



# Enabling the Immune System to Fight Cancer

Third Quarter 2021 Presentation  
11 November 2021

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## Table of Contents

Highlights Q3 2021

Operational Update Q3 2021

Key financials Q3 2021 & Newsflow

# Highlights Q3 2021

## **New Phase II trial in NSCLC – UV1 to be investigated with pembrolizumab**

- 138 patients
- Drammen Hospital is the sponsor
- 8-10 sites in Norway

## **Successful Capital Raise**

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

## Highlights Q3 2021 (cont.)

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### Further encouraging results from the Phase I clinical trial of UV1 combined with pembrolizumab in malignant melanoma

- 30 patients split on two cohorts
- Data from cohort 1 were presented in June at the ASCO 2021 Annual Meeting.
- Results from cohort 2 were announced on 12 August 2021
- **2-year survival data from cohort 1 were announced on 13 October 2021**
- **Consistent set of data showing strong initial signals of clinical response and a good safety profile supporting use of UV1 in combination treatments**

## Highlights Q3 2021 (cont.)

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### **Fast Track designation confirms our confidence in the therapeutic potential of UV1**

**Fast Track designation**, mandates the FDA to facilitate the development and expedite review of drugs and biologics:

- intended to treat serious or life-threatening conditions and
- that demonstrate the potential to address unmet medical needs

**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

## Highlights Q3 2021 (cont.)



### UV1 - Fast Track Benefits

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

# Highlights Q3 2021 (cont.)

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## Continued progress in the broad UV1 Phase II program

- **INITIUM (154 patients):** Ultimovacs sponsored trial in malignant melanoma in which UV1 is combined with nivolumab and ipilimumab.
  - **91 patients enrolled as of 10 November 2021 (compared to 68 patients in the previous quarterly report)**
- **NIPU (118 patients):** trial in mesothelioma, UV1 in combination with nivolumab and ipilimumab. Oslo University Hospital is the sponsor of the NIPU study. Bristol-Myers Squibb and Ultimovacs have entered into agreements with OUS to support the execution of the trial.
  - **45 patients enrolled as of 10 November 2021 (compared to 38 patients in the previous quarterly report)**
- **The DOVACC trial (184 patients):** Collaboration study with NSGO-CTU, ENGOT and AstraZeneca in ovarian cancer, UV1 is combined with durvalumab and Olaparib.
  - **Regulatory approval in place and first site opened, first patient expected during Q4 2021**
- **FOCUS (75 patients):** trial in collaboration with the Immunological Tumor Group at University Medicine Halle, Germany, where UV1 will be given in combination with pembrolizumab in head and neck cancer patients.
  - **5 patients enrolled as of 10 November 2021 (compared to none in the previous quarterly report)**

## **Highlights Q3 2021 (cont.)**

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### **Covid-19 impact**

- The effect of the pandemic on the biotech industry and the general ability to conduct clinical trials is still uncertain and dependent on the speed of return to a more normal situation
- Ultimovacs continues to monitor the impact from COVID-19 on its clinical trials and to implement activities to minimize the impact on patient recruitment
- Ultimovacs will update the guidance for INITIUM and our investigator-initiated Phase II trials in our Q4 2021 report
- Enrollment updates will continue to be provided in each quarterly report

## **Highlights Q3 2021 (cont.)**

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### **TENDU**

- Enrollment of the first cohort of three patients was completed in Q2 2021
- In June 2021, the Drug Safety Monitoring Board allowed the dose to be increased to 400 µg for the next three patients in cohort 2
- The first patient in the second cohort was enrolled in September 2021



## Table of Contents

Highlights Q3 2021

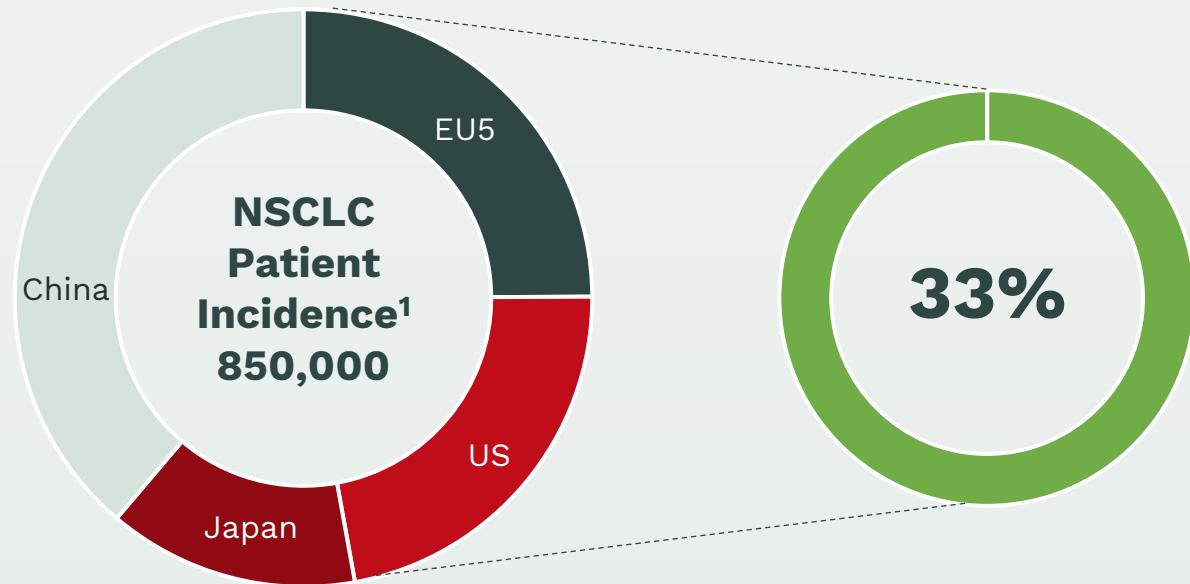
Operational Update Q3 2021

Key Financials Q3 2021 & Newsflow

# UV1 with strong potential to enhance standard of care for NSCLC patients

## ABOUT NSCLC

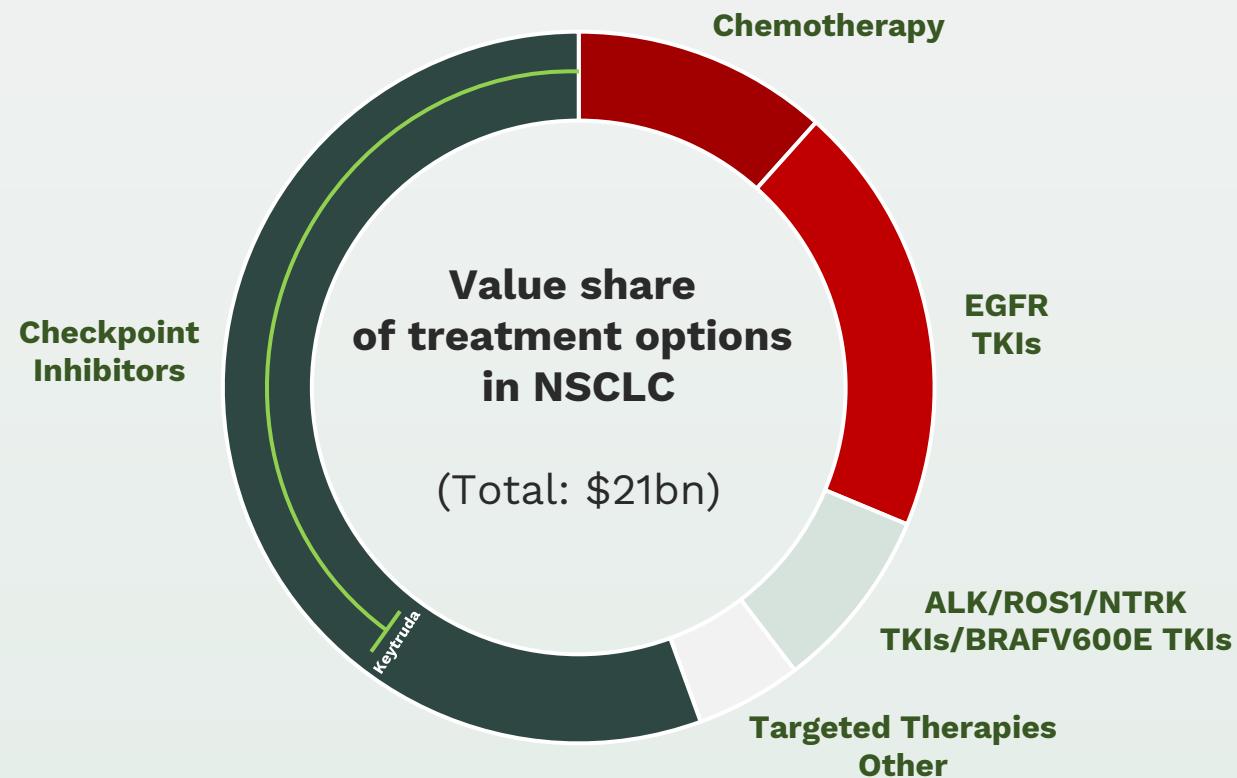
- Among the most common cancer in men and women
- NSCLC represents ~85% of all lung cancers
- Poor prognosis: 5 year survival at ~25%<sup>2</sup>



**1/3 of the total NSCLC population is potentially eligible for UV1/Pembrolizumab treatment**

# UV1 as a valuable combination treatment to pembrolizumab in NSCLC

## Global NSCLC Market Value



- Checkpoint inhibitors (CPIs) are standard of care for advanced & recurrent NSCLC with a ~56% value share (in US\$)
- Pembrolizumab's<sup>1</sup> market share of CPIs in NSCLC is ~ 67% (in US\$)
- UV1 to be combined with best selling CPI in NSCLC

Source: Global Data - Data related to 2020

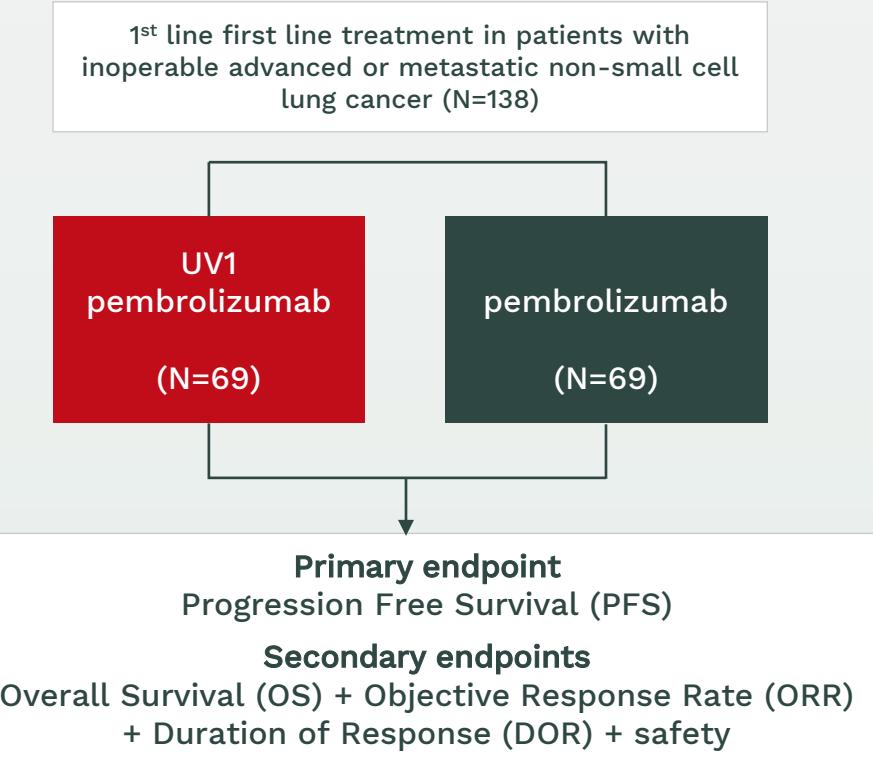
1. Pembrolizumab is indicated as monotherapy treatment for patients with stage IIIB/IIIC or stage IV NSCLC for treatment in the first-line setting in patients with tumor expressing PDL1 above 50% and no EGFR or ALK translocation

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# LUNGVAC: New phase II trial of UV1 in NSCLC

- **LUNGVAC: advanced or metastatic non-small cell lung cancer**

- **Combination:** Pembrolizumab (Keytruda)
- **Patients:** 138 patients, 8-10 hospitals in Norway
- **Milestones:** First patient expected enrolment H1 2022
- Topline results expected end of 2024
- **Contributors:** Sponsored by Drammen Hospital with Odd Terje Brustugun, MD PhD. as principal investigator



# Broad Phase II UV1 Pipeline with >650 Patients

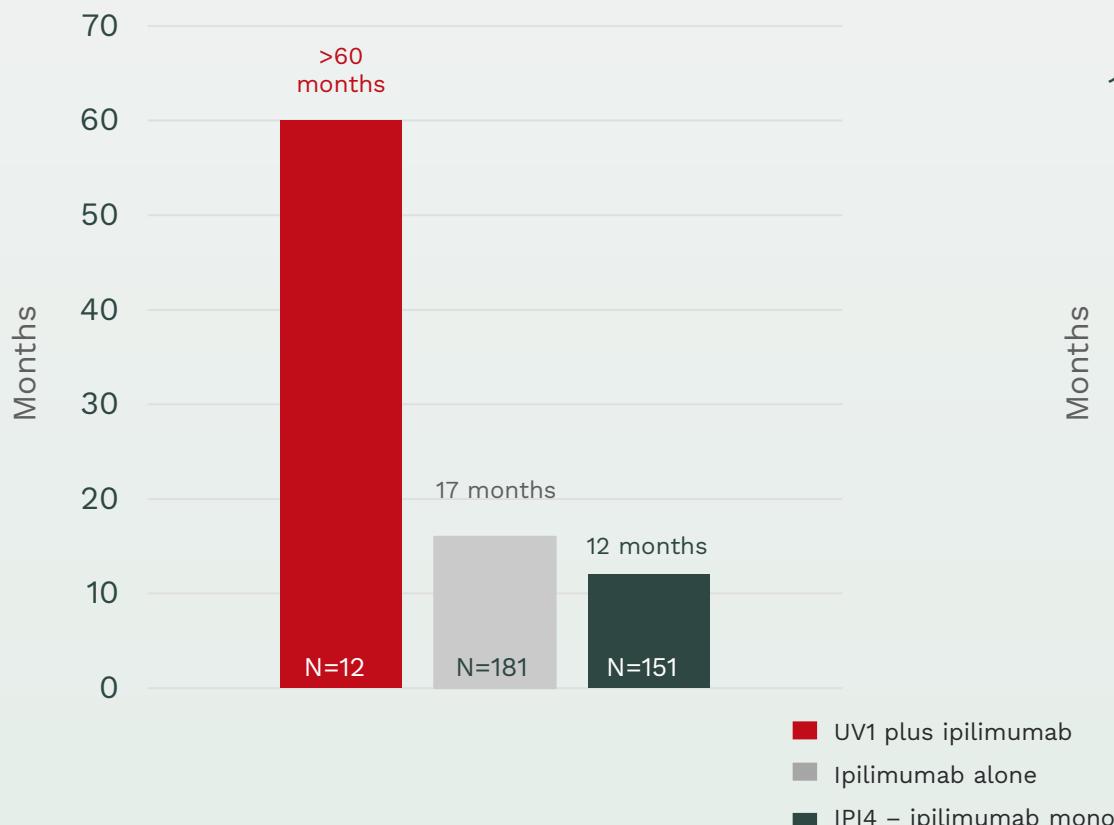
	Indication	Clinical trial information	Pre-clinical	Phase I	Phase II	Phase III	Contributors
UV1	First line metastatic malignant melanoma	With pembrolizumab 30 patients					
	First line metastatic malignant melanoma	With ipilimumab & nivolumab 154 patients			INITIUM		
	Second line mesothelioma	With ipilimumab & nivolumab 118 patients			NIPU		 Bristol-Myers Squibb <sup>1</sup>  Oslo University Hospital
	Second line ovarian cancer	With durvalumab & olaparib 184 patients			DOVACC		 NSGO  ENGOT <sup>1</sup> AstraZeneca 
	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 9-12 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.

# UV1 Phase 1: Positive 5-Year Safety and Efficacy in Malignant Melanoma

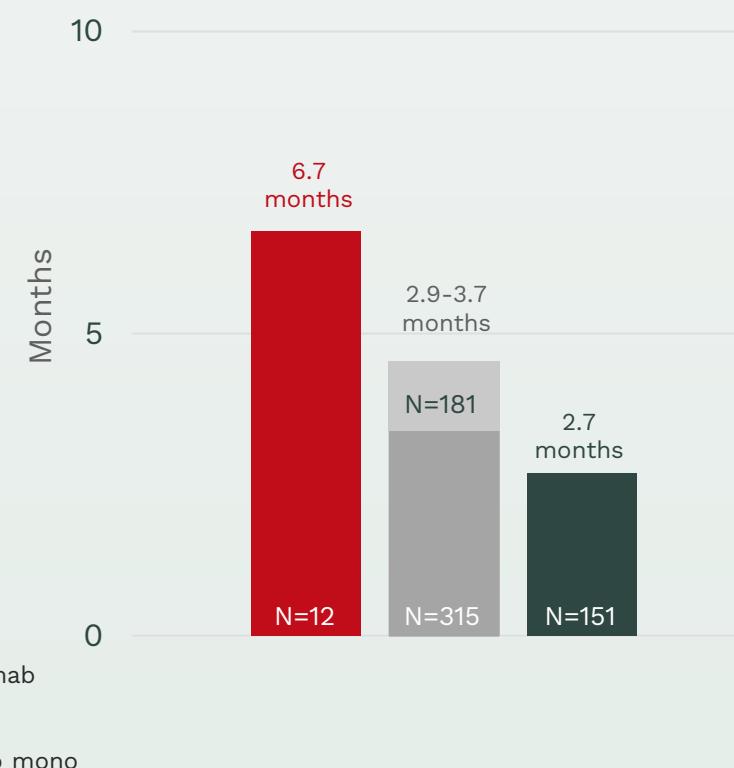
## Median Overall Survival

Topline readout of Phase 1 trials at Year 5<sup>1</sup>  
vs historical comparison with monotherapy<sup>2</sup> and  
IPI4 study<sup>3</sup>



## Median Progression Free Survival

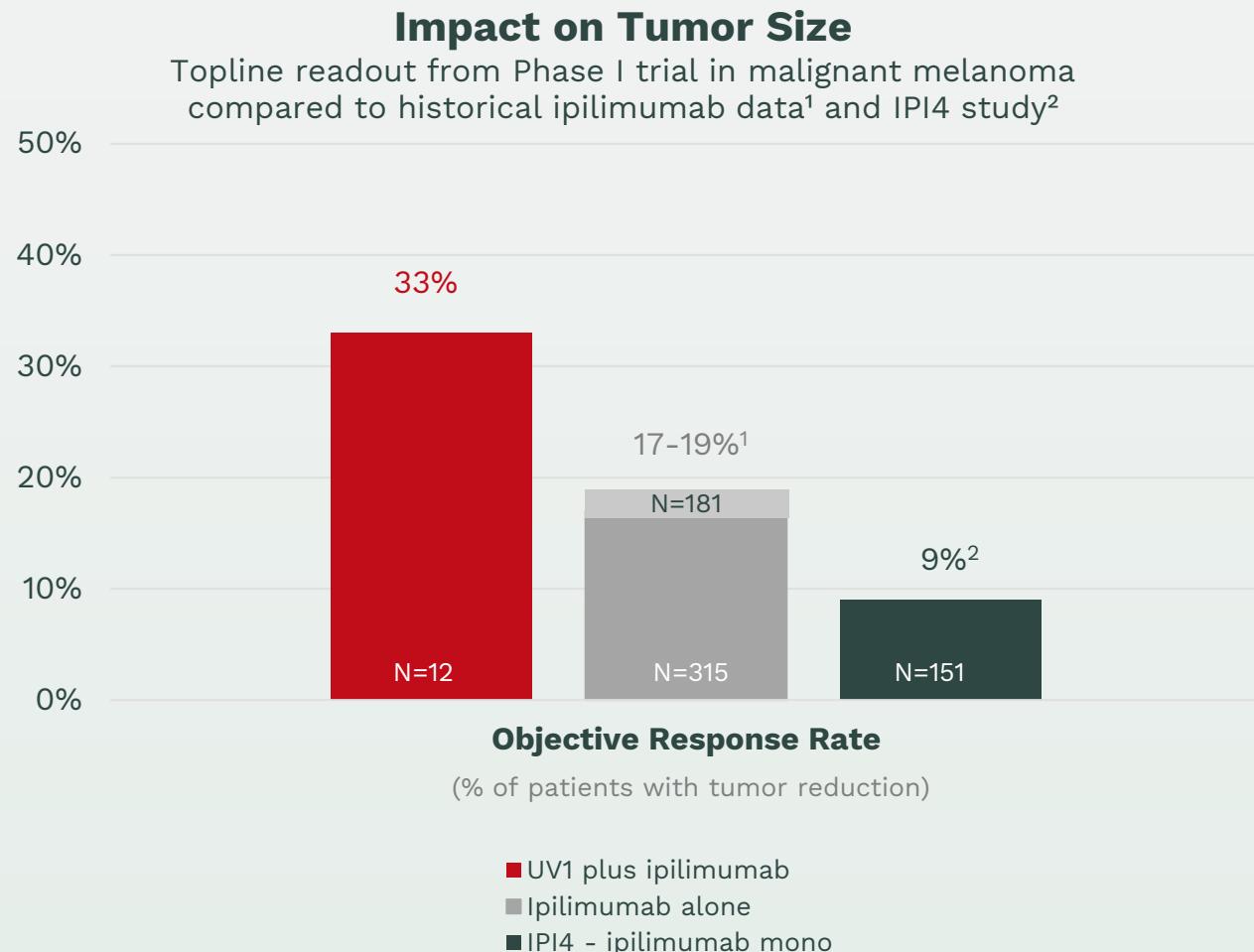
Topline readout of Phase 1 trials at Year 5<sup>1</sup>  
vs historical comparison with monotherapy<sup>2</sup> and  
IPI4 study<sup>3</sup>



- Safety profile supports clinical progression
- Signals of clinical efficacy observed

# Phase I UV1 + ipilimumab in Malignant Melanoma

Strong response rates vs. historical ipilimumab data



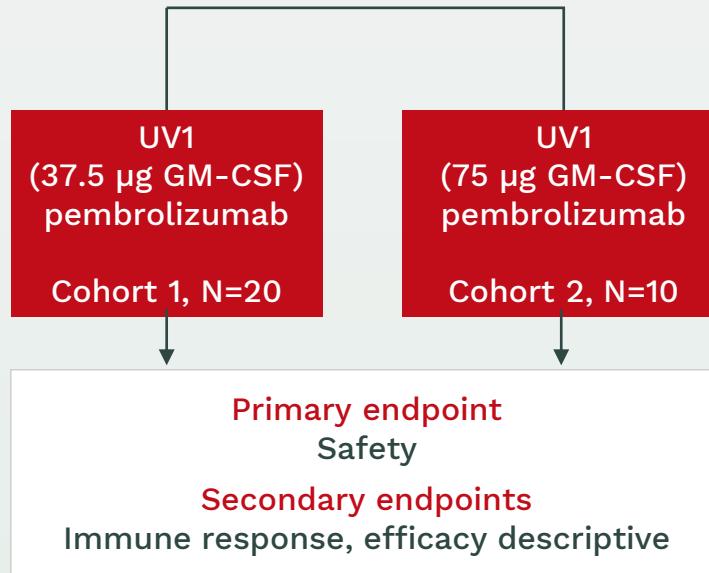
<sup>1</sup> Robert C et al. Lancet Oncol. 2019; 20: 1239-51 (n=181), Larkin J et al. N Engl J Med. 2015 Jul 2;373(1):23-34 (n=315)

<sup>2</sup> Historical control for the melanoma study: Aamdal, E. et al (2021) Ipilimumab in a real-world population: A prospective phase IV trial with long-term follow-up. Int. J. Cancer. <https://doi.org/10.1002/ijc.33768>

# Phase I UV1 + pembrolizumab in Malignant Melanoma

Encouraging results with good safety and strong signals of efficacy

## Phase I Trial Design



## Key results as of Q4 2021:

- Good safety profile supporting use of UV1 in combination treatments
  - Safety of combination similar to PD1 antibody (e.g., pembrolizumab) alone, except injection site reactions
- Consistent set of data showing strong initial signals of clinical response

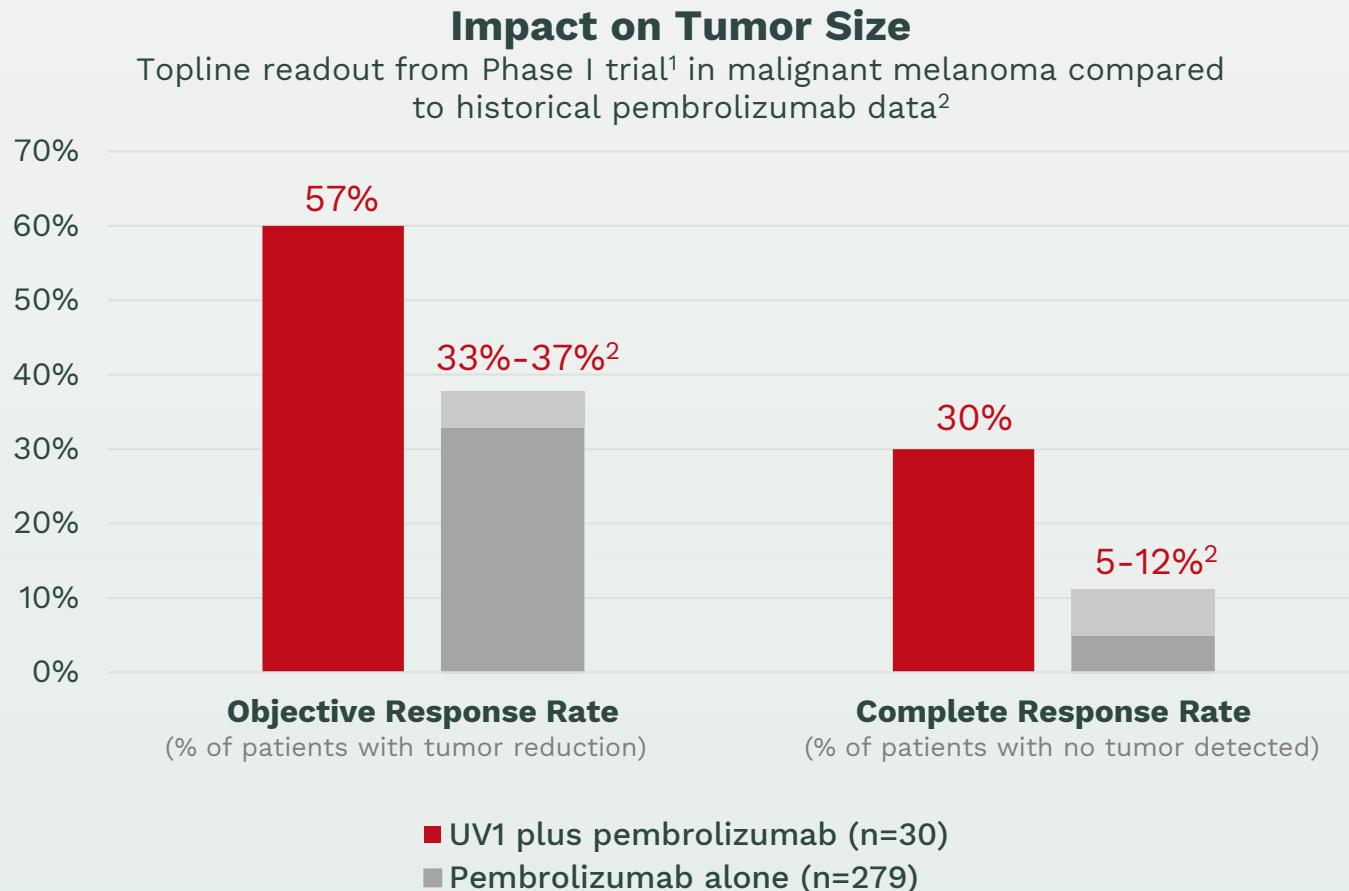
# Phase I UV1 + pembrolizumab in Malignant Melanoma

## 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>
  - stable disease (SD) 2/30<sup>1</sup>
  - progressive disease (PD) 11/30
- Objective response rate (ORR) 57%,  
Complete response rate (CR) 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%

# Phase I UV1 + pembrolizumab in Malignant Melanoma

Strong response rates vs. historical pembrolizumab data



<sup>1</sup> Cohort 1 at 18 months, Cohort 2 at 12 months.

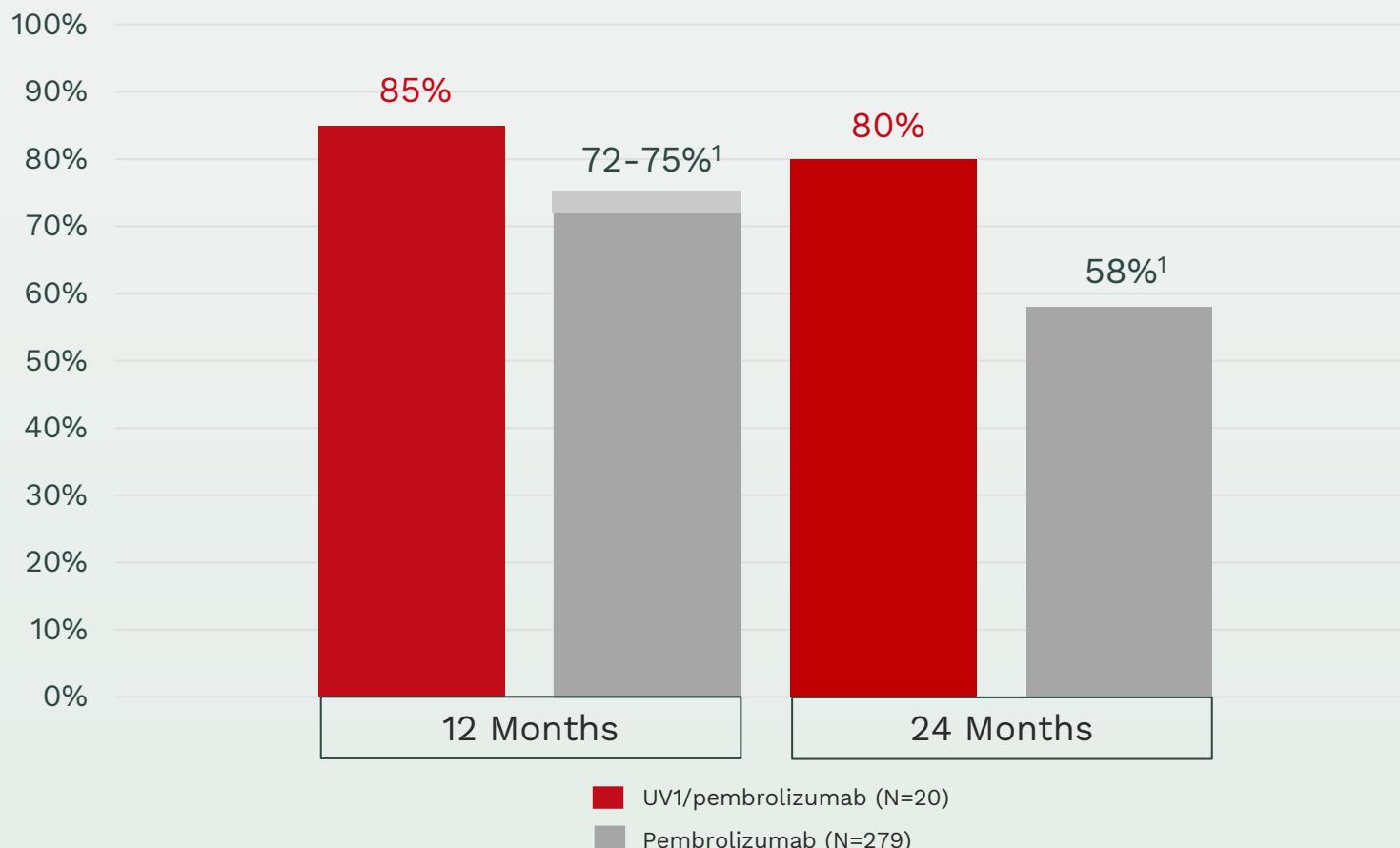
<sup>2</sup> Data from KEYNOTE-006 (Robert C, 2019). KEYNOTE-006 is the pivotal study referred to in the Keytruda (pembrolizumab) package inserts. Data from Robert C (2019) is a post-hoc non-planned analysis. UV1/pembrolizumab phase I/II trial measured by iRECIST. KEYNOTE-006 was measured by RECIST 1.1.

# Phase I UV1 + pembrolizumab in Malignant Melanoma

Encouraging OS & mPFS vs. historical pembrolizumab data

## Overall Survival at 12 and 24 months – Cohort 1

Topline readout from Phase I trial in malignant melanoma compared to historical pembrolizumab data<sup>1</sup>



## Median Progression Free Survival

### UV1 + pembrolizumab:

- Cohort 1: 18.9 months
- Cohort 2: not reached at 12 months
- Cohort 1+2 combined: not reached at 12 months

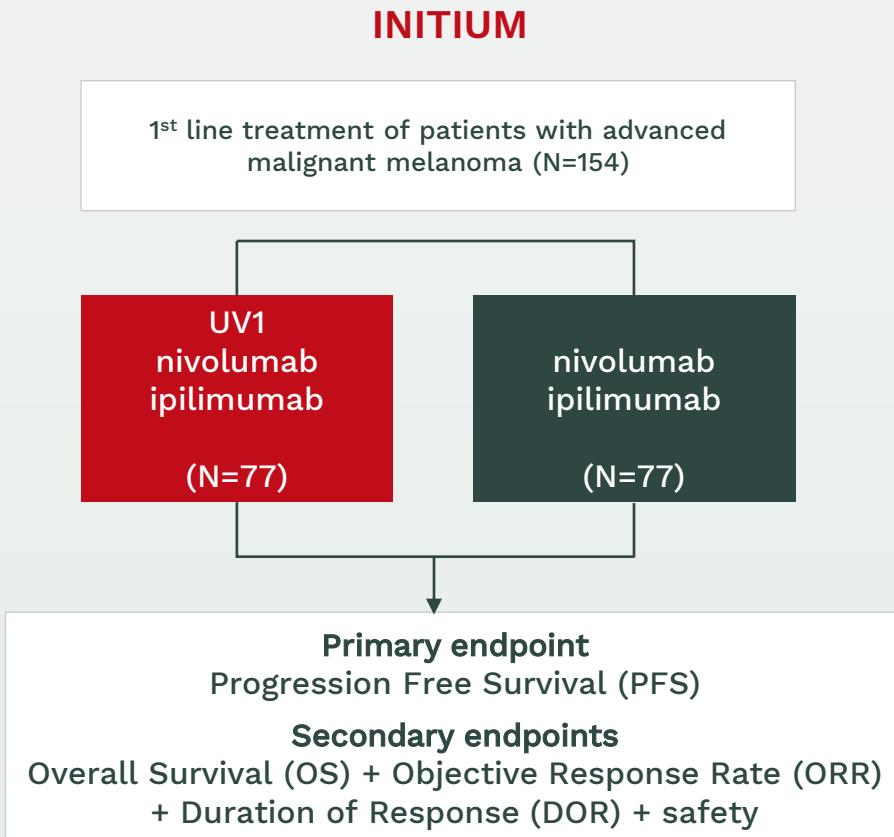
### Pembrolizumab:

- 5.5-11.6 months<sup>1</sup>

# Next Steps for UV1 in Advanced Malignant Melanoma

## – INITIUM Phase II trial

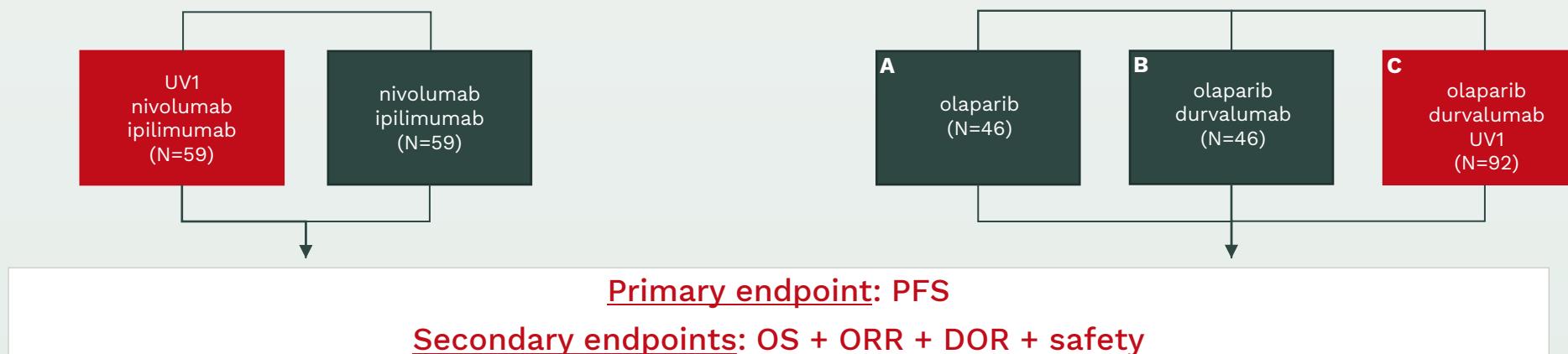
- **INITIUM Phase II combination trial with nivolumab and ipilimumab in malignant melanoma ongoing**
  - Enrollment ongoing since June 2020
  - 154 patients in 38 sites in 4 countries (US, UK, Belgium and Norway)
  - 91 patients enrolled as of 10 November 2021 (Q3 2021 reporting)
  - Topline results expected H2 2022



# NIPU & DOVACC Phase II Trials

NIPU: Malignant pleural mesothelioma

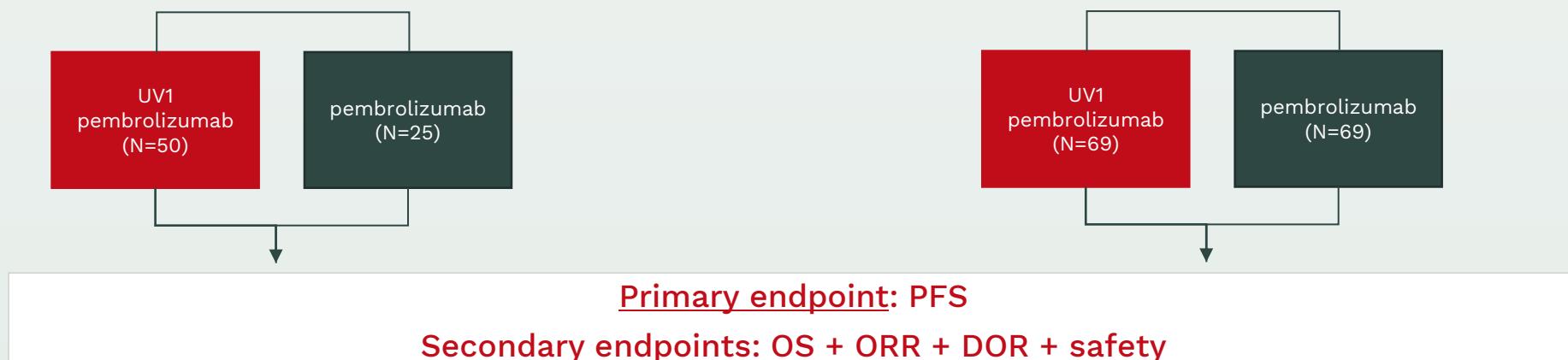
- **Combination:** nivolumab, ipilimumab
- **Contributors:** Oslo University Hospital (sponsor); BMS
- **Patients:** 118 from 6 sites: Norway, Sweden, DK, Spain, Australia
- Enrollment ongoing since June 2020
- 45 patients enrolled as of 10 November 2021 (Q3 2021 reporting)
- **Milestones:** Topline results expected H2 2022



# FOCUS and LUNGVAC Phase II Trials

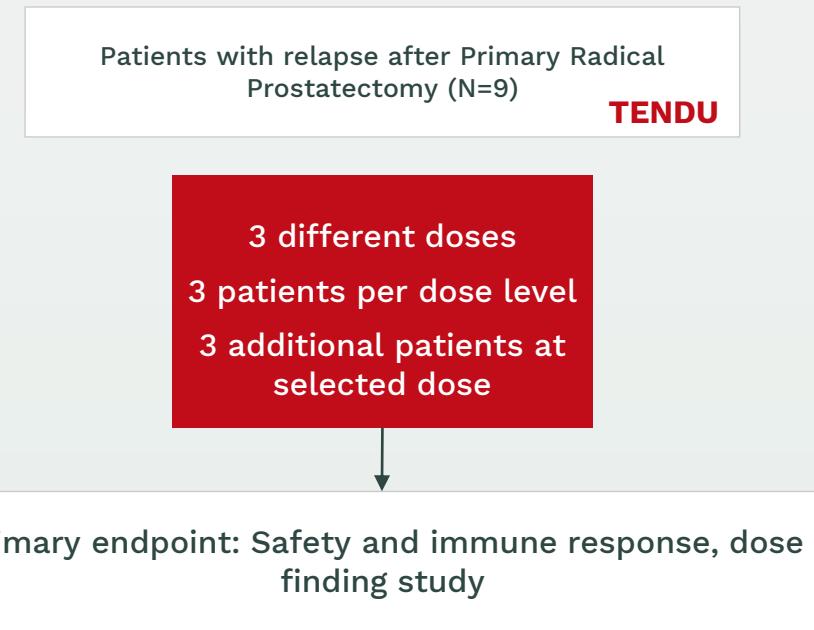
FOCUS: Head and neck squamous cell carcinoma

- **Combination:** pembrolizumab
- **Contributors:** Sponsored by Halle University Hospital network
- **Patients:** 75 from 10 sites in Germany
- First patient enrolled August 2021
- 5 patients enrolled as of 10 November 2021 (Q3 2021 reporting)
- **Milestones:** Topline results expected 2023



# 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, these are targeted by antibodies that already exist in our body, as a result of childhood vaccination programs in the U.S. and Europe
- The **TENDU trial** investigates a prostate cancer specific vaccine based on the TET technology
  - Conducted at Oslo University Hospital
  - 9 patients will be enrolled
  - 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
  - Enrollment of the first cohort of three patients was completed in Q2 2021
  - In June, the Drug Safety Monitoring Board allowed the dose to be increased to 400 µg for the next three patients in cohort 2
  - **First patient in second cohort enrolled in September 2021**





## Table of Contents

Highlights Q3 2021

Operational Update Q3 2021

Key Financials Q3 2021 & Newsflow

## Private Placement in October 2021

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- 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
- **The net proceeds of the private placement will be used for:**
  - (i) financing of the LUNGVAC Phase II trial evaluating UV1 in non-small cell lung cancer,
  - (ii) bringing the UV1 platform into Phase III readiness,
  - (iii) further development of the Tetanus-Epitope-Targeting (“TET”) technology platform, and
  - (iv) general corporate purposes
- Following the Private Placement, the Company has a share capital of NOK 3,422,176.10 divided into 34,221,761 shares, each with a par value of NOK 0.10

# Key financials

## Key financials per Q3-2021 - Ultimovacs Group

NOK (000)	Q3-20	Q3-21	YTD20	YTD21	FY20
<b>Total revenues</b>	-	-	-	-	-
Payroll and payroll related expenses	13 115	23 314	36 327	50 031	50 989
External R&D and IPR expenses (incl. grants)	15 307	16 031	53 334	52 631	60 870
Other operating expenses (incl. depreciation)	2 695	3 171	8 897	10 241	12 287
<b>Total operating expenses</b>	<b>31 116</b>	<b>42 517</b>	<b>98 558</b>	<b>112 903</b>	<b>124 146</b>
<b>Operating profit (loss)</b>	<b>-31 116</b>	<b>-42 517</b>	<b>-98 558</b>	<b>-112 903</b>	<b>-124 146</b>
Net financial items	391	-791	2 587	-668	3 594
<b>Profit (loss) before tax</b>	<b>-30 725</b>	<b>-43 308</b>	<b>-95 971</b>	<b>-113 570</b>	<b>-120 552</b>
Net increase/(decrease) in cash and cash eq.	-29 186	-32 880	54 582	-90 751	42 058
<b>Cash and cash equivalents at end of period</b>	<b>453 523</b>	<b>347 804</b>	<b>453 523</b>	<b>347 804</b>	<b>440 925</b>
Number of FTEs at end of period	19	21	19	21	19

### Comments:

#### Payroll expenses

- Higher cost in Q3-21 than the same period in 2020 due to:
  - share-option costs (MNOK 12 higher), a non-cash item
  - two additional full-time employees in this period compared to Q3-20

#### External R&D and IPR expenses

- R&D costs approximately at the same level as the previous year. Amounts are shown net of grants, which are higher in the 2021 periods.

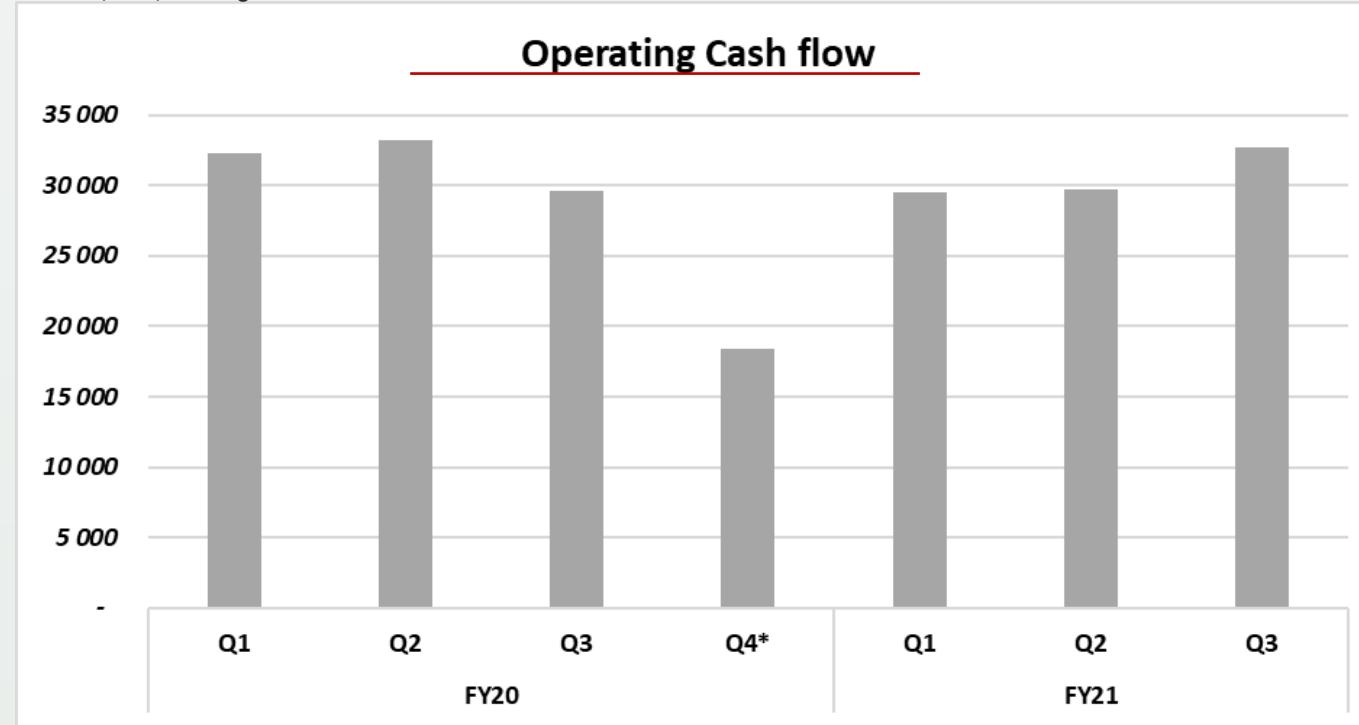
#### Other operating expenses

- Slight increase from the previous year

**Net cash of MNOK 348 at the end of Q3 2021  
(prior to the October 2021 capital raise)**

# Key financials – operating cash flow

NOK (000) – Negative amounts



\* Q4-20 are adjusted (increased) by MNOK 5 to exclude the receival of public grants from Skattefunn. No other adjustments made.

## Comments:

- The negative operating cashflow in Q3-21 is approximately at the same level as in the previous quarters in 2021.
- A further increase in negative operating cashflow related to R&D should be expected going forward with the initiation of new phase II trials (DOVACC and LUNGVAC), increased patient recruitment in ongoing trials and other R&D costs

## Key financials – quarterly overview

### Key financials per Q3-2021 - Ultimovacs Group

NOK (000)	Q1-20	Q2-20	Q3-20	Q4-20	Q1-21	Q2-21	Q3-21
<b>Total revenues</b>	-	-	-	-	-	-	-
Payroll and payroll related expenses	10 015	13 197	13 115	14 662	12 203	14 514	23 314
External R&D and IPR expenses (incl. grants)	18 089	19 938	15 307	7 537	16 012	20 588	16 031
Other operating expenses (incl. depreciation)	3 155	3 048	2 695	3 390	3 000	4 069	3 171
<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>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>
Net financial items	922	1 274	391	1 007	-2 582	2 706	-791
<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>
Net increase/(decrease) in cash and cash equivalents	-31 479	115 247	-29 186	-12 524	-28 213	-29 657	-32 880
<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>
Number of FTEs at end of period	19	19	19	19	21	21	21

# Expected News Flow and Milestones

	2021	2022	2023	2024
	Q4			
MALIGNANT MELANOMA	 Cohort 1 2-yr update Phase I US   Fast Track designation	H2: Topline results Phase II INITIUM  Q3: Cohort 2, 2-yr update Phase I US  H2: Topline results Phase II NIPU		
MALIGNANT PLEURAL MESOTHELIOMA				
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		By end of 2024: Topline results Phase II LUNGVAC
TET PLATFORM		Final safety data TENDU		

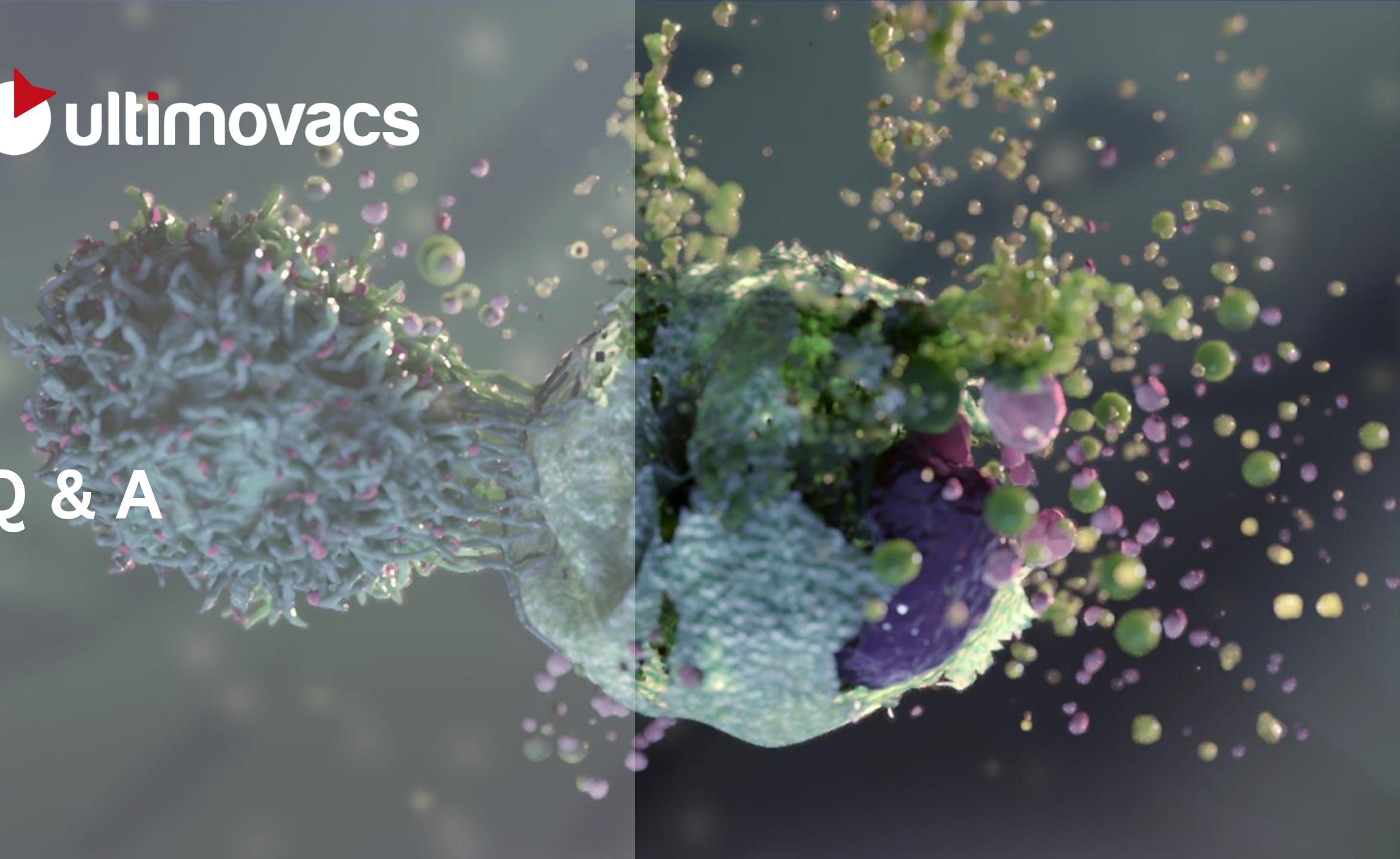
## Key Takeaways from the Q3 2021 Report

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- 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 strengthening of the encouraging results from the Phase I clinical trial of UV1 combined with pembrolizumab in malignant melanoma
- **Dual Fast Track designation confirms our confidence in the therapeutic potential of UV1**
- Updated guidance for read-out of the Phase II trials will be given in the Q4 2021 report
- The development of the TET platform continues – no safety issues in the TENDU trial so far, next dosing level initiated
- Successful capital raise of MNOK 270 in October 2021



Q & A





Enabling the Immune System to Fight Cancer

For questions

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