



Fourth Quarter 2022 Results

Ultimovacs ASA, 16 February 2023

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Q4 2022 highlights: On track and prepared for readouts during H1 2023 for first Phase II studies with the universal cancer vaccine, UV1

- Ultimovacs is on track and prepared for key value inflection points during the first half of 2023
 - Topline readouts from the first two UV1 Phase II clinical trials, INITIUM for patients with metastatic melanoma and NIPU for patients with metastatic pleural mesothelioma
- Overall, good progress in Ultimovacs' clinical program:
 - INITIUM
 - NIPU
 - TENDU (Ph I)] **Completed patient enrollment**
 - FOCUS: 50 out of 75 patients enrolled, readout expected H1 2024
 - DOVACC & LUNGVAC progressing, although delayed initiation. Readout expected H2 2024 & H2 2025
- UV1-103 biomarker data is raising attention; support strong clinical responses from UV1 also in patients considered less likely to respond to monotherapy checkpoint inhibition
- Expected financial runway extended until mid-2024

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Broad Phase II program ongoing with enrollment of more than 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	67% ¹	H1 2024		FOCUS ●		MARTIN-LUTHER-UNIVERSITÄT HALLE-WITTENBERG
	Ovarian cancer	Durvalumab & olaparib	184	<10% ¹	H2 2024		DOVACC ●		NSGO-CTU AstraZeneca ³ ENGOT European Network of Gynaecological Oncological Trial groups
	Non-small cell lung cancer (NSCLC)	Cemiplimab ⁴	138	<10% ¹	H2 2025		LUNGVAC ●		VESTRE VIKEN DRAMMEN HOSPITAL
TET	Prostate cancer	Dose finding trial, monotherapy	12	Completed	H2 2023	TENDU ●			

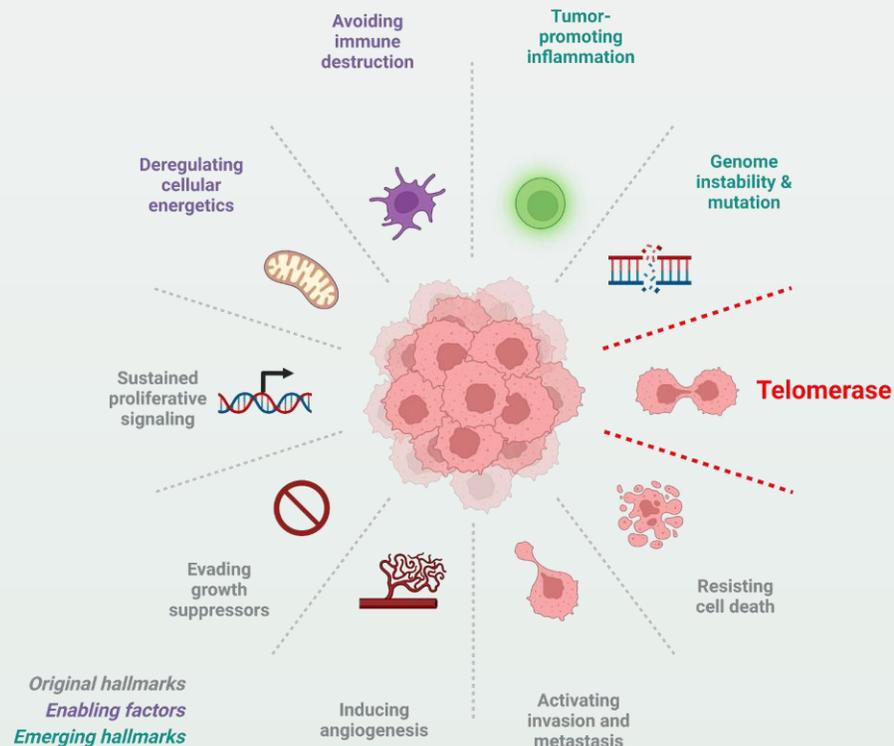
Patient enrollment and expected readouts

Clinical trial program	Enrollment and expected readout timeline
INITIUM (Phase II malignant melanoma):	Enrollment of 156 patients completed **  Expected readout: H1 2023
NIPU (Phase II pleural mesothelioma):	Enrollment of 118 patients completed  Expected readout: H1 2023
FOCUS (Phase II head and neck cancer):	50 out of 75 patients enrolled (vs. 41 in Q3 2022) Expected readout: H1 2024
DOVACC* (Phase II ovarian cancer):	17 out of 184 patients enrolled (vs. 7 in Q3 2022) Expected readout: H2 2024
LUNGVAC* (Phase II non-small cell lung cancer):	2 out of 138 patients treated with cemiplimab, 3 patients treated with pembrolizumab before change of CPI 1.1.23. Expected readout: H2 2025
TENDU (Phase I prostate cancer):	Enrollment of 12 patients completed  Expected readout: H2 2023

* Expected readout timelines will be updated with the Q4 2023 reporting.

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

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

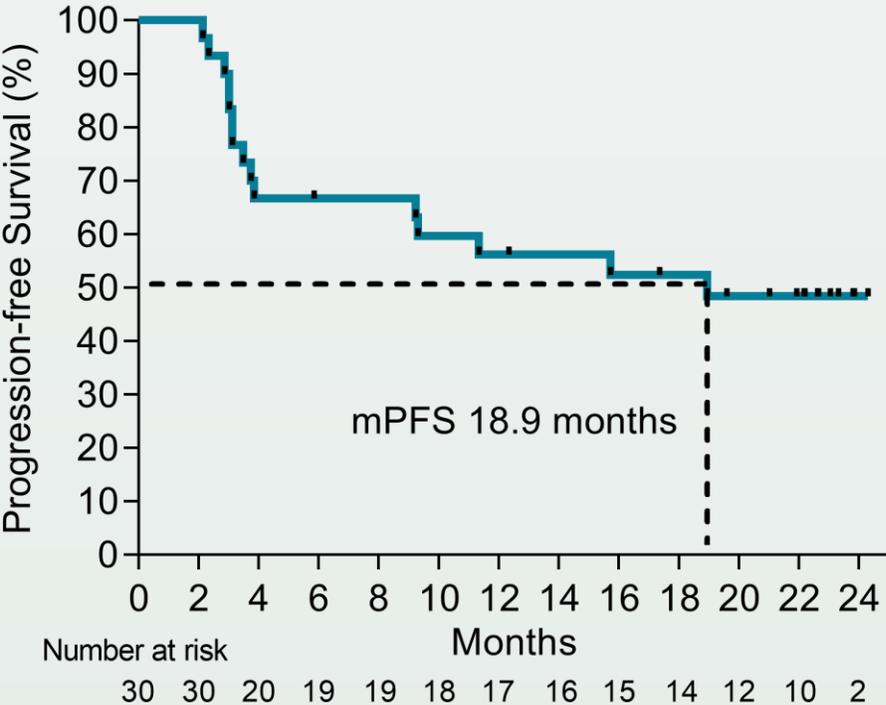
Enduring

Present throughout tumor evolution: primary to metastatic cancer

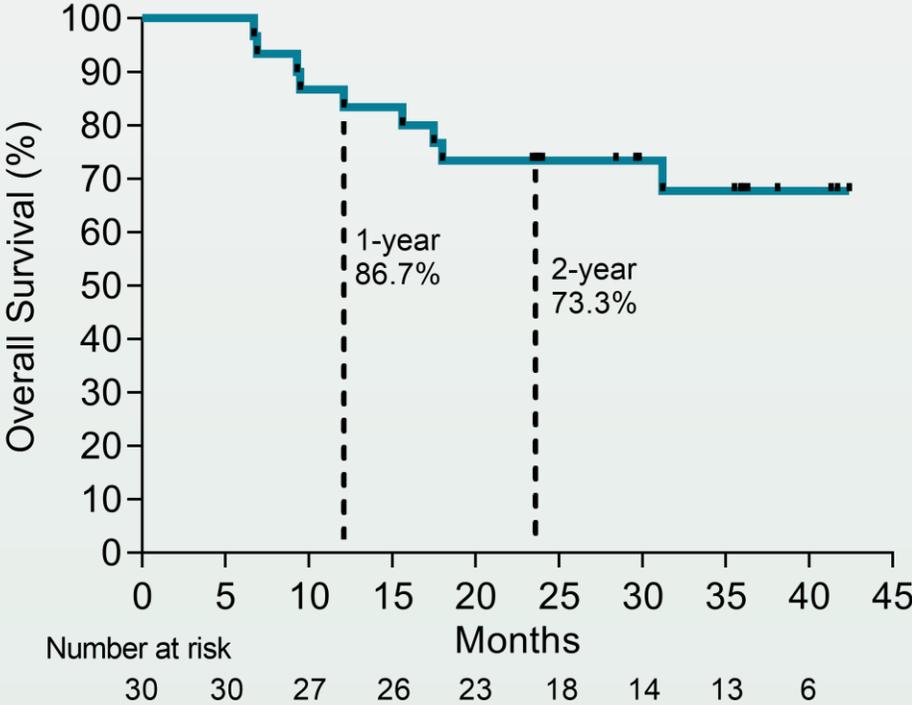
Enduring and relevant immune response over time

The data from the UV1-103 study (U.S.) shows promising progression-free and overall survival rates in malignant melanoma

Progression-free Survival (n=30)

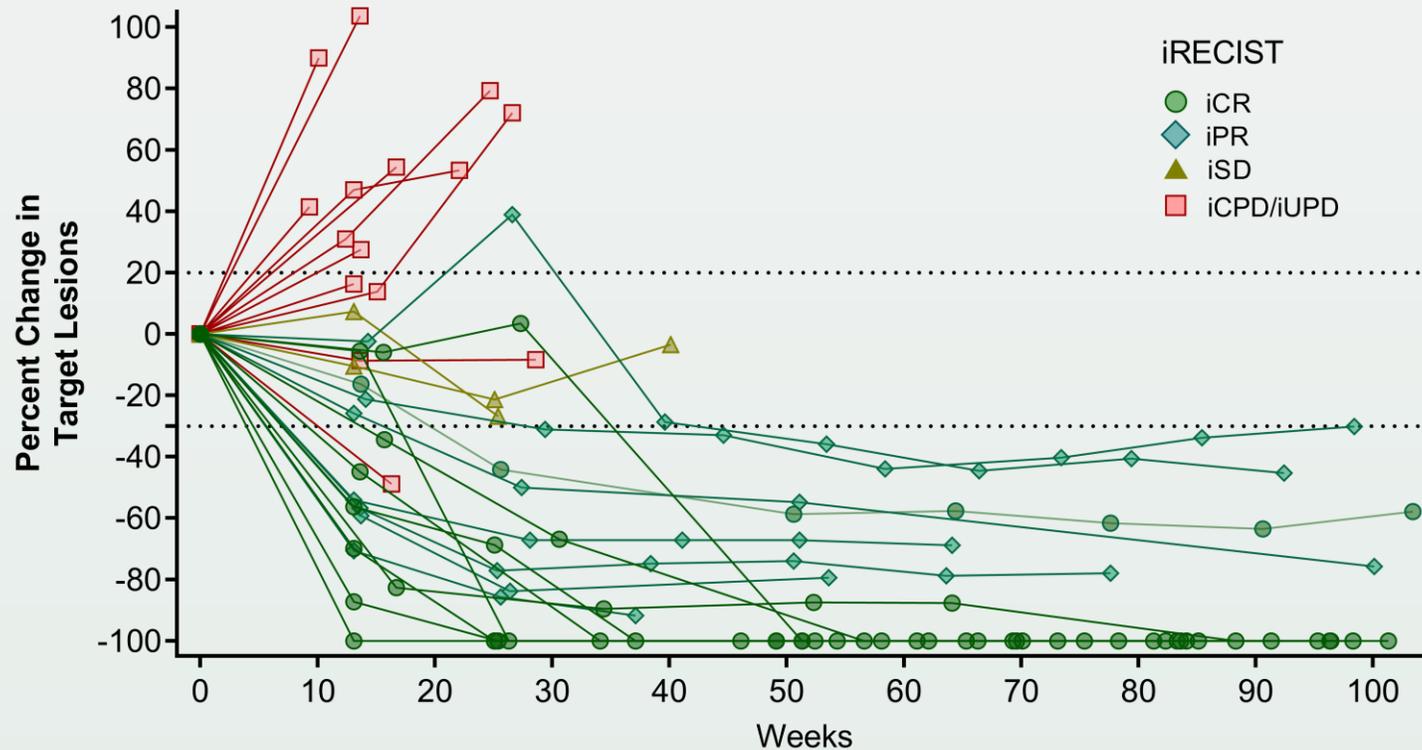


Overall Survival (n=30)



Deep and durable clinical responses to UV1 + pembrolizumab

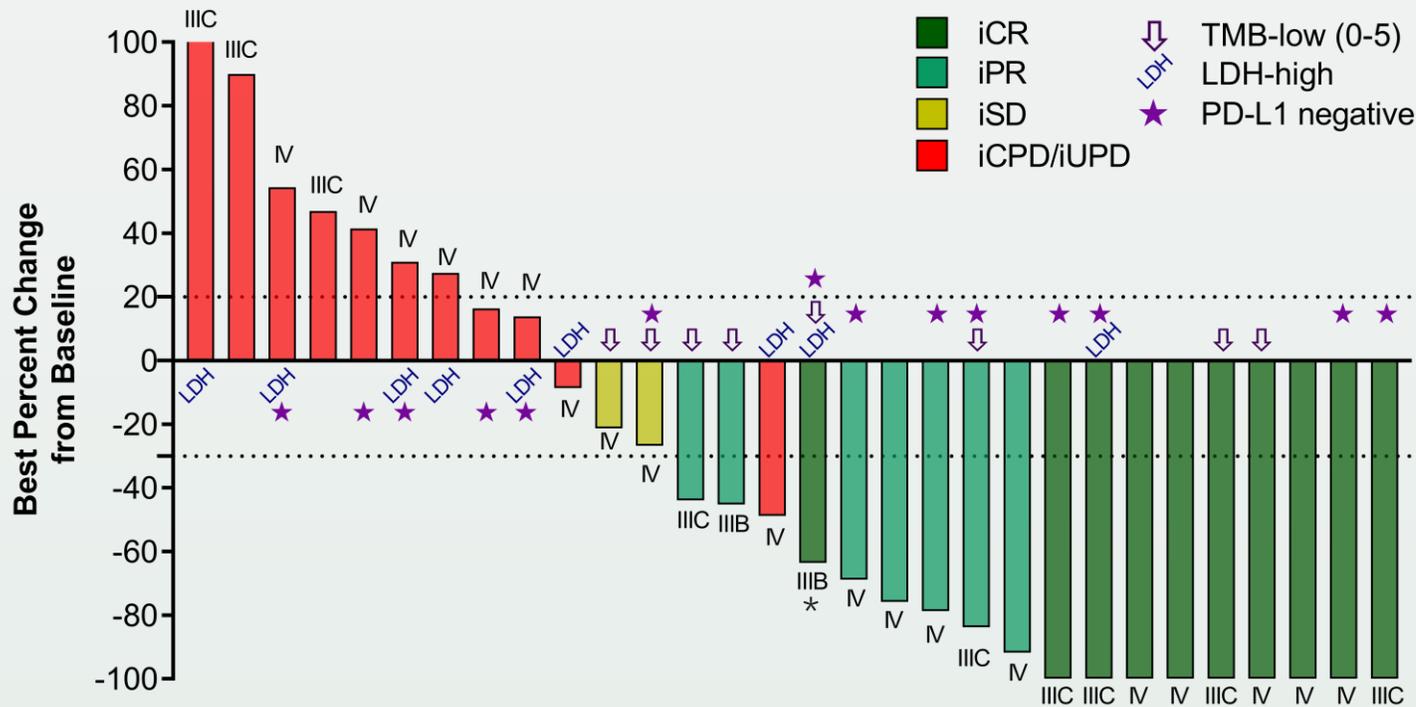
Responses lasting up to 2 years (maximum follow-up)



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

Robust clinical responses in patients typically obtaining reduced CPI efficacy

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



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

ORR: 34-42%

CR: 5-14%

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

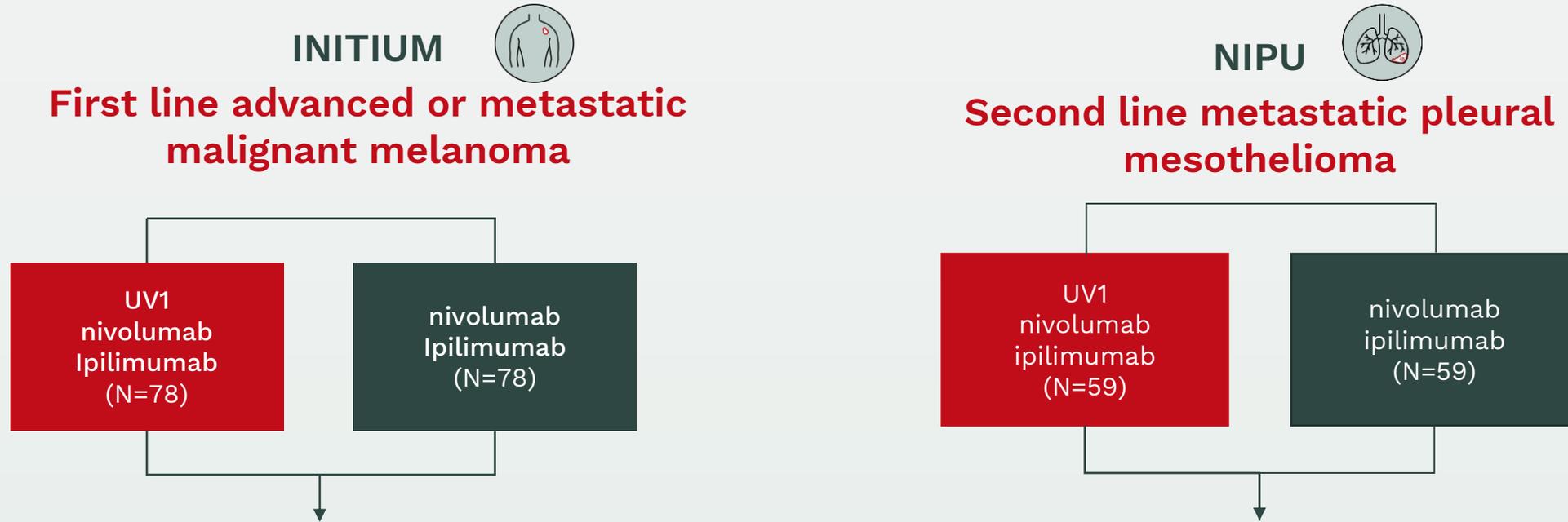
CR PD-L1 neg: 5.8%

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

* 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

Near-term key inflection points: Topline readouts from the first two UV1 Phase II trials, INITIUM and NIPU, expected in H1 2023

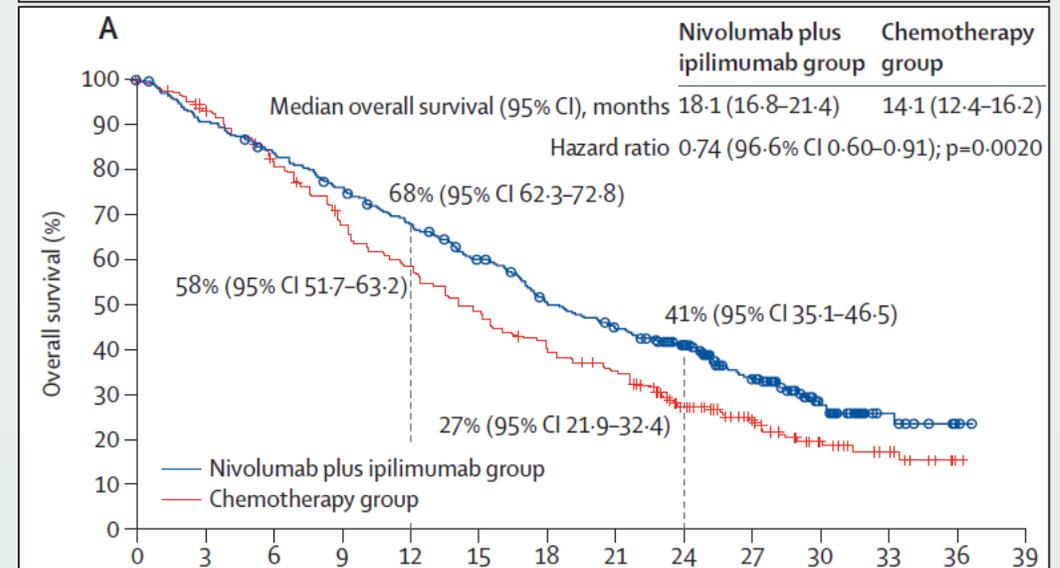
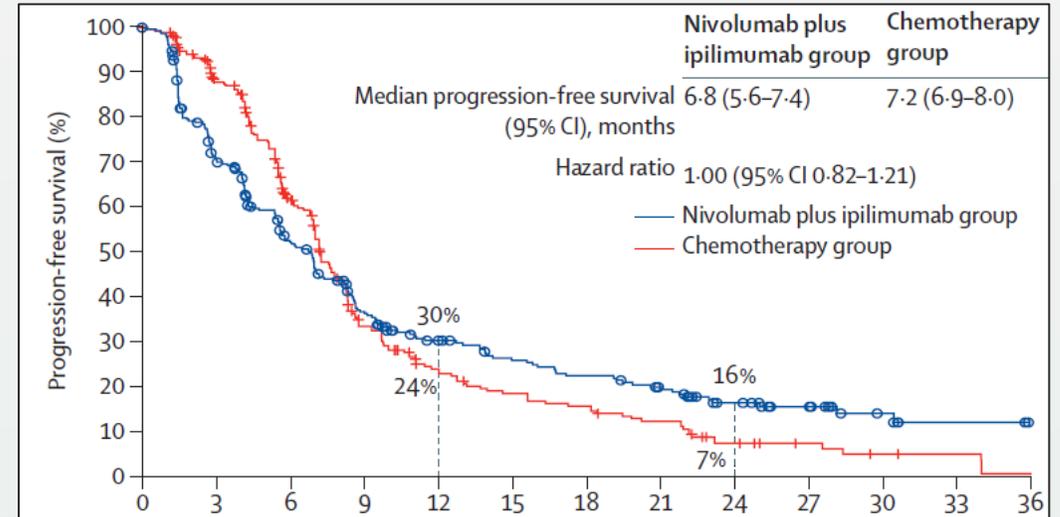


Primary endpoint: Progression Free Survival (PFS)

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

Endpoints in randomized clinical trials

- The gold standard endpoint in oncology is overall survival
- Progression-free survival (PFS) is an endpoint widely used as a surrogate for overall survival (OS) in Phase II
- An endpoint in a clinical trial is an event or outcome that can be measured objectively
- The illustrations to the right present PFS and OS from the CheckMate 743 study leading to approval of ipilimumab and nivolumab as 1st line treatment in mesothelioma

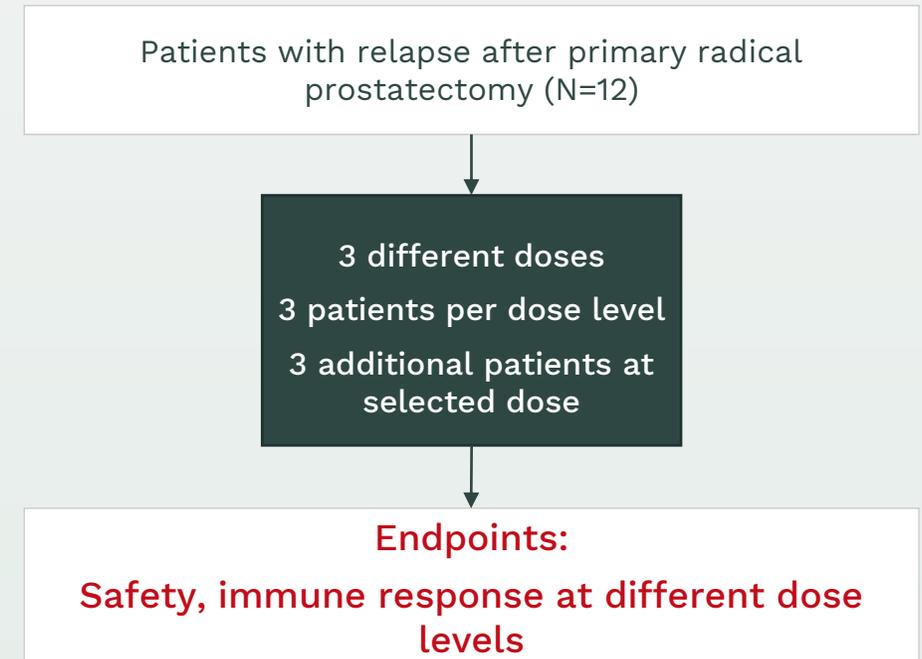


The cleaning of data before final topline results are available is a lengthy process

- 
- Cleaning activities are primarily done after the pre-defined number of endpoints are reached
 - Survival status will be checked on all patients
 - Independent read of all unread CT scans
 - All data will need to be entered into the database
 - All hospitals in all countries will be monitored **on site** by a Clinical Research Associate
 - All databases need to be reconciliated
 - Database lock requires all queries to be resolved
 - Statistical analysis to be performed (including tables and figures)
 - Topline results available to be communicated to the Sponsor

The TENDU Phase I trial: First clinical evaluation of a TET vaccine adjuvant

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



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Q4 2022 Key Financials

- Increase in operating expenses as expected
 - FY 2022 (MNOK 184) vs. FY 2021 (MNOK 164): +12%
 - Generally increased activity level, but increase in R&D costs have been lower than previously indicated (with some delayed milestones, partly due to longer start-up time in clinical trials)
 - Q4 2022 (MNOK 72) vs. Q4 2021 (MNOK 51): + 42%
 - Option expenses and related social security tax accrual, which fluctuates with the company share price, were MNOK 17 higher in Q4 2022 than in Q4 2021
 - Significant non-cash cost elements in Q4 2022 (primarily related to share option costs)
- MNOK 425/MUSD 42 in cash by end of Q4 2022, expected financial runway extended until mid-2024
 - Going forward, the operating expense level should be expected to increase further compared to 2022, with quarterly variations
 - Driven by further progress in the phase II trials, CMC development and other R&D activities

Key financials

Key financials per Q4-2022 - Ultimovacs Group

NOK (000)	Q4-21	Q4-22	FY21	FY22
Total revenues	-	-	-	-
Payroll and payroll related expenses	11 885	31 630	61 916	71 466
External R&D and IPR expenses (incl. grants)	35 538	35 289	88 169	91 029
Other operating expenses (incl. depreciation)	3 507	5 335	13 748	21 135
Total operating expenses	50 930	72 255	163 832	183 631
Operating profit (loss)	-50 930	-72 255	-163 832	-183 631
Net financial items	-222	1 742	-890	15 839
Profit (loss) before tax	-51 152	-70 513	-164 722	-167 792
Net increase/(decrease) in cash and cash eq.	227 856	-42 137	137 106	-155 426
Cash and cash equivalents at end of period	574 168	425 309	574 168	425 309
Number of FTEs at end of period	24	23	24	23

- Net cash of MNOK 425 by the end of Q4 2022

Comments:

Payroll expenses

- Total payroll expenses were higher in Q4-22 and FY22 compared to the previous year;
 - Q4-22 vs. Q4-21: Regular salary costs were approximately at the same level, but significant increase in Total payroll expenses primarily due to share option costs (with a reversal in Q4-21 vs. significant cost in Q4-22)
 - FY22 vs. FY21: Regular salary costs somewhat higher due to 2 additional FTEs during the year. Share option costs including related social security tax accrual were also somewhat higher in FY22.

External R&D and IPR expenses

- R&D costs were approximately at the same level in both Q4-21 and Q4-22, as well as in FY21 and FY22.

Other operating expenses

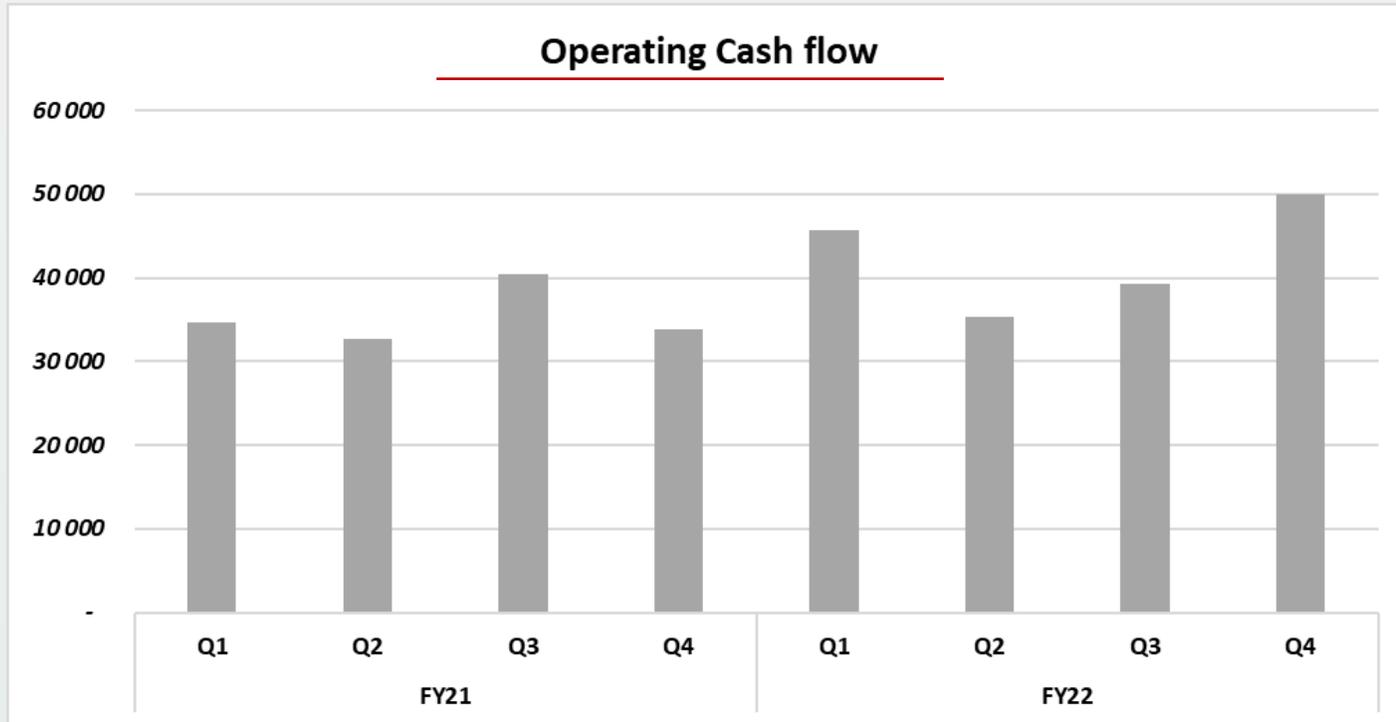
- Increase from the previous year primarily due to higher activity level (business development, travel and other)

Net financial items

- FY22: Comprised of interest of MNOK 9 and net foreign exchange gain of MNOK 7 (from EUR account and EUR/NOK future contracts)

Key financials – quarterly operating cash flow

NOK (000) – Negative amounts



Note: excluding incoming public grants

Comments:

- Operating cash flow has increased mainly because of increased activity level within R&D (incl. execution of the broad Phase II program)
- Quarterly variations should be expected, mainly driven by R&D expenses that will be influenced by several factors such as:
 - initiation of sites and patient recruitment in clinical trials
 - milestones in larger projects
 - CMC development
 - other R&D expenses, including TET
- The deviation between operating cash flow and total loss in Q4-22 is primarily related to year end accruals (MNOK 5) as well as non-cash costs related to the option scheme (MNOK 13)

Key financials – quarterly overview

Key financials per Q4-2022 - Ultimovacs Group

NOK (000)	Q1-21	Q2-21	Q3-21	Q4-21	Q1-22	Q2-22	Q3-22	Q4-22
Total revenues	-	-	-	-	-	-	-	-
Payroll and payroll related expenses	12 203	14 514	23 314	11 885	11 384	14 340	14 112	31 630
External R&D and IPR expenses (incl. grants)	16 012	20 588	16 031	35 538	14 725	16 272	24 743	35 289
Other operating expenses (incl. depreciation)	3 000	4 069	3 171	3 507	5 791	4 810	5 200	5 335
Total operating expenses	31 215	39 171	42 517	50 930	31 900	35 421	44 055	72 255
Operating profit (loss)	-31 215	-39 171	-42 517	-50 930	-31 900	-35 421	-44 055	-72 255
Net financial items	-2 582	2 706	-791	-222	-4 699	13 045	5 752	1 742
Profit (loss) before tax	-33 798	-36 465	-43 308	-51 152	-36 600	-22 376	-38 303	-70 513
Net increase/(decrease) in cash and cash equivalents*	-28 213	-29 657	-32 880	227 856	-44 507	-31 837	-29 726	-42 137
Cash and cash equivalents at end of period	409 288	381 799	347 804	574 168	523 706	486 338	469 063	425 309
Number of FTEs at end of period	21	21	21	24	23	23	23	23

*not including effects of change in exchange rate

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Cancer vaccines are on the agenda this year

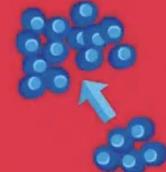
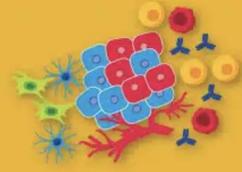
AACR American Association for Cancer Research*

CANCER RESEARCHERS / OTHER HEALTH CARE PROFESSIONALS

PATIENTS, CAREGIVERS, AND ADVOCATES

GET INVOLVED

HOT TOPICS IN IMMUNOTHERAPY IN 2023

<p>Combination of Agents That Target Independent Pathways</p> 	<p>Advancing Effective Cell Therapies for Solid Tumors</p> 
 <p>Drugs That Target Inhibitory Molecules In the Tumor Microenvironment</p>	 <p>Developing More Effective Cancer Vaccines</p>

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Review Article | Published: 23 August 2022

Cancer vaccines: the next immunotherapy frontier



WHAT'S HOT FORECASTS
 1 | in
 Jan 05, 2023 | Tony Hitchcock

Cancer Vaccines: What's Hot in 2023

Personalized cancer vaccines – a new reality

At the end of 2022 we saw reports on positive data from studies on personalized cancer vaccines used in combination with a checkpoint inhibitor targeting melanoma. This is one of a number of new classes of therapeutic cancer vaccines that train the immune system to identify and attack tumor cells once patients have been diagnosed with a specific cancer; they have the potential to target a wide range of solid tumors, including, breast, lung, colon and brain tumors.

Current Opinion in Oncology

Articles & Issues | For Authors | Journal Info

MELANOMA AND OTHER SKIN NEOPLASMS: EDITED BY OLIVER BECHTER AND GIL AWADA

Therapeutic cancer vaccination against telomerase: clinical developments in melanoma

Ellingsen, Espen Basmo; Bjørheim, Jens; Gaudernack, Gustav

Author Information

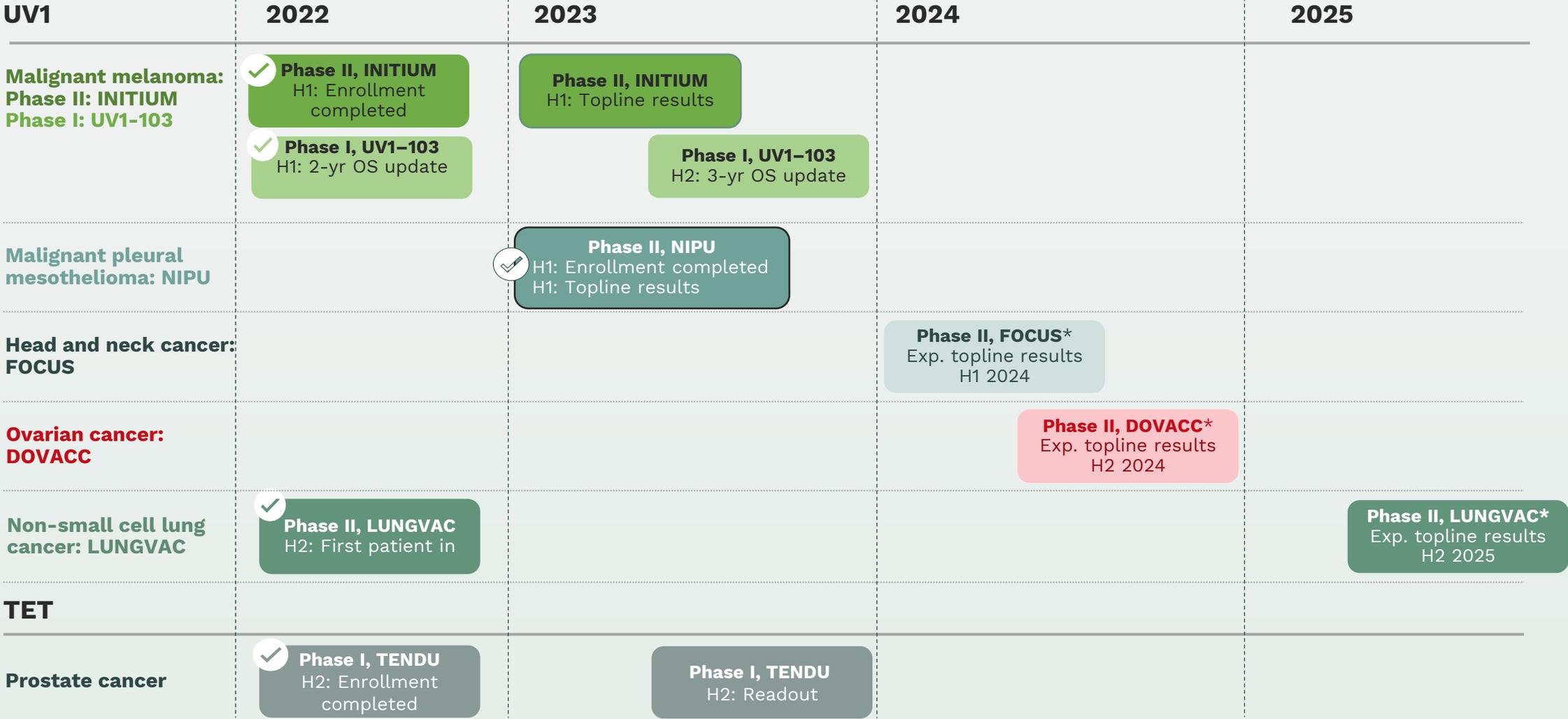
Current Opinion in Oncology 35(2);p 100-106, March 2023. | DOI: 10.1097/CCO.0000000000000922

Where to meet us: Events & Conferences

An overview of some of the events and conferences where Ultimovacs will participate during H1 2023*:

Events & Conferences	When	Where
JPM Week	January 8-12	San Francisco
Redeye Fight Cancer	January 19	Stockholm
IO 360 Conference	February 7-10	NYC
SACHS CEO forum	March 1-2	Zürich
Cowen Healthcare Conference	March 6-8	Boston
EQT BioCapital Europe	March 8-9	Amsterdam
Carnegie Nordic Healthcare	March 14-16	Stockholm
European Lung Cancer Congress 2023	March 29-April 1	Copenhagen
American Association for Cancer Research 2023	April 14-19	Orlando
Kempen Life Science Conference	April 25-26	Amsterdam
Cancer Immunotherapy (CIMT)	May 3-5	Mainz
NY Academy of Science: Frontiers in Immuno-Oncology	May 14-15	NYC
BioEquity	May 14-16	Dublin
ABGSC Life Science Summit	May 30-31	Stockholm
SACHS IO Forum	June 2	Chicago
ASCO	June 1-7	Chicago
BIO International Convention	June 5-8	Boston

Expected news flow and milestones: key value inflection points during the next 6-30 months



*Readout estimates for FOCUS, DOVACC and LUNGVAC will be updated with the Q4 2023 report

Summary

- Completed enrollment in INITIUM, NIPU and TENDU (Phase I)
- On track to expected topline readout during H1 2023 in the UV1 Phase II trials INITIUM and NIPU
- UV1 well positioned in the emerging cancer vaccine landscape
 - Universal (target, patients, and at all stages of cancer)
 - Off-the-shelf, simple logistics, easy to use (intradermal injections)
- Biomarker analyses from the UV1-103 trial indicates possible broader applicability of UV1 in combination with anti-PD1 checkpoint inhibitors
- Expected financial runway extended until mid-2024



Q&A

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