



# Enabling the Immune System to Fight Cancer

First Quarter 2022 Presentation

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## Highlights Q1 2022 – continued strong progress towards key milestones

- **INITIUM and NIPU on track to expected topline readout during H1 2023 with good patient enrollment**
- **Extended patent protection in the US for UV1 when used as combination treatment**
- **Complete disappearance of tumors observed in yet another patient in UV1-103, raising the complete response rate in the study to 33%**
- **Median overall survival reached at 66.3 months for the Phase I study in malignant melanoma where UV1 is combined with ipilimumab**
- **Continue to present to the medical and scientific community, valuable data from the clinical development activities**
- **Good progress in the development of TET**

# Highlights Q1 2022: Progress in UV1 Phase II Program is Encouraging

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

- **INITIUM:** 137 out of 154 patients enrolled, compared to 120 patients in the Q4 2022 report
- **NIPU:** 78 out of 118 patients enrolled, compared to 66 patients in the Q4 2022 report
- **DOVACC:** 4 out of 184 patients enrolled, compared to 2 patients in the Q4 2022 report
- **FOCUS:** 18 out of 75 patients enrolled, compared to 10 patients in the Q4 2022 report
  
- **LUNGVAC:** First patient expected to be enrolled during Q2 2022

## Highlights Q1 2022: Extended patent protection for UV1

Extended patent protection for UV1 when used as combination treatment

- Notice of Allowance received from USPTO on a patent application for the use of vaccine-checkpoint inhibitor combinations to treat cancer
- This will cover cancer treatments that include the UV1 peptide vaccine in combination with an anti-CTLA-4, anti-PD-1 or anti-PD-L1 antibody checkpoint inhibitor
- The patent will provide additional commercial protection for UV1 until **at least June 2037**
- Similar Ultimovacs patent applications are pending in other territories worldwide





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## Phase I trials – mOS reached at 66.3 months in the UV1 + ipilimumab trial

Median overall survival reached at 66.3 months for the Phase I study in malignant melanoma where UV1 is combined with ipilimumab

### Completed Phase I trials in follow-up

Clinical trial <sup>4</sup>	Overall Survival (OS) <sup>1</sup>					Median OS (months)	mPFS <sup>2</sup> (months)
	Year 1	Year 2	Year 3	Year 4	Year 5		
Prostate (n=22)	95 %	86 %	73 %	55 %	50 %	61.8	n.a. <sup>3</sup>
NSCLC (n=18)	72 %	50 %	44 %	39 %	33 %	28.2	10.7
Malignant Melanoma (n=12)	75 %	75 %	67 %	50 %	50 %	66.3	6.7

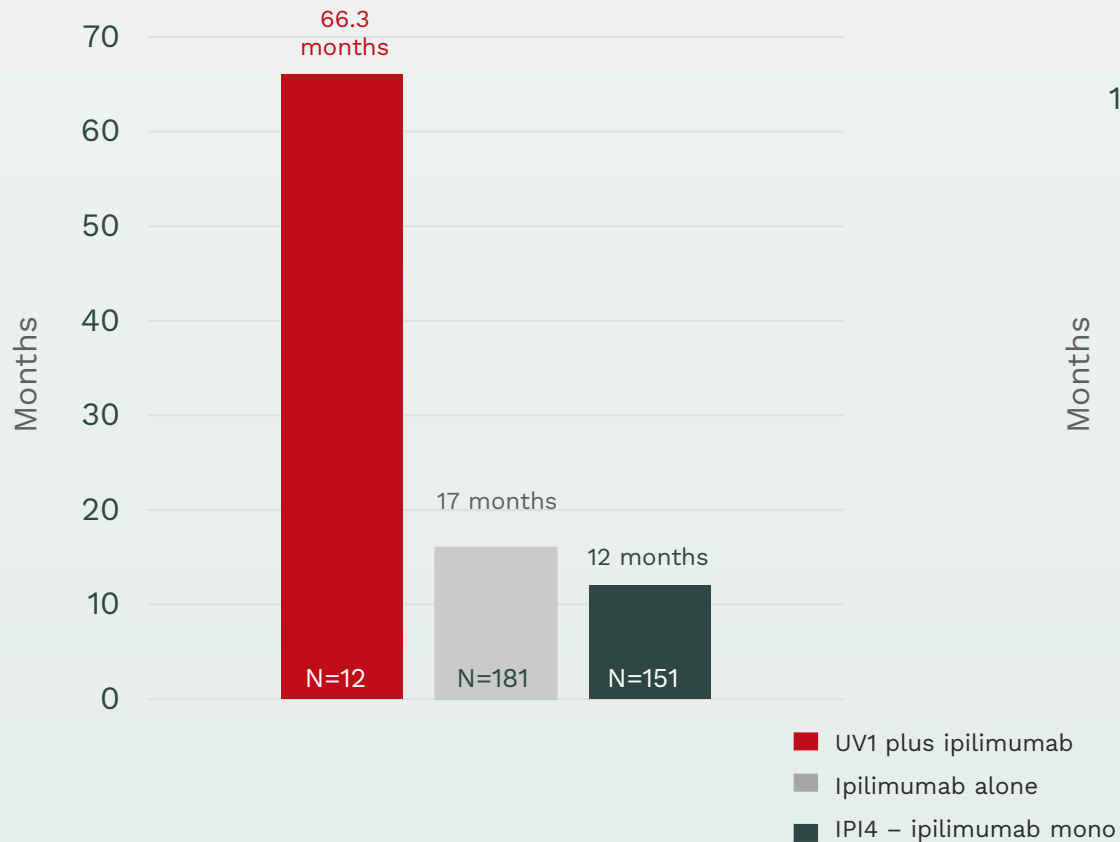


# Phase I UV1 + ipilimumab in Malignant Melanoma

Good safety profile and signals of clinical efficacy

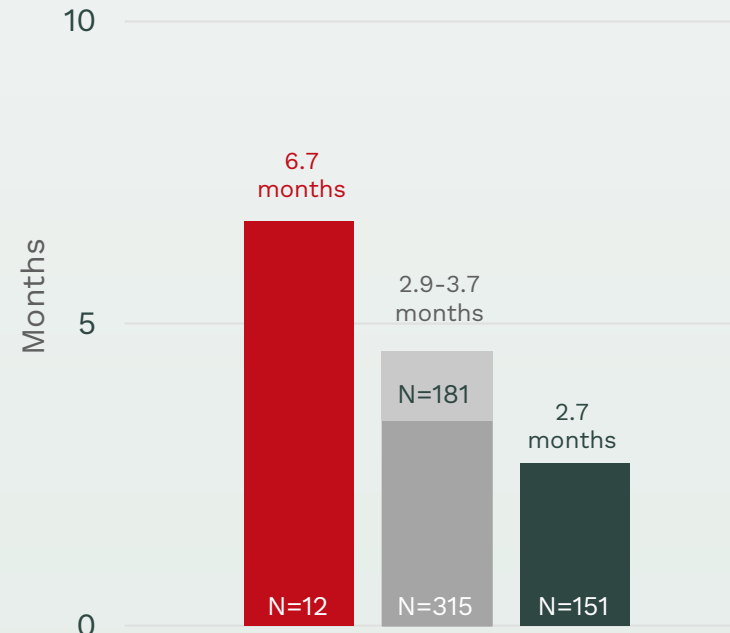
## Median Overall Survival

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

# Broad Phase II UV1 Pipeline with >650 Patients

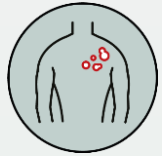
	Indication	Clinical trial information	Expected topline readout	Phase I	Phase II	Phase III	Contributors
UV1	Malignant melanoma	With pembrolizumab 30 patients	-	UV1-103 			
	Malignant melanoma	With ipilimumab & nivolumab 154 patients	H1 2023		INITIUM 		
	Pleural mesothelioma	With ipilimumab & nivolumab 118 patients	H1 2023		NIPU 		 <sup>1</sup> 
	Ovarian cancer	With durvalumab & olaparib 184 patients	End of 2023*		DOVACC 		 <sup>1</sup>   <small>European Network of Gynaecological Oncological Trial groups</small>
	Head and neck cancer	With pembrolizumab 75 patients	End of 2023*		FOCUS 		 Martin-Luther University Halle
	Non-small cell lung cancer (NSCLC)	With pembrolizumab 138 patients	End of 2024*		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.

\* FOCUS, DOVACC and LUNGVAC: Readout estimates will be updated with the Q4 2022 report

# Next Steps for UV1 in Advanced or Metastatic Malignant Melanoma

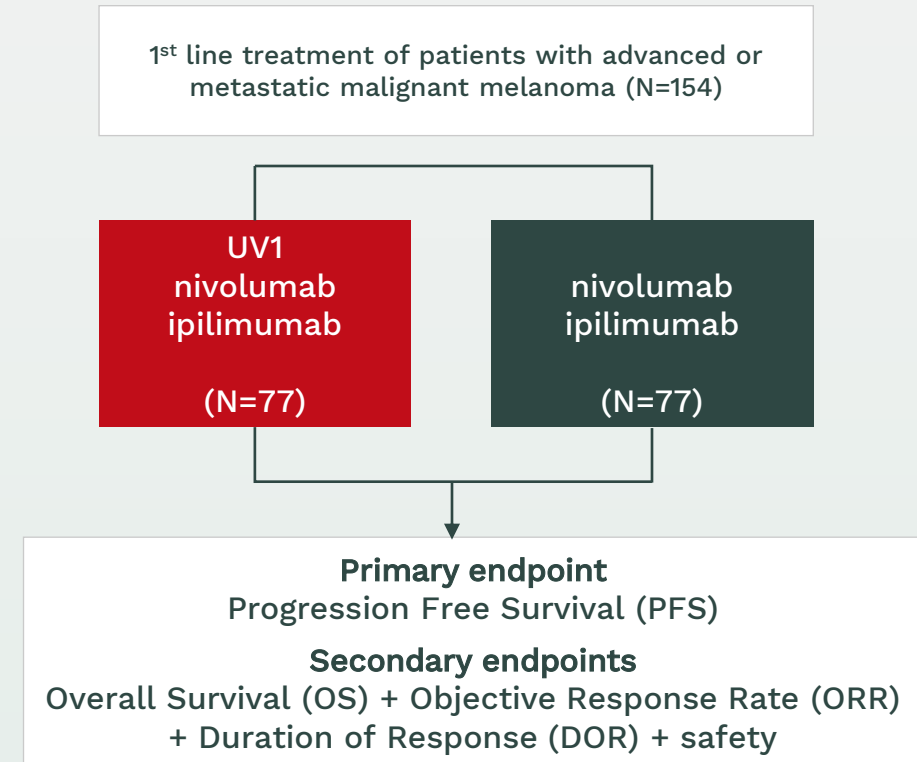
## – INITIUM UV1 Phase II trial



### INITIUM: First line advanced or metastatic malignant melanoma

- **Combination:** nivolumab, ipilimumab
- First patient enrolled June 2020
- **Patients:** 154 patients from 39 sites in 4 countries: US, UK, Belgium and Norway
- 137 patients enrolled as of 11 May 2022 (Q1 2022 reporting)
- **Milestones:** Topline results expected H1 2023, after 70 patients have progressed or died

### INITIUM



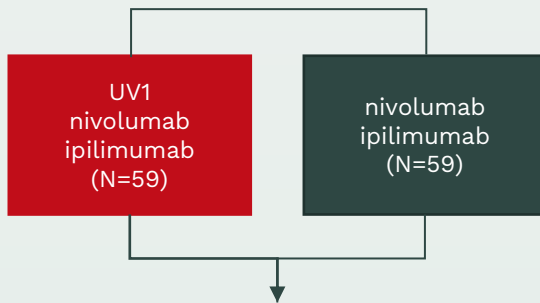


# NIPU & DOVACC UV1 Phase II Trials



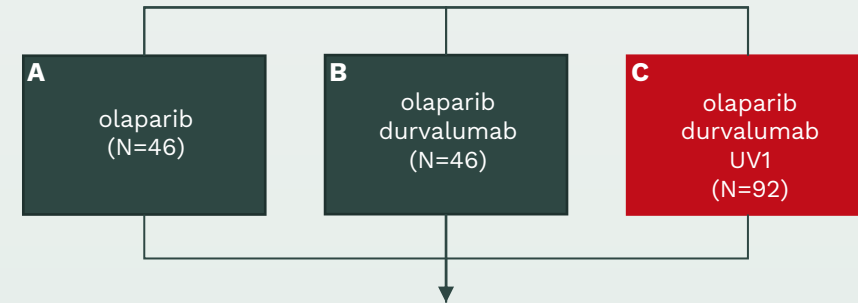
## NIPU: Second line malignant pleural mesothelioma

- **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
- 78 patients enrolled as of 11 May 2022 (Q1 2022 reporting)
- **Milestones:** Topline results expected H1 2023, after 69 patients have progressed or died



## DOVACC: Ovarian cancer, second maintenance

- **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
- 4 patients enrolled as of 11 May 2022 (Q1 2022 reporting)
- **Milestones:** Topline results have been expected during 2023. This guidance will be updated with the Q4 2022 report



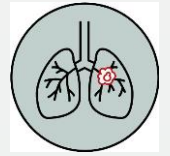
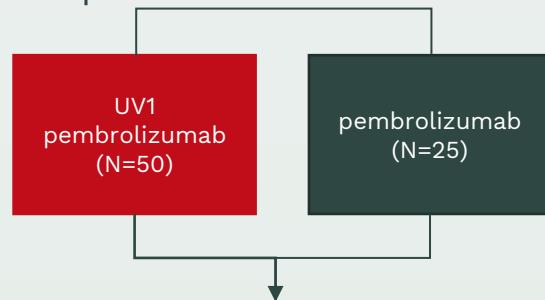
**Primary endpoint: PFS**  
**Secondary endpoints: OS + ORR + DOR + safety**

# FOCUS and LUNGVAC UV1 Phase II Trials



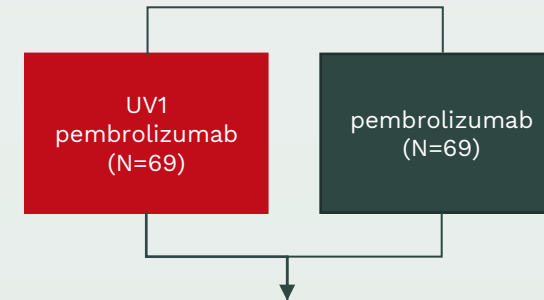
## FOCUS: Metastatic or recurrent head and neck squamous cell carcinoma

- **Combination:** pembrolizumab
- **Contributors** : Sponsored by Halle University Hospital network
- **Patients:** 75 from 10 sites in Germany
- First patient enrolled August 2021
- 18 patients enrolled as of 11 May 2022 (Q1 2022 reporting)
- **Milestones:** Topline results have been expected during 2023. This guidance will be updated with the Q4 2022 report



## LUNGVAC: Advanced or metastatic non-small cell lung cancer (NSCLC)

- **Combination:** pembrolizumab
- **Contributors:** Sponsored by Drammen Hospital
- **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



Primary endpoint: PFS

Secondary endpoints: OS + ORR + DOR + safety

## Supplementary study to INITIUM will include 20 patients

- A supplementary study to the INITIUM trial will be initiated after enrollment of the 154 patients is completed
- Data collected from the patients in the supplementary study
  - will not be part of the primary and secondary endpoint analyses of INITIUM, and
  - will not affect the timeline for topline read-out
- *Objective:* to further support that an immune response specific to the UV1 vaccine transfers into anti-tumor activity and clinical benefit for the patients
- 20 patients in a single arm UV1 cohort will all receive experimental treatment, i.e. the triple combination of UV1, ipilimumab and nivolumab



# 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
  - Eight patients enrolled as of Q1 2022 reporting, three in each of the first two dosing cohorts, and two in the third dosing cohort
  - **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 patients in the third dosing cohort
  - **May recruit up to three additional patients (on top of three in each dosing cohort) at the highest dose level provided there are no safety issues**
- 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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**Key Financials Q1 2022 & Newsflow**

## Key Financials Q1 2022

Operating expenses – development and variations

- R&D and IPR expenses: Underlying growth due to increased activity level in the clinical development program, but quarterly variations due to milestone payments in large projects
- Payroll expenses: Underlying expenses fairly stable, but some quarterly variations due to share price driven allowances and reversals of allowances for social security tax related to the share option program

**Total cash of MNOK 523 (~\$54M) by the end of Q1 2022**

**Expected financial runway to first half of 2024**



# Key financials

## Key financials per Q1-2022 - Ultimovacs Group

NOK (000)	Q1-21	Q1-22	FY21
<b>Total revenues</b>	-	-	-
Payroll and payroll related expenses	12 203	11 384	61 916
External R&D and IPR expenses (incl. grants)	16 012	14 725	88 169
Other operating expenses (incl. depreciation)	3 000	5 791	13 748
<b>Total operating expenses</b>	<b>31 215</b>	<b>31 900</b>	<b>163 832</b>
<b>Operating profit (loss)</b>	<b>-31 215</b>	<b>-31 900</b>	<b>-163 832</b>
Net financial items	-2 582	-4 699	-890
<b>Profit (loss) before tax</b>	<b>-33 798</b>	<b>-36 600</b>	<b>-164 722</b>
Net increase/(decrease) in cash and cash eq.	-28 213	-44 507	137 106
<b>Cash and cash equivalents at end of period</b>	<b>409 288</b>	<b>523 706</b>	<b>574 168</b>
Number of FTEs at end of period	21	23	24

### Comments:

#### **Payroll expenses**

- Lower personnel costs in Q1-22 compared to Q1-21 due to reversal of social security tax related to options. When disregarding costs related to the share-based compensation and cost reductions from government grants, the personal expenses in Q1-22 were MNOK 1.5 higher than in Q1-21, primarily due to two additional full-time employees.

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

- Slightly lower R&D costs in Q1-22 compared to the same period in FY21. R&D costs are, however, expected to increase compared to Q1-22 with further progress in the phase II trials, CMC development and other R&D activities.

#### **Other operating expenses**

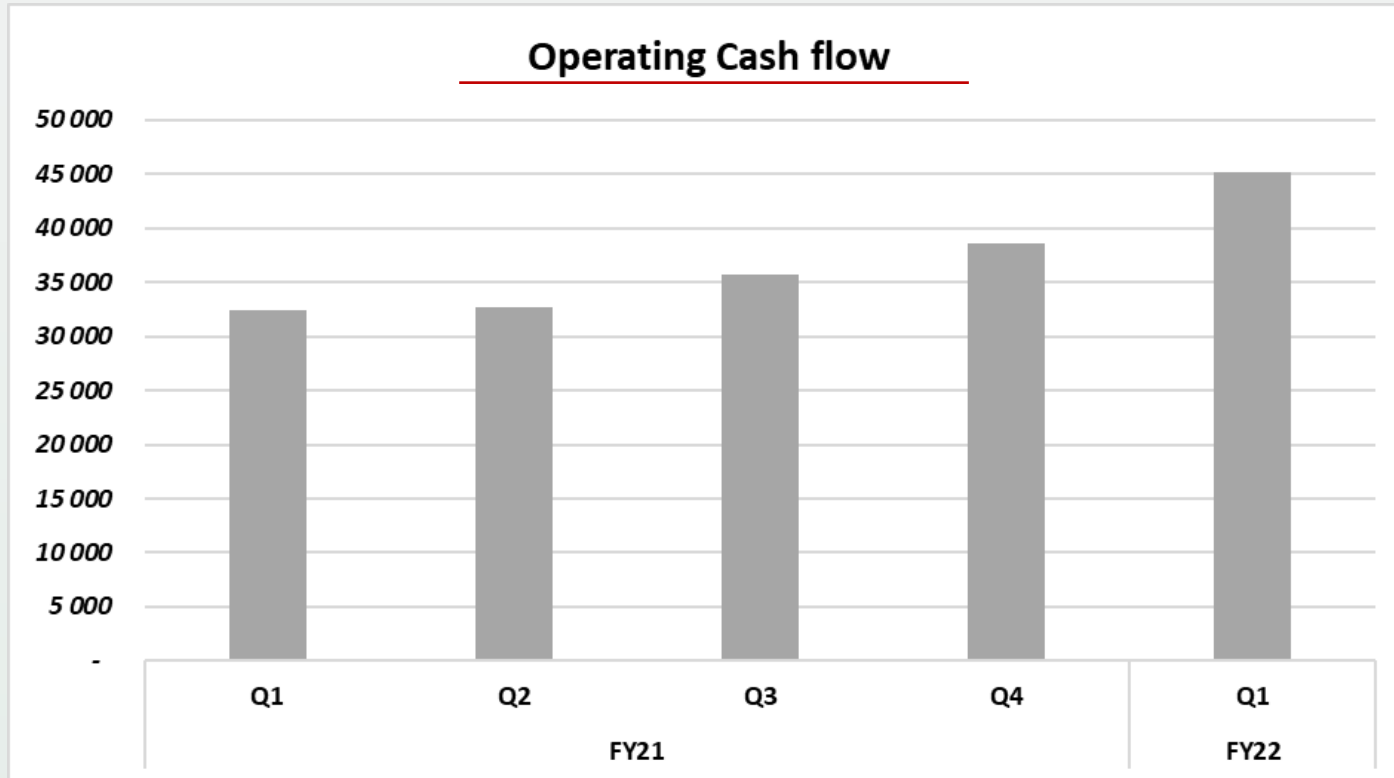
- Increase from the previous year primarily due to more activities within business development and investor relations, as well as increase in travel expenses.

#### **Cash position**

- Net cash of MNOK 523 by the end of Q1 2022

# Key financials – operating cash flow

NOK (000) – Negative amounts



Note: excluding public grants

## Comments:


- The negative operating cash flows have increased steadily since Q1-21 due to higher activity in the broad clinical development program, including initiation of sites and increased patient recruitment in the four ongoing phase II trials, as well as an increase in other R&D costs
- Ultimovacs had significant outstanding account payables (supplier payables) of MNOK 23 as per 31.12.2021 which was converted to net cash outflows of MNOK 16 during Q1-22, resulting in a significant difference between operating expenses and operating cash flow.

## Key financials – quarterly overview

### Key financials per Q1-2022 - Ultimovacs Group

NOK (000)	Q1-21	Q2-21	Q3-21	Q4-21	Q1-22
<b>Total revenues</b>	-	-	-	-	-
Payroll and payroll related expenses	12 203	14 514	23 314	11 885	11 384
External R&D and IPR expenses (incl. grants)	16 012	20 588	16 031	35 538	14 725
Other operating expenses (incl. depreciation)	3 000	4 069	3 171	3 507	5 791
<b>Total operating expenses</b>	<b>31 215</b>	<b>39 171</b>	<b>42 517</b>	<b>50 930</b>	<b>31 900</b>
<b>Operating profit (loss)</b>	<b>-31 215</b>	<b>-39 171</b>	<b>-42 517</b>	<b>-50 930</b>	<b>-31 900</b>
Net financial items	-2 582	2 706	-791	-222	-4 699
<b>Profit (loss) before tax</b>	<b>-33 798</b>	<b>-36 465</b>	<b>-43 308</b>	<b>-51 152</b>	<b>-36 600</b>
Net increase/(decrease) in cash and cash eq.uivalen	-28 213	-29 657	-32 880	227 856	-44 507
<b>Cash and cash equivalents at end of period</b>	<b>409 288</b>	<b>381 799</b>	<b>347 804</b>	<b>574 168</b>	<b>523 706</b>
Number of FTEs at end of period	21	21	21	24	23

# Expected News Flow and Milestones: Key value inflection points during the next 12-24 months

	2021	2022	2023	2024	
<b>U</b> <b>V</b> <b>1</b>  <b>T</b> <b>E</b> <b>T</b>	<p>Q4</p> <p>✓ <b>Phase I, UV1-103</b> Cohort 1 2-yr update</p> <p>✓ <b>Fast Track + Orphan Drug</b> designations</p> <p></p>	<p><b>Phase I, UV1-103</b></p> <p>Q3: 2-yr OS update (all 30 patients) Q4: Cohort 1, 3-yr OS update</p>	<p><b>Phase II, INITIUM</b> H1: Topline results</p>		
	<p>MALIGNANT MELANOMA</p>				
	<p>MALIGNANT PLEURAL MESOTHELIOMA</p>			<p><b>Phase II, NIPU</b> H1: Topline results</p>	
	<p>OVARIAN CANCER</p>	<p>✓ <b>Phase II, DOVACC</b> First patient in</p>		<p><b>Phase II, DOVACC*</b> Topline results</p>	
	<p>HEAD AND NECK CANCER</p>			<p><b>Phase II, FOCUS*</b> Topline results</p>	
	<p>NON-SMALL CELL LUNG CANCER</p>		<p><b>Phase II, LUNGVAC</b> H1: First patient in</p>		<p><b>Phase II, LUNGVAC*</b> By end of 2024: Topline results</p>
<p>PROSTATE CANCER</p>	<p>✓ <b>Phase I, TENDU</b> First patient 2<sup>nd</sup> cohort</p>	<p><b>Phase I, TENDU</b> Q4: Interim safety data</p>	<p>* FOCUS, DOVACC and LUNGVAC: Readout estimates will be updated with the Q4 2022 report</p>		

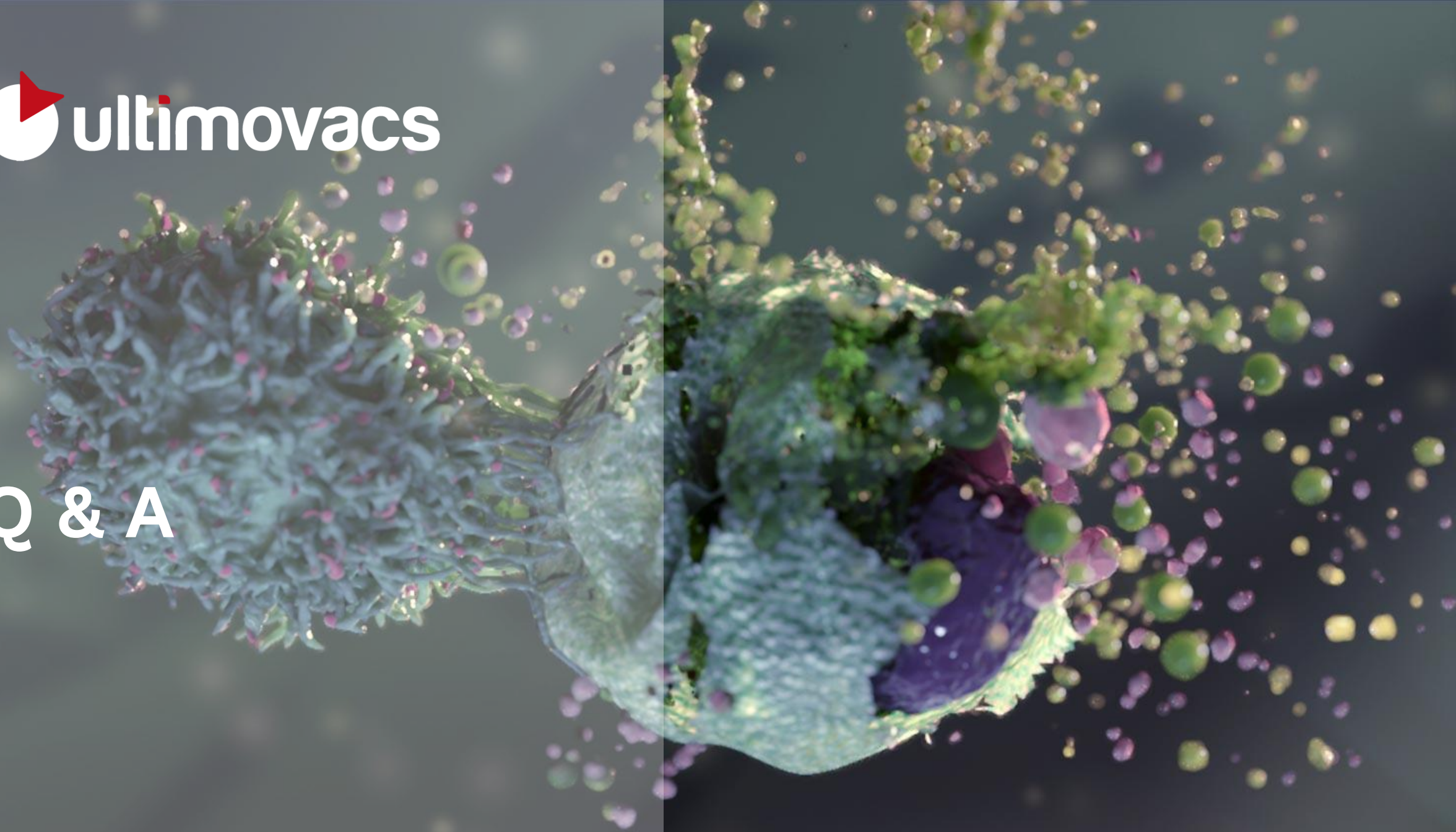
## Key Takeaways from the Q1 2022 Report

- **INITIUM and NIPU on track to expected topline readout during H1 2023 with good patient enrollment**
- **Extended patent protection in the US for UV1 when used as combination treatment**
- **Complete disappearance of tumors observed in yet another patient in UV1-103, raising the complete response rate in the study to 33%**
- **Median overall survival reached at 66.3 months for the Phase I study in malignant melanoma where UV1 is combined with ipilimumab**
- **Continue to present to the medical and scientific community, valuable data from the clinical development activities**
- **Good progress in the development of TET**
- **Strong cash position with expected financial runway to first half of 2024**





Q & A





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Inc

For questions

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