



# Enabling the Immune System to Fight Cancer

**Third Quarter 2023 Results**

**Ultimovacs ASA, November 8, 2023**

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## Q3 2023: Achieving a remarkable milestone for the UV1 cancer vaccine

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- **Promising results from the first randomized UV1 Phase II trial, NIPU in malignant mesothelioma**  
Data showed an encouraging and clinically meaningful improvement in overall survival when adding UV1 vaccination on top of ipilimumab and nivolumab – two of the most effective immunotherapies available
- First off-the-shelf universal cancer vaccine showing efficacy in a randomized trial; UV1 well positioned in the emerging cancer vaccine landscape
- **Sustained long-term survival data from Phase I study in malignant melanoma**  
Reporting from Phase I UV1-103 study reported no confirmed deaths between 3-year and 4-year follow-up of the patients in Cohort one
- **Near-term readout from the second and third UV1 Phase II trials, INITIUM and FOCUS**  
The patients in the UV1 Phase II trial in unresectable or metastatic malignant melanoma, INITIUM, are taking longer than anticipated to experience disease progression or death
- Thus, with acceptance from the regulatory authorities, the protocol has been amended to report topline readout when the last enrolled patient has completed follow-up for 18 months.  
Data to be reported in March/April 2024
- Third UV1 Phase II trial in head and neck cancer, FOCUS, completed enrollment in Q3 2023.  
Readout is expected in H2 2024

# Phase II program ongoing across five cancer indications investigating UV1 vaccination in combination with various checkpoint inhibitors (CPIs)

	Cancer indication	Checkpoint inhibitors	Patients (#)	Enrollment status	Expected topline readout	Phase I	Phase II	Investigator-initiated trial contributors
UV1	Pleural mesothelioma	Ipilimumab & nivolumab	118	✓	Results at ESMO, Oct 2023		NIPU ●	Bristol Myers Squibb <sup>1</sup> Oslo University Hospital
	Malignant melanoma	Ipilimumab & nivolumab	156	✓	H1 2024		INITIUM ●	
	Head and neck cancer	Pembrolizumab	75	✓	H2 2024		FOCUS ●	MARTIN-LUTHER-UNIVERSITÄT HALLE-WITTENBERG
	Ovarian cancer	Durvalumab & olaparib	184	25% <sup>2</sup>	H2 2024 <sup>3</sup>		DOVACC ●	NSGO-CTU AstraZeneca <sup>1</sup> ENGOT European Network of Gynecological Oncological Trial groups
	Non-small cell lung cancer (NSCLC)	Cemiplimab <sup>4</sup>	138	~10% <sup>2</sup>	H2 2025 <sup>3</sup>		LUNGVAC ●	VESTRE VIKEN DRAMMEN HOSPITAL
	Malignant melanoma	Ipilimumab	12	✓	✓	UV1-ipi ●		
	Malignant melanoma	Pembrolizumab	30	✓	✓	UV1-103 ●		
TET	Prostate cancer	Dose finding, monotherapy	12	✓	Q4 2023	TENDU ●		

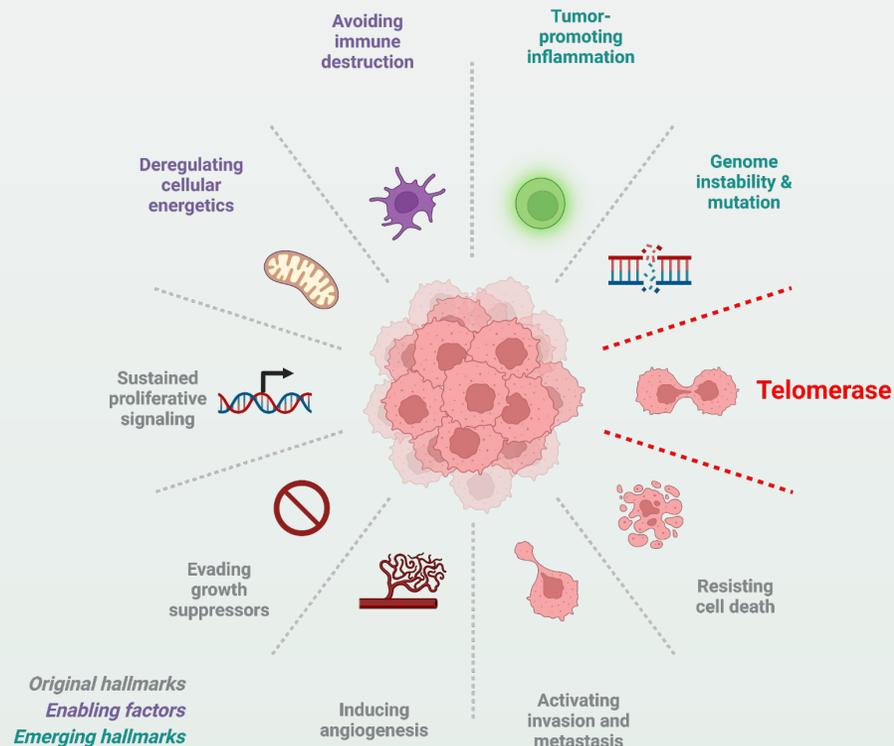
# Ultimovacs Third Quarter 2023 presentation

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- 1. Clinical update**
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# UV1 induces T cell responses against telomerase a “hallmark of cancer” present in 85-90% of the different tumor types

## 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

# UV1 clinical program consists of five comparative, randomized Phase II trials in different cancer types and CPI combinations

Trial design	 <b>1 NIPU</b>	 <b>2 INITIUM</b>	 <b>3 FOCUS</b>	 <b>4 DOVACC</b>	 <b>5 LUNGVAC</b>
<b>CPI combination</b>	Ipilimumab + nivolumab	Ipilimumab + nivolumab	Pembrolizumab	Durvalumab + olaparib	Cemiplimab
<b>Indication</b>	Second line mesothelioma	First line malignant melanoma	First line head and neck cancer	Second line ovarian cancer	First line non-small cell lung cancer
<b>Timeline</b>	2020 – 2023	2020 – 2023	2021 – 2023	2021 – 2024	2022 – 2025
<b>Expected topline results</b>	<b>Announced October 2023</b>	<b>H1 2024</b>	<b>H2 2024</b>	H2 2024 <sup>1</sup>	H2 2025 <sup>1</sup>
<b>No. of patients</b>	N=118	N=156	N=75	N=184	N=138
<b>Enrollment status<sup>2</sup></b>	<b>100% recruited</b>	<b>100% recruited</b>	<b>100% recruited</b>	<b>25% recruited</b>	<b>~ 10% recruited</b>
<b>Sites &amp; countries</b>	6 sites in NO, SE, DK, ES, AU,	40 sites in US, NO, BE, UK	10 sites in DE	>40 sites in NO, SE, DK, FI, BE, NL, DE, AT, LT, EE, GR	8-10 sites in NO

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

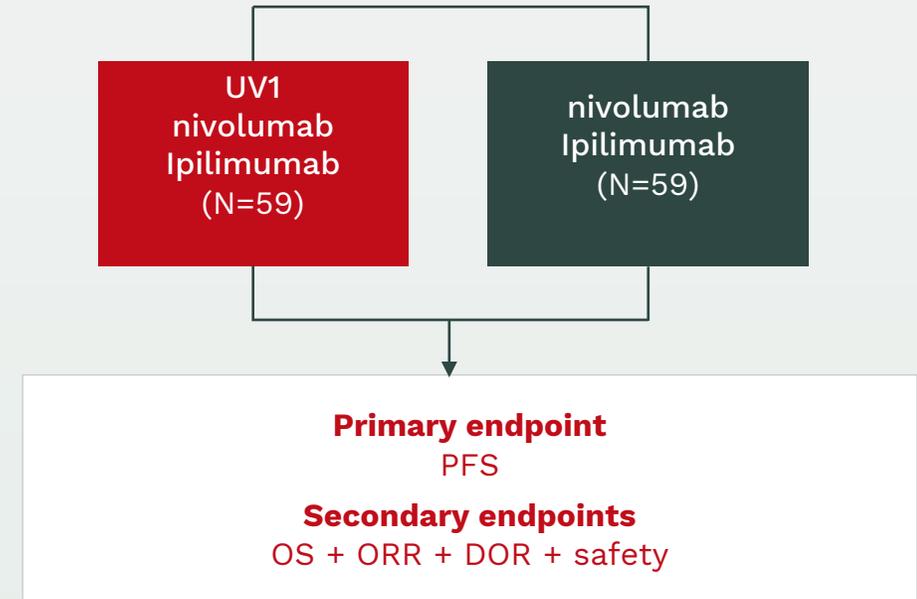
**Secondary endpoints: Overall Survival (OS) + Objective Response Rate (ORR) + Duration of Response (DOR) + safety**

1. DOVACC and LUNGVAC: Readout estimates will be updated with the Q4 2023 report



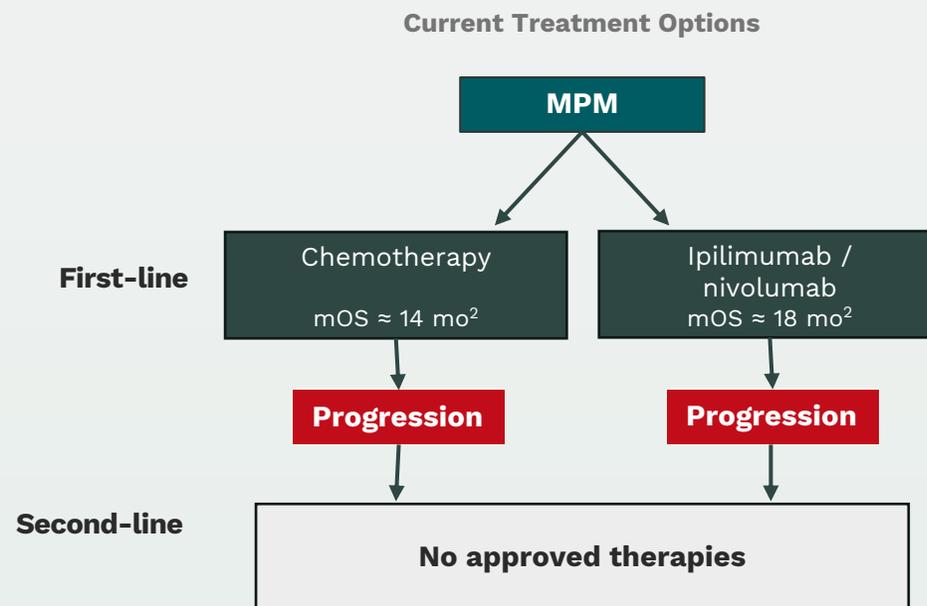
# NIPU - Second line malignant pleural mesothelioma (MPM)

- Investigator-initiated trial led by Oslo University Hospital, supported by Ultimovacs and Bristol Meyer Squibbs
- Enrolled 118 patients with inoperable malignant pleural mesothelioma from six sites in Australia, Spain, Denmark, Sweden and Norway
- First patient enrolled June 2020, last patient enrolled in January 2023.
- Encouraging survival results presented at ESMO 2023
- The FDA granted Orphan Drug Designation to UV1 for treatment of patients with mesothelioma in October 2023



# MPM is one of the most challenging cancers to treat

- Most patients:
  - Are diagnosed with advanced disease
  - Have poor prognosis and few therapeutic options
  - Don't have surgery as an option
- Chemotherapy has been the Standard of Care (SoC) for the past 20 years
- Ipilimumab and nivolumab (IPI-NIVO) was approved in 1st line treatment by regulatory authorities in 2020/2021<sup>1</sup>
- Despite current improvement in SoC, patients with MPM remain an underserved population with a high unmet medical need



# The NIPU baseline demographics is relatively balanced

**OPDIVO + YERVOY**  
(nivolumab) (pilotumab)  
**UV1 vaccine**

**OPDIVO + YERVOY**  
(nivolumab) (pilotumab)

		<b>UV1 plus IPI-NIVO (n=59)</b>	<b>IPI-NIVO (n=59)</b>	<b>Total (N=118)</b>
<b>Sex – n (%)</b>	Female	14 (23.7)	12 (20.3)	26 (22.0)
	Male	45 (76.3)	47 (79.7)	92 (78.0)
<b>Age</b>	Median	71	72	71
	Range	39-79	42-83	39-83
<b>ECOG – n (%)</b>	0	17 (28.8)	18 (30.5)	35 (29.7)
	1	42 (71.2)	41 (69.5)	83 (70.3)
<b>Histology – n (%)</b>	Epithelioid	44 (74.6)	47 (79.7)	91 (77.1)
	Sarcomatoid	5 (8.5)	4 (6.8)	9 (7.6)
	Biphasic	5 (8.5)	7 (11.9)	12 (10.2)
	Rhabdoid	1 (1.7)	0 (0)	1 (0.8)
	Unknown	4 (6.8)	1 (1.7)	5 (4.2)
<b>PD-L1 – n (%)</b>	<1	31 (52.5)	32 (54.2)	63 (53.4)
	1-49	6 (10.2)	4 (6.8)	10 (8.5)
	≥50	2 (3.4)	4 (6.8)	6 (5.1)
	Unknown	20 (33.9)	19 (32.2)	39 (33.1)

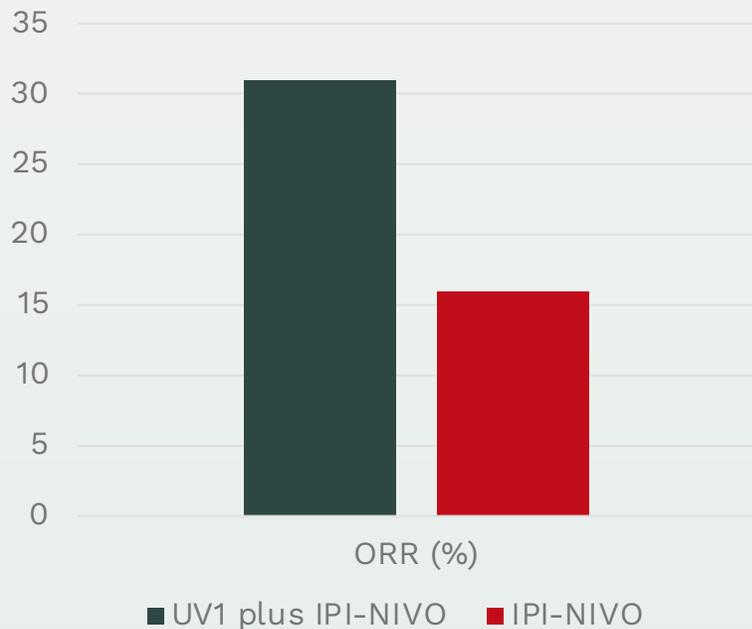
## UV1 Maintains an Excellent Safety Profile in the NIPU study

### **The addition of UV1 to IPI-NIVO was safe and did not noticeably increase occurrences of serious adverse events**

- In the NIPU trial, the percentage of patients with serious adverse events was similar in both arms
  - UV1 plus IPI-NIVO: 36 patients (61.0%)
  - IPI-NIVO: 35 patients (59.3%)

# Near doubling of ORR and clinically meaningful prolonged survival

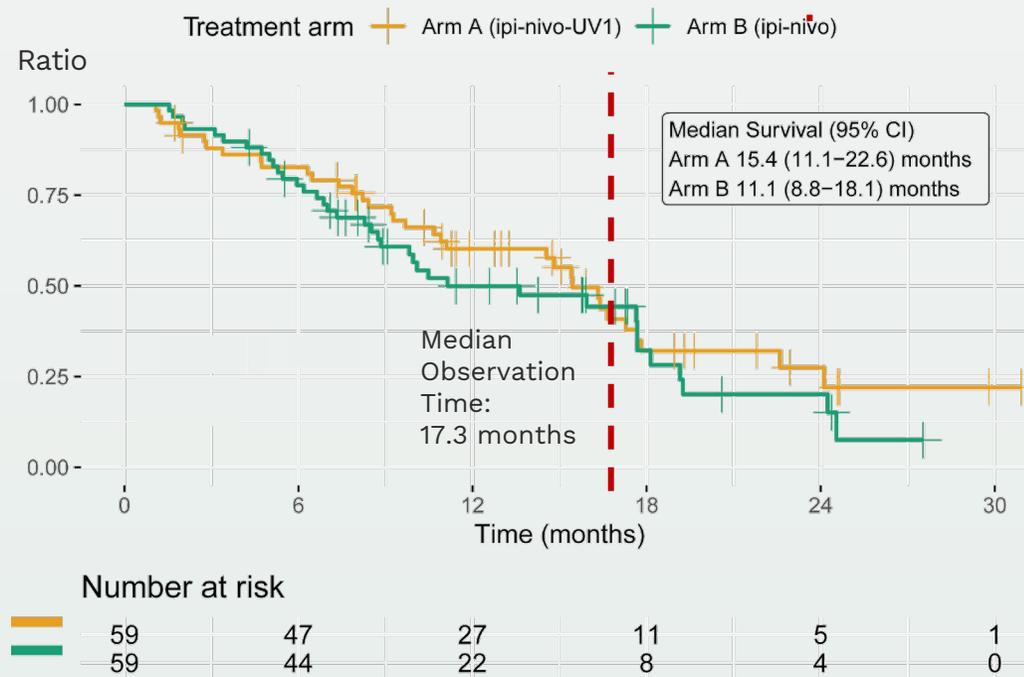
**Objective Response Rates (per BICR)**



**Objective Response Rate (per BICR)**

Arm A (UV1 plus IPI-NIVO): 31%  
 Arm B (IPI-NIVO): 16%  
 Odds Ratio 2.44 (80% CI, 1.35-4.49, 1-sided p value = 0.028)

**Overall Survival\***



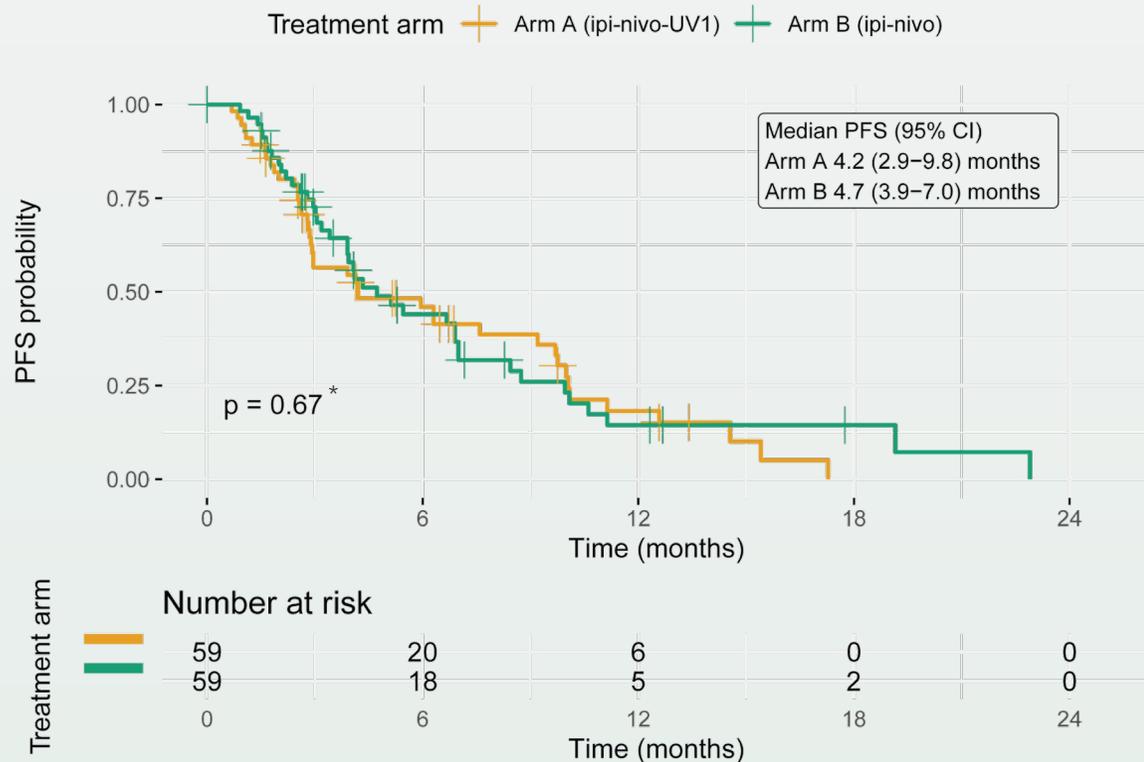
Number at risk: Number of patients confirmed alive at each given timepoint

**Overall Survival†**

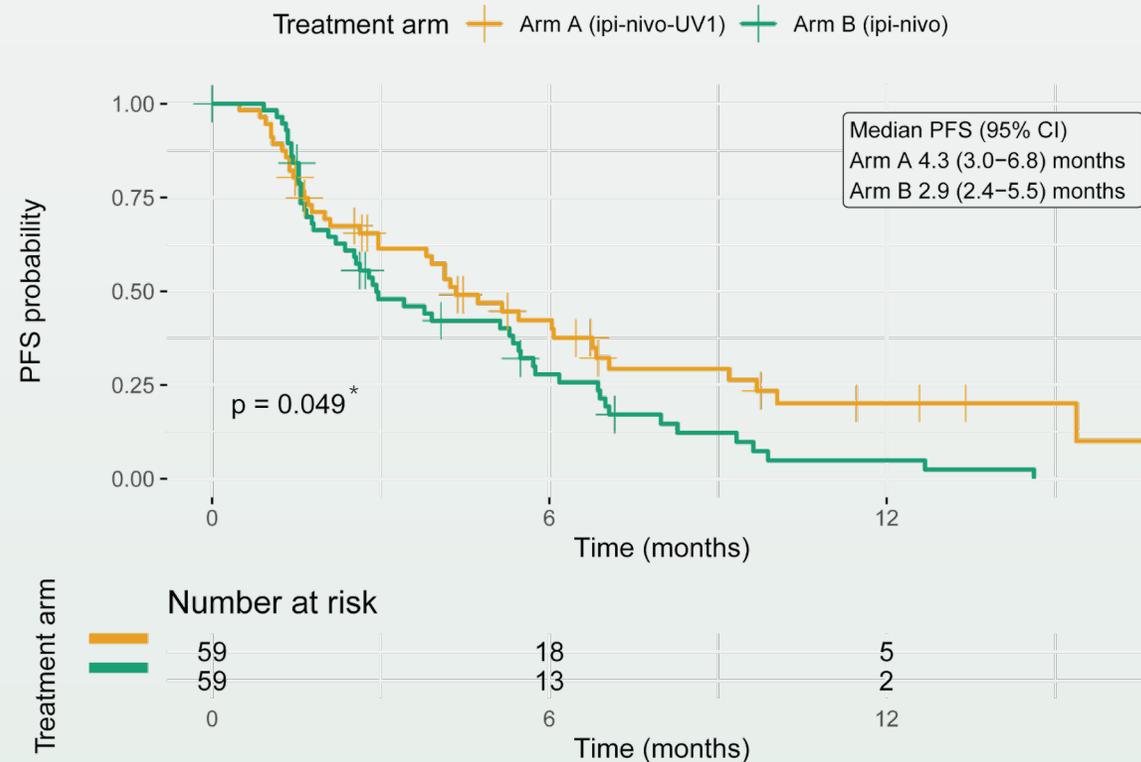
UV1 plus IPI-NIVO improved overall survival (OS), reducing the risk of death by 27% (HR=0.73 [80% CI, 0.53-1.00], 1-sided p value = 0.0985), with a median OS of 15.4 months (95% CI, 11.1-22.6) versus 11.1 months (95% CI, 8.8-18.1) for IPI-NIVO alone.

# Progression-free survival (PFS) reported by BICR and Investigator Assessment

**Blinded Independent Central Review (BICR)**



**Investigator Assessment**



**Progression-free survival based on BICR<sup>†</sup>**  
 HR = 1.01 (80% CI 0.75–1.36, 1-sided p value = 0.4895)

**Progression-free survival based on Investigator Assessment**  
 HR = 0.60 (80% CI 0.45–0.81, 1-sided p value = 0.0125)

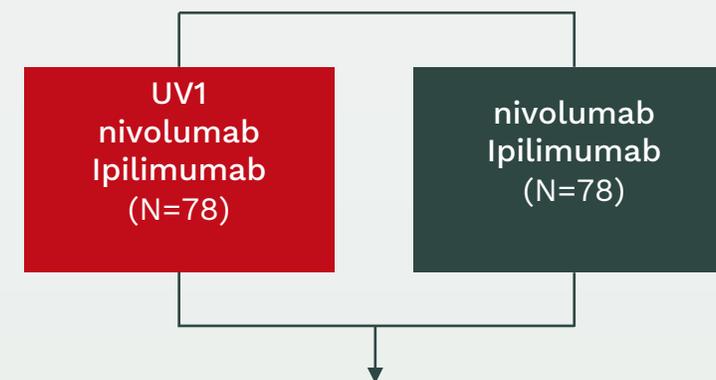
## Assessing next steps for UV1 in mesothelioma

- Ultimovacs management agrees with the trial investigators' recommendation to advance UV1 to the next phase of development
- Ultimovacs will
  - carefully evaluate the current results from NIPU together with more detailed analyses as well as more updated data as it matures
  - discuss with regulatory authorities and Key Opinion Leaders how these results should define the optimal way forward into a phase III trial
  - complete a market analysis as a basis for a possible decision to move into a UV1 Phase III trial in mesothelioma

# INITIUM – unresectable or metastatic malignant melanoma



- Sponsored by Ultimovacs
- Enrolled 156 patients from 39 sites in four countries: US, UK, Belgium and Norway.
- First patient enrolled June 2020, last patient enrolled in July 2022
- Supplementary single-arm study completed
  - Enrollment of 21 patients, treated with UV1 + ipi/nivo
  - Not included in topline results from INITIUM
  - Results will provide in-depth data on biological activity and mode of action of the vaccine induced T cells



**Primary endpoint**  
PFS

**Secondary endpoints**  
OS + ORR + DOR + safety

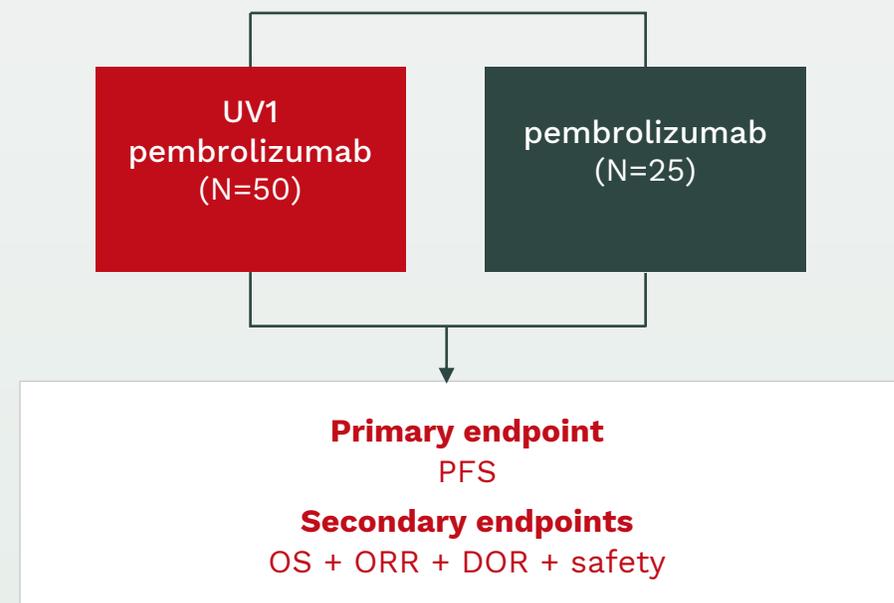
## INITIUM - updated timeline for topline readout

- Since it is taking longer than anticipated for the patients in the INITIUM study to experience cancer progression, the study protocol for INITIUM has been amended to enable data analysis to start in mid-January 2024, after
  - the last enrolled patient has been followed up for 18 months
  - the patients will have a median follow-up time of approximately 24 months
- The protocol amendment is based on acceptance by relevant regulatory authorities
- The amendment will maintain the integrity of the study statistics without materially affecting the scientific value of the clinical trial
- Topline readout of the trial expected approximately two to three months after mid-January 2024

# FOCUS - metastatic or recurrent head and neck squamous cell carcinoma



- Investigator-initiated trial sponsored by Halle University Hospital network, supported by Ultimovacs
- Enrolled 75 patients from ten sites in Germany
- First patient enrolled August 2021, last patient enrolled in August 2023
- FOCUS is a landmark study: The data will be analyzed 12 months after enrollment of the last patient
- **Topline results expected H2 2024**, which will include readout of all endpoints up to 12 months and the primary endpoint PFS at 6 months

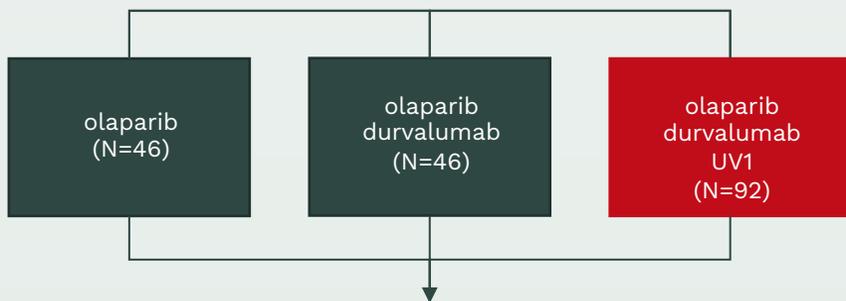


# DOVACC and LUNGVAC UV1 Phase II Trials

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



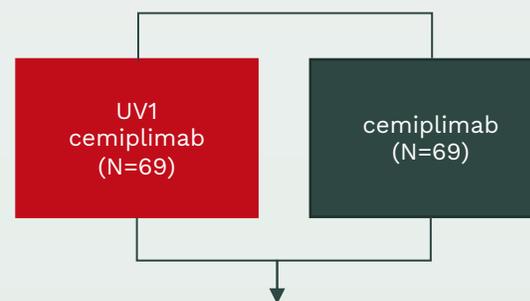
- **Combination:** olaparib, durvalumab
- **Contributors:** NSGO/ENGOT (sponsor), AstraZeneca
- **Patients:** 184 from more than 40 sites in more than 10 European countries
- **Recruitment:** 25%
- First patient enrolled December 2021
- 46 patients enrolled as of November 7, 2023 (Q3 2023 reporting)
- **Milestones:** Topline results expected H2 2024 (to be updated in Q4 reporting)



## 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
- 13 patients\* enrolled as of November 7, 2023 (Q3 2023 reporting)
- **Milestones:** Topline results expected H2 2025 (to be updated in Q4 reporting)



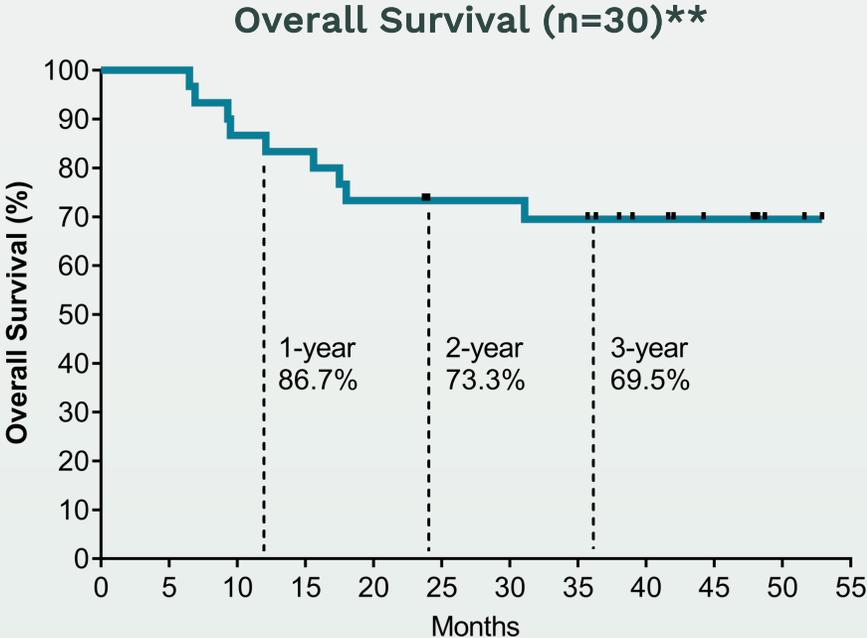
**Primary endpoint: PFS**

**Secondary endpoints: OS + ORR + DOR + safety**

# Sustained long-term overall survival in Phase I trial UV1-103 in malignant melanoma patients treated with pembrolizumab and UV1 vaccination

## Overall survival (OS)

- Cohort 1+2 combined after 12 months: 86.7%
- Cohort 1+2 combined after 24 months: 73.3%
- Cohort 1+2 combined after 36 months: 69.5%
  
- Cohort 1\* after 48 months: 73.8%
- No confirmed deaths between 3-year and 4-year follow-up

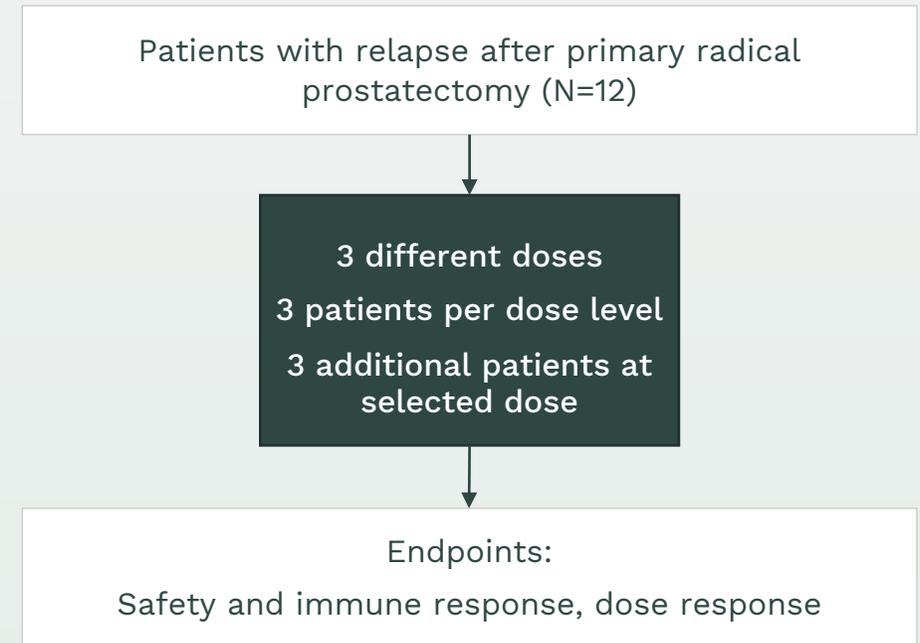


- Median progression free survival (mPFS): 18.9 months
- UV1 has demonstrated a good safety profile; no unexpected safety issues have been observed in the trial
- Patients will continue to be followed for long-term survival

\* 4-year follow-up of cohort 1+2 combined will be reported Q2 2024  
\*\* Published in Ellingsen et al, Clinical Cancer Research (2023)

# The TENDU phase 1 trial: First clinical evaluation of the TET technology

- 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
- Conducted at Oslo University Hospital
- Enrollment of 12 patients completed
- Study results will be reported during **Q4 2023**
- No safety concerns to date



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# Q3 2023 Key Financials

## Cash and liquidity

- MNOK 300/MUSD 27 in cash by end of Q3 2023
- Expected financial runway to H2 2024, through the topline readouts in INITIUM and FOCUS

## EBIT and PBT

- EBIT: Q3 2023 MNOK -55 and YTD 2023 MNOK -156
- Profit before tax: Q3 2023 MNOK -56 and YTD 2023 MNOK -133

## Operating expenses – development and variations

- Payroll expenses: Underlying salary expenses fairly stable, but some quarterly variations in total personnel expenses due to share price driven allowances related to the share option program
- R&D and IPR expenses: Higher level than previous year driven by clinical trial activities and manufacturing (CMC) activities, but level in Q3 2023 clearly lower than Q2 2023 illustrating the significant quarterly variations in these costs.
- Going forward, the operating expense level should be expected to continue at a fairly high level, with quarterly variations, driven by further progress in and finalization of the phase II trials, CMC development and other R&D activities.

# Key financials

## Key financials per Q3-2023 - Ultimovacs Group

NOK (000)	Q3-22	Q3-23	YTD22	YTD23	FY22
<b>Total revenues</b>	-	-	-	-	-
Payroll and payroll related expenses	14 112	24 518	39 836	49 879	71 466
- Payroll expenses not incl. option costs and grants	13 979	14 751	36 486	40 211	50 878
- Share option costs and public grants	133	9 767	3 351	9 668	20 589
External R&D and IPR expenses (incl. grants)	24 743	26 831	55 740	91 482	91 029
Other operating expenses (incl. depreciation)	5 200	3 356	15 800	14 748	21 135
<b>Total operating expenses</b>	<b>44 055</b>	<b>54 705</b>	<b>111 376</b>	<b>156 109</b>	<b>183 631</b>
<b>Operating profit (loss)</b>	<b>-44 055</b>	<b>-54 705</b>	<b>-111 376</b>	<b>-156 109</b>	<b>-183 631</b>
Net financial items	5 752	-1 117	14 097	22 801	15 839
<b>Profit (loss) before tax</b>	<b>-38 303</b>	<b>-55 822</b>	<b>-97 279</b>	<b>-133 308</b>	<b>-167 792</b>
Net increase/(decrease) in cash and cash eq.	-29 726	-37 583	-106 070	-138 721	-155 426
<b>Cash and cash equivalents at end of period</b>	<b>469 063</b>	<b>300 273</b>	<b>469 063</b>	<b>300 273</b>	<b>425 309</b>
Number of FTEs at end of period	23	24	23	24	23

- Net cash of MNOK 300 by the end of Q3 2023

## Comments:

### Payroll expenses

- Total payroll expenses were higher in Q3 2023 and YTD23 compared to same periods the previous year:
  - Regular salary costs were higher in Q3 2023 and YTD23 compared to same periods in 2022 primarily due to one more FTE in 2023 and annual salary adjustment per January 2023.
  - Share option expenses incl. social security tax accrual related to share options, which fluctuates with the company share price, explains most of the difference in total payroll costs between the quarters and YTD periods.

### External R&D and IPR expenses

- R&D costs were slightly higher in Q3 2023 and significantly higher in YTD23 compared to the same periods in 2022, with the main contributors to the increase being the INITIUM and NIPU clinical trials and manufacturing (CMC) activities.

### Other operating expenses

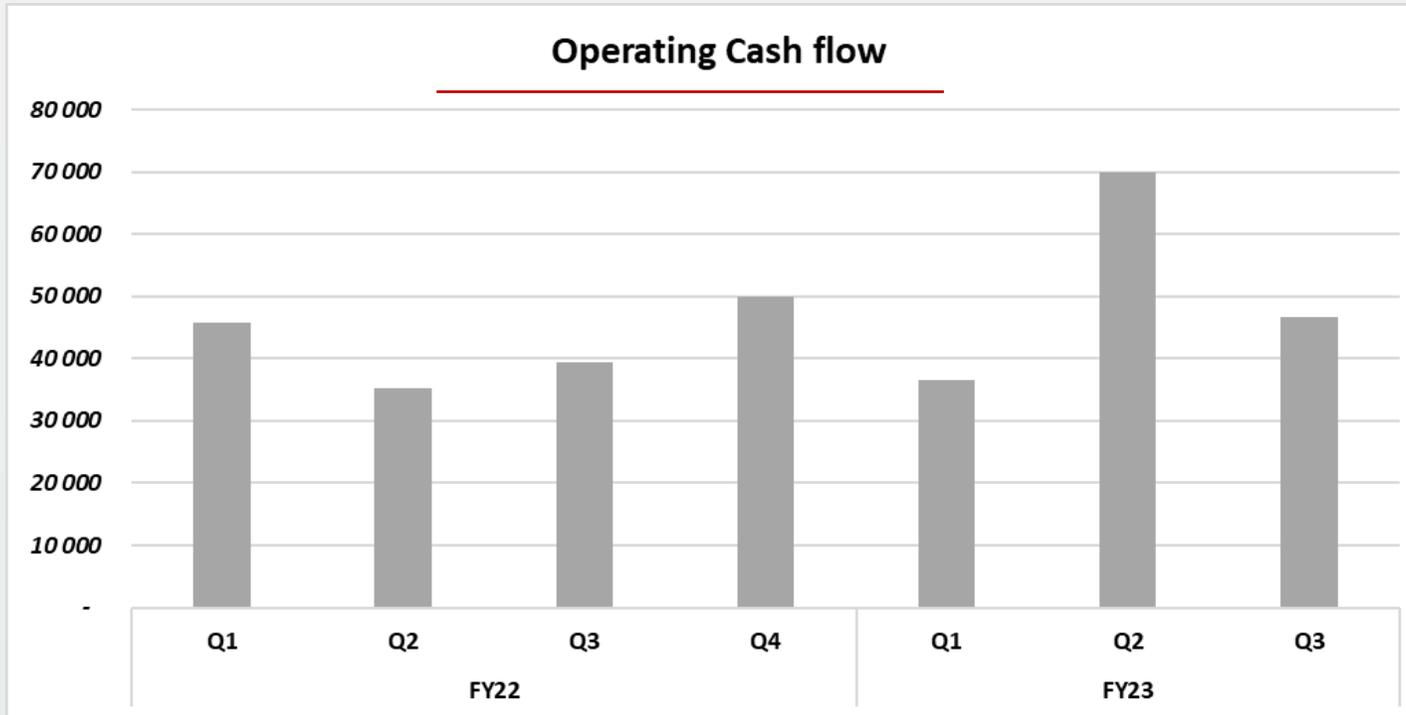
- A slight decrease from the previous year

### Net financial items

- Comprised primarily of interest from bank and net foreign exchange losses (from EUR account and EUR/NOK future contracts)

# Key financials – quarterly operating cash flow

NOK (000) – Negative amounts



## Comments:

- Negative operating cash-flow in Q3 2023 was appr. MNOK -47, less than EBIT of -55 due to changes in working capital and the non-cash share option cost element
- Continued 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

**Note:** excluding incoming public grants

# Key financials – quarterly overview

## Key financials per Q3-2023 - Ultimovacs Group

<b>NOK (000)</b>	<b>Q1-22</b>	<b>Q2-22</b>	<b>Q3-22</b>	<b>Q4-22</b>	<b>Q1-23</b>	<b>Q2-23</b>	<b>Q3-23</b>
<b>Total revenues</b>	-	-	-	-	-	-	-
Payroll and payroll related expenses	11 384	14 340	14 112	31 630	21 002	4 359	24 518
- Payroll expenses not incl. option costs and grants	13 406	9 100	13 979	14 392	14 652	10 808	14 751
- Share option costs and public grants	-2 022	5 239	133	17 238	6 350	-6 449	9 767
External R&D and IPR expenses (incl. grants)	14 725	16 272	24 743	35 289	23 707	40 944	26 831
Other operating expenses (incl. depreciation)	5 791	4 810	5 200	5 335	6 053	5 338	3 356
<b>Total operating expenses</b>	<b>31 900</b>	<b>35 421</b>	<b>44 055</b>	<b>72 255</b>	<b>50 763</b>	<b>50 641</b>	<b>54 705</b>
<b>Operating profit (loss)</b>	<b>-31 900</b>	<b>-35 421</b>	<b>-44 055</b>	<b>-72 255</b>	<b>-50 763</b>	<b>-50 641</b>	<b>-54 705</b>
Net financial items	-4 699	13 045	5 752	1 742	16 652	7 266	-1 117
<b>Profit (loss) before tax</b>	<b>-36 600</b>	<b>-22 376</b>	<b>-38 303</b>	<b>-70 513</b>	<b>-34 111</b>	<b>-43 375</b>	<b>-55 822</b>
Net increase/(decrease) in cash and cash equivalents*	-44 507	-31 837	-29 726	-42 137	-33 952	-67 185	-37 583
<b>Cash and cash equivalents at end of period</b>	<b>523 706</b>	<b>486 338</b>	<b>469 063</b>	<b>425 309</b>	<b>405 528</b>	<b>344 104</b>	<b>300 273</b>
Number of FTEs at end of period	23	23	23	23	24	24	24

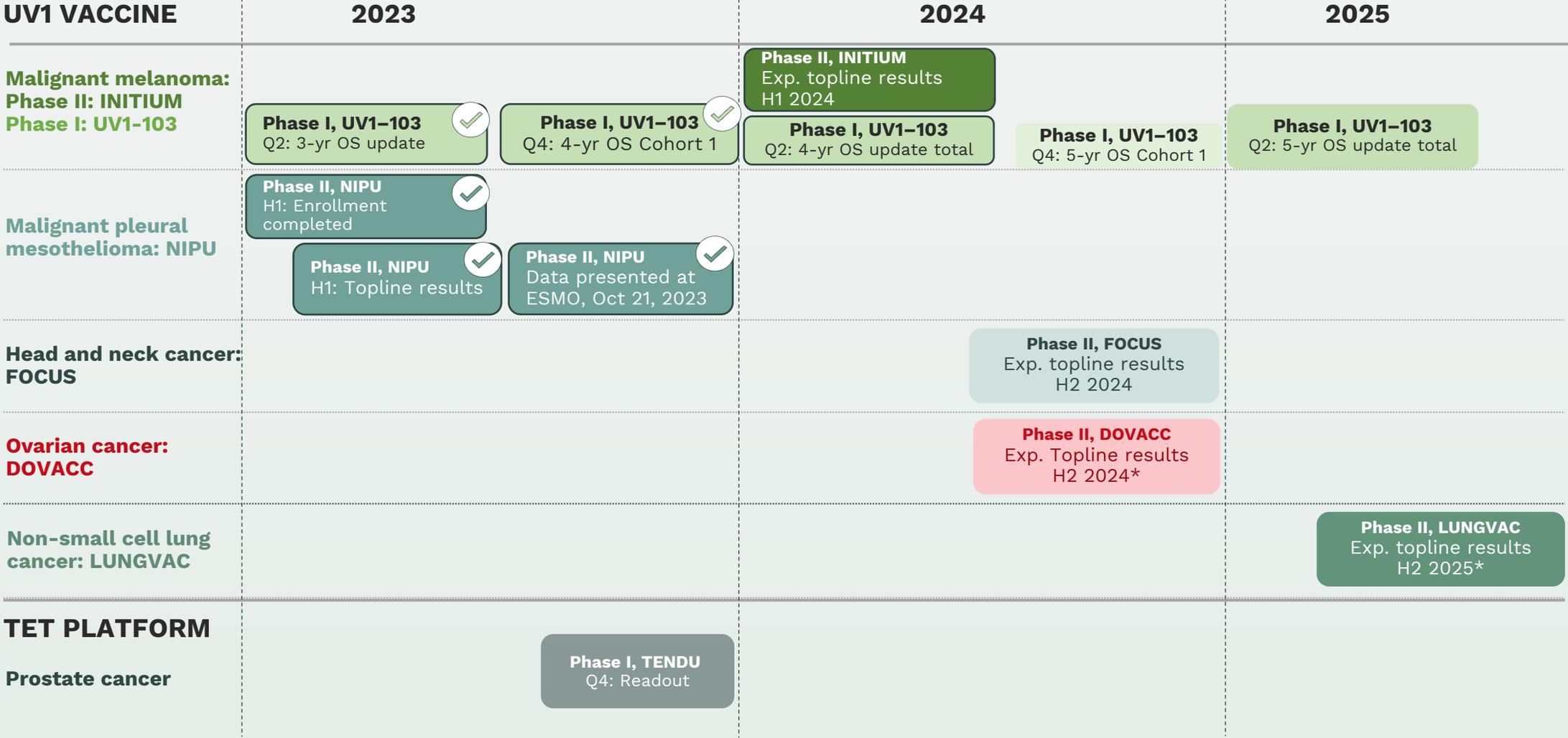
\*not including effects of change in exchange rate

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# Newsflow & milestones: Key value inflection points during the next year and within current financial runway



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

# Key take-aways and next steps

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- Encouraging data from NIPU, first randomized Phase II trial in the broad UV1 clinical program
- Malignant mesothelioma is a hard-to-treat cancer, with UV1 results exceeding expectations
- Discussing with regulatory authorities and Key Opinion Leaders regarding the path forward for UV1 in mesothelioma
- Preparing for analysis of data from the second randomized Phase II trial, INITIUM, to start in mid-January 2024
- FOCUS readout during H2 2024
- Readout timeline for DOVACC and LUNGVAC to be updated at Q4 2023 reporting
- TENDU results to be reported during Q4 2023
- Intensifying business development activities by sharing recent data with potential partners
- Expected financial runway to H2 2024, across data readout from the two next Phase II trials



Q&A

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