



# 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 <sup>3</sup> Oslo University Hospital
	Head and neck cancer	Pembrolizumab	75	67% <sup>1</sup>	H1 2024		FOCUS ●		MARTIN-LUTHER-UNIVERSITÄT HALLE-WITTENBERG
	Ovarian cancer	Durvalumab & olaparib	184	<10% <sup>1</sup>	H2 2024		DOVACC ●		NSGO-CTU AstraZeneca <sup>3</sup> ENGOT European Network of Gynaecological Oncological Trial groups
	Non-small cell lung cancer (NSCLC)	Cemiplimab <sup>4</sup>	138	<10% <sup>1</sup>	H2 2025		LUNGVAC ●		VESTRE VIKEN DRAMMEN HOSPITAL
TET	Prostate cancer	Dose finding trial, monotherapy	12	Completed	H2 2023	TENDU ●			

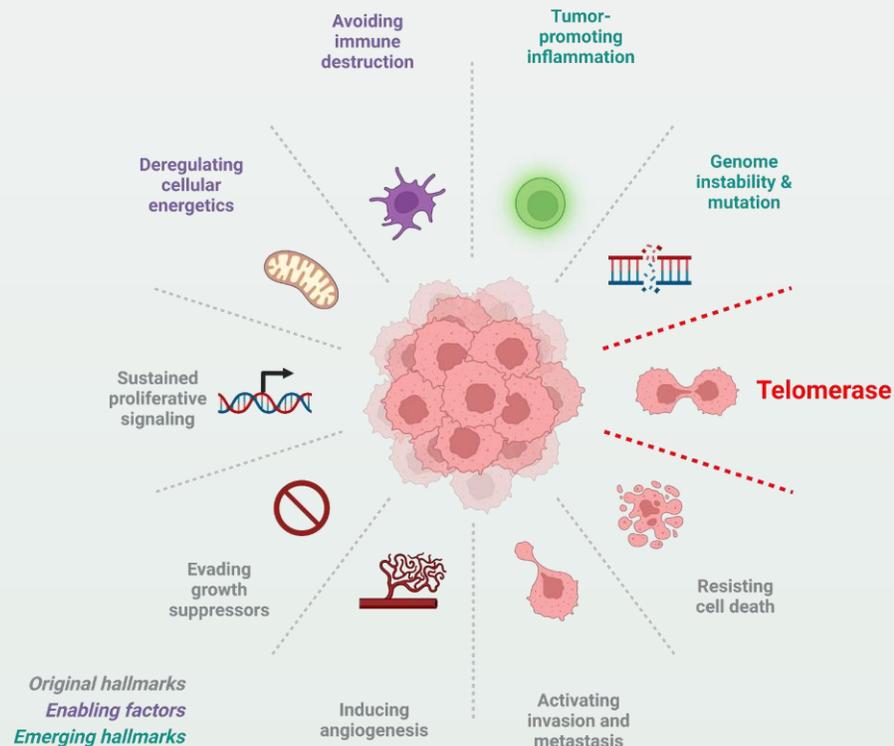
# Patient enrollment and expected readouts

Clinical trial program	Enrollment and expected readout timeline
INITIUM (Phase II malignant melanoma):	Enrollment of 156 patients <b>completed</b> **  Expected readout: H1 2023
NIPU (Phase II pleural mesothelioma):	Enrollment of 118 patients <b>completed</b>  Expected readout: H1 2023
FOCUS (Phase II head and neck cancer):	<b>50</b> out of 75 patients enrolled (vs. 41 in Q3 2022) Expected readout: H1 2024
DOVACC* (Phase II ovarian cancer):	<b>17</b> out of 184 patients enrolled (vs. 7 in Q3 2022) Expected readout: H2 2024
LUNGVAC* (Phase II non-small cell lung cancer):	<b>2</b> 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 <b>completed</b>  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 Cancer<sup>1</sup>



### Telomerase Characteristics

### UV1 Vaccine Qualities

#### Universal

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

Applicable to a broad range of cancer types

#### Essential

Tumor cells depend on expressing telomerase

High relevance in heterogenous tumor environments

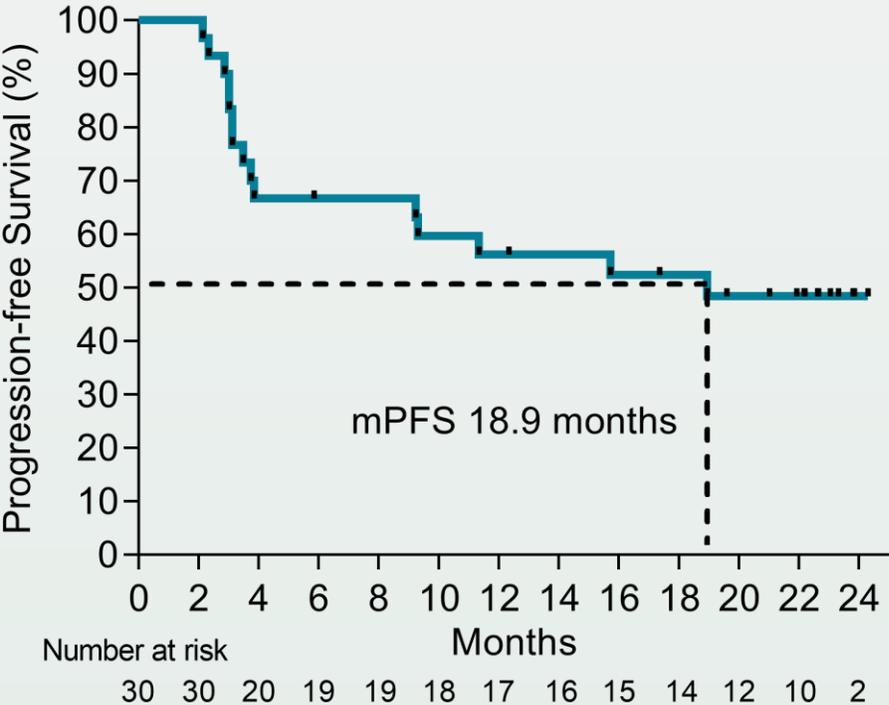
#### Enduring

Present throughout tumor evolution: primary to metastatic cancer

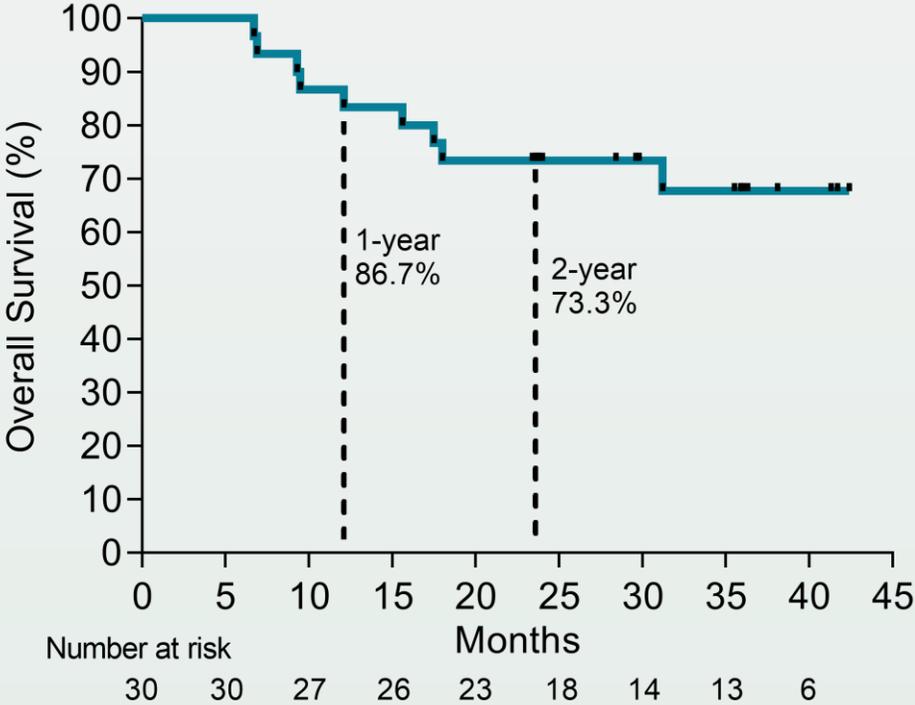
Enduring and relevant immune response over time

# 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)

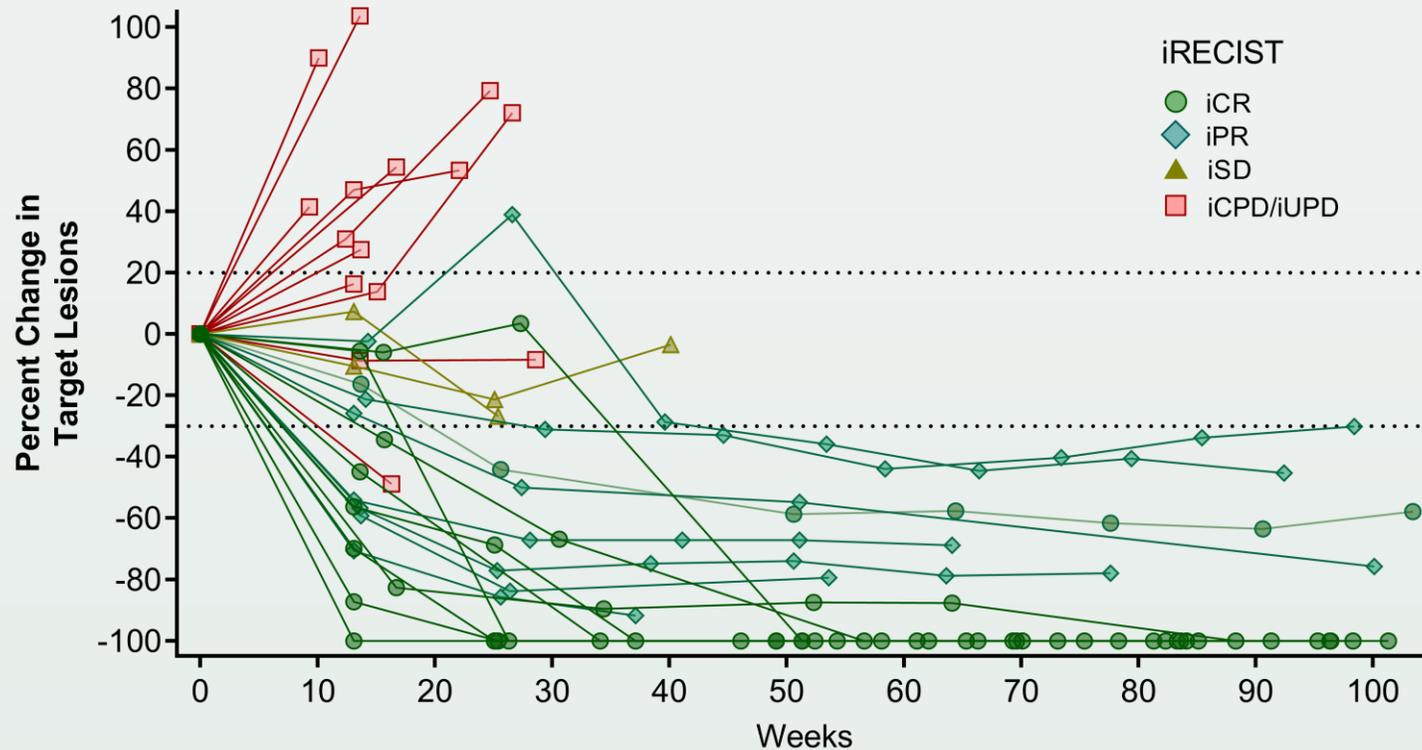


Overall Survival (n=30)



# Deep and durable clinical responses to UV1 + pembrolizumab

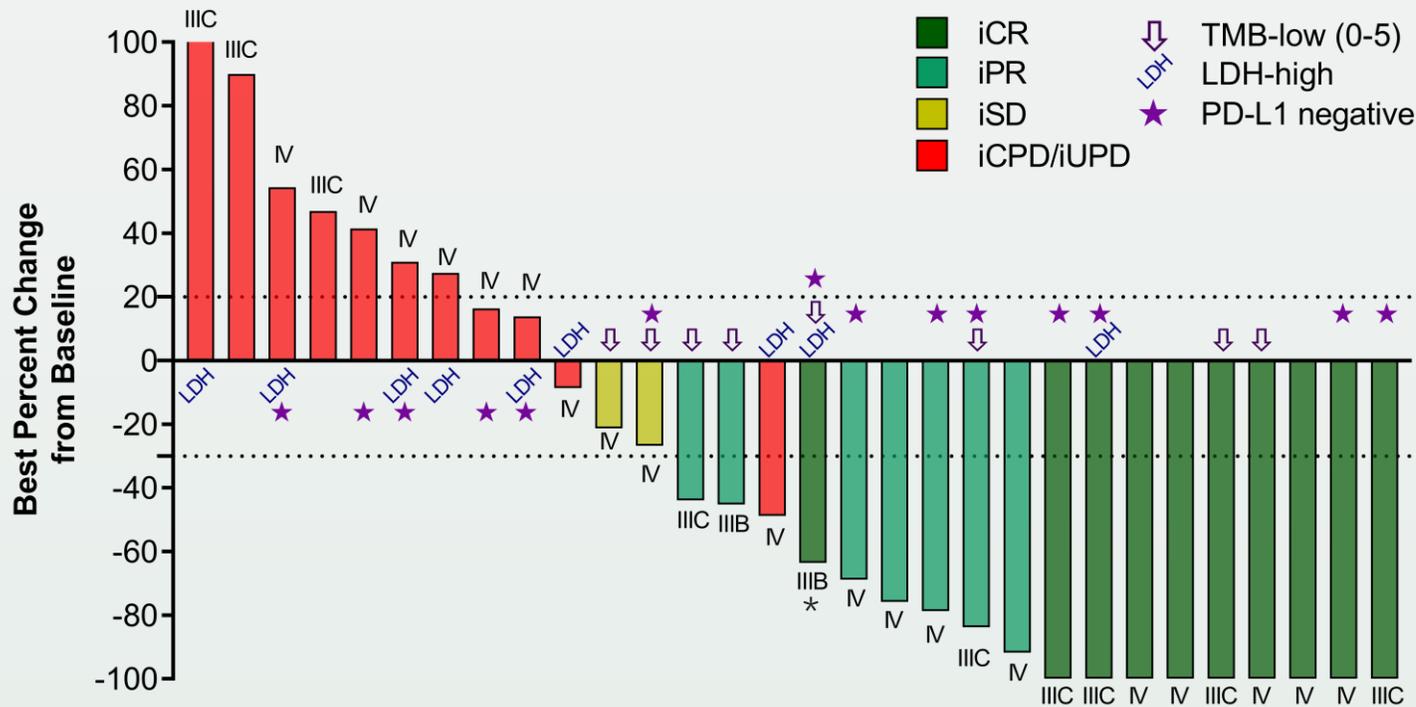
Responses lasting up to 2 years (maximum follow-up)



- 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%)

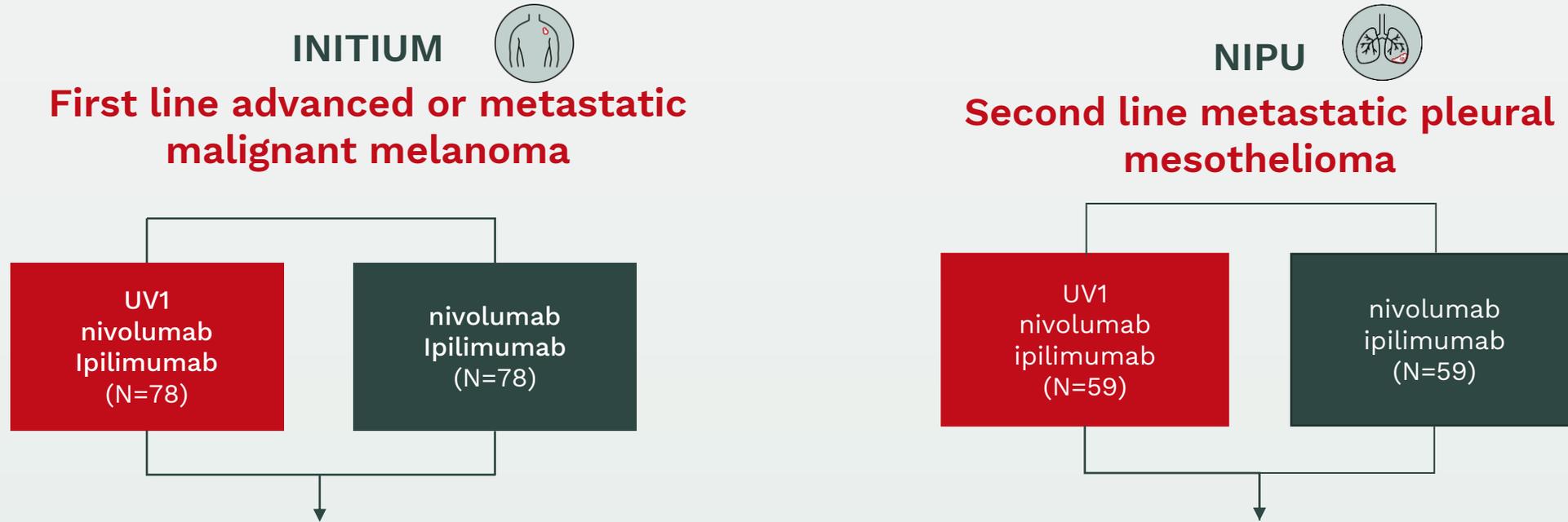
**CR PD-L1 neg:** 5.8%

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

\* 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

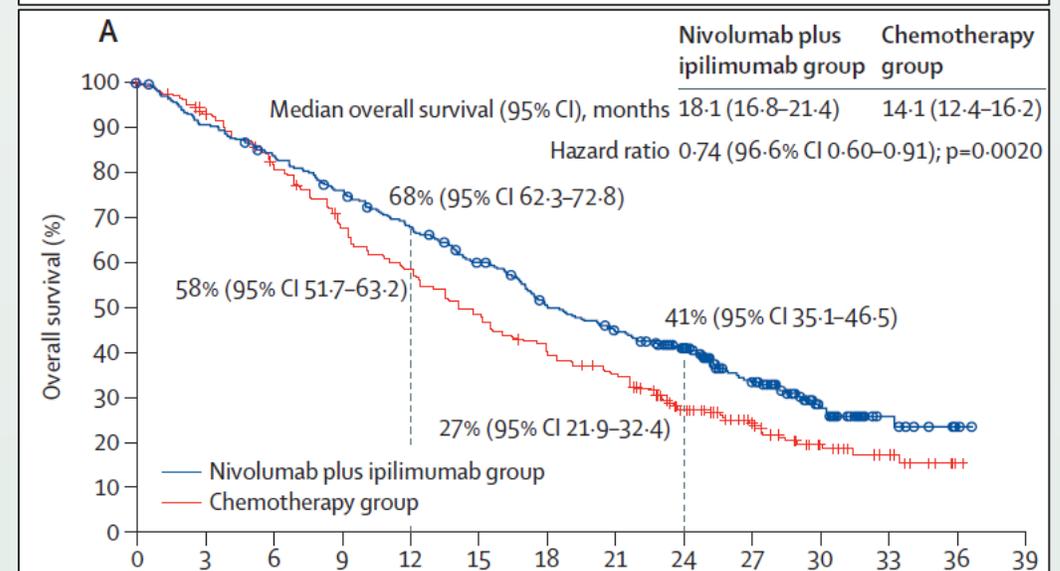
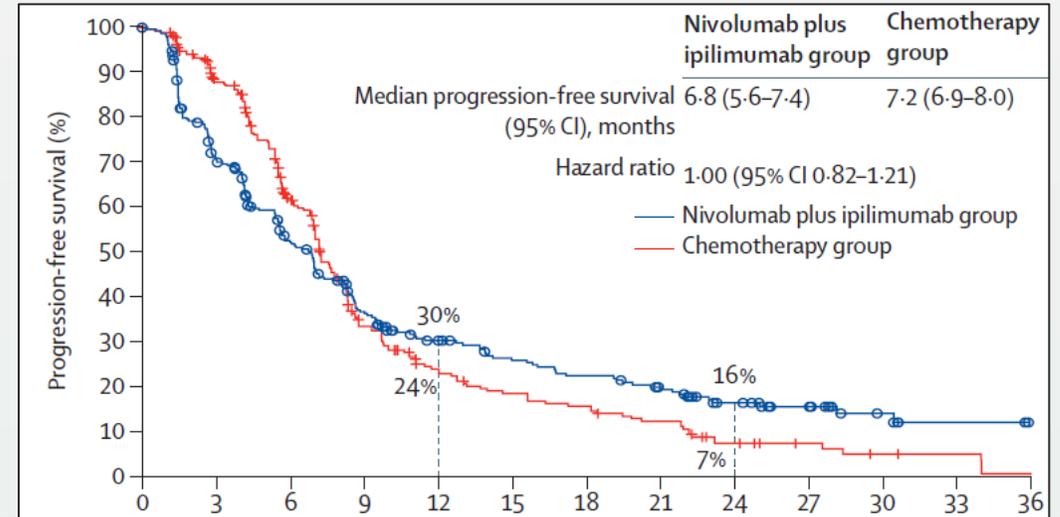


**Primary endpoint:** Progression Free Survival (PFS)

**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 1<sup>st</sup> line treatment in mesothelioma

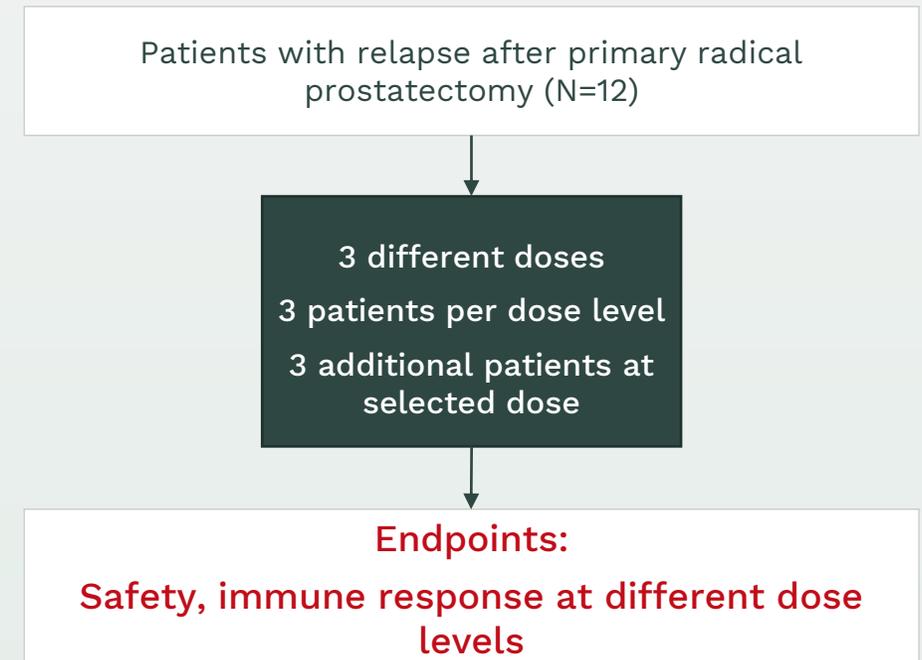


# The cleaning of data before final topline results are available is a lengthy process

- 
- 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
<b>Total revenues</b>	-	-	-	-
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
<b>Total operating expenses</b>	<b>50 930</b>	<b>72 255</b>	<b>163 832</b>	<b>183 631</b>
<b>Operating profit (loss)</b>	<b>-50 930</b>	<b>-72 255</b>	<b>-163 832</b>	<b>-183 631</b>
Net financial items	-222	1 742	-890	15 839
<b>Profit (loss) before tax</b>	<b>-51 152</b>	<b>-70 513</b>	<b>-164 722</b>	<b>-167 792</b>
Net increase/(decrease) in cash and cash eq.	227 856	-42 137	137 106	-155 426
<b>Cash and cash equivalents at end of period</b>	<b>574 168</b>	<b>425 309</b>	<b>574 168</b>	<b>425 309</b>
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

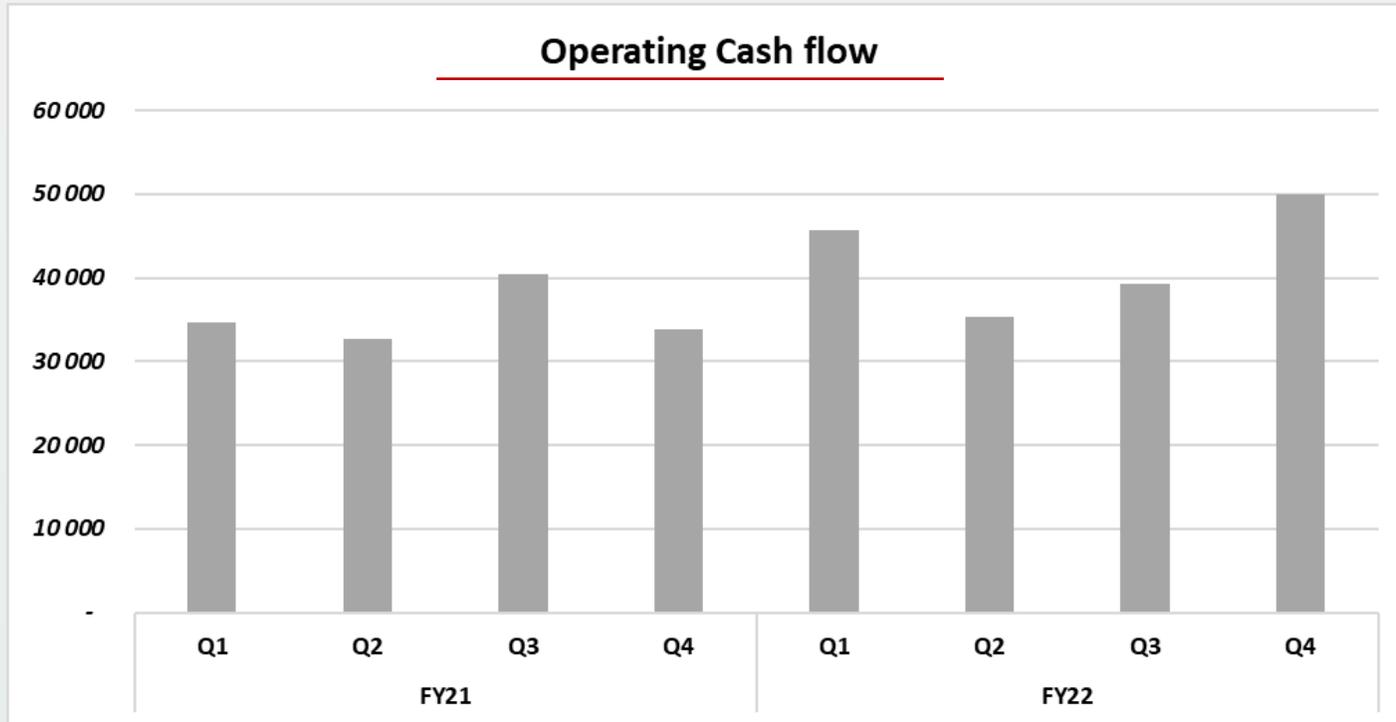
- Increase from the previous year primarily due to higher activity level (business development, travel and other)

### 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
<b>Total revenues</b>	-	-	-	-	-	-	-	-
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
<b>Total operating expenses</b>	<b>31 215</b>	<b>39 171</b>	<b>42 517</b>	<b>50 930</b>	<b>31 900</b>	<b>35 421</b>	<b>44 055</b>	<b>72 255</b>
<b>Operating profit (loss)</b>	<b>-31 215</b>	<b>-39 171</b>	<b>-42 517</b>	<b>-50 930</b>	<b>-31 900</b>	<b>-35 421</b>	<b>-44 055</b>	<b>-72 255</b>
Net financial items	-2 582	2 706	-791	-222	-4 699	13 045	5 752	1 742
<b>Profit (loss) before tax</b>	<b>-33 798</b>	<b>-36 465</b>	<b>-43 308</b>	<b>-51 152</b>	<b>-36 600</b>	<b>-22 376</b>	<b>-38 303</b>	<b>-70 513</b>
Net increase/(decrease) in cash and cash equivalents*	-28 213	-29 657	-32 880	227 856	-44 507	-31 837	-29 726	-42 137
<b>Cash and cash equivalents at end of period</b>	<b>409 288</b>	<b>381 799</b>	<b>347 804</b>	<b>574 168</b>	<b>523 706</b>	<b>486 338</b>	<b>469 063</b>	<b>425 309</b>
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

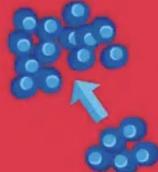
**AACR** American Association for Cancer Research\*

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

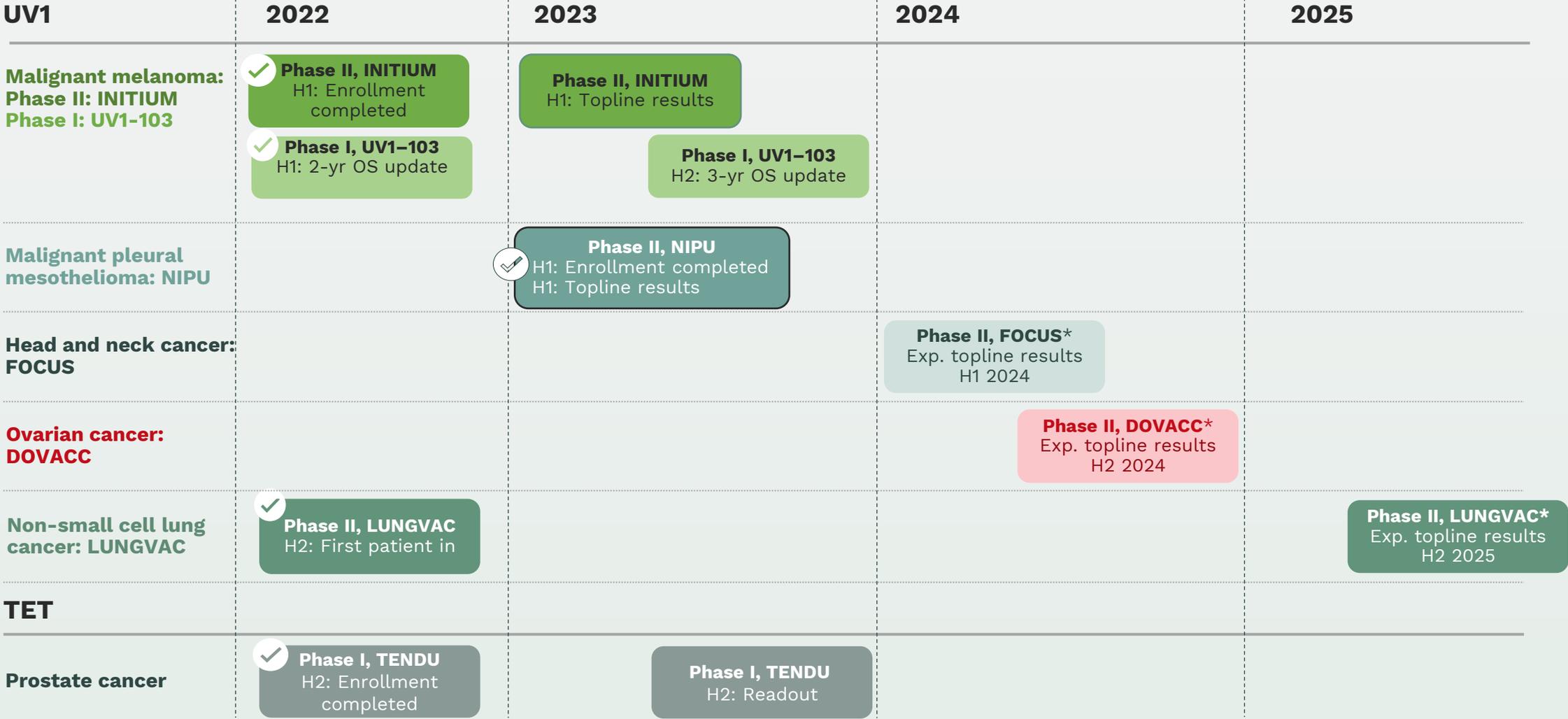
Current Opinion in Oncology 35(2);p 100-106, March 2023. | DOI: 10.1097/CCO.0000000000000922

# 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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