



# Enabling the Immune System to Fight Cancer

Fourth Quarter 2021 Presentation  
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## Highlights Q4 2021 - Summary

- Good clinical progress with increased patient enrollment rate in INITIUM and NIPU
- Ultimovacs has coped well with the challenges caused by Covid-19
  - minor adjustments in the guidance on topline readout for INITIUM and NIPU
- FDA Fast Track and Orphan Drug Designations received for UV1 in the lead indication, metastatic melanoma
- New UV1 Phase II trial in Non-small Cell Lung Cancer (NSCLC) announced
- Successful Capital Raise (MNOK 270/MUSD 30)
- Further encouraging results from the Phase I clinical trial of UV1 combined with pembrolizumab in malignant melanoma
- Good progress in the development of TET and no safety concerns observed in the two first patient cohorts in the TENDU study

# Highlights Q4 2021: Progress in UV1 Phase II Program is Encouraging

## Continued good progress in the broad UV1 Phase II program

- **INITIUM:** 120 out of 154 patients enrolled, compared to 91 patients in the Q3 report
- **NIPU:** 66 out of 118 patients enrolled, compared to 45 patients in the Q3 report
- **DOVACC:** 2 out of 184 patients enrolled, compared to none in the Q3 report
- **FOCUS:** 10 out of 75 patients enrolled, compared to 5 patients in the Q3 report

Ultimovacs will continue to provide enrollment updates in each quarterly report. Although we remain optimistic regarding progress in our broad clinical program, the effect of the pandemic on the biotech industry and the conduct of clinical trials is still uncertain.

# Highlights Q4 2021: Updated Guidance INITIUM and NIPU

## Readout of topline data INITIUM and NIPU

- >75% of patients in INITIUM enrolled, >55% of patients in NIPU enrolled
- Patient enrollment rate has increased in both trials the last quarter

## Updated guidance:

- INITIUM and NIPU have now estimated readouts during the **first half of 2023** vs. previous guidance in second half of 2022

# Highlights Q4 2021: Readout on recent UV1 Phase II Studies

## Readout of topline data DOVACC, FOCUS and LUNGVAC

- DOVACC and FOCUS are still in their early stages of hospitals/clinical site activation
- The start-up phase of both has taken somewhat longer than originally planned. Ultimovacs has guided that the readouts of topline results were expected to take place in 2023
- In LUNGVAC, first patient is expected to be enrolled during the first half of 2022 with topline results expected by the end of 2024

Once each of these trials has progressed sufficiently to provide a reliable trajectory, Ultimovacs will review guidance and expects to give an update with the Q4 2022 report

# Highlights Q4 2021: New UV1 Phase II Trial triggered Capital Raise

## **New Phase II trial in NSCLC announced in October 2021**

- **UV1 to be investigated in combination with pembrolizumab**
  - 138 patients
  - First patient expected to be enrolled during H1 2022

## **Successful Capital Raise**

- A private placement was successfully completed on 26 October 2021
- Gross proceeds of MNOK 270 (MUSD 30) raised



# Highlights Q4 2021: Recognition from the FDA



- Ultimovacs receives Dual “Fast Track” designation from the FDA, for:
  - UV1 as add-on therapy to pembrolizumab for the treatment of unresectable or metastatic melanoma
  - UV1 as add-on therapy to ipilimumab for the treatment of unresectable or metastatic melanoma
- Through the “Fast Track” designation for UV1, the following benefits are provided by the FDA:
  - Facilitates the development and expedites the review of UV1
  - Enables early and frequent communication with the FDA to support UV1’s development
  - Provides eligibility for Accelerated Approval and Priority Review in case certain required criteria are met
  - Entitles to a Rolling Review of the Biologic License Application (BLA) by the FDA
- **Fast Track designation confirms our confidence in the therapeutic potential of UV1**

## Highlights Q4 2021: Another Recognition from the FDA



- UV1 has received “Orphan Drug” designation from the FDA in the treatment of malignant melanoma
  - The intention of the program is to support and advance the development and evaluation of new treatments for rare diseases that affect fewer than 200,000 people in the U.S. with unmet medical needs
  - Orphan drug designation provides certain benefits, including:
    - seven-year market exclusivity upon regulatory approval if received
    - exemption from FDA application fees
- **Metastatic melanoma is UV1’s lead indication, and it is currently being studied as first-line treatment for metastatic melanoma in the INITIUM trial as add-on therapy to checkpoint inhibitors ipilimumab and nivolumab**



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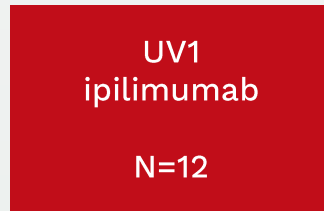
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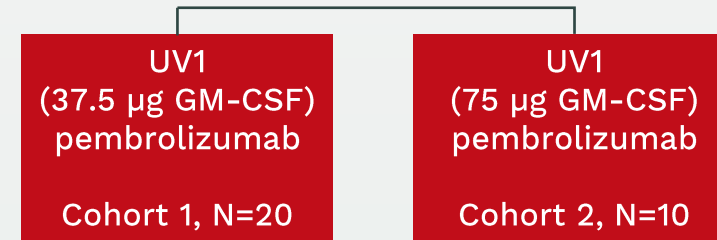
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# Fast Track Designation Supported by Strong Phase I Efficacy and Safety Data

## UV1 + ipilimumab Phase I Trial Design



## UV1 + pembrolizumab Phase I Trial Design



### Key results:

- Good safety profile supporting use of UV1 in combination with ipilimumab
- Consistent set of data showing strong initial signals of clinical response
- Results were published in [Frontiers in Immunology](#) in May 2021
- Poster presentation at [SITC Annual Meeting 2021](#) documenting mechanistic effects of UV1 in this trial

### Key results as of Q4 2021:

- Good safety profile supporting use of UV1 in combination with pembrolizumab
  - Safety of combination similar to pembrolizumab alone, except injection site reactions
- Consistent set of data showing strong initial signals of clinical response and efficacy
- Data reported at ASCO 2021 and updates presented in the Q3 2021 financial report

# Phase I UV1 + pembrolizumab in Malignant Melanoma

## Strong signals of efficacy

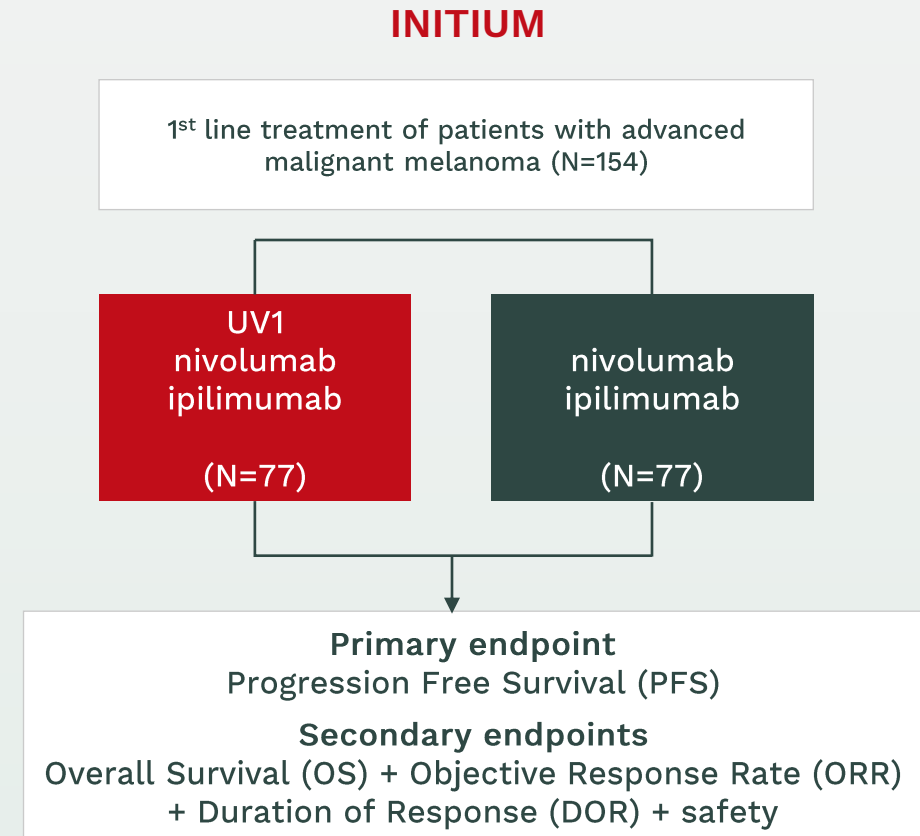
- The **Response Rates** for the 30 patients in cohort 1 and cohort 2 combined, as measured by iRECIST:
  - complete response (CR) 9/30
  - partial response (PR) 8/30<sup>1</sup> } **Objective response rate (ORR) 57%,  
Complete response rate (CR) 30%**
  - stable disease (SD) 2/30<sup>1</sup>
  - progressive disease (PD) 11/30
- **Median Progression Free Survival (mPFS):**
  - Cohort 1: 18.9 months
  - Cohort 2: not reached at 12 months
  - Cohort 1+2 combined: not reached at 12 months
- **Overall Survival (OS):**
  - Cohort 1 after 12 months: 85%
  - Cohort 1 after 24 months: 80%
  - Cohort 2 after 12 months: 90%










# Next Steps for UV1 in Advanced Malignant Melanoma

## – INITIUM Phase II trial

- **INITIUM: Phase II combination trial with nivolumab and ipilimumab in malignant melanoma**
  - First patient enrolled June 2020
  - 154 patients from 39 sites in 4 countries: US, UK, Belgium and Norway
  - 120 patients enrolled as of 16 February 2022 (Q4 2021 reporting)
  - Topline results expected H1 2023, after 70 patients have progressed or died



# Broad Phase II UV1 Pipeline with >650 Patients

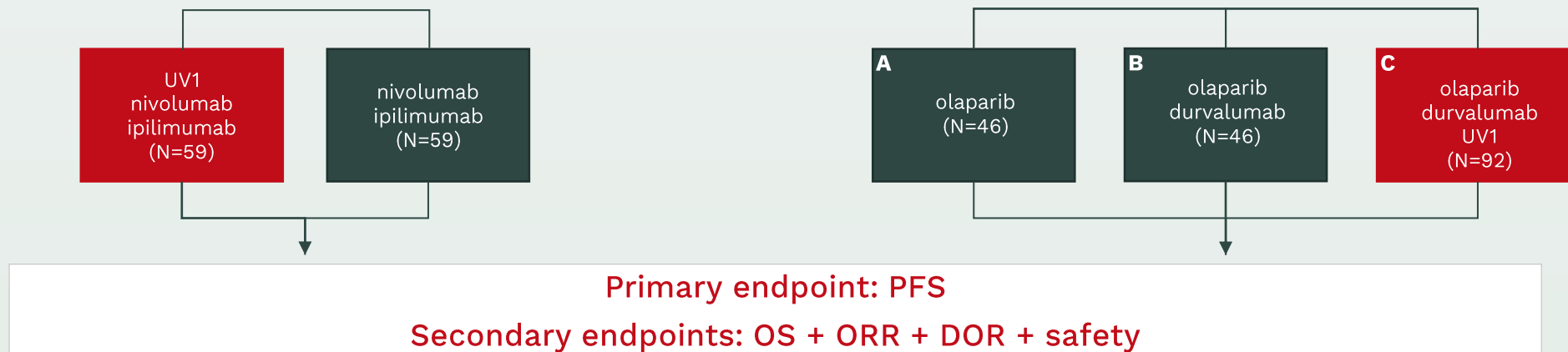
	Indication	Clinical trial information	Pre-clinical	Phase I	Phase II	Phase III	Contributors
UV1	First line metastatic malignant melanoma	With pembrolizumab 30 patients		●			
	First line metastatic malignant melanoma	With ipilimumab & nivolumab 154 patients			INITIUM ●		
	Second line mesothelioma	With ipilimumab & nivolumab 118 patients			NIPU ●		 <sup>1</sup> 
	Second line ovarian cancer	With durvalumab & olaparib 184 patients			DOVACC ●		   <sup>1</sup> European Network of Gynaecological Oncological Trial groups
	First line head and neck cancer	With pembrolizumab 75 patients			FOCUS ●		 Martin-Luther University Halle
	First line NSCLC	With pembrolizumab 138 patients			LUNGVAC ●		
TET	Prostate cancer	Dose finding trial, monotherapy 9 patients		TENDU ●			

**Note:** UV1 Phase II development is supported by good safety profile and signals of clinical efficacy observed in three Phase I trials where 52 patients with prostate cancer, lung cancer or malignant melanoma were included. Patients in these studies have been followed for at least five years.

# NIPU & DOVACC Phase II Trials

## NIPU: Malignant pleural mesothelioma

- **Combination:** nivolumab, ipilimumab
- **Contributors:** Oslo University Hospital (sponsor); BMS
- **Patients:** 118 from 6 sites in Norway, Sweden, Denmark, Spain and Australia
- First patient enrolled June 2020
- 66 patients enrolled as of 16 February 2022 (Q4 2021 reporting)
- **Milestones:** Topline results expected H1 2023, after 69 patients have progressed or died



## DOVACC: Ovarian cancer

- **Combination:** olaparib, durvalumab
- **Contributors :** NSGO/ENGOT, Astra Zeneca
- **Patients:** 184 from more than 40 sites in more than 10 European countries
- First patient enrolled December 2021
- 2 patients enrolled as of 16 February 2022 (Q4 2021 reporting)
- **Milestones:** Topline results have been expected during 2023. This guidance will be updated with the Q4 2022 report

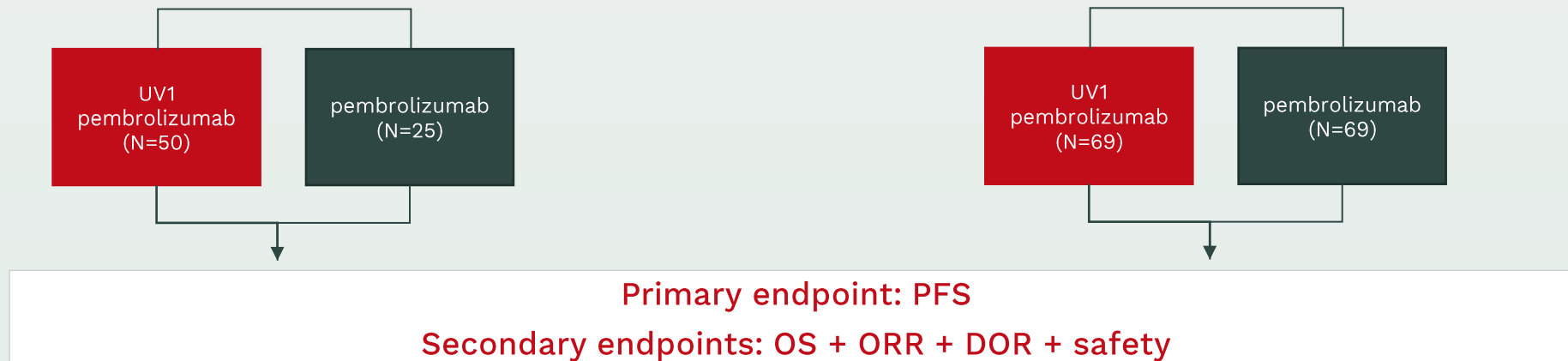
# FOCUS and LUNGVAC Phase II Trials

## FOCUS: Head and neck squamous cell carcinoma

- **Combination:** pembrolizumab
- **Contributors** : Sponsored by Halle University Hospital network
- **Patients:** 75 from 10 sites in Germany
- First patient enrolled August 2021
- 10 patients enrolled as of 16 February 2022 (Q4 2021 reporting)
- **Milestones:** Topline results have been expected during 2023. This guidance will be updated with the Q4 2022 report

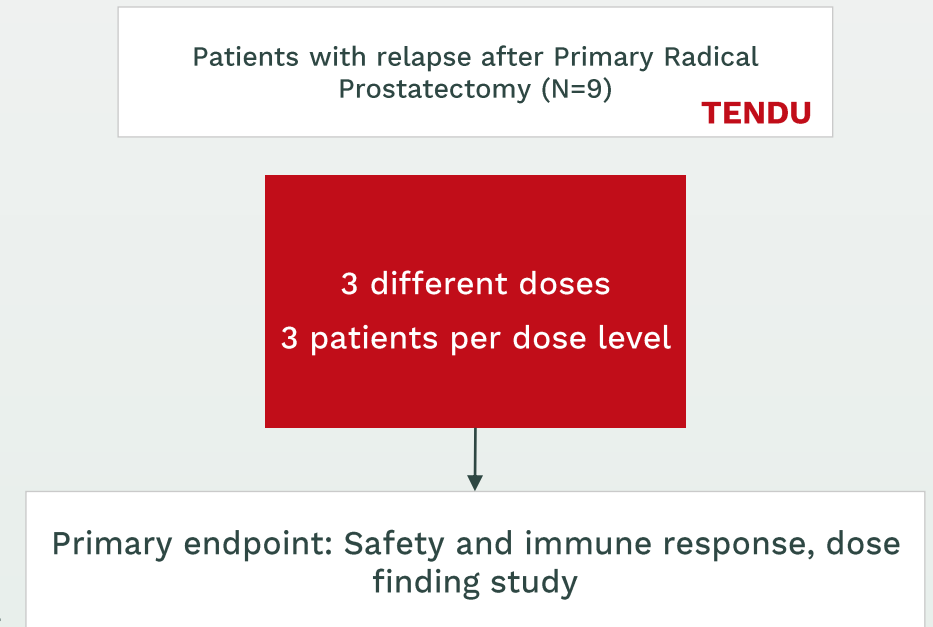
## LUNGVAC: Advanced or metastatic NSCLC

- **Combination:** pembrolizumab
- **Contributors:** Sponsored by Drammen Hospital with Odd Terje Brustugun, MD PhD. as principal investigator
- **Patients:** 138 patients from 8-10 hospitals in Norway
- First patient expected to be enrolled in H1 2022
- **Milestones:** Topline results have been expected by the end of 2024. This guidance will be updated with the Q4 2022 report



# TET Technology Platform and the TENDU Phase I Trial

- The **TET technology platform**:
  - allows for a beneficial safety profile and simplified administration since the antigens and adjuvant are part of the same molecule
  - ADJUVANT technology: tetanus antigens are built into TENDU to potentiate the vaccine.
- The **TENDU trial** investigates a prostate cancer specific vaccine based on the TET technology
  - Conducted at Oslo University Hospital
  - 6 out of 9 patients enrolled in the first two cohorts, each with three patients
  - **No safety concerns emerged in the first two dose level cohorts**  
In early February 2022, Ultimovacs announced that the Drug Safety Monitoring Board allowed the dose to be increased to 960 mcg for the next three patients in the third and final dose cohort
- This Phase I trial will provide valuable information on safety and immune activation toward the further development of new vaccine solutions based on the TET technology







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## Private Placement in October 2021 *(also reported in the Q3 report/presentation)*

- On 26 October 2021, Ultimovacs successfully carried out a private placement of 2,160,000 new shares at a subscription price of NOK 125 per share, raising gross proceeds of NOK 270 million
- More than 100 investors took part in the private placement
- Increased geographical footprint of the shareholder base
- **The net proceeds of the private placement will be used for:**
  - (i) the LUNGVAC Phase II trial,
  - (ii) bringing the UV1 platform into Phase III readiness,
  - (iii) further development of TET, and
  - (iv) general corporate purposes

**Based on current cash, plans and expectations, Ultimovacs is funded to the first part of 2024**

# Key financials

## Key financials per Q4-2021 - Ultimovacs Group

NOK (000)	Q4-20	Q4-21	FY20	FY21
<b>Total revenues</b>	-	-	-	-
Payroll and payroll related expenses	14 662	11 885	50 989	61 916
External R&D and IPR expenses (incl. grants)	7 537	35 538	60 870	88 169
Other operating expenses (incl. depreciation)	3 390	3 507	12 287	13 748
<b>Total operating expenses</b>	<b>25 588</b>	<b>50 930</b>	<b>124 146</b>	<b>163 832</b>
<b>Operating profit (loss)</b>	<b>-25 588</b>	<b>-50 930</b>	<b>-124 146</b>	<b>-163 832</b>
Net financial items	1 007	-222	3 594	-890
<b>Profit (loss) before tax</b>	<b>-24 582</b>	<b>-51 152</b>	<b>-120 552</b>	<b>-164 722</b>
Net increase/(decrease) in cash and cash eq.	-12 524	227 856	42 058	137 106
<b>Cash and cash equivalents at end of period</b>	<b>440 925</b>	<b>574 168</b>	<b>440 925</b>	<b>574 168</b>
Number of FTEs at end of period	19	24	19	24

### Comments:

#### *Payroll expenses*

- Higher personnel costs in FY21 compared to FY20 due to 2.5 additional FTEs employed during the year and higher (+MNOK 8) employee share option costs (no cash effect). The decrease in Q4-21 compared to Q4-20 is mainly due to a reversal of share option costs.

#### *External R&D and IPR expenses*

- Significantly higher R&D costs in Q4-21 and FY21 compared to the same periods the previous year, due to the initiation of the DOVACC and FOCUS trials, further progression in INITIUM, NIPU and TENDU, as well as increase in other CMC and R&D costs.

#### *Other operating expenses*

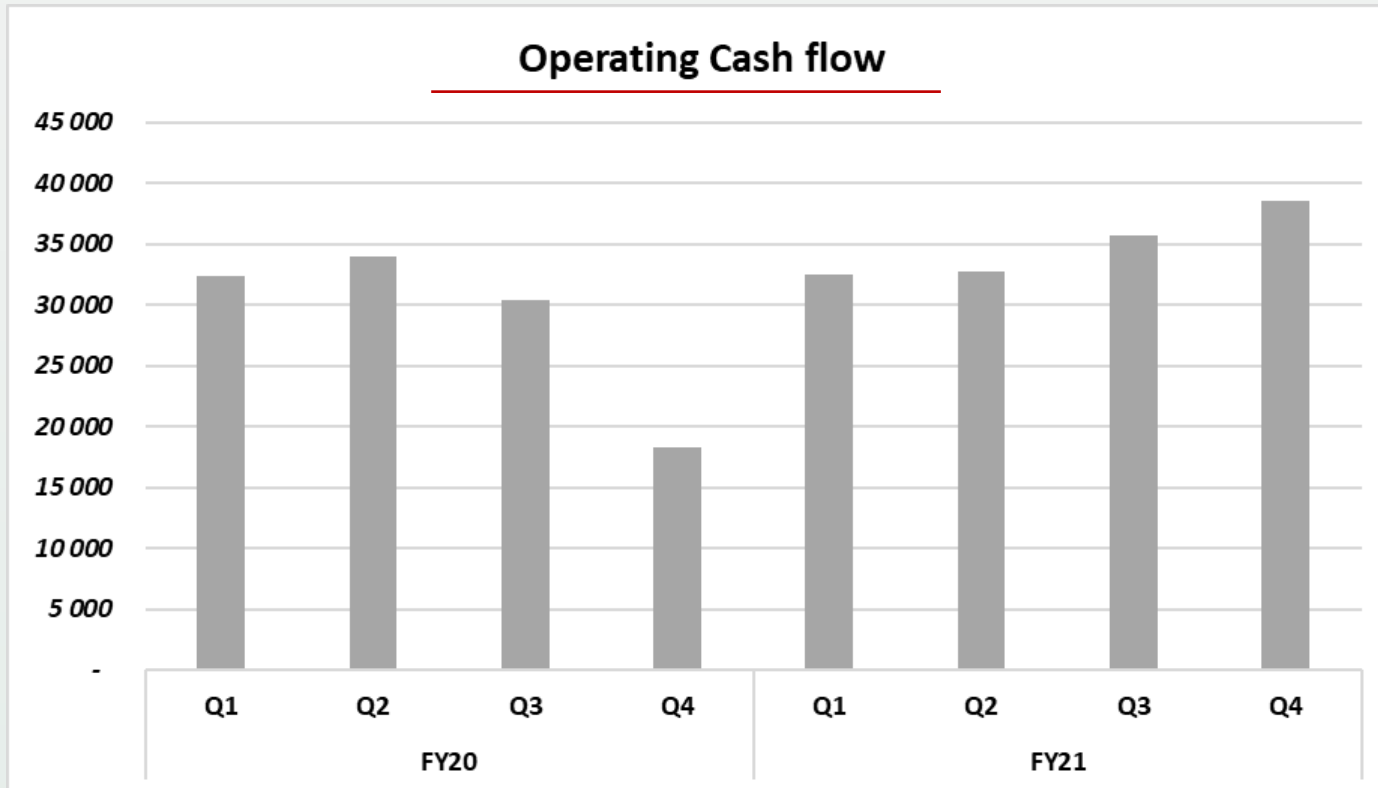
- Slight increase from the previous year

#### *Cash position*

- Net cash of MNOK 574 at the end of Q4 2021**

# Key financials – operating cash flow

NOK (000) – Negative amounts



## Comments:

- The negative operating cash flows (excluding public grants) have increased every quarter in FY21 due to the initiation of sites and increased patient recruitment in the four ongoing phase II trials as well as an increase in other R&D costs






## Key financials – quarterly overview

### Key financials per Q4-2021 - Ultimovacs Group

NOK (000)	Q1-20	Q2-20	Q3-20	Q4-20	Q1-21	Q2-21	Q3-21	Q4-21
<b>Total revenues</b>	-	-	-	-	-	-	-	-
Payroll and payroll related expenses	10 015	13 197	13 115	14 662	12 203	14 514	23 314	11 885
External R&D and IPR expenses (incl. grants)	18 089	19 938	15 307	7 537	16 012	20 588	16 031	35 538
Other operating expenses (incl. depreciation)	3 155	3 048	2 695	3 390	3 000	4 069	3 171	3 507
<b>Total operating expenses</b>	<b>31 259</b>	<b>36 183</b>	<b>31 116</b>	<b>25 588</b>	<b>31 215</b>	<b>39 171</b>	<b>42 517</b>	<b>50 930</b>
<b>Operating profit (loss)</b>	<b>-31 259</b>	<b>-36 183</b>	<b>-31 116</b>	<b>-25 588</b>	<b>-31 215</b>	<b>-39 171</b>	<b>-42 517</b>	<b>-50 930</b>
Net financial items	922	1 274	391	1 007	-2 582	2 706	-791	-222
<b>Profit (loss) before tax</b>	<b>-30 337</b>	<b>-34 909</b>	<b>-30 725</b>	<b>-24 582</b>	<b>-33 798</b>	<b>-36 465</b>	<b>-43 308</b>	<b>-51 152</b>
Net increase/(decrease) in cash and cash equivalents	-31 479	115 247	-29 186	-12 524	-28 213	-29 657	-32 880	227 856
<b>Cash and cash equivalents at end of period</b>	<b>367 686</b>	<b>483 159</b>	<b>453 523</b>	<b>440 925</b>	<b>409 288</b>	<b>381 799</b>	<b>347 804</b>	<b>574 168</b>
Number of FTEs at end of period	19	19	19	19	21	21	21	24



# Expected News Flow and Milestones

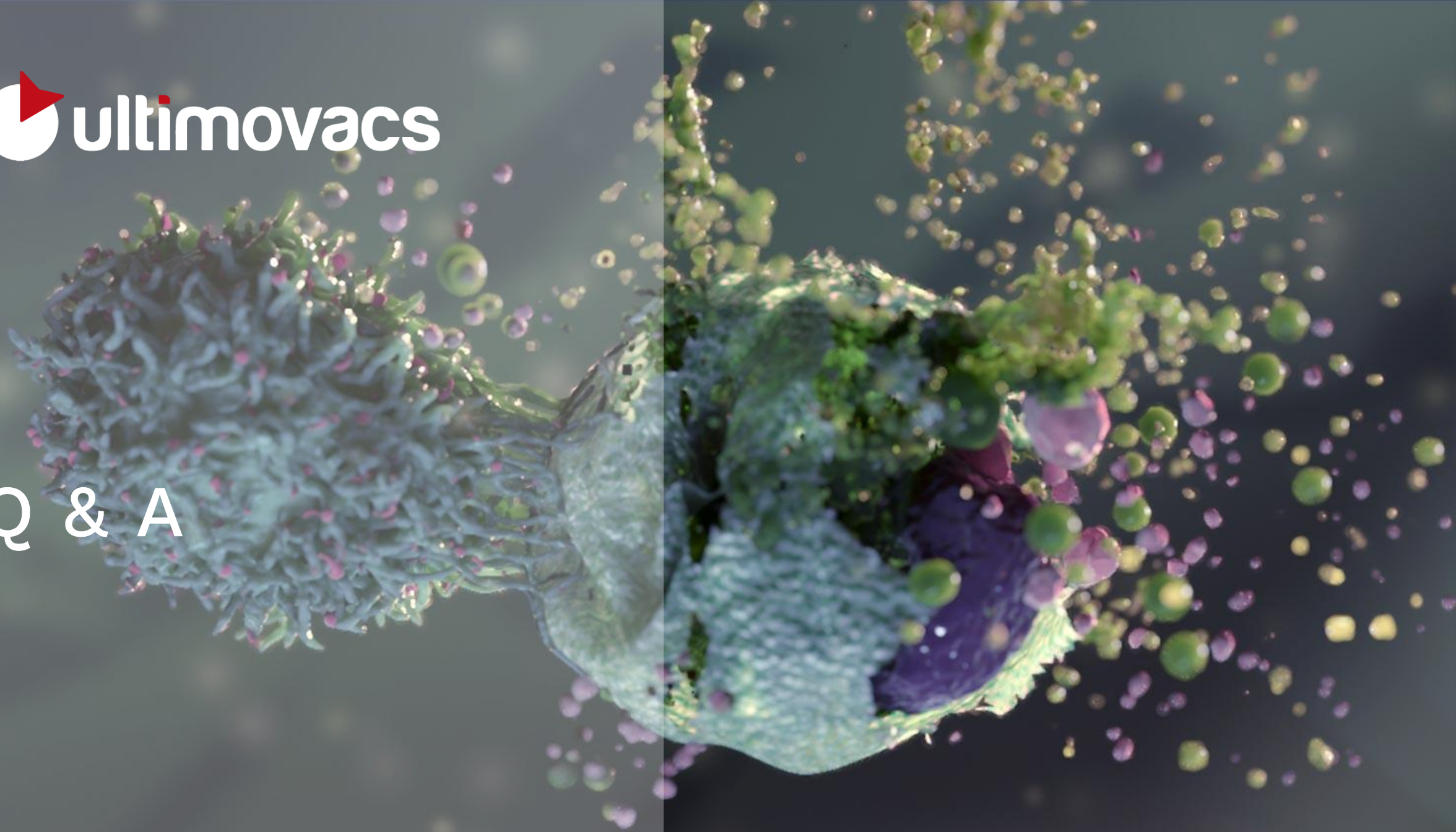
	2021	2022	2023	2024
	Q4			
U V 1	MALIGNANT MELANOMA	 Cohort 1 2-yr update Phase I w/pembro.  Fast Track + Orphan Drug designations 	Q3: Cohort 2, 2-yr OS update Q4: Cohort 1, 3-yr OS update Phase I w/ pembrolizumab	H1: Topline results Phase II INITIUM
	MALIGNANT PLEURAL MESOTHELIOMA			H1: Topline results Phase II NIPU
	OVARIAN CANCER	 First patient in Phase II DOVACC		Topline results Phase II DOVACC*
	HEAD AND NECK CANCER			Topline results Phase II FOCUS*
	NON-SMALL CELL LUNG CANCER		H1: First patient in Phase II LUNGVAC	
T E T	 First patient 2 <sup>nd</sup> cohort TENDU	Q4: Final safety data TENDU	* DOVACC, FOCUS and LUNGVAC: Readout estimates will be updated with the Q4 2022 report	

# Key Takeaways from the Q4 2021 Report

- Good clinical progress with increased patient enrollment rate in INITIUM and NIPU
- Ultimovacs has coped well with the challenges caused by Covid-19
  - minor adjustments in the guidance on topline readout for INITIUM and NIPU
- New Phase II trial in NSCLC
  - a further extension of the broad UV1 Phase II program - 5 indications, different combinations, >650 patients at close to 100 hospitals in appr. 15 countries
- Further encouraging results from the Phase I clinical trial of UV1 combined with pembrolizumab in malignant melanoma
- FDA Fast Track and Orphan Drug Designations received for UV1 in the lead indication, metastatic melanoma
- Good progress in the development of TET and no safety concerns observed in the two first patient cohorts in TENDU
- Successful Capital Raise (MNOK 270/MUSD 30) – estimated financial runway to the first part of 2024



Q & A





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Inc

For questions

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