First Quarter 2023 Results

Ultimovacs ASA, 10 May 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***
- ***Near term key value inflection points; readouts from three randomized Phase II clinical trials within a year***

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***

Q1 2023 highlights: Prepared for multiple catalysts over the next months as the UV1 Phase II randomized clinical program advances

- A rigorous data-driven strategy towards regulatory approval
  - Lead product, universal cancer vaccine UV1, is investigated in five randomized, comparative Phase II clinical trials in cancers with different disease stages, tumor types, biology, and different treatment regimens, enrolling patients in Europe, the U.S. and Australia
- More than 50% of the 670 cancer patients in the five randomized Phase II clinical trials enrolled to date
- NIPU: Enrollment completed in Q1 2023, reiterates readout expected in **H1 2023**
  - INITIUM: Enrollment completed in Q2 2022, readout timeline extended and now expected in **H2 2023**
  - FOCUS: Enrollment on track > 80%, readout expected in **H1 2024**
  - DOVACC & LUNGVAC: Trials in early stage, readout expected H2 2024 and H2 2025
- Strengthened IP protection of lead asset
  - Notice of intention to grant patent on UV1 in combination with checkpoint inhibitors in Europe until at least 2037, in addition to the counterpart patent granted for the U.S. last year
- Continued expected runway until mid-2024 through readouts from three Phase II studies

Ultimovacs First Quarter 2023 presentation

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Broad Phase II program ongoing, will enroll more than 670 patients

	Indication	Checkpoint inhibitor(s)	Patients (#)	Recruited	Expected topline readout	Phase I	Phase II	Phase III	IIT Contributors
UV1	Malignant melanoma	*Ipilimumab*	*12*	*Completed*	*Completed*	*UV1-ipi*			
	Malignant melanoma	*Pembrolizumab*	*30*	*Completed*	*Completed*	*UV1-103*			
	Malignant melanoma	*Ipilimumab & nivolumab*	*156*	*Completed*	*H2 2023*		*INITIUM*		
	Pleural mesothelioma	*Ipilimumab & nivolumab*	*118*	*Completed*	*H1 2023*		*NIPU*		Bristol Myers Squibb[3], Oslo University Hospital
	Head and neck cancer	*Pembrolizumab*	*75*	*>80%[1]*	*H1 2024*		*FOCUS*		MARTIN-LUTHER-UNIVERSITÄT HALLE-WITTENBERG
	Ovarian cancer	*Durvalumab & olaparib*	*184*	*<20%[1]*	*H2 2024*		*DOVACC*		NSGO-CTU, AstraZeneca[3], ENGOT
	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*			

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 Q1 2023 reporting. 2: FOCUS, DOVACC and LUNGVAC: Readout estimates will be updated with the Q4 2023 report
3: Supply agreements. 4: As per 1 January 2023

Clinical program: Update on patient enrollments, per 9 May 2023

Clinical trial program	Enrollment and expected readout timeline
INITIUM (Phase II malignant melanoma):	***Enrollment of 156 patients completed***** ***Expected readout: H2 2023***
NIPU (Phase II pleural mesothelioma):	***Enrollment of 118 patients completed*** ***Expected readout: H1 2023***
FOCUS* (Phase II head and neck cancer):	***61 out of 75 patients enrolled (vs. 50 in Q4 2022)*** ***Expected readout: H1 2024***
DOVACC* (Phase II ovarian cancer):	***24 out of 184 patients enrolled (vs. 17 in Q4 2022)*** ***Expected readout: H2 2024***
LUNGVAC* (Phase II non-small cell lung cancer):	***7 out of 138 patients (vs. 2 in Q4 2022).*** ***Expected readout: H2 2025***
TENDU (Phase I prostate cancer):	***Enrollment of 12 patients completed*** ***Expected readout: H2 2023***

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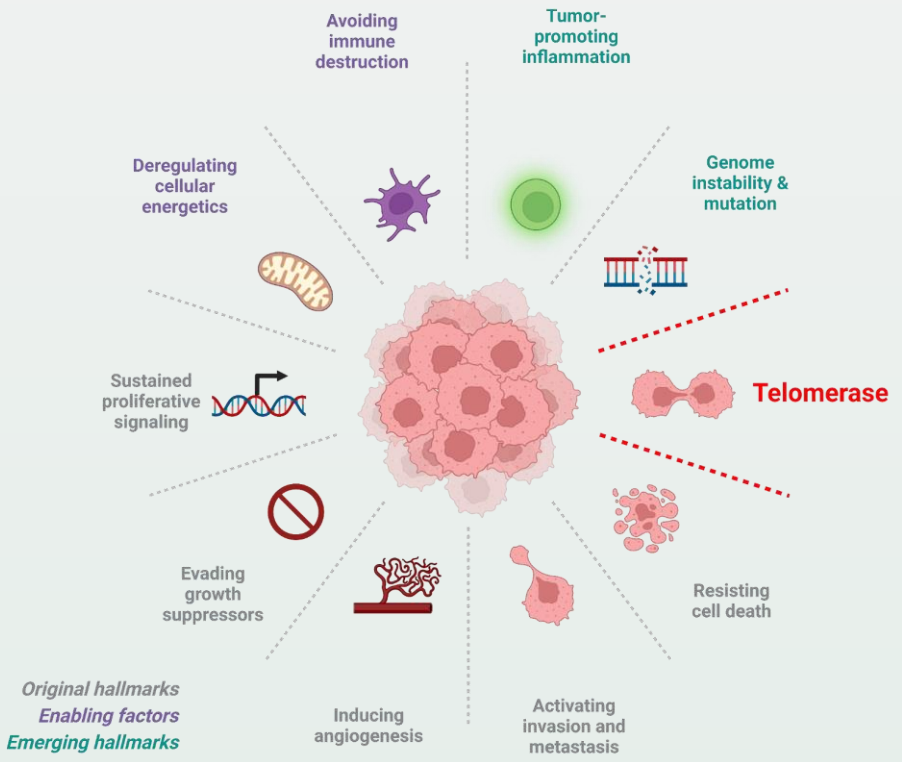
**** Expected readout timelines will be updated with the Q4 2023 reporting.***
***** Enrollment is ongoing in the single arm supplementary study. This will not impact the timeline for readout from INITIUM.***

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*

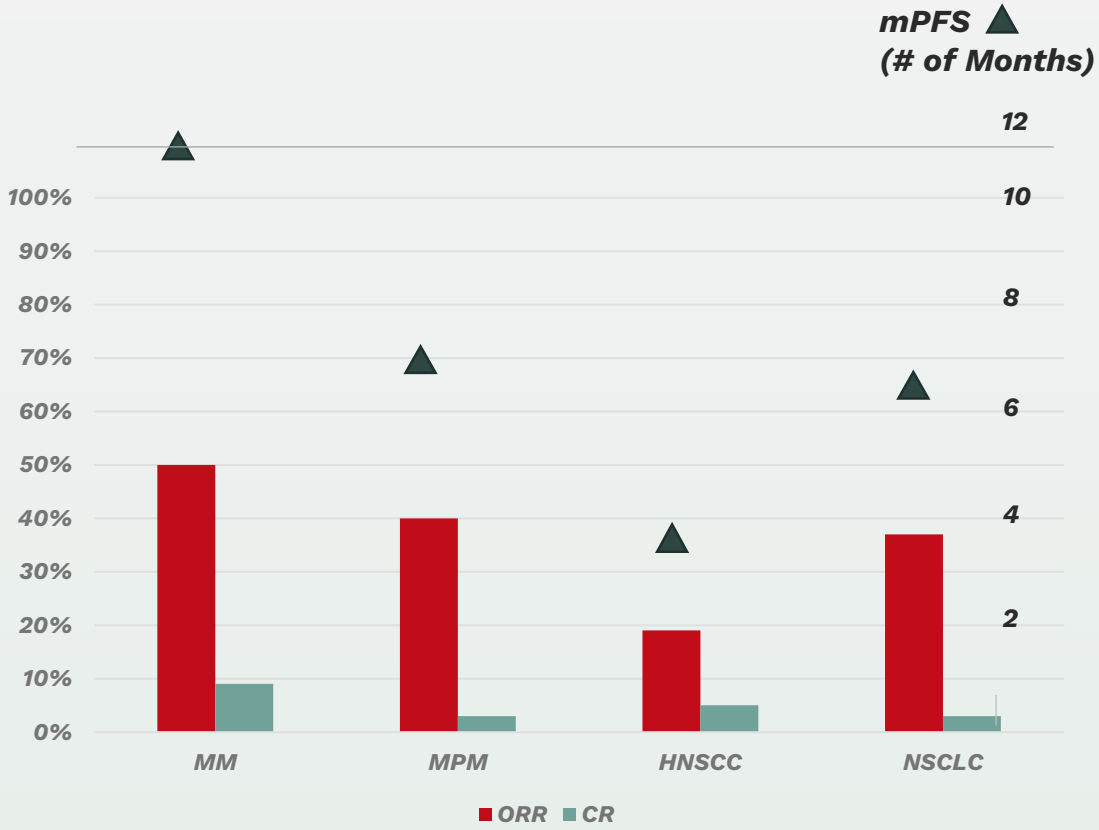
1. *Hanahan D et al. Cell (2011) - Figure created with Biorender.*
2. *Kim et al. Science (1994)*
3. *Shay et al. European Journal of Cancer (1997)*

UV1 Phase II program: a data-driven strategy towards regulatory approval

- Broad comparative clinical program investigating UV1 across various tumor types and diverse biology
- The objective is to understand if adding UV1 on top of checkpoint inhibitors:
  - Delays or avoids disease progression
  - Increases response to immunotherapy
  - Extends survival for cancer patients

Indication selection criteria:

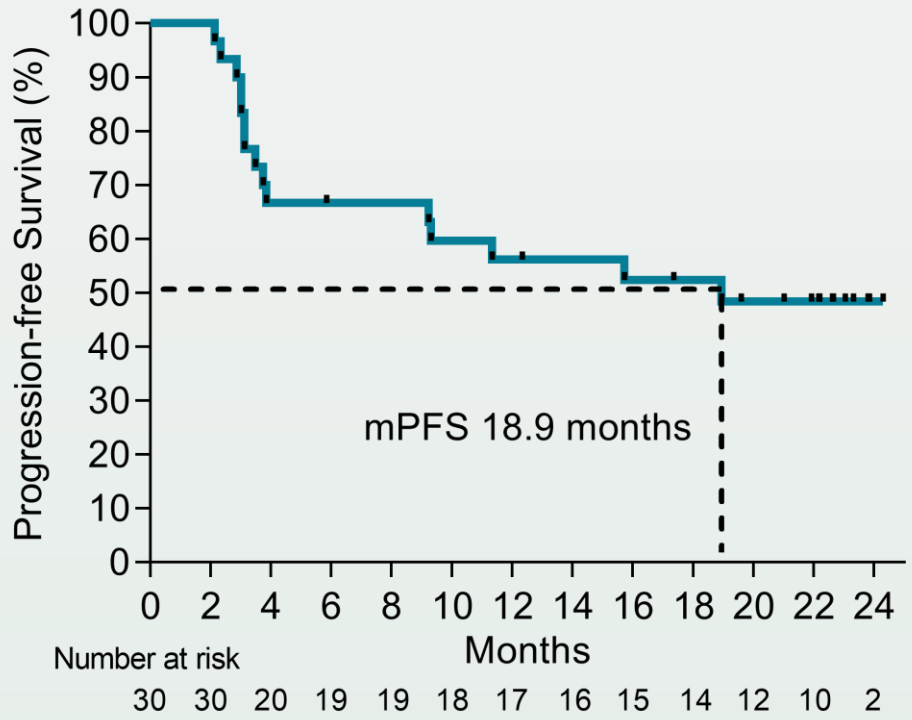
- ❑ Checkpoint inhibitors = Standard of Care
- ❑ Cancer express telomerase
- ❑ Unmet medical need



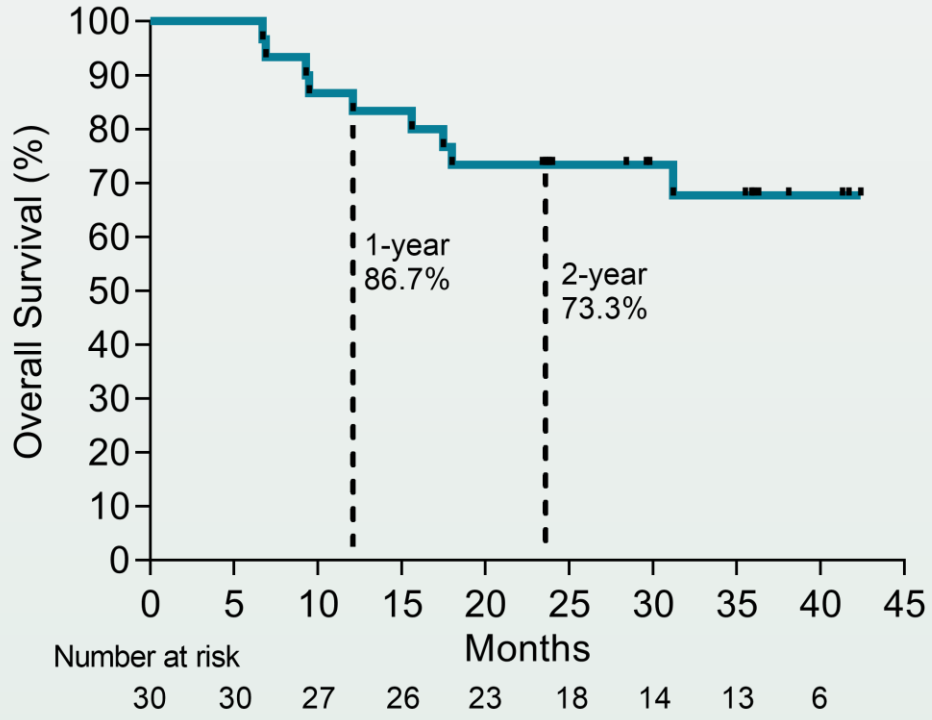
References:
Malignant Melanoma (MM): Checkmate 067
Malignant Pleural Mesothelioma (MPM): Checkmate 743 (First-line treatment)
Head and neck squamos cell carcinomas (HNSCC): Keynote 048
Non-Small Cell Lung Cancer (NSCLC): Study 1624
Ovarian Cancer: Not yet approved; Phase III DUO-O showed positive results

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

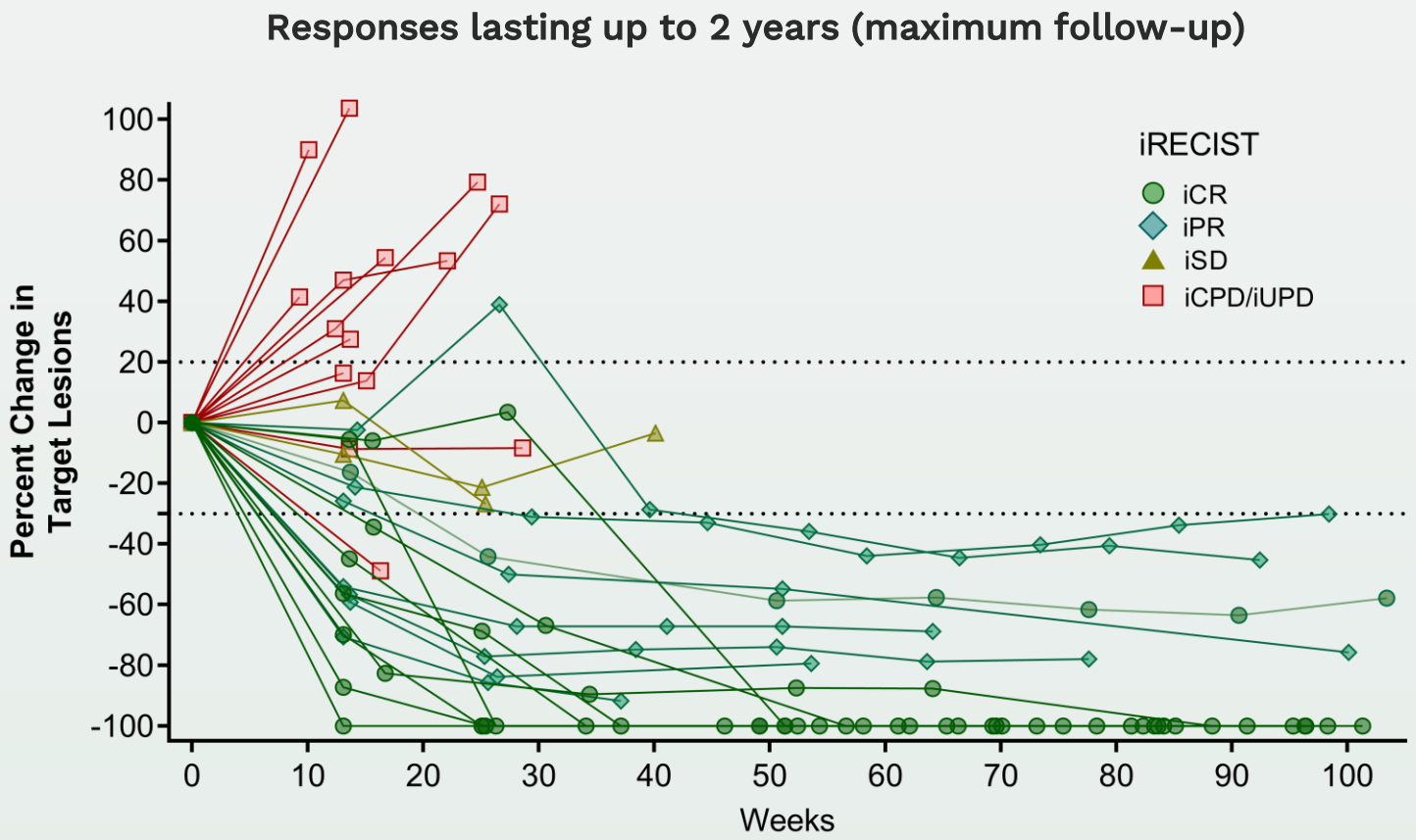
Progression-free Survival (n=30)



Overall Survival (n=30)



Deep and durable clinical responses to UV1 + pembrolizumab

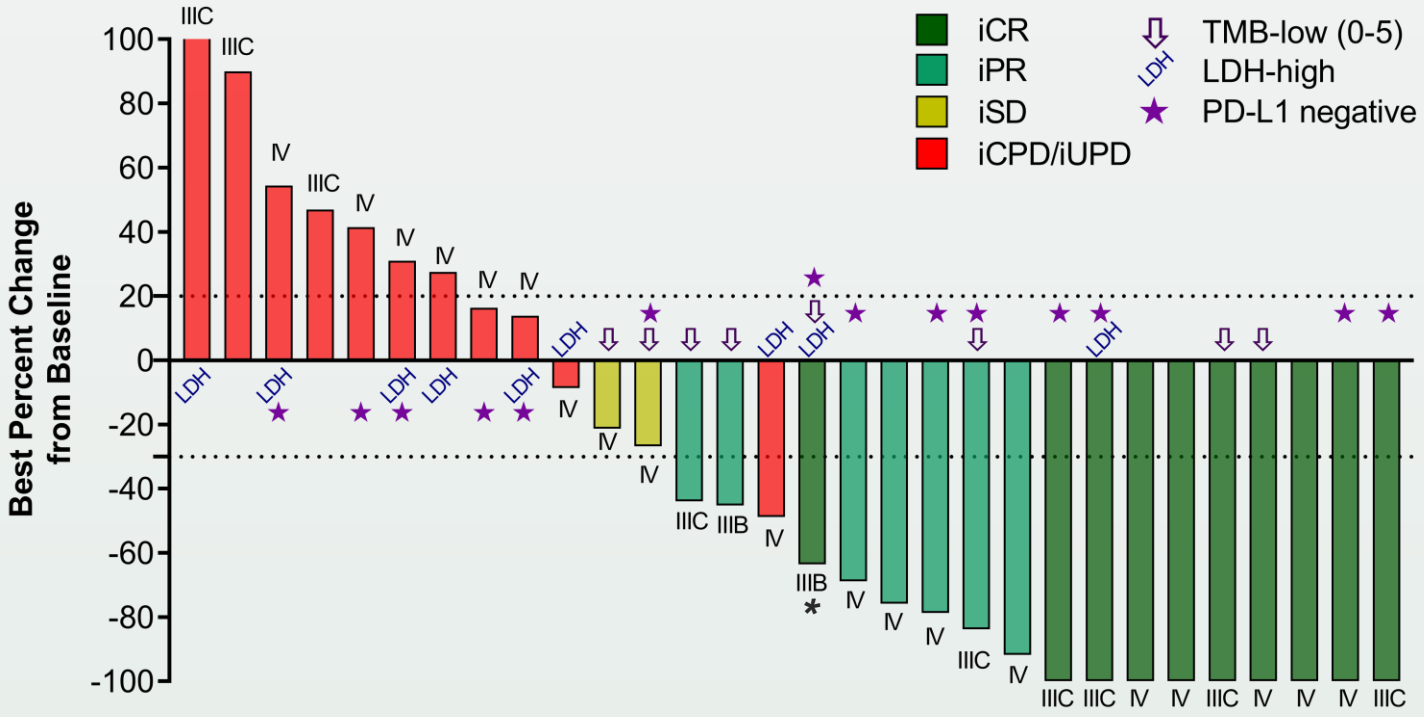


- ***Patients were followed with CT scans for up to two years***
- ***57% of patients achieved an objective response to the treatment (>30% reduction in tumor size)***
- ***33% of patients achieved complete response (complete disappearance of the tumor)***
- ***94% of the objective responses lasted more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

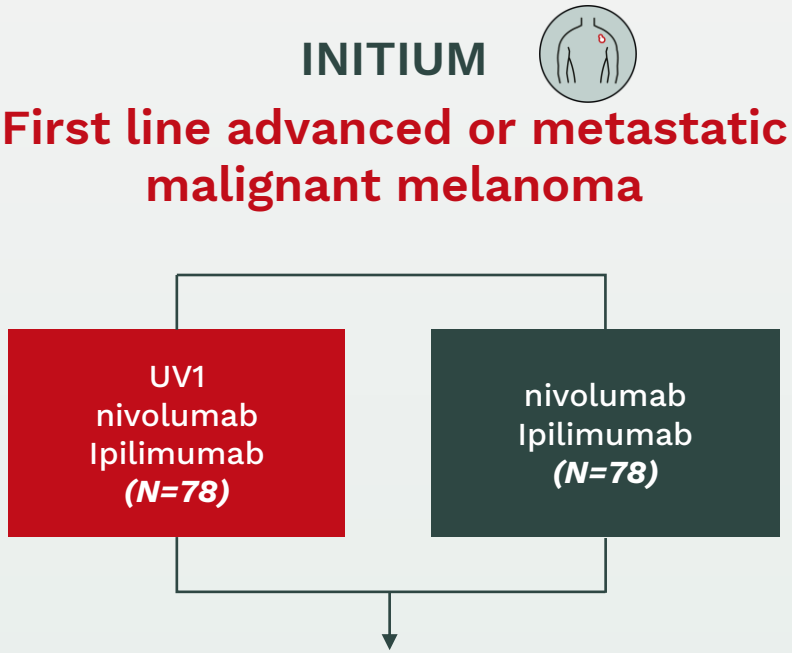
CR: 5-14% *CR PD-L1 neg: 5.8%*

** 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*

Updated timeline for readout from the UV1 Phase II INITIUM trial in malignant melanoma

- ***INITIUM is an Ultimovacs-sponsored randomized, Phase II trial, evaluating UV1 in combination with ipilimumab and nivolumab***
- ***156 patients with metastatic malignant melanoma were enrolled in the study between June 2020 and July 2022, in the U.S., U.K., Belgium and Norway***
- ***Results will be disclosed after cancer progression, or death, has been verified in 70 patients. Based on the clinical trial design and comparable historical data, the study results were anticipated during first half of 2023***
- ***However, it is taking longer than estimated for the patients in the INITIUM study to experience disease progression – which is positive for patients***
- ***Although Ultimovacs and the investigators do not have access to the data, we are optimistic and encouraged for the patients***
- ***The change in guidance has minor financial implications for Ultimovacs***
- ***Sub-study continues to enroll patients***

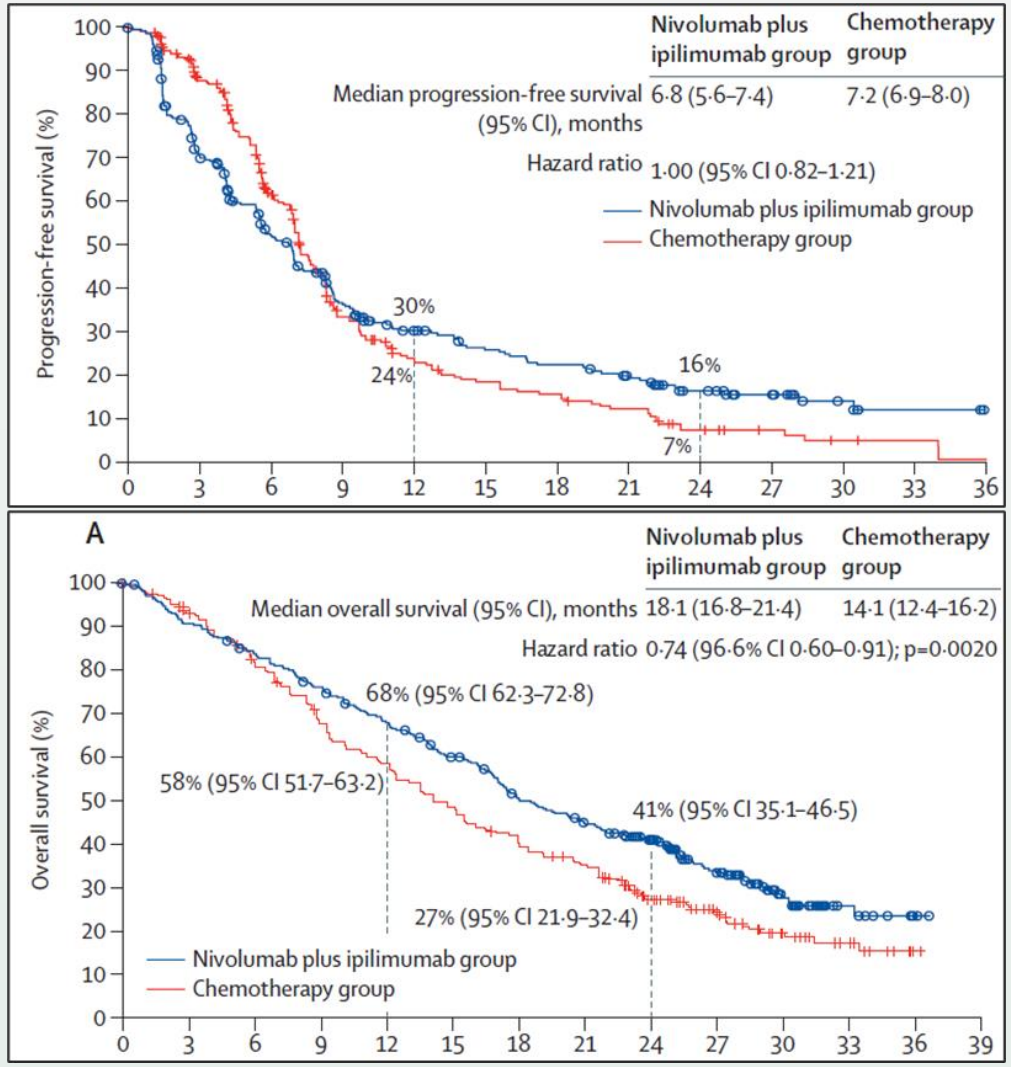


Primary endpoint: Progression Free Survival (PFS)

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

About Malignant Pleural Mesothelioma

- MPM is considered an aggressive cancer with high mortality rate and few therapeutic options
- The cancer takes several decades to develop after patients often have been environmentally and occupationally exposed to asbestos
- FDA approved nivolumab (Opdivo®) + ipilimumab (Yervoy®) as first-line mesothelioma treatment based on the trial CheckMate 743 in October 2020
- Patients who were treated with the Opdivo and Yervoy immunotherapy combination:
  - ***The mPFS was 6.8 months***
  - ***The mOS was 18.1 months***

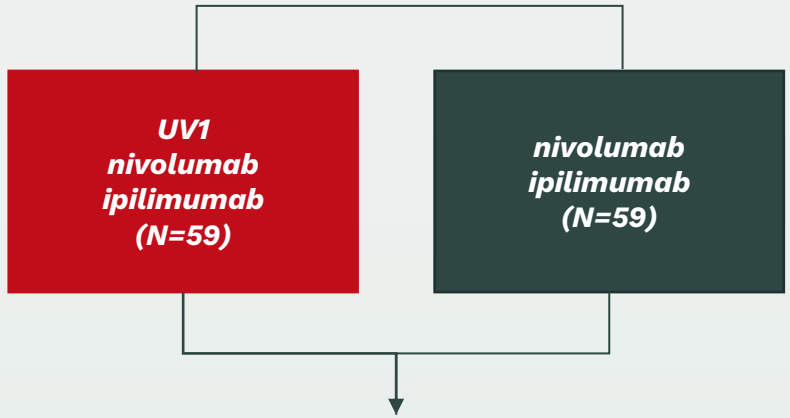


Readout still expected in Q2 2023 from the UV1 Phase II NIPU trial in metastatic malignant pleural mesothelioma (MPM)

- NIPU is a randomized, investigator-initiated Phase II clinical trial sponsored by Oslo University Hospital with support from Bristol-Myers Squibb and Ultimovacs. Principal Investigator is Prof. MD Ph.D Åslaug Helland
- 118 patients were enrolled between June 2020 and January 2023 in Scandinavia, Spain and Australia
- The study evaluates UV1 in combination with ipilimumab and nivolumab as second-line treatment for patients with MPM after progression on first-line standard platinum doublet chemotherapy

NIPU

Second line metastatic malignant pleural mesothelioma



Primary endpoint: Progression Free Survival (PFS)

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

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Q1 2023 Key Financials

Cash and liquidity

- MNOK 406/MUSD 39 in cash by end of Q1 2023
- Expected financial runway until mid-2024 (no change in guiding)

EBIT and PBT

- EBIT Q1 2023 was MNOK -51
- Profit before tax Q1 2023 was MNOK -34

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: Significantly higher than Q1 2022, but lower than the Q3 and Q4 2022.
- Going forward, the operating expense level should be expected to increase further compared to 2022 and Q1 2023, with quarterly variations, driven by further progress in the phase II trials, CMC development and other R&D activities

Key financials

Key financials per Q1-2023 - Ultimovacs Group

NOK (000)	Q1-22	Q1-23	FY22
Total revenues	-	-	-
Payroll and payroll related expenses	11 384	21 002	71 466
- Payroll expenses not incl. option costs and grants	13 406	14 652	50 878
- Share option costs and public grants	-2 022	6 350	20 589
External R&D and IPR expenses (incl. grants)	14 725	23 707	91 029
Other operating expenses (incl. depreciation)	5 791	6 053	21 135
Total operating expenses	**31 900**	**50 763**	**183 631**
Operating profit (loss)	**-31 900**	**-50 763**	**-183 631**
Net financial items	-4 699	16 652	15 839
Profit (loss) before tax	**-36 600**	**-34 111**	**-167 792**
Net increase/(decrease) in cash and cash eq.	-44 507	-33 952	-155 426
Cash and cash equivalents at end of period	**523 706**	**405 528**	**425 309**
Number of FTEs at end of period	23	24	23

- Net cash of MNOK 405 by the end of Q1 2023

Comments:

Payroll expenses

- Total payroll expenses were higher in Q1 2023 compared to same period the previous year;
  - Regular salary costs were a little higher in Q1 2023 compared to Q1 2022 primarily due to one more FTE this quarter and annual salary adjustment per January 2023.
  - Option expenses incl. social security tax accrual related to share options, which fluctuates with the company share price, was MNOK 8.4 higher in Q1 2023 compared to Q1 2022, explaining most of the difference between these two quarters.

External R&D and IPR expenses

- R&D costs were significantly higher in Q1 2023 compared to Q1 2022, with the main contributors to the increase being the INITIUM trial and manufacturing (CMC) activities.

Other operating expenses

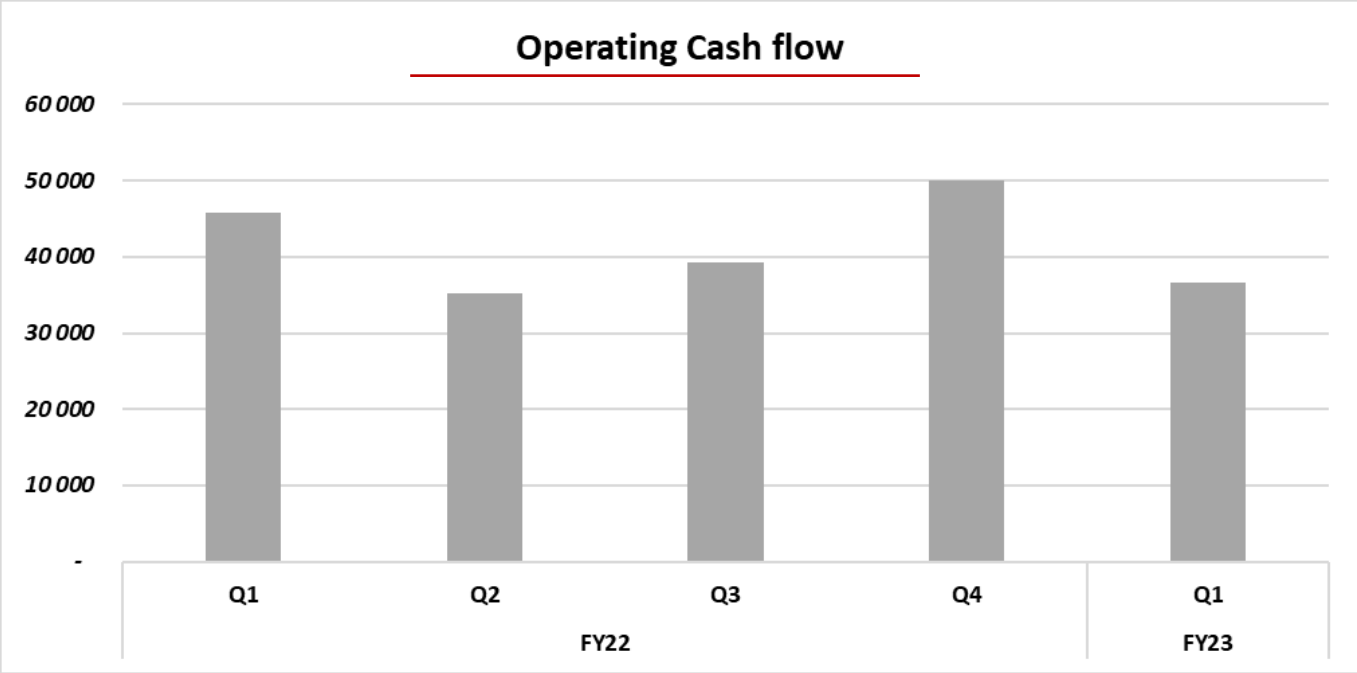
- Slight increase from the previous year primarily due to higher activity level (business development, travel and other).

Net financial items

- Comprised primarily of interest of MNOK 3.2 and net foreign exchange gain of MNOK 14.0 (from EUR account and EUR/NOK future contracts)

Key financials – quarterly operating cash flow

NOK (000) – Negative amounts



Note: excluding incoming public grants

Comments:

- Negative operating cash-flow in Q1 2023 was appr. MNOK -37, significantly lower than EBIT of MNOK -51 due to changes in working capital
- 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

Key financials – quarterly overview

Key financials per Q1-2023 - Ultimovacs Group

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

*not including effects of change in exchange rate

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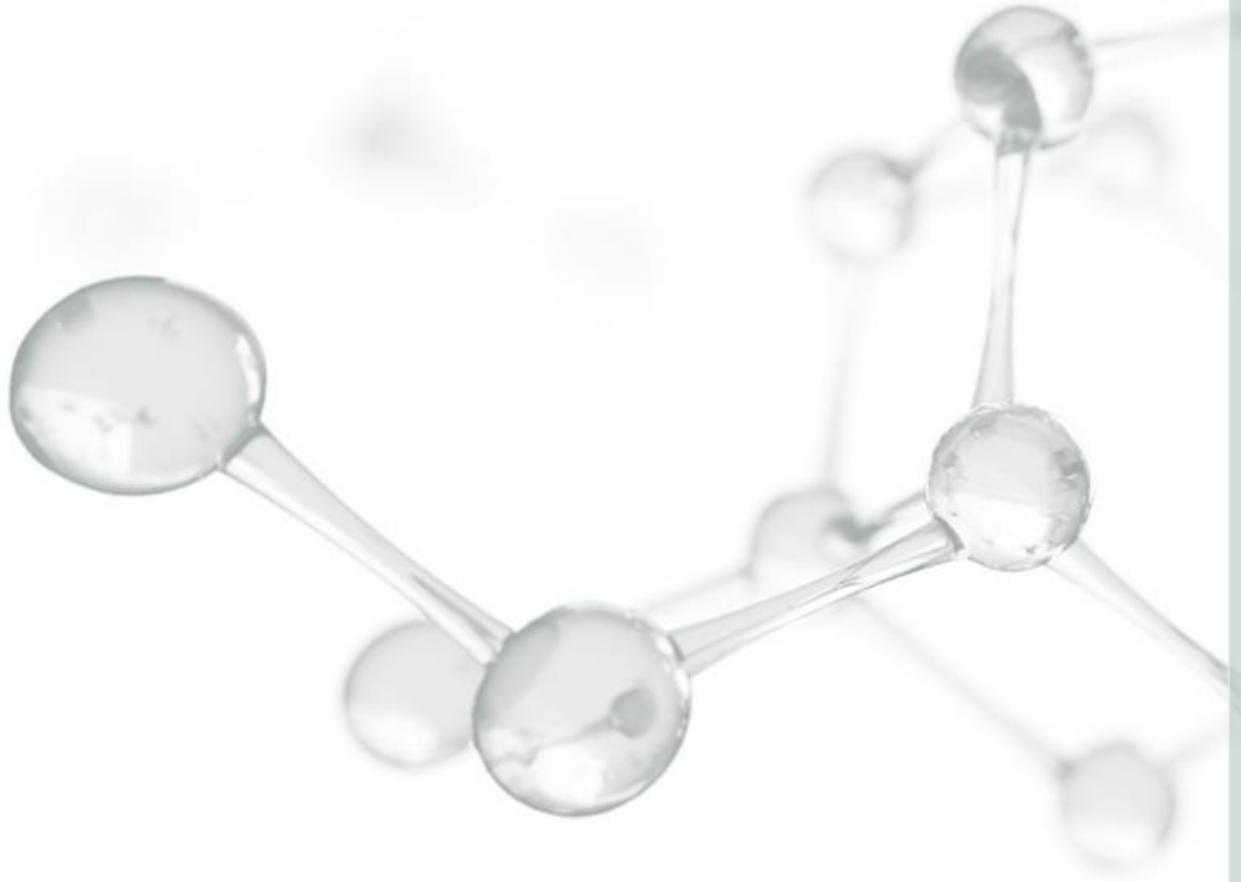

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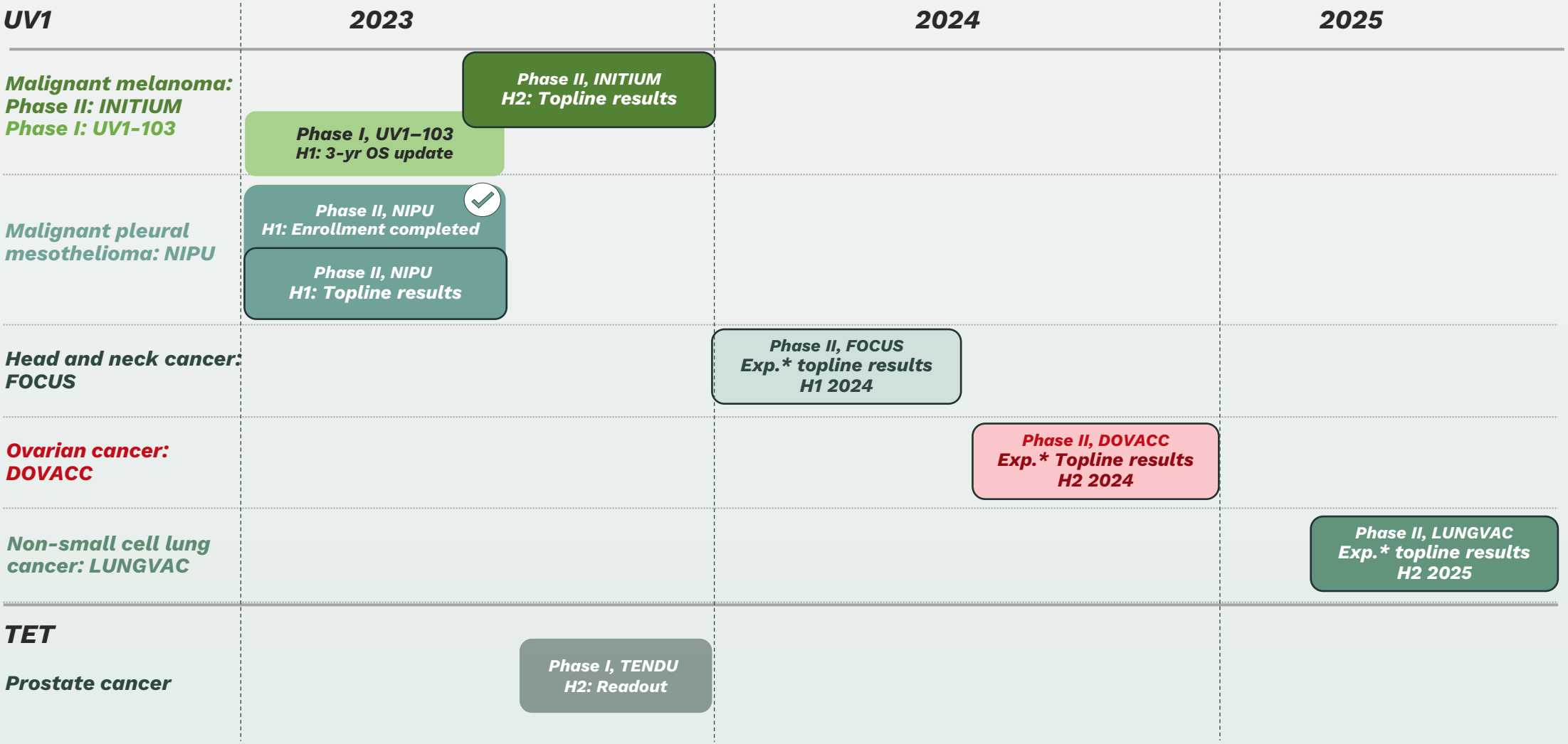
Expected milestones: Key value inflection points during the next years



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

Increasingly favourable timing for cancer vaccine randomized Phase II readouts in the evolving immune-oncology landscape

Moderna, Merck data support claim of cancer vaccine's promise

Data presented at AACR suggest a personalized shot made with messenger RNA may amplify the effects of a widely prescribed cancer immunotherapy.

Published April 16, 2023

Jonathan Gardner
Senior Reporter

Home • Best in Biotech

Cancer vaccines: 10 biotech companies that have changed the game

By Roohi Mariam Peter
April 6, 2023 - Updated on April 10, 2023 10 minutes • Share

UV1 has a strong competitive profile: It is universal and easy-to-use, has low production costs and simple administration

❶ *Universal and easy to use*

- ***UV1 is an off-the-shelf product, i.e. can be administered locally, facilitating broad access***
- ***No need for patient screening before treatment***
- ***8 intradermal injections***

❷ *Low cost production*

- ***Straight forward manufacturing process***

❸ *Simple logistics*

- ***Normal refrigeration***
- ***Low handling costs (manpower) for hospitals and community centers***

Investor Day, Tuesday 20 June: Meet the team for afterwork in Bergen

Investor Days: Meet the Team

Ultimovacs will host Investor Days in several cities. Thanks to everyone who attended our event in Oslo!
Similar events are planned to follow in Bergen, Gothenburg, Stavanger, Stockholm, and Trondheim, based on interest in the registration form.

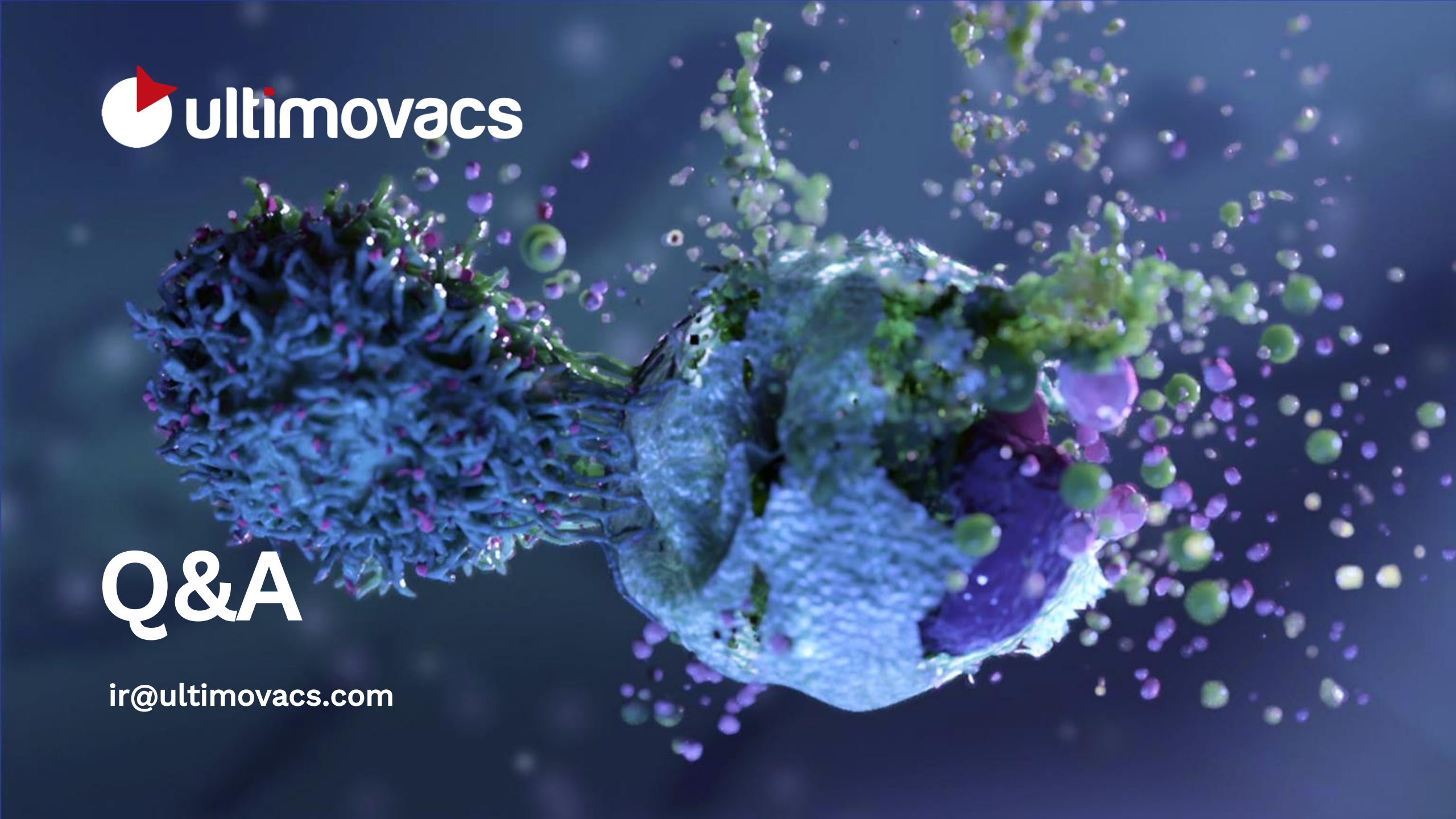
The events will feature presentations by management, after which there will be an opportunity for dialogue with members of the Ultimovacs team. Light refreshments will be served. The Meet the Team events are open to investors, business and collaboration partners, and friends and supporters of the company.

Please register for an invitation to Investor Days in a city close to you – **here** .

Sign up on our website or email IR@ultimovacs.com

Summary: Ultimovacs' first quarter 2023

- Completed enrollment in UV1 Phase II trial NIPU in January 2023
- Patients in INITIUM trial are taking longer to experience disease progression compared to historical data, encouraging and very positive for the patients
- Several key value inflection points ahead: Expected topline readout from randomized, comparative Phase II trials during; H1 2023 NIPU, H2 2023 INITIUM & H1 2024 FOCUS
- Rising interest on cancer vaccines in the evolving immune-oncology landscape; ease-of-use essential to improve access to treatment for patients
- Strengthened protection with UV1 + CPI combination patent in Europe, in addition to the U.S.
- Continued expected runway until mid-2024, through readouts from three Phase II studies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