



# Enabling the Immune System to Fight Cancer

Third Quarter 2021 Presentation  
11 November 2021

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# Highlights Q3 2021

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## 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.)

### 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.)

### **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.)

## 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.)

### 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.)

### 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



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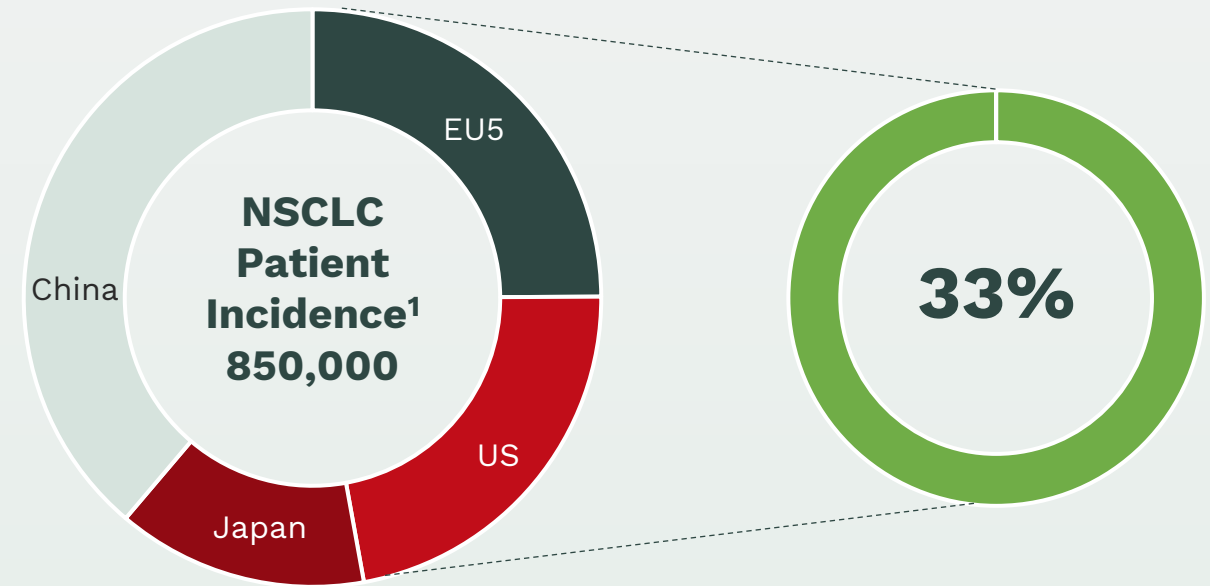
Operational Update Q3 2021

Key Financials Q3 2021 & Newsflow

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

## ABOUT NSCLC

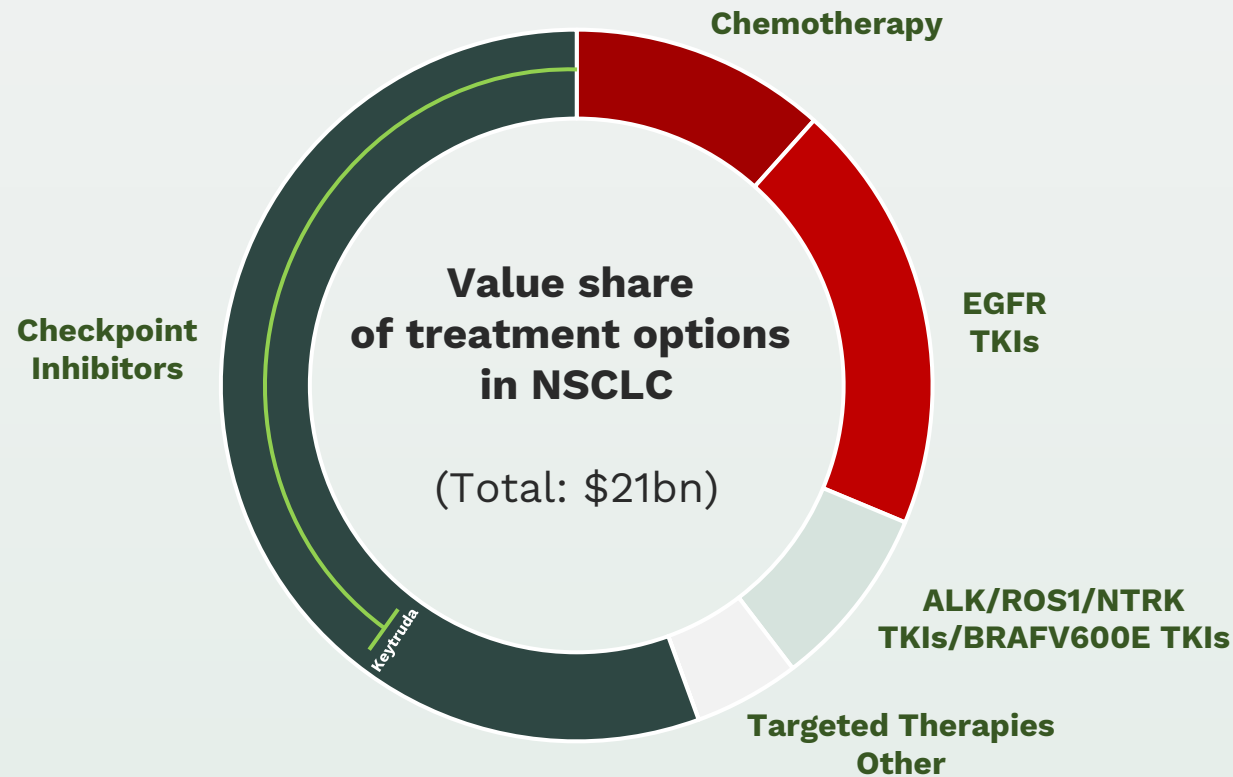
- Among the most common cancer in men and women
- NSCLC represents ~85% of all lung cancers
- Poor prognosis: 5 year survival at ~25%<sup>2</sup>



**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



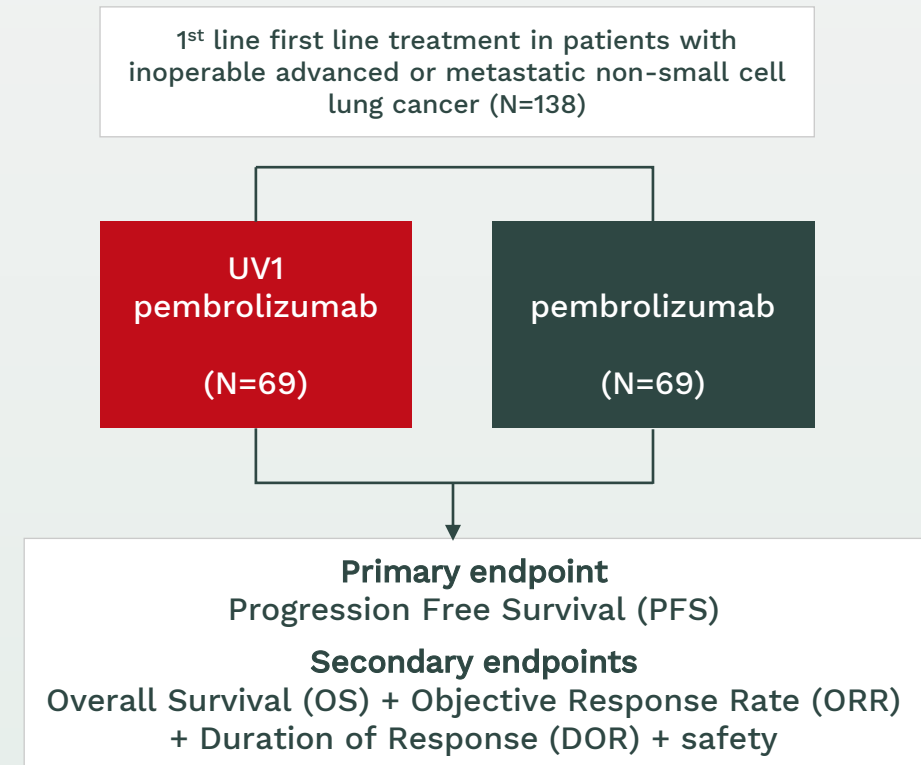
- Checkpoint inhibitors (CPIs) are standard of care for advanced & recurrent NSCLC with a ~56% value share (in US\$)
- Pembrolizumab's<sup>1</sup> market share of CPIs in NSCLC is ~ 67% (in US\$)
- UV1 to be combined with best selling CPI in NSCLC

Source: Global Data - Data related to 2020










# 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

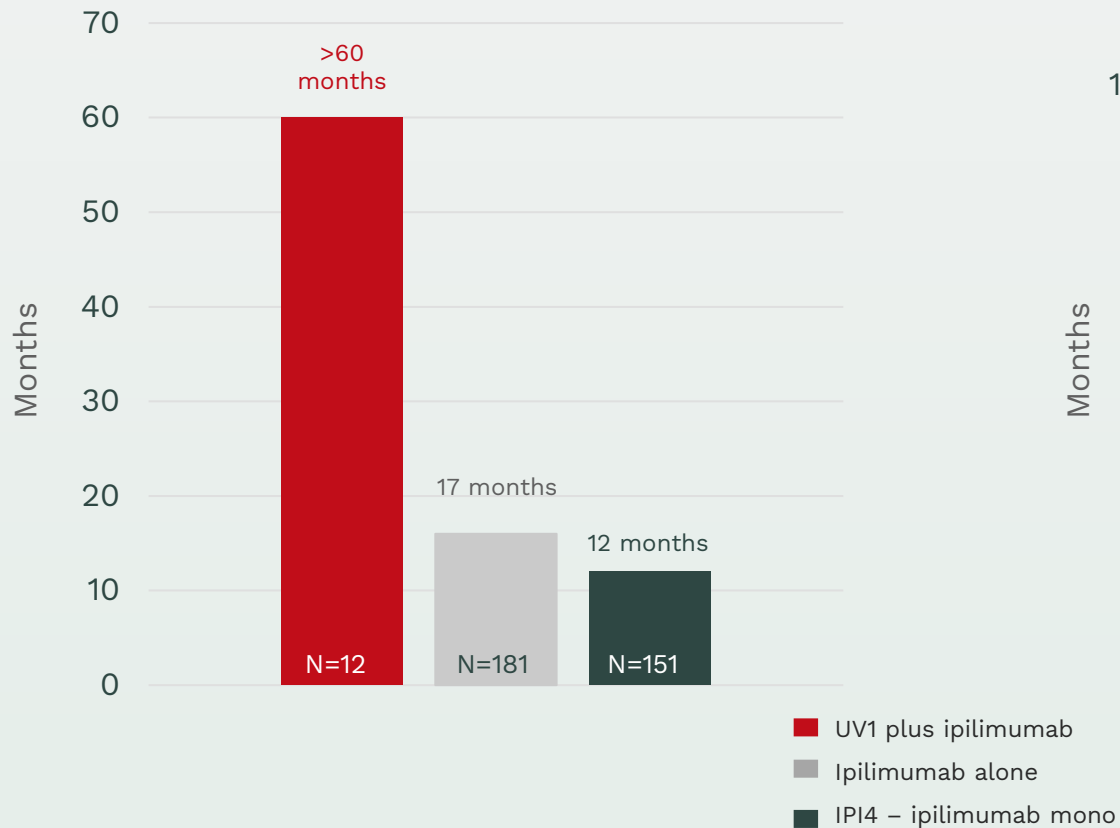
	Indication	Clinical trial information	Pre-clinical	Phase I	Phase II	Phase III	Contributors
UV1	First line metastatic malignant melanoma	With pembrolizumab 30 patients		●			
	First line metastatic malignant melanoma	With ipilimumab & nivolumab 154 patients			INITIUM ●		
	Second line mesothelioma	With ipilimumab & nivolumab 118 patients			NIPU ●		 <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 9-12 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

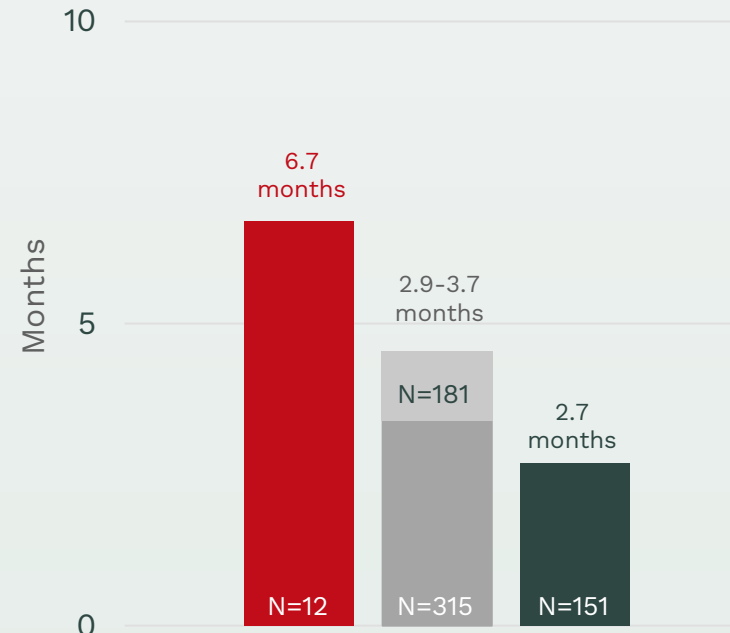
## Median Overall Survival

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

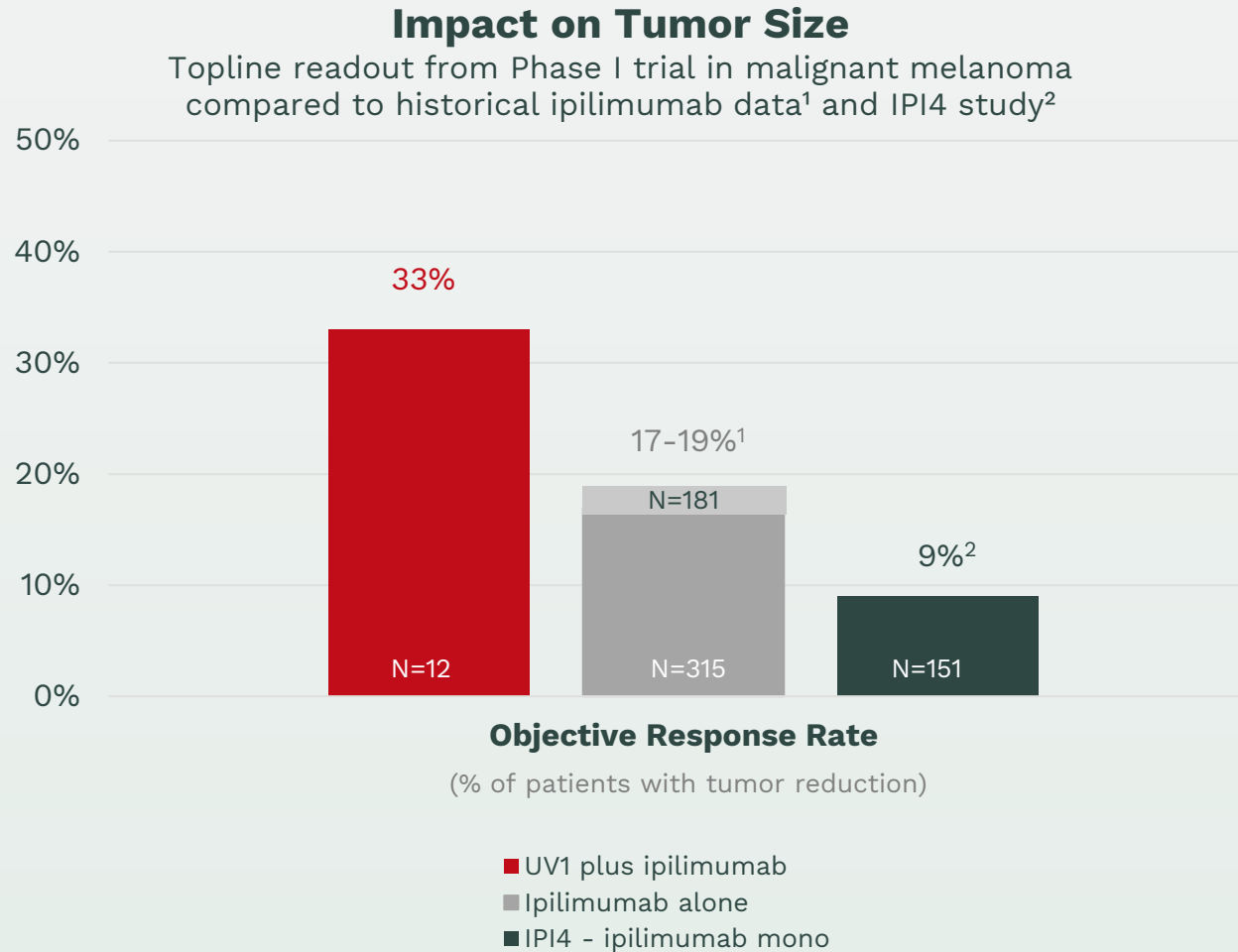
Topline readout of Phase 1 trials at Year 5<sup>1</sup>  
vs historical comparison with monotherapy<sup>2</sup> and  
IPI4 study<sup>3</sup>



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

# Phase I UV1 + ipilimumab in Malignant Melanoma

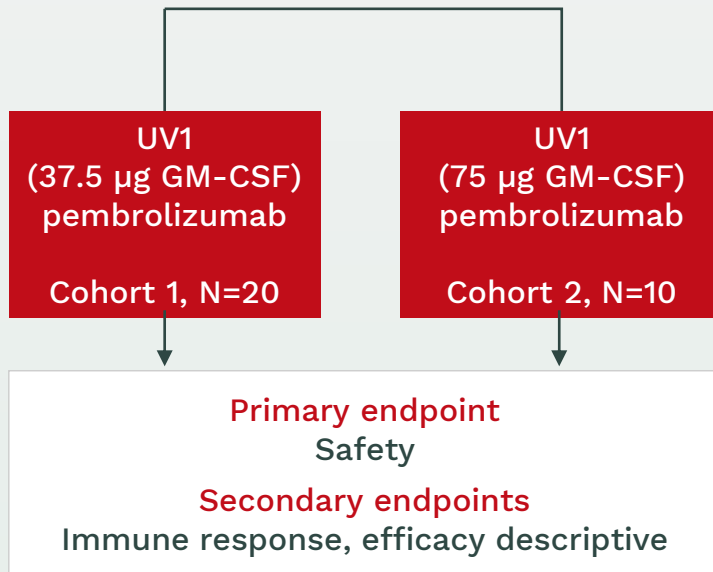
Strong response rates vs. historical ipilimumab data



# 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



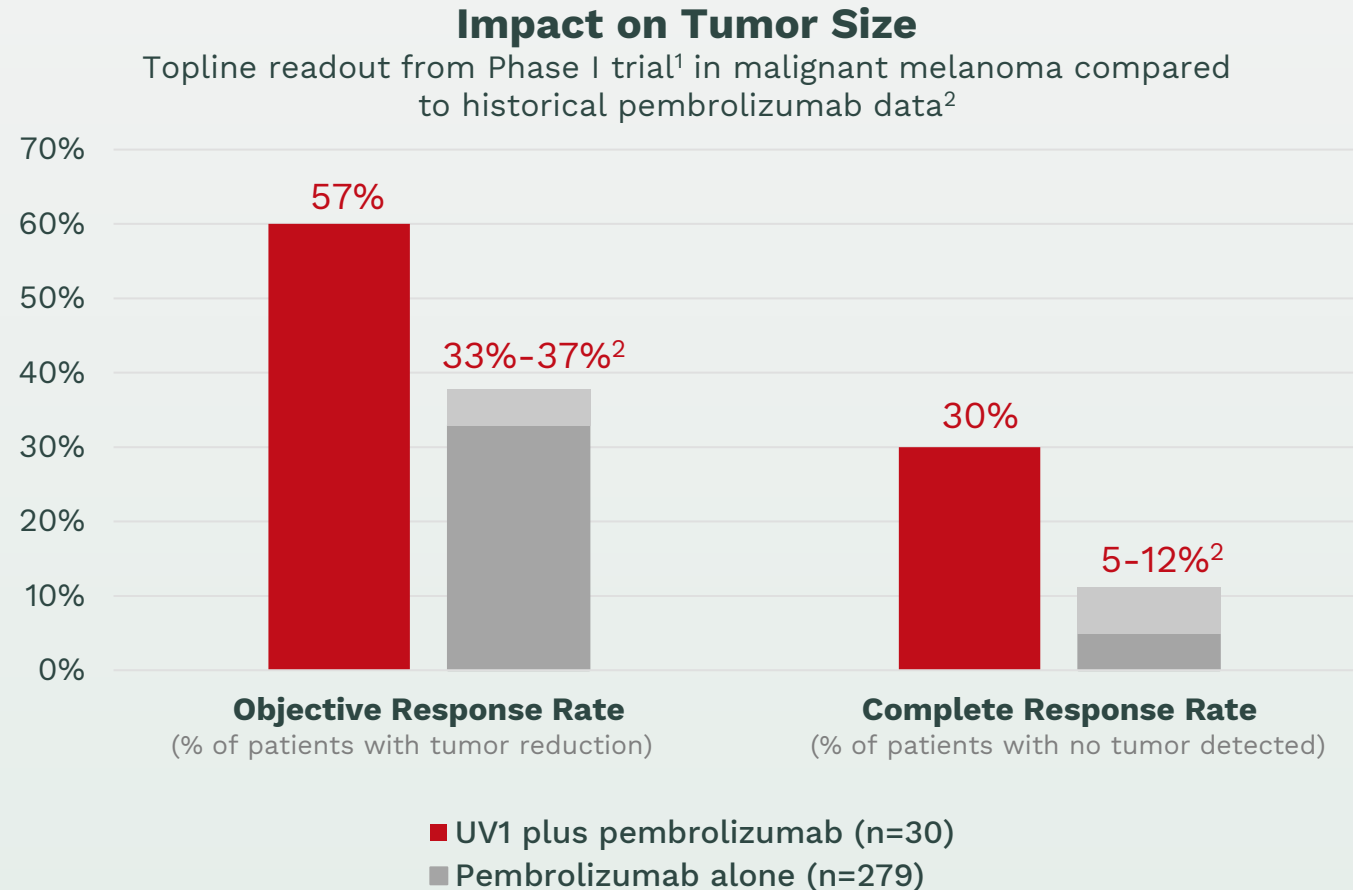
# Phase I UV1 + pembrolizumab in Malignant Melanoma

## 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> } **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%

# 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.

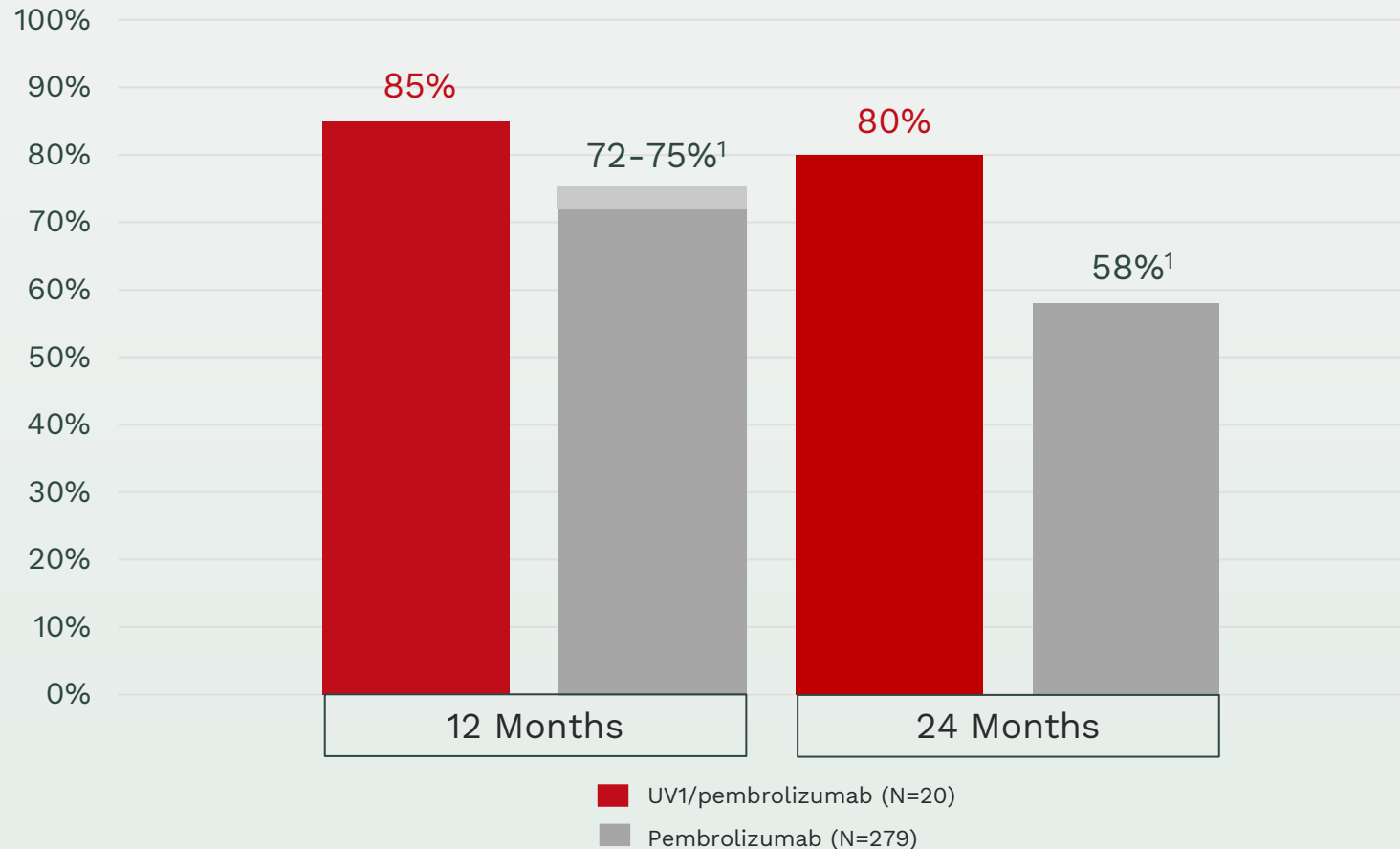
UV1/pembrolizumab phase I/II trial measured by iRECIST  
KEYNOTE-006 was measured by RECIST 1.1.

# 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

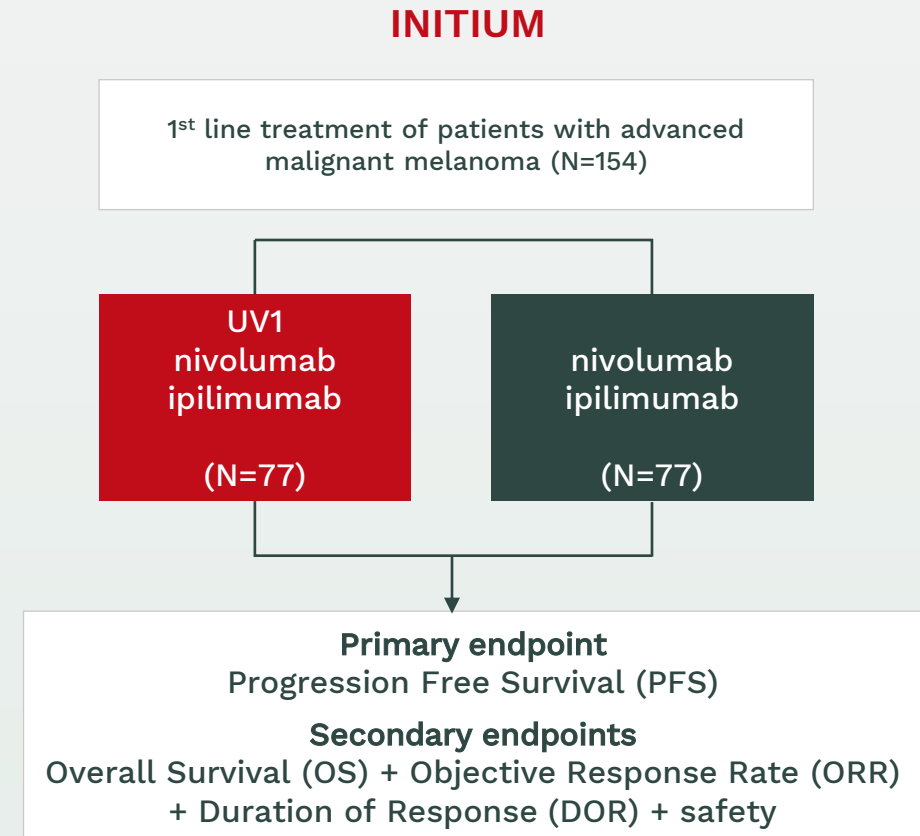
### Pembrolizumab:

- 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



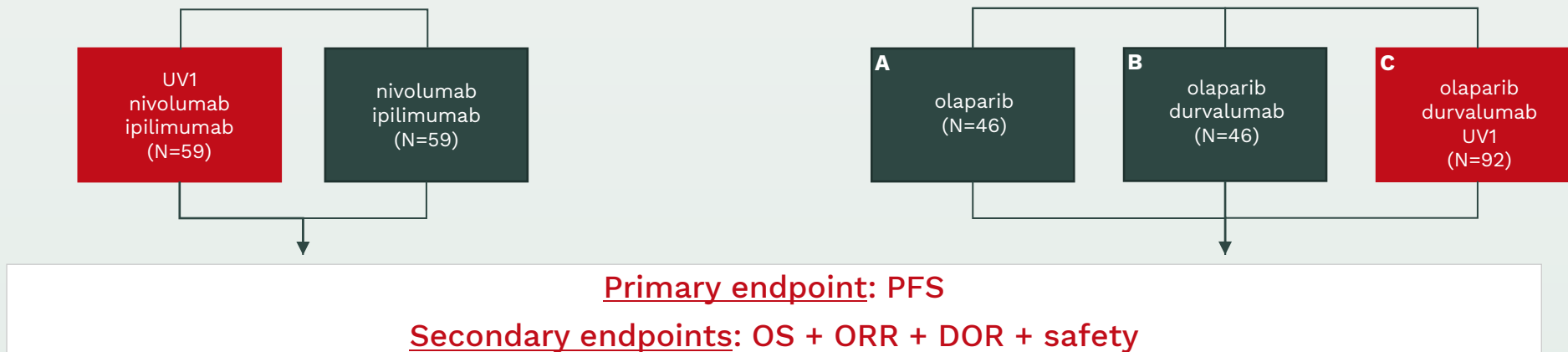
# NIPU & DOVACC Phase II Trials

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

DOVACC: Ovarian cancer

- **Combination:** olaparib, durvalumab
- **Contributors :** NSGO/ENGOT, Astra Zeneca
- **Patients:** 184 from >40 sites in ~10 European countries
- **Milestones:** FPFV expected Q4 2021  
Topline results expected 2023

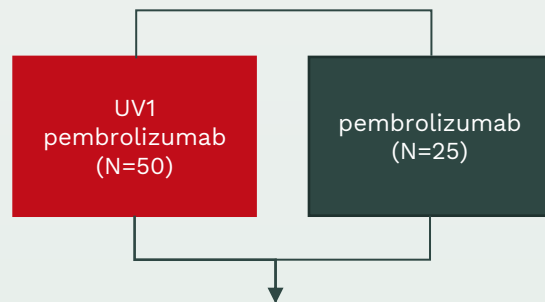




# FOCUS and LUNGVAC Phase II Trials

## 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

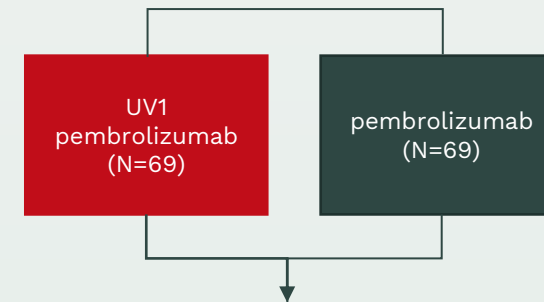


Primary endpoint: PFS

Secondary endpoints: OS + ORR + DOR + safety

## LUNGVAC: Advanced or metastatic NSCLC

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

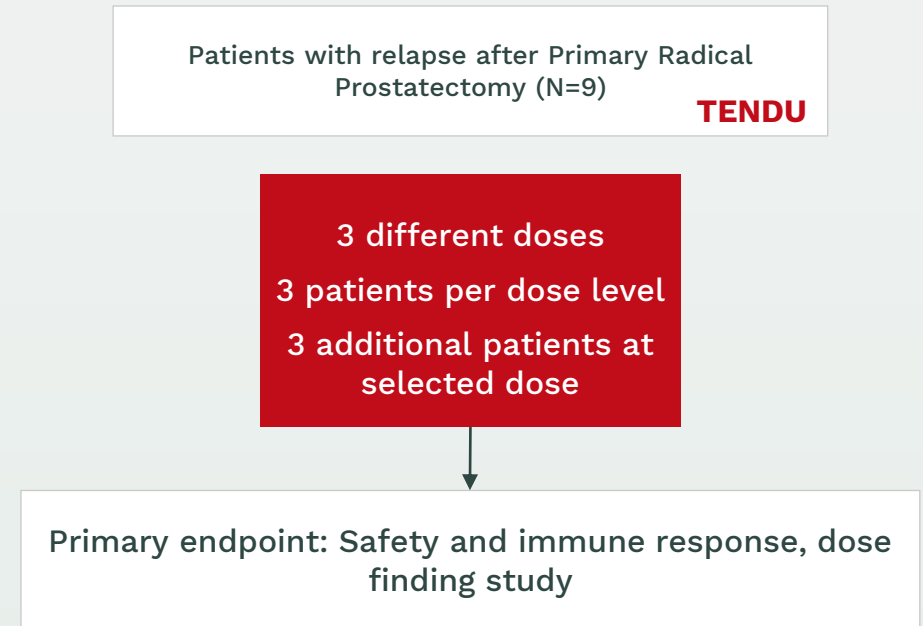


Primary endpoint: PFS

Secondary endpoints: OS + ORR + DOR + safety

# 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**





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**Key Financials Q3 2021 & Newsflow**

## Private Placement in October 2021

- 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.

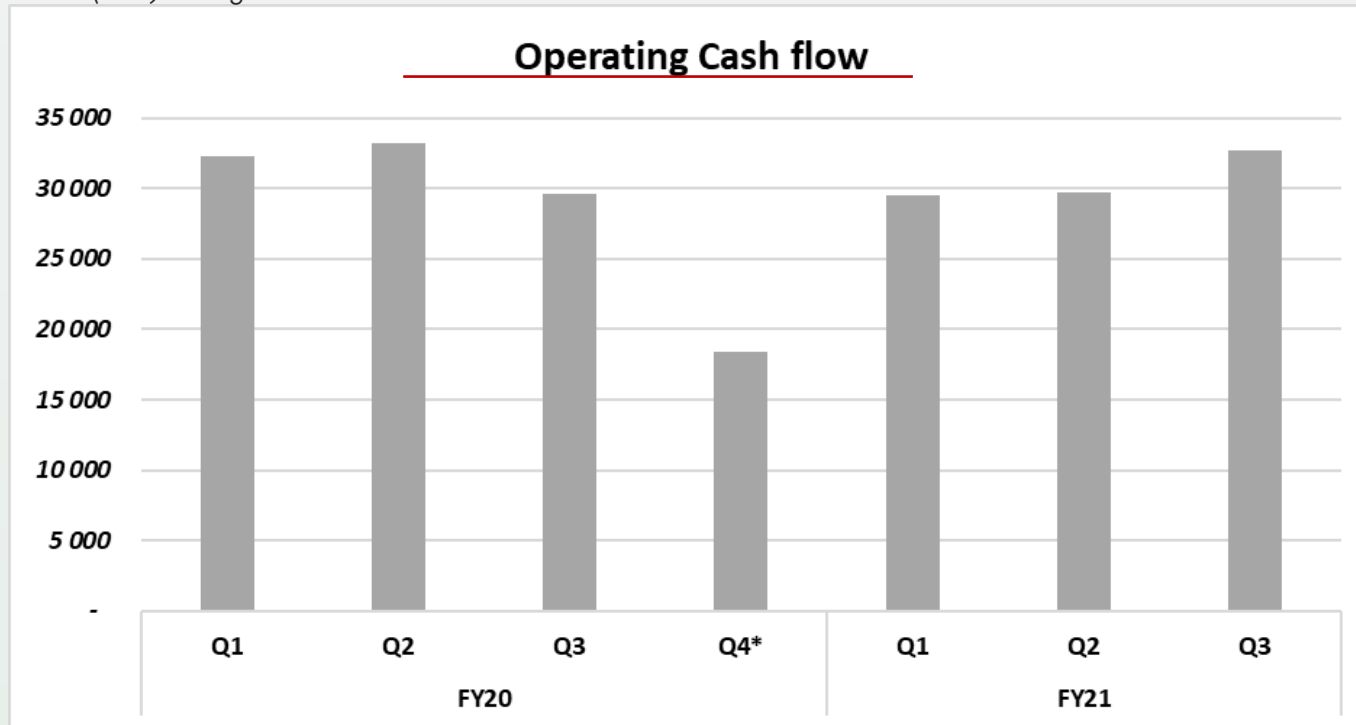
#### *Other operating expenses*

- 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 receipt 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 eq.uivalents	-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

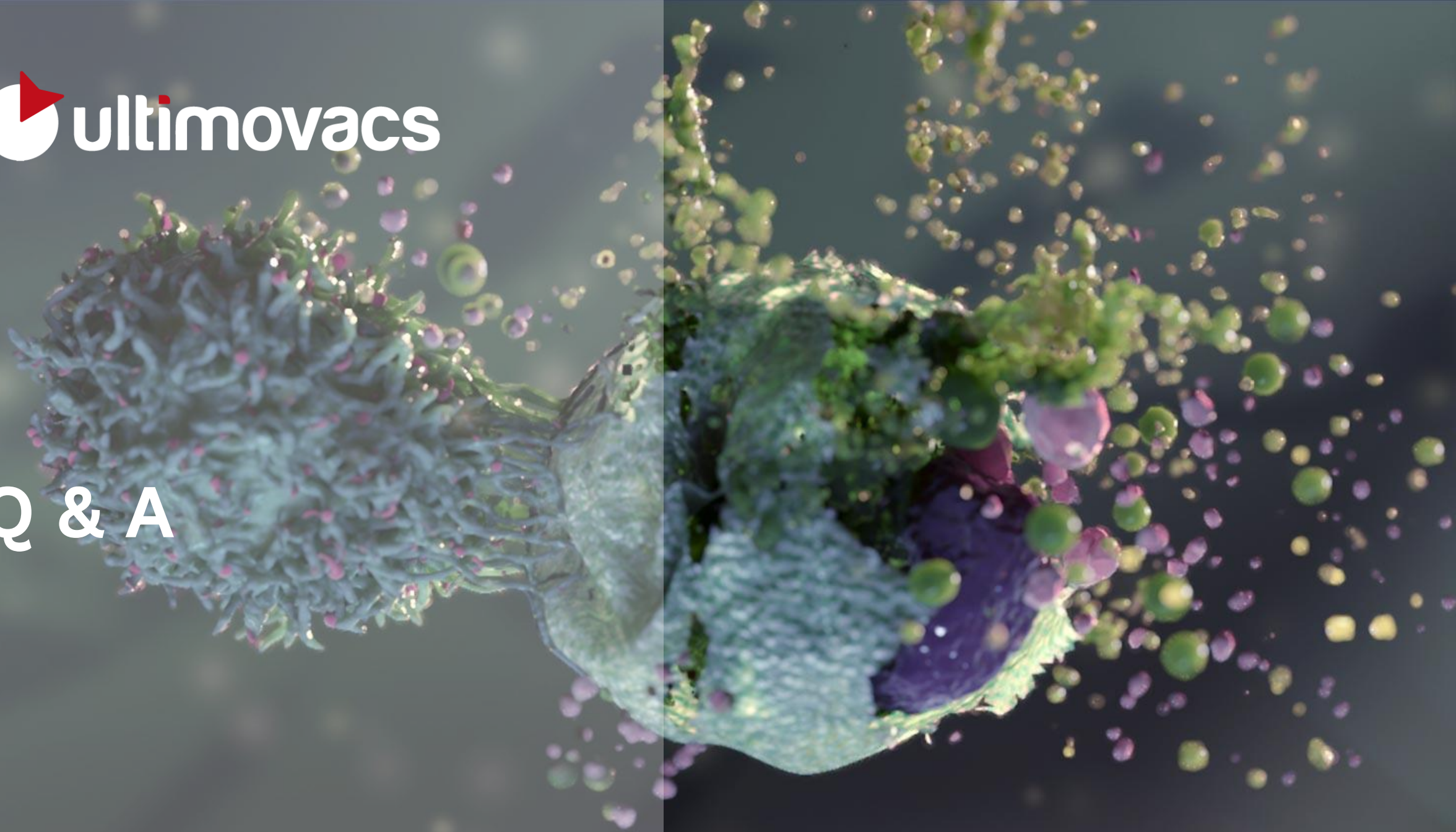
	2021	2022	2023	2024
	Q4			
MALIGNANT MELANOMA	<ul style="list-style-type: none"> <li>✓ Cohort 1 2-yr update Phase I US</li> <li>✓ Fast Track designation</li> </ul>	<ul style="list-style-type: none"> <li>H2: Topline results Phase II INITIUM</li> </ul>		
MALIGNANT PLEURAL MESOTHELIOMA		<ul style="list-style-type: none"> <li>Q3: Cohort 2, 2-yr update Phase I US</li> <li>H2: Topline results Phase II NIPU</li> </ul>		
OVARIAN CANCER	<ul style="list-style-type: none"> <li>First patient in Phase II DOVACC</li> </ul>		<ul style="list-style-type: none"> <li>Topline results Phase II DOVACC</li> </ul>	
HEAD AND NECK CANCER			<ul style="list-style-type: none"> <li>Topline results Phase II FOCUS</li> </ul>	
NON-SMALL CELL LUNG CANCER		<ul style="list-style-type: none"> <li>H1: First patient in Phase II LUNGVAC</li> </ul>		<ul style="list-style-type: none"> <li>By end of 2024: Topline results Phase II LUNGVAC</li> </ul>
TET PLATFORM		<ul style="list-style-type: none"> <li>Final safety data TENDU</li> </ul>		

# Key Takeaways from the Q3 2021 Report

- **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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