## Ultimovacs

## Second Quarter 2023 Results

Ultimovacs ASA, 22 August 2023

Carlos de Sousa, CEO Jens Bjørheim, CMO Hans Vassgård Eid, CFO

## Disclaimer

This presentation has been prepared by Ultimovacs ASA ("Ultimovacs" or the "Company") for information purposes only and does not constitute an offer to sell common shares of the Company or a recommendation in relation to the shares of the Company. Neither shall the presentation or any part of it, nor the fact of its distribution or communication, form the basis of, or be relied on in connection with any contract, commitment or investment decision in relation thereto.

This presentation contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this presentation are forward-looking statements and as such, are based on management's current expectations and beliefs about future events at the date of this presentation. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "hope," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Such forward-looking statements involve known and unknown risks, uncertainties and other factors that could cause actual events, results or achievements to differ materially from the events, results or achievements expressed or implied by the forward-looking statements contained in this presentation. Given these risks, uncertainties and other factors, recipients of this presentation are cautioned not to place undue reliance on these forward-looking statements.

The information included in this presentation may be subject to updating, completion, revision and amendment, and such information may change materially. Except as required by law, we are under no duty to update any of these forward-looking statements after the date of this presentation to conform our prior statements to actual results or revised expectations.

No representation or warranty (express or implied) is made as to, and no reliance should be placed on, the accuracy, completeness or fairness of the information and opinions contained in this presentation, no reliance should be placed on such information. Neither Ultimovacs nor any of its owners, affiliates advisors or representatives accept any responsibility, liability or loss whatsoever arising directly or indirectly from the use of this presentation.

By accepting this presentation, you acknowledge that you are solely responsible for your own assessment of the market and the market position of the Company and that you will conduct your own analysis and be solely responsible for forming your own view of the potential future performance of the Company's business



## 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; data from three randomized Phase II clinical trials expected 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







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

	Indication	Checkpoint inhibitor(s)	Patients (#)	Enrolled	Expected topline readout	Phase I	Phase II	Investigator- Initiated Trial Contributors
	Malignant melanoma	Ipilimumab	12	Completed	Completed	UV1-ipi		
	Malignant melanoma	Pembrolizumab	30	Completed	Completed	UV1-103		
UV1	Malignant melanoma	Ipilimumab & nivolumab	156	Completed	H1 2024			
	Pleural mesothelioma	Ipilimumab & nivolumab	118	Completed	H1 2023, data in Q4		NIPU	<sup>(1)</sup> Bristol Myers Squibb <sup>® 3</sup> Oslo University Hospital
	Head and neck cancer	Pembrolizumab	75	Completed	H2 2024		FOCUS	MARTIN-LUTHER-UNIVERSITÄT HALLE-WITTENBERG
	Ovarian cancer	Durvalumab & olaparib	184	>20%1	H2 2024		DOVACC	CONSERVE developed active constraints
	Non-small cell lung cancer (NSCLC)	Cemiplimab⁴	138	< <b>10</b> %¹	H2 2025			• 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: DOVACC and LUNGVAC: Readout estimates will be updated with the Q4 2023 report 3: Supply agreements. 4: As per 1 January 2023 Q2 2023 highlights: Waiting for the data from three UV1 Phase II trials

- INITIUM: Unresectable or metastatic malignant melanoma (N=156)
  - Readout after 70 confirmed cases of disease progression or death, which has not yet occured
  - Topline results expected H1 2024. Assuming continued slow progression, alternative approaches for data readout will be considered, with acceptance of the regulatory authorities
- NIPU: Malignant pleural mesothelioma (N=118)
  - PFS not met in central review, but significant improvement of PFS in local review
  - Positive trend of improvement in overall survival observed in the UV1 arm
  - Detailed and updated data including OS to be presented Q4 2023 at a medical conference
- FOCUS: Head and neck cancer (N=75)
  - Readout of PFS and OS after minimum 12 months follow up, expected during H2 2024
- Financials: Expected financial runway to H2 2024, through reporting of data from the three randomized Phase II studies



## Q2 2023 highlights: Scientific acknowledgment and advancement

- More than 300 cancer patients have received treatment with UV1; no safety concerns reported to date
- Strong 3-year survival data reported from the UV1-103 study; all patients in cohort 2 who were alive after 2 years remained alive after 3 years
- Publication of clinical and biomarker analyses of the UV1-103 Phase I trial in prestigious Clinical Cancer Research, a renowned peer-reviewed journal by the American Association for Cancer Research
- Ultimovacs granted combination patent in Europe and Japan counterpart of the US patent; protecting UV1 cancer vaccine and checkpoint inhibitor combinations until at least 2037
- CSO Gustav Gaudernack awarded the Norwegian Tech Awards' Honorary Prize as an outstanding pioneer in the fight against cancer
- Presentation of TET technology platform and the results from the TENDU study planned for Q4





### Ultimovacs Second Quarter 2023 presentation



## Contents

- 1. Operations
- 2. Financials
- 3. Newsflow



UV1 clinical program consists of five comparative, randomized Phase II <u>trials</u> in different cancer types, biologies, and CPI combinations



Primary endpoint: Progression Free Survival (PFS)

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

Ultimovacs

2. DOVACC and LUNGVAC readout estimates will be updated with the Q4 2023 report

## Clinical trials enrollment updates, per 21 August 2023

Clinical trial program	Enrollment and expected readout timeline
INITIUM (Phase II malignant melanoma):	Enrollment of 156 patients completed** Expected readout: H1 2024
NIPU (Phase II pleural mesothelioma):	Enrollment of 118 patients completed Expected presentation of data: Q4 2023
FOCUS (Phase II head and neck cancer):	Enrollment of 75 patients completed Expected readout: H2 2024
DOVACC (Phase II ovarian cancer):	37 out of 184 patients enrolled, up from 24 in the previous quarterly report Expected readout: H2 2024*
LUNGVAC (Phase II non-small cell lung cancer):	11 out of 138 patients, up from 7 in the previous quarterly report Expected readout: H2 2025*
TENDU (Phase I prostate cancer):	Enrollment of 12 patients completed Expected readout: Q4 2023



\* 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.

## INITIUM – unresectable or metastatic malignant melanoma



- Sponsored by Ultimovacs
- Enrolled 156 patients from 39 sites in four countries: US, UK, Belgium and Norway
- Recruitment: 100%. First patient enrolled June 2020, last patient enrolled in July 2022
- All patients followed for longer than 12 months
- Readout after 70 cases of progression or death; 70 events have not been reached per date
- Top line results expected H1 2024. Assuming continued slow progression in number of events, Ultimovacs will explore alternative approaches for data readout with acceptance of the regulatory authorities.





#### Q2 2023 Report, Non-Confidential **11**

### NIPU - Second line malignant metastatic pleural mesothelioma (MPM)

- Investigator-initiated trial led by Oslo University Hospital, supported by Ultimovacs and Bristol Meyer Squibbs
- Enrolled 118 patients from six sites in five countries: Australia, Spain, Denmark, Sweden and Norway
- **Recruitment: 100%.** First patient enrolled June 2020, last patient enrolled in January 2023.
- Readout in Q2 2023 showed Progression-Free Survival (PFS) not met by central review but showed significant positive PFS outcome by local review at the study centers in all the five countries
- Furthermore, an encouraging trend in Overall Survival (OS) benefit was observed in the UV1 arm compared to the control arm
- Data has not been publicly disclosed yet. Updated, topline data expected presented at a medical conference in Q4 2023
- Ultimovacs is preparing for discussions with FDA on the path forward in MPM, following potentially continued strong OS data

ltimovacs





## 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
- **Recruitment: 100%.** 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, and will include readout of all endpoints up to 12 months and the primary endpoint PFS at 6 months





### Ultimovacs First Quarter 2023 presentation



## Contents

- 1. Operations
- 2. Financials
- 3. Newsflow



## Q2 2023 Key Financials

#### Cash and liquidity

- MNOK 344/MUSD 32 in cash by end of Q2 2023
- Expected financial runway to H2 2024 (changed from mid-2024), i.e., through the reporting of overall survival data in NIPU and the topline readouts in INITIUM and FOCUS

#### EBIT and PBT

- EBIT: Q2 2023 MNOK -51 and YTD 2023 MNOK -101
- Profit before tax: Q2 2023 MNOK -43 and YTD 2023 MNOK -77

#### **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 previous quarters driven by clinical trial activities and manufacturing (CMC) activities.
- Going forward, the operating expense level should be expected to continue at a fairly high level, with quarterly variations, driven by further progress in the phase II trials, CMC development and other R&D activities.



## Key financials

#### Key financials per Q2-2023 - Ultimovacs Group

NOK (000)	Q2-22	Q2-23	YTD22	YTD23	FY22
Total revenues	-	-	-	-	-
Payroll and payroll related expenses	14 340	4 359	25 724	25 361	71 466
- Payroll expenses not incl. option costs and grants	9 100	10 808	22 506	25 460	50 878
<ul> <li>Share option costs and public grants</li> </ul>	5 239	-6 449	3 217	-99	20 589
External R&D and IPR expenses (incl. grants)	16 272	40 944	30 997	64 651	91 029
Other operating expenses (incl. depreciation)	4 810	5 338	10 600	11 392	21 135
Total operating expenses		50 641	67 321	101 404	183 631
Operating profit (loss)	-35 421	-50 641	-67 321	-101 404	-183 631
Net financial items	13 045	7 266	8 346	23 918	15 839
Profit (loss) before tax	-22 376	-43 375	-58 976	-77 486	-167 792
Net increase/(decrease) in cash and cash eq.	-31 837	-68 100	-76 344	-102 052	-155 426
Cash and cash equivalents at end of period	486 338	<b>344 104</b>	486 338	344 104	425 309
Number of FTEs at end of period	23	24	23	24	23

Net cash of MNOK 344 by the end of Q2 2023

#### **Comments:**

#### Payroll expenses

- Total payroll expenses were lower in Q2 2023 compared to same period the previous year, and at the same level YTD23 as YTD22;
  - Regular salary costs were higher in Q2 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, was MNOK 13 higher in Q2 2023 compared to Q2 2022, explaining most of the difference this quarter compared to previous year.

#### External R&D and IPR expenses

 R&D costs were significantly higher in Q2 2023 and YTD23 compared to the same periods in 2022, with the main contributors to the increase being clinical trials 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 from bank and net foreign exchange gains (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 Q2 2023 was appr.
   MNOK -70, significantly more than EBIT of -50 due to changes in working capital and the negative, noncash 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



## Key financials – quarterly overview

### Key financials per Q2-2023 - Ultimovacs Group

NOK (000)	Q1-22	Q2-22	Q3-22	Q4-22	Q1-23	Q2-23
Total revenues		-	-	-	-	-
Payroll and payroll related expenses	11 384	14 340	14 112	31 630	21 002	4 359
<ul> <li>Payroll expenses not incl. option costs and grants</li> </ul>	13 406	9 100	13 979	14 392	14 652	10 808
- Share option costs and public grants	-2 022	5 239	133	17 238	6 350	-6 449
External R&D and IPR expenses (incl. grants)	14 725	16 272	24 743	35 289	23 707	40 944
Other operating expenses (incl. depreciation)		4 810	5 200	5 335	6 053	5 338
Total operating expenses	31 900	35 421	44 055	72 255	50 763	50 641
Operating profit (loss)	-31 900	-35 421	-44 055	-72 255	-50 763	-50 641
Net financial items	-4 699	13 045	5 752	1 742	16 652	7 266
Profit (loss) before tax	-36 600	-22 376	-38 303	-70 513	-34 111	-43 375
Net increase/(decrease) in cash and cash equivalents*		-31 837	-29 726	-42 137	-33 952	-68 100
Cash and cash equivalents at end of period	523 706	486 338	469 063	425 309	405 528	344 104
Number of FTEs at end of period		23	23	23	24	24

\*not including effects of change in exchange rate



### Ultimovacs First Quarter 2023 presentation



### Contents

- 1. Operations
- 2. Financials
- 3. Newsflow



## Newsflow & milestones: Key value inflection points during the next year



Ultimovacs

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

#### Investor Days: Meet the Team in Trondheim

We are hosting an Investor Day in Trondheim Thursday 24. August, 17:00 – 18:30.

The event will feature presentations by management, followed by time for a dialogue with members of the team and light refreshments. These events are open to investors, business and collaboration partners, and friends and supporters of the company.

Please click <u>here</u> to register for an invitation to Investor Day in Trondheim, or another city close to you, or contact IR@ultimovacs.com

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



## Summary: A transformational year ahead - waiting for data from <u>three UV1 Phase II trials in different cancer indications and biologies</u>

- Patients in INITIUM trial are taking longer to experience disease progression compared to historical data. 70 events are still outstanding, which is very positive for the patients
- The extension in the INITIUM readout timeline has minor cost implications. However, assuming continued slow progression, Ultimovacs will consider alternative approaches for data readout
- Awaiting updated Overall Survival data from NIPU in Q4 2023; preparing for discussions with regulatory authorities regarding the path forward in mesothelioma
- Strengthened patent protection with UV1 + CPI combination patent granted in Europe & Japan, in addition to the U.S.
- TET update planned for Q4 2023, including presentation of results from TENDU trial
- Expected financial runway to H2 2024, across data readout from three Phase II trials
- Transformational year ahead for the Company



## Ultimovacs

# Q&A

ir@ultimovacs.com