



Empower the Immune System to *Fight Cancer*

First Quarter 2024 Business Update and Financial Results

Ultimovacs ASA, May 7, 2024

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First quarter 2024 – Summary

- **We remain confident in UV1’s potential and are committed to bringing Ultimovacs across the next important data points, FOCUS and DOVACC results**
 - Positive Phase I data with UV1
 - NIPU: UV1 demonstrated clinically relevant beneficial differences in risk of death and objective response rates. Positive feedback from investigators and regulatory authorities.
 - Immunotherapies regularly fail in some indications while succeeding in other ones – it is standard development practice to evaluate multiple indications simultaneously, when MoA has broad potential
- **Phase II program: Data-driven approach with five randomized controlled trials in various indications. Near-term topline results expected from Phase II trials**
 - FOCUS: head and neck squamous cell carcinoma: Enrollment complete, readout expected *Q3 2024*
 - DOVACC: Second-line treatment of ovarian cancer: Enrolling, readout expected *H1 2025*
- **The negative INITIUM results have had important consequences for the Company. Implemented cash preservation initiatives extends the anticipated financial runway to the fourth quarter of 2025, beyond the anticipated topline readout of the FOCUS and DOVACC trials**

UV1 regulatory designations in mesothelioma

- **EMA Orphan Drug Designation** has been granted to UV1 for treatment of mesothelioma (February 2024)
- **FDA Fast Track Designation** has been granted for UV1 as add-on therapy to ipilimumab and nivolumab for treatment of malignant pleural mesothelioma (February 2024)
- **FDA Orphan Drug Designation** has been granted to UV1 for treatment of mesothelioma (October 2023)

Investigating UV1 across cancer indications and combinations

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



01

Clinical update

Phase II program: Capture Broad Potential and Right Development Path

- Positive Phase I data with UV1
 - Robust and long-lasting immune responses after UV1 vaccination
 - Apparent synergy with checkpoint inhibitors (CPIs)
 - Strong efficacy signals and beneficial safety profile support development in Phase II trials
- Strategy for clinical program in Phase II
 - Objectives: **Capture broad potential and right development path for UV1**
 1. Multiple trials in different indications where telomerase is expressed
 2. Multiple endpoints to capture UV1 efficacy and define the best Phase III design
 3. Multiple CPI combinations – both dual and single agent
 4. Extensive patient tissue sampling to characterize treatment effect

Rationale behind different combination approaches

Anti-CTLA-4 and PD-1

INITIUM and NIPU trials

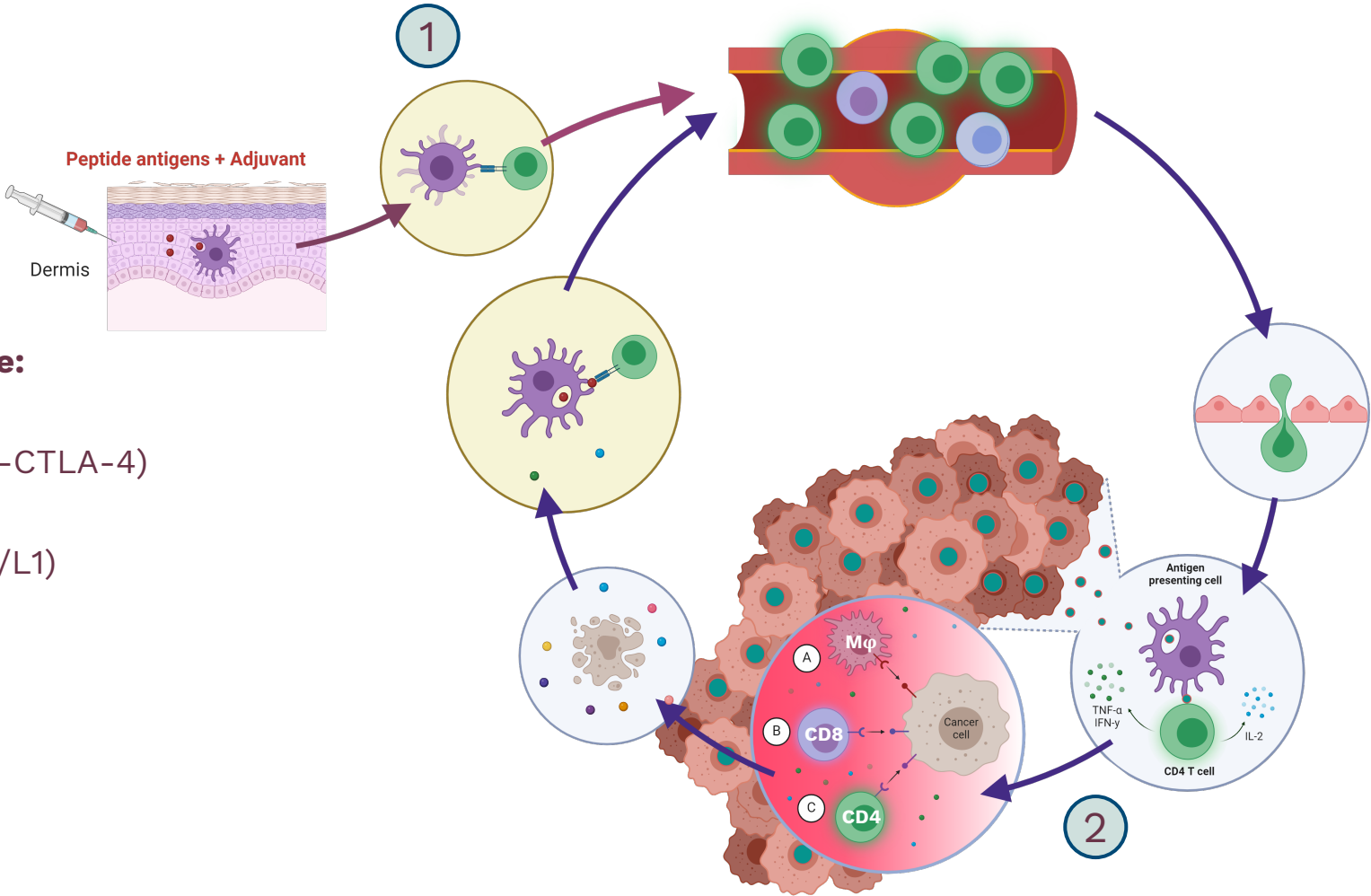
- Most effective SoC immunotherapy in immunogenic solid tumors
 - Represents an opportunity to improve on best-in-class CPIs thereby setting a new efficacy standard
 - Higher hurdle to improve efficacy (already a high bar)
- Mechanistically, anti-CTLA-4 is hypothesized to generate stronger vaccine-induced T cell responses
- The CPI combination comes with significant toxicities and current indications are limited

Anti-PD-1/L1

FOCUS, DOVACC, and LUNGVAC trials

- Widely established SoC in multiple indications (>35)
- Lack of anti-tumor T cell responses firmly established as an efficacy bottleneck
 - Strong rationale for adding UV1 to strengthen and extend efficacy to more patients (e.g. PD-L1 negative as in the 103 trial)
- Additional treatments on top of PD-1/L1 have been shown to improve outcomes for patients as compared to PD-1/L1 alone
- Lower hurdle to improve efficacy
- Competitive space with multiple agents being tested in combination with PD-1 vs. PD-1 alone

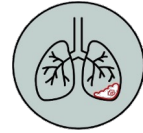
Rationale behind different combination approaches



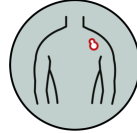
Immune checkpoint blockade to improve:

- 1 T cell priming and expansion (anti-CTLA-4)
- 2 T cell effector function (anti-PD-1/L1)

A wide-ranging randomized controlled UV1 Phase II program



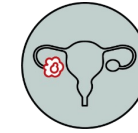
NIPU



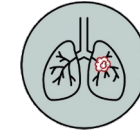
INITIUM



FOCUS



DOVACC



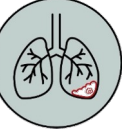
LUNGVAC

	NIPU	INITIUM	FOCUS	DOVACC	LUNGVAC
Indication	Second line mesothelioma	First line malignant melanoma	First line head and neck cancer	Second line ovarian cancer	First line non-small cell lung cancer
Immunotherapy combination +/- UV1	Ipilimumab Nivolumab	Ipilimumab Nivolumab	Pembrolizumab	Durvalumab Olaparib	Cemiplimab
Study conduct	118 patients 6 sites 5 countries Europe, Australia	156 patients 39 sites 4 countries Europe, US	75 patients 10 sites Germany	184 patients 35 sites 10 countries Europe	138 patients 9 sites Norway
Enrollment status				>50%	20%
Topline results	Announced October 2023	Announced March 2024	Q3 2024	H1 2025	H1 2026

Primary endpoint: Progression-free survival

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

NIPU: Second-line malignant pleural mesothelioma



Sponsor: Oslo University Hospital

Contributors: BMS, Ultimovacs

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

[NCT04300244](#)

2L malignant metastatic pleural mesothelioma

N=118

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

UV1
Ipilimumab
Nivolumab
(N=59)

Ipilimumab
Nivolumab
(N=59)

Primary endpoint:

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

Secondary endpoints:

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

Status:

Enrollment completed between June 2020 and January 2023

Milestones:

Results presented at the ESMO Congress in Madrid, October 2023

Encouraging response rate and survival outcomes

No added toxicity compared to ipilimumab and nivolumab alone

- Safety profile of UV1 plus ipilimumab and nivolumab is comparable to that of ipilimumab and nivolumab alone

Primary endpoint progression-free survival not met according to BICR

- Analysis of progression-free survival (PFS) failed to demonstrate statistical significance according to blinded independent central review (BICR). Investigator assessment performed as a pre-defined supportive analysis at the study hospitals, showed an improved PFS in patients receiving UV1 vaccination for all histological subtypes combined, and for the epithelioid subtype especially (Eur J Cancer March 2024)

Clinically relevant improvements on secondary endpoints:

- Improved survival: The combination UV1 plus ipilimumab and nivolumab improved overall survival, reducing the risk of death by 27%
- Reduced tumor burden: The combination UV1 plus ipilimumab and nivolumab gave an objective response rate of 31%, as compared to 16% with ipilimumab and nivolumab alone (per BICR)
- Granted **FDA Fast Track Designation and EMA Orphan Drug designation** based on the trial results

Conclusion:

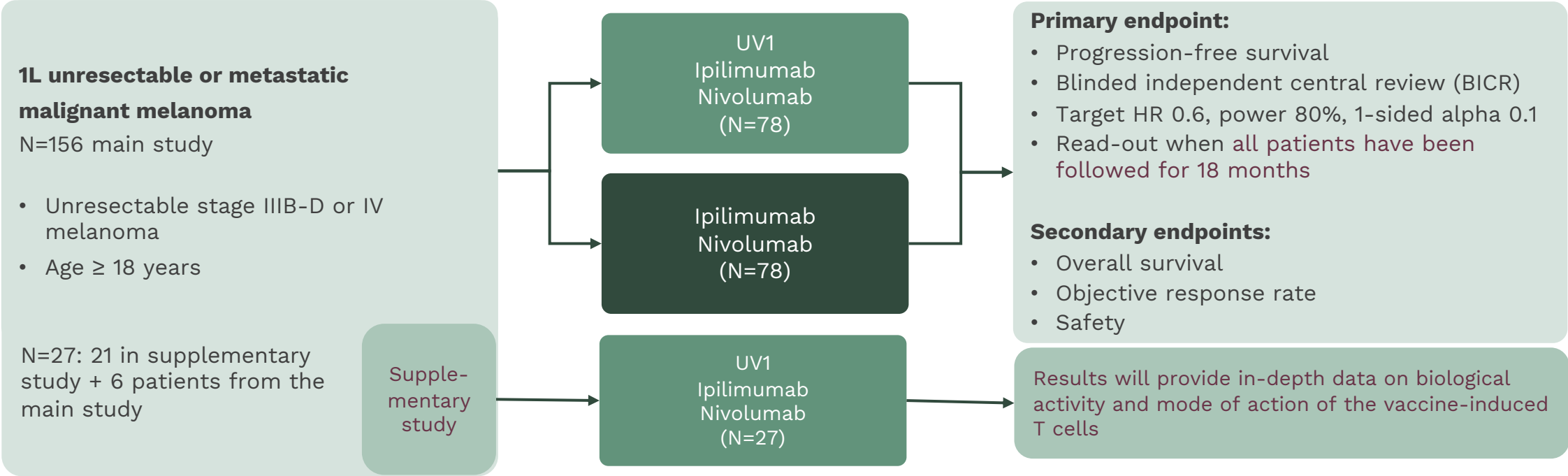
- Lead investigators conclusion and regulatory authority feedback warrant further development of UV1 in mesothelioma

INITIUM: First-line advanced melanoma



Sponsor: Ultimovacs

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



Status:
 Enrollment completed between June 2020 – July 2022

Milestones:
 Topline results reported in March 2024, abstract will be presented at ASCO 2024 in June

Results from the INITIUM trial

No added toxicity compared to ipilimumab and nivolumab alone

- Safety profile of UV1 plus ipilimumab and nivolumab is comparable to that of ipilimumab and nivolumab alone

Topline read-out

- Ipilimumab and nivolumab demonstrated unprecedented and unexpected efficacy in this population based on historical data
- Primary and secondary endpoint results does not warrant further development of UV1 in combination with ipilimumab and nivolumab in unresectable advanced melanoma
- UV1 did not provide efficacy on top of ipilimumab and nivolumab in the INITIUM trial. Malignant melanoma is a highly immunogenic tumor type where expansion of T cells by ipilimumab and nivolumab only, may be sufficient to control tumor growth

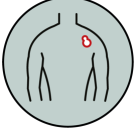
INITIUM Supplementary Study

- The study will provide in-depth data on biologic activity and mode of action of the T cells induced by the UV1 vaccination on top of ipilimumab and nivolumab.

Next in line: UV1 in combination with single agent PD-1/L1



NIPU



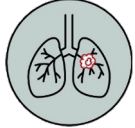
INITIUM



FOCUS



DOVACC



LUNGVAC

Indication

Second line mesothelioma

First line malignant melanoma

First line head and neck cancer

Second line ovarian cancer

First line non-small cell lung cancer

Immunotherapy combination +/- UV1

**Ipilimumab
Nivolumab**

**Ipilimumab
Nivolumab**

Pembrolizumab

**Durvalumab
Olaparib**

Cemiplimab

Study conduct

118 patients
6 sites
5 countries
Europe, Australia

156 patients
39 sites
4 countries
Europe, US

75 patients
10 sites
Germany

184 patients
35 sites
10 countries
Europe

138 patients
9 sites
Norway

Enrollment status



>50%

20%

Topline results

Announced
October 2023

Announced
March 2024

Q3 2024

H1 2025

H1 2026

Primary endpoint: Progression-free survival

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

FOCUS: First-line head and neck cancer



Sponsor: Halle University Hospital Network
Contributors: Ultimovacs
Sites and countries: 10 hospitals in Germany
[NCT05075122](https://clinicaltrials.gov/ct2/show/study/NCT05075122)

1L head and neck cancer
N=75

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

UV1
Pembrolizumab
(N=50)

Pembrolizumab
(N=25)

Primary endpoint:

- Progression-free survival rate at 6 months

Secondary endpoints:

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

Status:
Enrollment completed between August 2021 – August 2023

Milestones:
Topline results expected **Q3 2024**
Includes readout of all endpoints up to 12 months and primary endpoint at 6 months

FOCUS: Background

- Head and neck squamous cell carcinoma (HNSCC) refers to a group of malignancies arising from the linings of the head and neck region (oral cavity, pharynx, lip, sinuses, and salivary glands)
- HNSCC is the 7th most common cancer globally (appx. 890.000 new cases in 2020)
- Telomerase highly expressed to confer cancer cell survival in HNSCC
- Pembrolizumab considered a standard of care of first-line treatment of patients with PD-L1 positive (>1%) HNSCC

DOVACC: Relapsed ovarian cancer

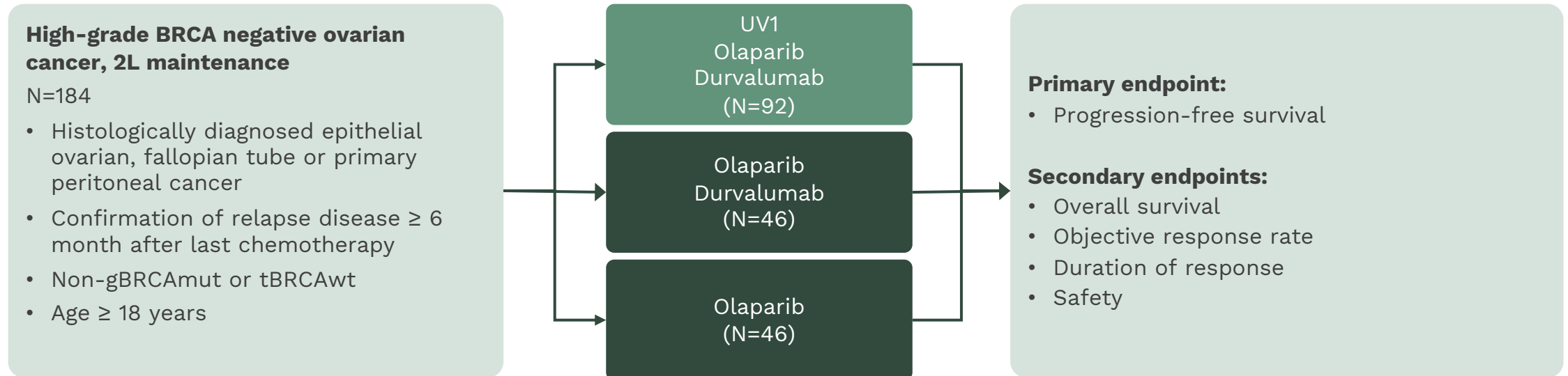


Sponsor: NSGO/ENGOT

Contributors: AstraZeneca, Ultimovacs

Sites and countries: 35 hospitals, 10 countries in Europe

[NCT04742075](#)



Status:

First patient enrolled in December 2021

Enrollment per Q1 2024 reporting: 99 patients (>50%)

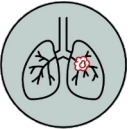
Milestones:

Topline results expected **H1 2025**

DOVACC: Background

- Ovarian cancer is a malignancy arising from surface epithelium in the ovaries. It is the second most common gynecologic malignancy and is the leading cause of death from gynaecological cancer.
- Ovarian cancer is the 18th most common cancer overall
- Standard treatment for advanced ovarian cancer include surgery, chemotherapy, PARP-inhibitors and bevacizumab.
- Several studies have shown added efficacy with parp-inhibitor and check point inhibitor combination
- Telomerase is highly expressed in ovarian cancer to confer cancer cell survival

LUNGVAC: First-line non-small cell lung cancer



Sponsor: Drammen Hospital
Contributors: Ultimovacs
Sites and countries: 9 hospitals in Norway
[NCT05344209](#)

1L advanced or metastatic non-small cell lung cancer
N=138

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

UV1
Cemiplimab
(N=69)

Cemiplimab
(N=69)

Primary endpoint:
Progression-free survival

Secondary endpoints:

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

Status:
First patient enrolled in October 2022
Enrollment per Q1 2024 reporting: 27 patients (20%)

Milestones:
Topline results expected **H1 2026**



02

Financial update

Q1 2024 Key Financials

Cash and liquidity

- MNOK 220/MUSD 20 in cash by end of Q1 2024
- Activity level prioritization and operational adjustments are implemented to sustain the financial runway, including a workforce reduction of approximately 40%.
- The cash preservation initiatives extend the anticipated cash runway to the fourth quarter of 2025, beyond the anticipated topline readout of the FOCUS and DOVACC trials.
- Based on current plans and forecast, the cash burn rate is estimated to be approximately 15 MNOK per quarter towards the end of 2025

EBIT and PBT

- EBIT: Q1 2024 MNOK -29
- Profit before tax: Q1 2024 MNOK -23

Operating expenses – development and variations

- R&D and IPR expenses: Slightly lower in Q1 2024 than the previous quarters
- Going forward, the operating expense level should be expected to continue at a fairly high level for some time, before operational adjustments and workforce reductions start having effect in the second half of 2024.

P&L and Cash

Key financials per Q1-2024 - Ultimovacs Group

NOK (000)	Q1-23	Q1-24	FY23
Total revenues	-	-	-
Payroll and payroll related expenses	21 002	-2 425	75 130
- Payroll expenses not incl. option costs and grants	14 652	15 445	56 314
- Share option costs and public grants	6 350	-17 871	18 816
External R&D and IPR expenses (incl. grants)	23 707	24 589	121 145
Other operating expenses (incl. depreciation)	6 053	6 484	19 460
Total operating expenses	50 763	28 647	215 736
Operating profit (loss)	-50 763	-28 647	-215 736
Net financial items	16 652	5 895	26 497
Profit (loss) before tax	-34 111	-22 752	-189 239
Net increase/(decrease) in cash and cash eq.	-33 952	-43 659	-177 640
Cash and cash equivalents at end of period	405 528	219 962	266 559
Number of FTEs at end of period	24	25	25

- Net cash of MNOK 220 by the end of Q1 2024

Comments

Payroll expenses

- Due to a significant one-off item, total payroll expenses were lower in Q1 2024 compared to Q1 2023 (a negative cost of MNOK 2.4 in Q1 2024 vs MNOK 21 in Q1 2023):
 - **Regular salary costs:** slightly higher in Q1 2024 compared to the same period in 2023, primarily due to one more FTE in 2024 and regular annual salary adjustment.
 - **Share option costs:** due to the significant drop in the company share price in Q1 2024, the social security tax accrual related to share options, which fluctuates with the Company share price, was fully reversed, resulting in a positive accounting effect of MNOK 21.0 (cost reduction). This accounting element explains most of the difference between Q1 2024 and Q1 2023.

External R&D and IPR expenses

- Approximately at the same level as in the corresponding quarter the previous year. The main drivers of R&D costs in Q1 2024 were the INITIUM trial and manufacturing (CMC) activities.

Other operating expenses

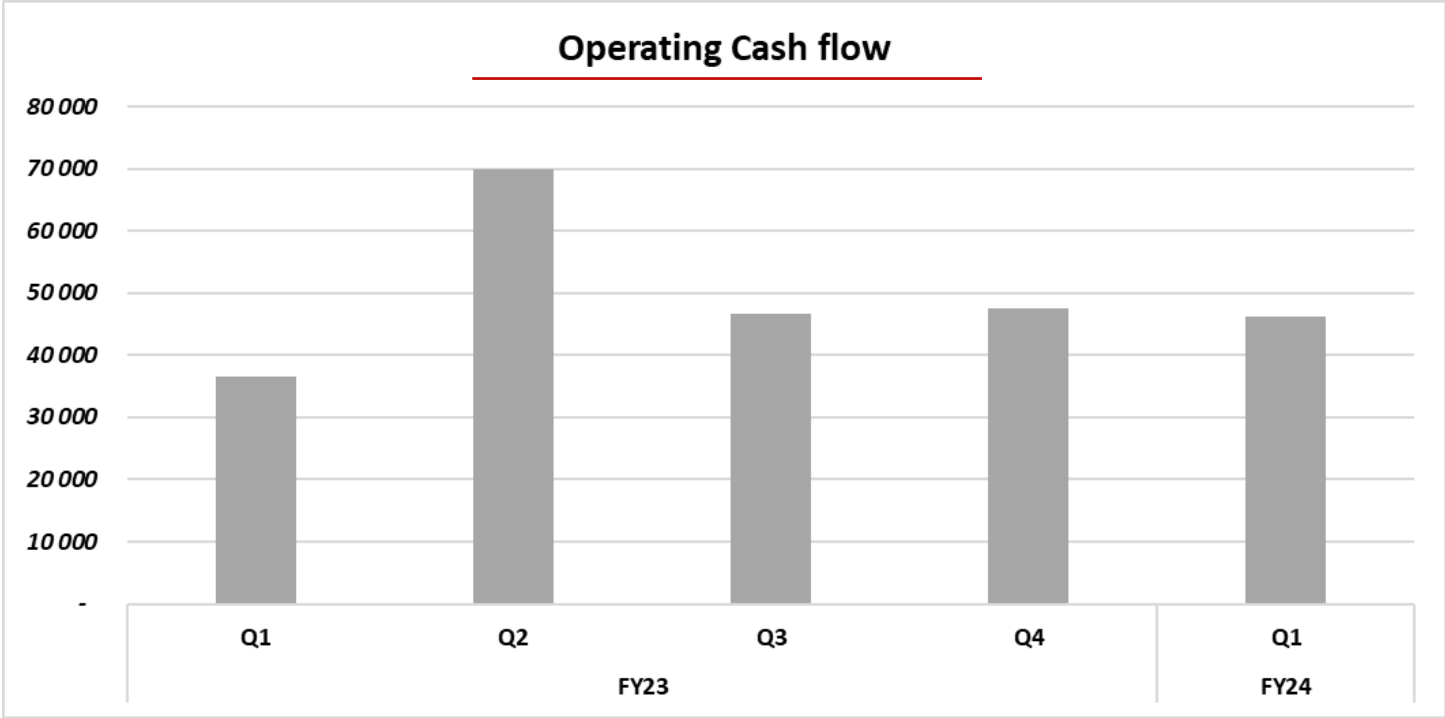
- No major changes from previous year

Net financial items

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

Quarterly operating cash flow

NOK (000) – Negative amounts



Note: excluding incoming public grants

Comments

- Negative operating cash-flow in Q1 2024 was appr. MNOK -46, higher than EBIT of MNOK -23, primarily due to the reversal of the social security tax approval related to share options of MNOK 21.
- Continued quarterly variations should be expected. It is, however, expected that the cash flow on average will decrease significantly the next quarters compared to previous quarters due to implementation of cash preservation initiatives and completion of activities.

Quarterly overview P&L and Cash

Key financials per Q1-2024 - Ultimovacs Group

NOK (000)	Q1-23	Q2-23	Q3-23	Q4-23	Q1-24
Total revenues	-	-	-	-	-
Payroll and payroll related expenses	21 002	4 359	24 518	25 251	-2 425
- Payroll expenses not incl. option costs and grants	14 652	10 808	14 751	16 103	15 445
- Share option costs and public grants	6 350	-6 449	9 767	9 148	-17 871
External R&D and IPR expenses (incl. grants)	23 707	40 944	26 831	29 663	24 589
Other operating expenses (incl. depreciation)	6 053	5 338	3 356	4 713	6 484
Total operating expenses	50 763	50 641	54 705	59 626	28 647
Operating profit (loss)	-50 763	-50 641	-54 705	-59 626	-28 647
Net financial items	16 652	7 266	-1 117	3 695	5 895
Profit (loss) before tax	-34 111	-43 375	-55 822	-55 931	-22 752
Net increase/(decrease) in cash and cash equivalents*	-33 952	-67 185	-37 583	-38 919	-43 659
Cash and cash equivalents at end of period	405 528	344 104	300 273	266 559	219 962
Number of FTEs at end of period	24	25	25	25	25

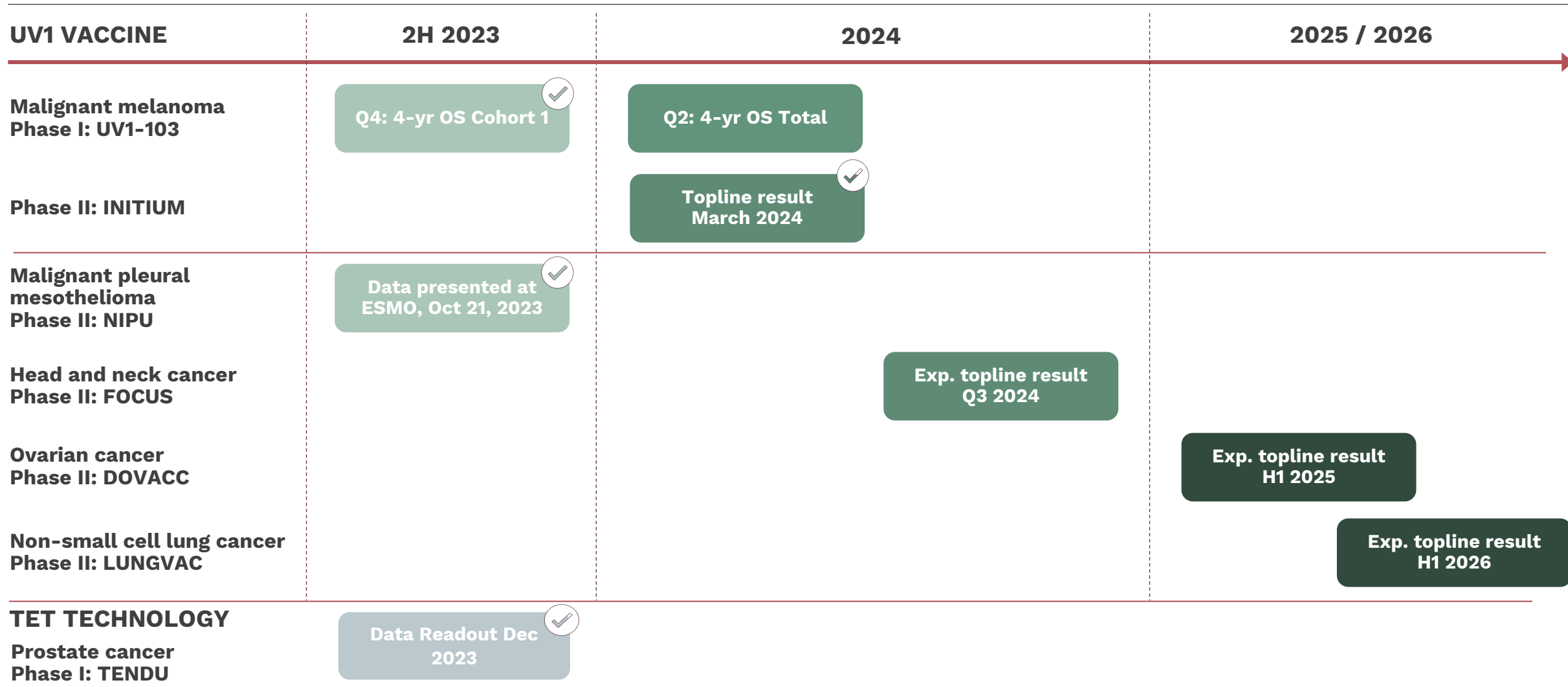
03

Newsflow



INTRODUCTION

Newsflow and milestones



Ultimovacs is Committed to Bringing UV1 Across the Next Major Value Inflection Points

- We remain confident in UV1's potential and are committed to bringing Ultimovacs across the next important data points, FOCUS and DOVACC results
- The investigators in the ongoing trials are also committed to bringing UV1 across the next important data points
- Our strategy for the development of UV1 that focuses on a Randomized Controlled Phase II program exploring diverse cancer types and immunotherapy combinations remains unchanged and proves that broad programs are important as we can expect different outcomes in a standard clinical development
- We are on course with our UV1 Phase II program: Data from the next Phase II trials with UV1 in various cancer indications, and as add-on to different immunotherapy combination, are expected in Q3 2024 and H1 2025
- The cash preservation initiatives extend the anticipated cash runway to the fourth quarter of 2025, beyond the anticipated topline readout of the FOCUS and DOVACC trials.

Q&A

