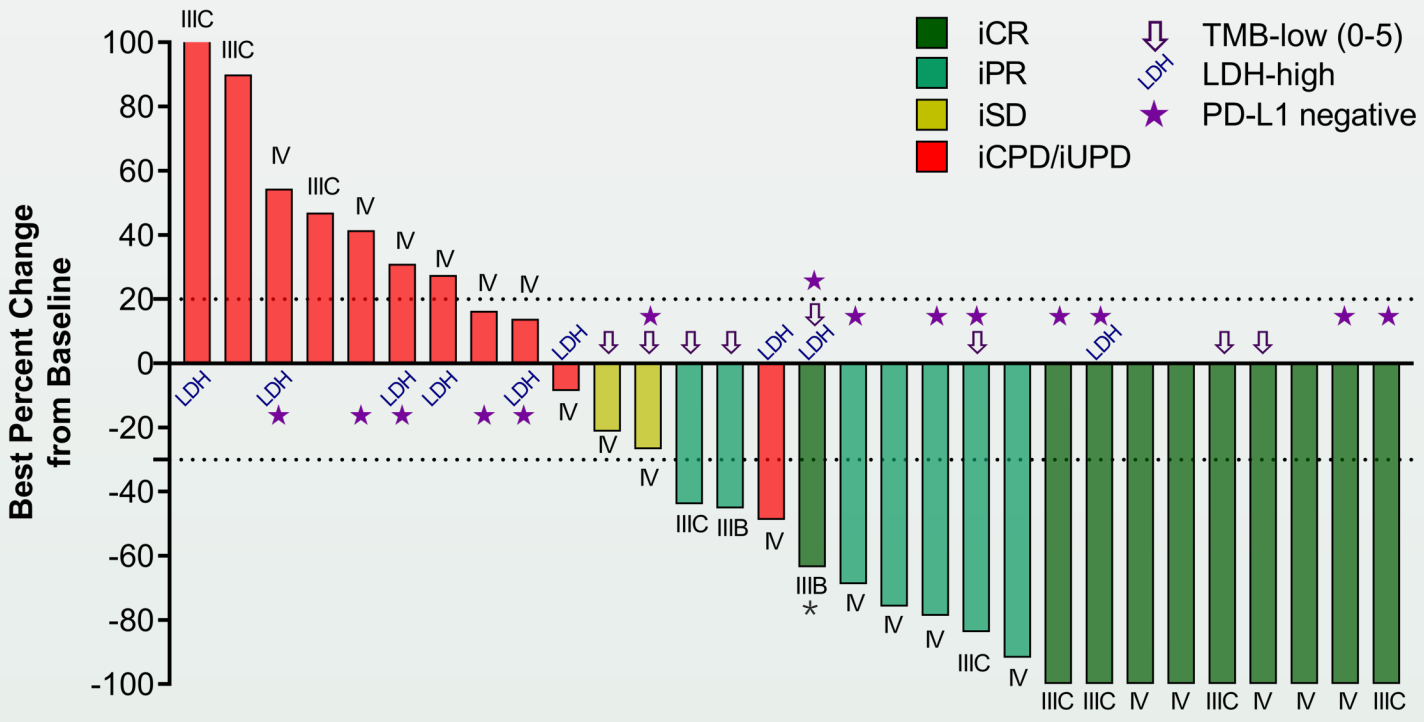


- Patients were followed with CT scans for up to two years
- 57% of patients achieved an objective response to the treatment (>30% reduction in tumor size)
- 33% of patients achieved complete response (complete disappearance of the tumor)
- 94% of the objective responses lasted more than 1 year

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

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	%
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%

* 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

Contents

Ultimovacs' UV1 pipeline consists of five comparative, randomized Phase II trials in more than 650 patients

Trial design	1 INITIUM	2 NIPU	3 FOCUS	4 DOVACC	5 LUNGVAC
CPI combination	Ipilimumab + nivolumab	Ipilimumab + nivolumab	Pembrolizumab	Durvalumab + olaparib	Cemiplimab
Indication	First line malignant melanoma	Second line mesothelioma	First line head and neck cancer	Second line ovarian cancer	First line non-small cell lung cancer
Timeline	2020 – 2023	2020 – 2023	2021 – 2023	2021 – 2023	2022 – 2024
Expected topline results	**H1 2023**	**H1 2023**	2023[1]	2023[1]	H2 2024[1]
No. of patients **Enrollment status** **Sites & countries**	N=156 **100% recruited** 40 sites in US, NO, BE, UK	N=118 **100% recruited** 6 sites in NO, SE, DK, ES, AU,	N=75 **> 50% recruited** 10 sites in DE	N=184 **< 10% recruited** >40 sites in NO, SE, DK, FI, BE, NL, DE, AT, LT, EE, GR	N=138 **< 10% recruited** 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

1. FOCUS, DOVACC and LUNGVAC: Readout estimates will be updated with the Q4 2022 report

INITIUM UV1 Phase II trial

INITIUM: First line advanced or metastatic malignant melanoma

- **Combination**: nivolumab, ipilimumab
- **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 June 2022
- **Milestones**: Top line results expected H1 2023

INITIUM

1st line treatment of patients with advanced or metastatic malignant melanoma (N=156)

UV1
nivolumab
ipilimumab

nivolumab
ipilimumab

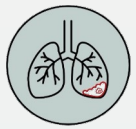
Primary endpoint
PFS

Secondary endpoints
OS + ORR + DOR + safety

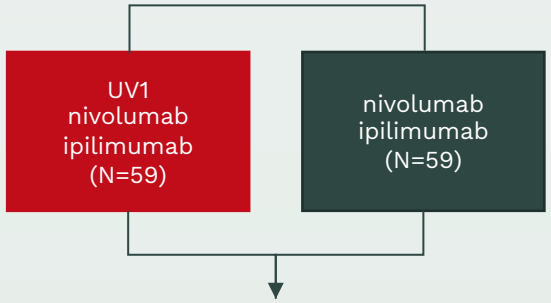
* A supplementary study will be initiated after enrollment of the 154 patients is completed. The objective is to further support that an immune response specific to the UV1 vaccine transfers into anti-tumor activity and clinical benefit for the patients. 20 additional patients will receive experimental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

NIPU & FOCUS UV1 Phase II Trials

NIPU: Second line malignant pleural mesothelioma

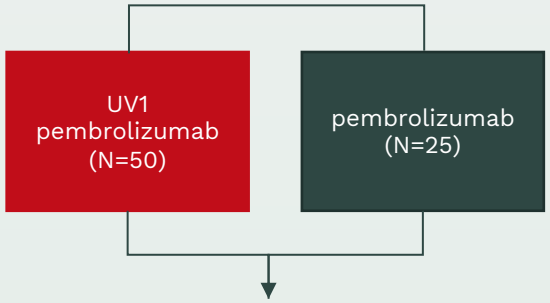


- **Combination:** nivolumab, ipilimumab
- **Contributors**: Oslo University Hospital (sponsor); BMS
- **Patients:** 118 from 6 sites in Norway, Sweden, Denmark, Spain and Australia
- **Recruitment**: 100%
- First patient enrolled June 2020
- Patient enrollment completed January 2023
- **Milestones**: Top line results expected H1 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**: >50%
- First patient enrolled August 2021
- 41 patients enrolled as of 9 November 2022 (Q3 2022 reporting)
- **Milestones**: Top line results have been expected during 2023. This guidance will be updated with the Q4 2022 report



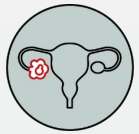
Primary endpoint: PFS

Secondary endpoints: OS + ORR + DOR + safety

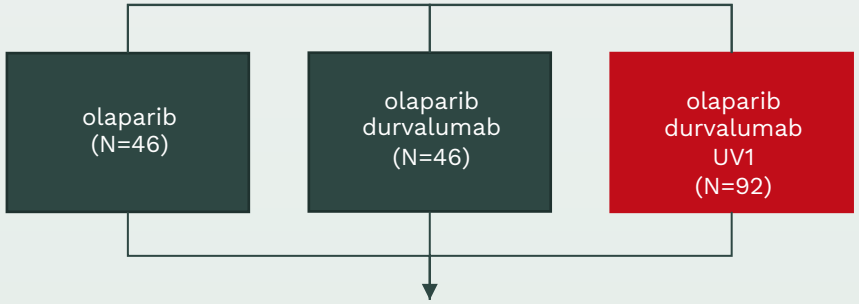
PFS = progression-free survival; OS = overall survival; ORR = overall response rate; DOR = duration of response

DOVACC and LUNGVAC UV1 Phase II Trials

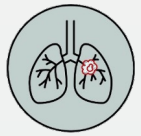
DOVACC: High-grade BRCA negative ovarian cancer, second line maintenance



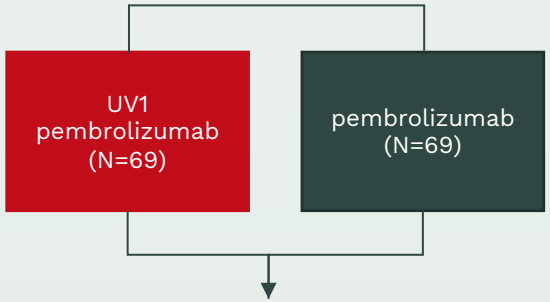
- **Combination**: olaparib, durvalumab
- **Contributors**: NSGO/ENGOT (sponsor), AstraZeneca
- **Patients**: 184 from more than 40 sites in more than 10 European countries
- **Recruitment**: <10%
- First patient enrolled December 2021
- 7 patients enrolled as of 9 November 2022 (Q3 2022 reporting)
- **Milestones:** Top line results expected during 2023. This guidance will be updated with the Q4 2022 report



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



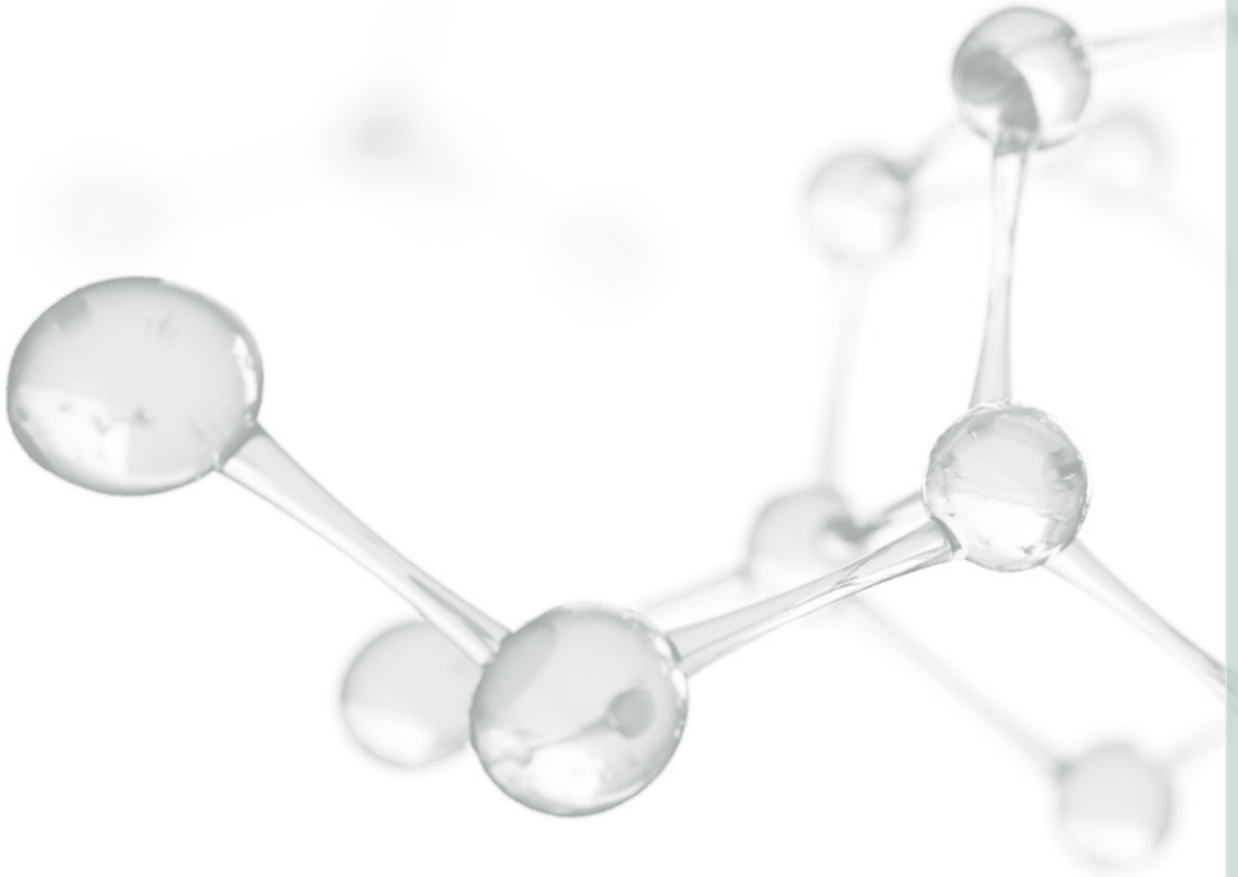
- **Combination**: cemiplimab
- **Contributors**: Sponsored by Drammen Hospital
- **Patients**: 138 patients from 8-10 hospitals in Norway
- **Recruitment**: <10%
- First patient enrolled October 2022
- 3 patients enrolled as of 9 November 2022 (Q3 reporting)
- **Milestones:** Top line results have been expected by the end of 2024. This guidance will be updated with the Q4 2022 report



Primary endpoint: PFS

Secondary endpoints: OS + ORR + DOR + safety

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

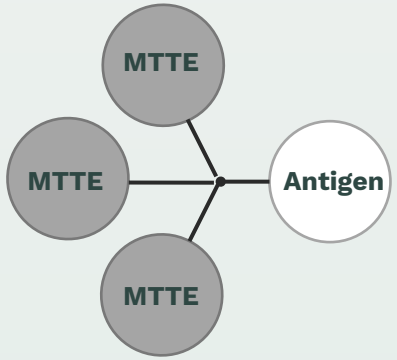


Contents

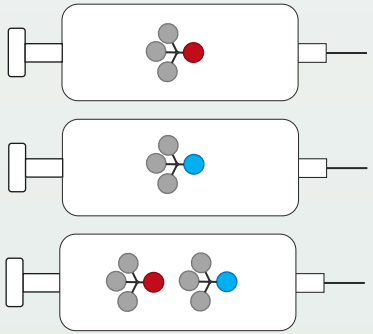
The TET (Tetanus-Epitope Targeting) adjuvant platform technology

- Ultimovacs' proprietary TET technology combines the two key components of a vaccine in one molecule: The cancer specific antigen and the immune response strengthening adjuvant
- Core element is the vaccine adjuvant, a tetanus toxin peptide sequence MTTE (Minimal Tetanus Toxin Epitope), a B cell epitope
- An innovative technology provides the flexibility to incorporate a variety of antigens to tailor vaccines to different cancer types

Adjuvant component



Cancer specific antigen: Directs the immune response towards the tumor

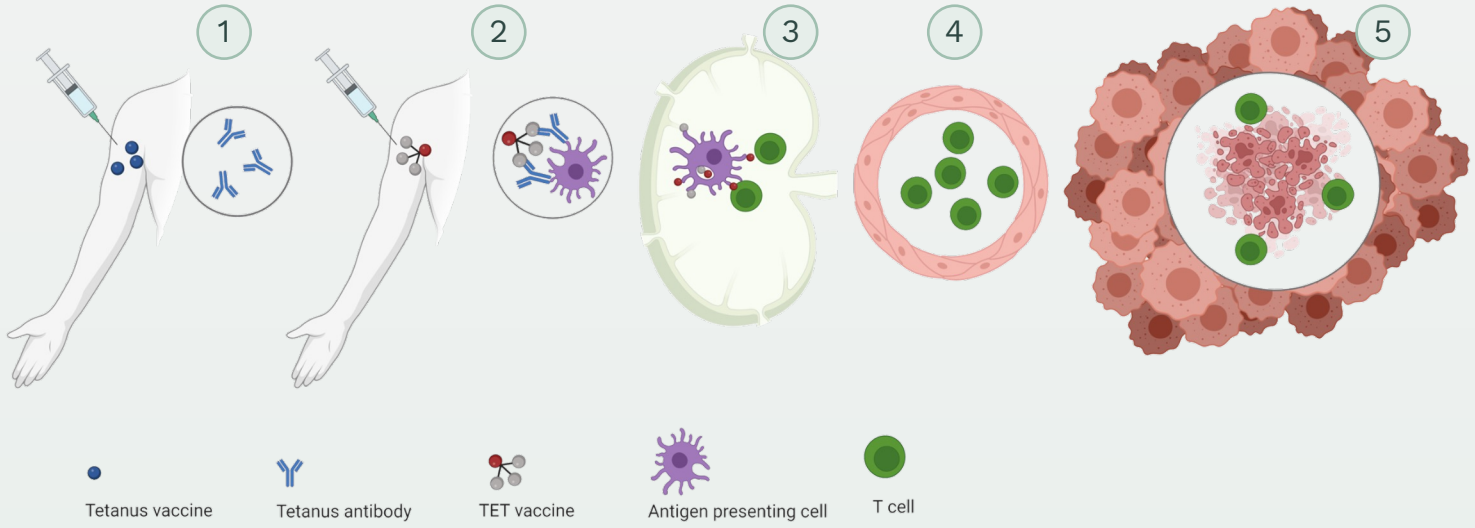


Fixed adjuvant component

Flexible cancer specific antigen components

Several cancer specific antigens may be combined in a single administration

TET adjuvant technology platform takes advantage of pre-existing immunity to increase the immune response



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

1. Tetanus vaccination induces production of tetanus antibodies.
2. The tetanus antibodies bind to the TET vaccine and form an immune complex, and the immune complex is taken up by an antigen presenting cell. Immune complex formation is known to increase 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

Patients with relapse after primary radical prostatectomy (N=12)

↓

3 different doses

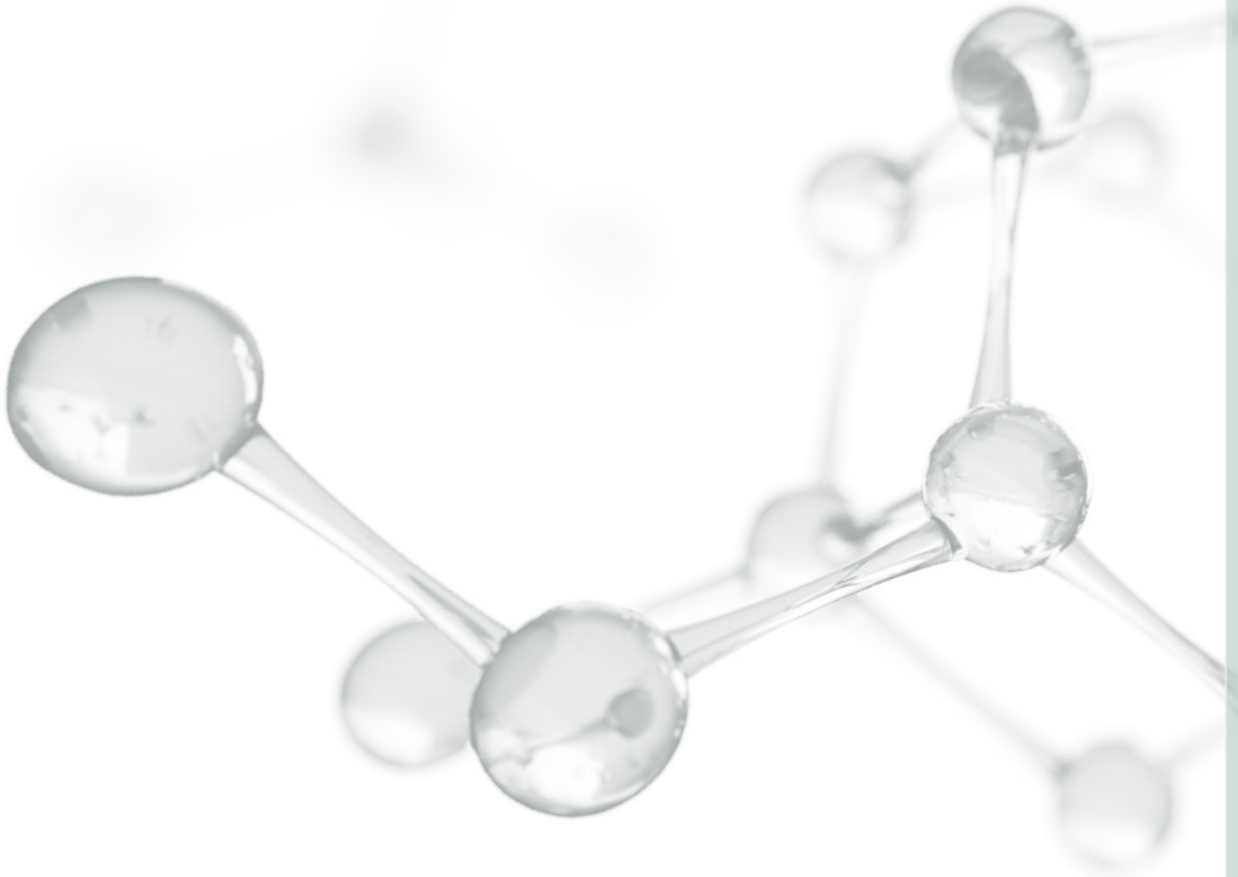
3 patients per dose level

3 additional patients at selected dose

↓

Endpoints:

Safety and immune response, dose response

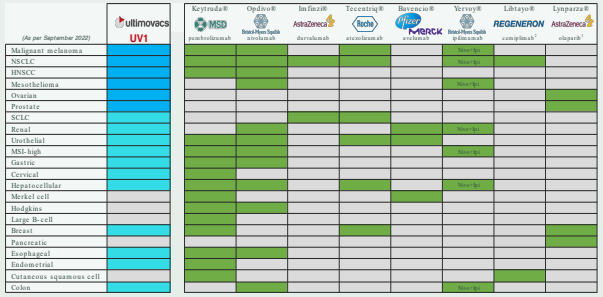


Contents

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

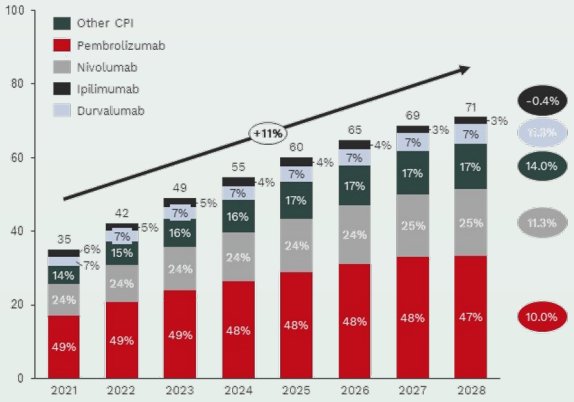
1 Combination with CPIs

- 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



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 c.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 in multiple cancer types[1]

(As per September 2022)	ultimovacs UV1	Keytruda® MSD pembrolizumab	Opdivo® Bristol-Myers Squibb nivolumab	Imfinzi® AstraZeneca durvalumab	Tecentriq® Roche atezolizumab	Bavencio® Pfizer Merck avelumab	Yervoy® Bristol-Myers Squibb ipilimumab	Libtayo® REGENERON cemiplimab[2]
Malignant melanoma							Nivo+Ipi	
NSCLC							Nivo+Ipi	
HNSCC								
Mesothelioma							Nivo+Ipi	
Ovarian								
Prostate								
SCLC								
Renal							Nivo+Ipi	
Urothelial								
MSI-high							Nivo+Ipi	
Gastric								
Cervical								
Hepatocellular							Nivo+Ipi	
Merkel cell								
Hodgkins								
Large B-cell								
Breast								
Pancreatic								
Esophageal								
Endometrial								
Cutaneous squamous cell								
Colon							Nivo+Ipi	

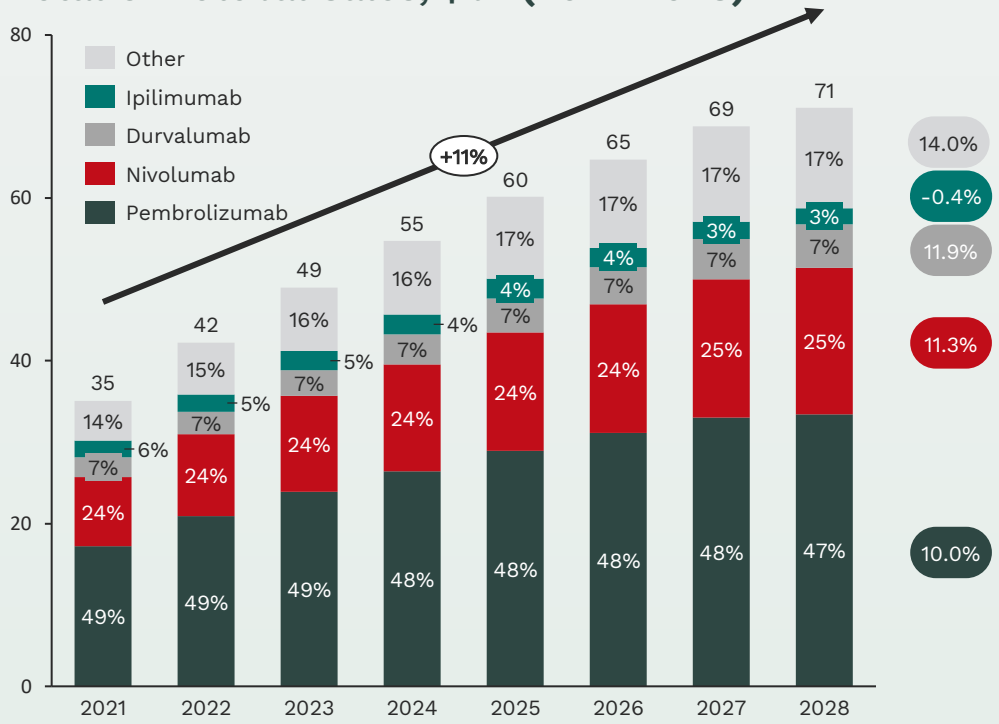
1. Global Data, 2022, Product package inserts Q2 2022
2. Also approved in Basal cell carcinoma
Note: other approved PD1/PD-L1 program: Dostarlimab (Jemperli), various additional approvals in China

UV1 clinical trials
UV1 growth opportunity
CPI approved indication

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**[1]
- 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

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

Sources: Thomas R, Al-Khadairi G, Roelands J, et al. NY-ESO-1 Based Immunotherapy of Cancer: Current Perspectives. Front Immunol. 2018;9:947. Published 2018 May 1. doi:10.3389/fimmu.2018.00947; Jaiswal PK, Goel A, Mittal RD. Survivin: A molecular biomarker in cancer. Indian J Med Res. 2015;141(4):389–397. doi:10.4103/0971-5916.159250; Zajac P, Schultz-Thater E, Tornillo L, et al. MAGE-A Antigens and Cancer Immunotherapy. Front Med (Lausanne). 2017;4:18. Published 2017 Mar 8. doi:10.3389/fmed.2017.00018

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 **intradermal** 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

Expected news flow and milestones: key value inflection points during the next 6-24 months

UV1	2022	2023	2024
Malignant melanoma	**Phase I, UV1–103** Q3: 2-yr OS update (all 30 patients) **Phase I, UV1–103** Q4: Cohort 1, 3-yr OS update **Phase II, INITIUM** Q2: Enrollment completed	**Phase II, INITIUM** H1: Topline results (1)	
Malignant pleural mesothelioma		**Phase II, NIPU** H1: Topline results (2)	
Head and neck cancer		**Phase II, FOCUS*** Topline results (3)	
Ovarian cancer		**Phase II, DOVACC*** Topline results (4)	
Non-small cell lung cancer	**Phase II, LUNGVAC** Q3: First patient in		**Phase II, LUNGVAC*** By end of 2024: Topline results (5)
TET			
Prostate cancer	**Phase I, TENDU** Q3: Interim safety data		

*FOCUS, DOVACC and LUNGVAC: Readout estimates will be updated with the Q4 2022 report

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 robust immune response (durability >7.5 years)
    - Broad Phase II development program highlights the significant commercial potential
        - Five Phase II randomized clinical combination trials ongoing
    - 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 shareholder base and good cash position
- **Multiple key value inflection points in the near term and over the next 24 months**

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

Patient		N (%)
Liver metastases		
	Yes	3 (25%)
	No	9 (75%)
LDH		
	above ULN	6 (50%)
	below ULN	6 (50%)
Prior therapy		
	Chemotherapy	2 (16.7%)
	BRAF/MEK inhibitor	2 (16.7%)
	ipilimumab	0 (0%)
Prior lines of therapy		
	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
Median age (range) - years	70.5 (30-87)
Male sex - no. (%)	21 (70)
ECOG performance status - no. (%)	
0	19 (63)
1	11 (37)
Elevated baseline LDH – no. (%) *	9 (31)
Stage (8th 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
Liver metastasis - no. (%)	4 (13)
BRAF V600E status – no. (%) †	
Mutated	10 (37)
PD-L1 status – no. (%) ¶	
Positive (≥1%)	8 (36)
Tumor mutation burden - no. (%) £	
High (≥20 mutations/Mb)	3 (18)
Intermediate (6-19 mut/Mb)	6 (35)
Low (1-5 mutations/Mb)	8 (47)

LDH=Lactate dehydrogenase. *One patient did not have baseline LDH registered; the denominator is 29. † Three patients had missing BRAF status; the denominator is 27. ¶ Eight Patients had either no available or non-evaluable samples for PD-L1 testing; the denominator is 22. £ Thirteen patients had either no available or non-evaluable samples for TMB testing; the denominator is 17.

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
Related to treatment*		
Any	21 (70.0)	6 (20.0)
Occurring in more than one patient or grade ≥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

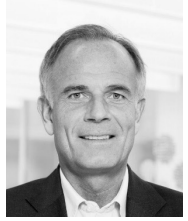
Ultimovacs is granted Orphan Drug designation from the FDA

- 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

Jonas Einarsson
Chairman of the board

- CEO of the Norwegian Radium Hospital Research Foundation
- Board member of several biotech companies
- One of the initiators behind the Norwegian Center of Expertise, Oslo Cancer Cluster



Henrik Schüssler
Board member

- CEO and board member of Gjelsten Holding AS
- Previously CFO and CEO of Norway Seafood
- Accounting/consulting experience from Ernst & Young

Haakon Stenrød
Board member

- Senior Investment Manager at Watrium
- Previously 12 years in the Investment Banking at ABG Sundal Collier, focusing on M&A, restructurings and capital markets advisory
- Board member of DF Capital, a UK challenger bank listed on AIM London

Leiv Askvig
Board member

- Investment Advisor at Sundt AS, a Norwegian family owned investment company
- Board member of Pandox AB, Eiendomsspar, Oncoinvent AS and Civita
- Previously Chairman of the Board of Oslo Stock Exchange and CEO of Sundal Collier & Co

Kari Grønås
Board member

- Extensive experience in drug development and commercialization within the pharmaceutical industry of new breakthrough products securing regulatory approvals, i.e. Xofigo, Hexvix
- Board positions in Spago Nanomedical AB, SoftOx AS and The Norwegian Lung Cancer Society

Aitana Peire
Board member

- Investment Manager of Canica's Future of Health assets. Board member in EXACT-Tx AS
- 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

Ketil Fjerdingen
Board member

- 25+ years experience from board and management positions in different companies and industries
- Ultimovacs' Chairman of the board from '11-'17

Eva S. Dugstad
Board member

- Manager for Business and Community Relations at Faculty of Mathematics and Natural Sciences, University of Oslo
- Previously Director for Business Development at Radforsk and President and EVP at the Institute for Energy Technology (IFE)
- Has been involved in various boards in both public and private sector and in several public expert panels

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