# Third Quarter 2022 Results

Ultimovacs ASA, 10 November 2022

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# Q3 2022 highlights: Continued strong progress towards key milestones

- Ultimovacs near key value inflection points
  - Readouts from the first two UV1 phase II clinical trials, INITIUM and NIPU, expected during the first half of 2023
- Overall, good patient enrollment continues in Ultimovacs' clinical program
  - First patients recruited in LUNGVAC; the fifth UV1 phase II clinical trial
  - INITIUM fully recruited in Q2 2022
- Encouraging clinical data and biomarker analyses from the phase I study UV1-103 in malignant melanoma with UV1 in combination with pembrolizumab
  - 3-year overall survival of 71% in cohort 1
  - 'Hard-to-treat patients' appear to have much to gain with the addition of UV1
- Funding remains strong:
  - MNOK 469/MUSD 43 in cash by end of Q3 2022, expected financial runway until first half of 2024

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# A broad phase II clinical program enrolling more than 650 patients

| | Indication | Clinical trial information | Expected topline readout | Phase I | Phase II | Phase III | Contributors |
|---|---|---|---|---|---|---|---|
| UV1 | **Malignant melanoma** | With ipilimumab<br>12 patients | Completed | **UV1-ipi** | | | |
| | **Malignant melanoma** | With pembrolizumab<br>30 patients | Completed | **UV1-103** | | | |
| | **Malignant melanoma** | With ipilimumab & nivolumab<br>156 patients | H1 2023 | | **INITIUM** | | |
| | **Pleural mesothelioma** | With ipilimumab & nivolumab<br>118 patients | H1 2023 | | **NIPU** | | Bristol Myers Squibb[1]<br>Oslo University Hospital |
| | **Ovarian cancer** | With durvalumab & olaparib<br>184 patients | End of 2023* | | **DOVACC** | | NSGO-CTU<br>AstraZeneca[1]<br>ENGOT |
| | **Head and neck cancer** | With pembrolizumab<br>75 patients | End of 2023* | | **FOCUS** | | MARTIN-LUTHER-UNIVERSITÄT HALLE-WITTENBERG |
| | **Non-small cell lung cancer (NSCLC)** | With pembrolizumab<br>138 patients | End of 2024* | | **LUNGVAC** | | VESTRE VIKEN DRAMMEN HOSPITAL |
| TET | **Prostate cancer** | Dose finding trial, monotherapy<br>9-12 patients | - | **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. Malignant melanoma (marked in red) is the lead indication for UV1.

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

1. Supply agreements with BMS and AZ

# Patient enrollment in clinical trials per Q3 2022 reporting date

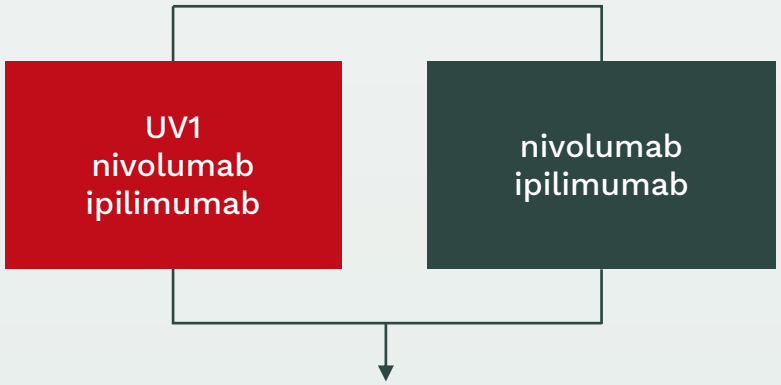
| Clinical trial: | Enrollment per Q3 reporting date: |
|---|---|
| INITIUM (ph II malignant melanoma): | Recruitment of 156 patients completed in July 2022*. |
| NIPU (ph II mesothelioma): | 108 out of 118 patients enrolled (vs. 92 in the Q2 2022 report) |
| FOCUS (ph II head and neck cancer): | 41 out of 75 patients enrolled (vs. 27 in the Q2 2022 report) |
| DOVACC (ph II ovarian cancer): | 7 out of 184 patients enrolled (vs. 6 in the Q2 2022 report) |
| LUNGVAC (ph II non-small cell lung cancer): | 3 out of 138 patients enrolled to date. The first patients was enrolled in October 2022. |
| TENDU (ph I prostate cancer): | 10 out of 12 patients enrolled to date (vs. 9 in the Q2 2022 report). |

*Enrollment is ongoing in the single arm supplementary study. This will not impact the timeline for readout from INITIUM.

# Near-term key inflection points: Readouts from the first two UV1 phase II trials, INITIUM and NIPU, expected in H1 2023

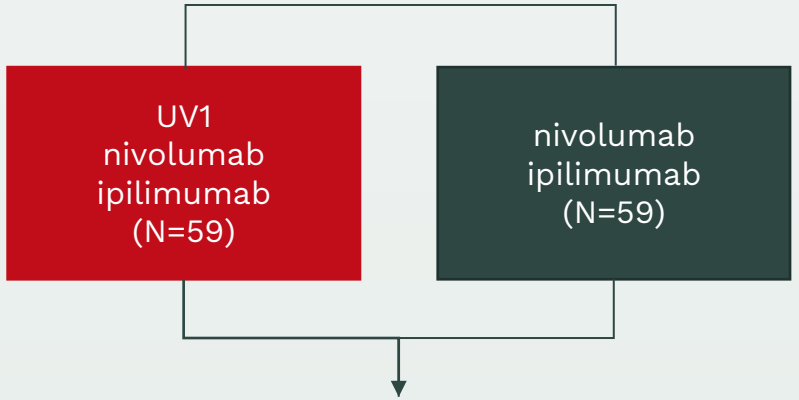
## INITIUM

**First line advanced or metastatic malignant melanoma**




## NIPU

**Second line malignant pleural mesothelioma**




**Primary endpoint:** Progression Free Survival (PFS)

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

# New data reported from UV1-103 study in malignant melanoma: Three-year overall survival of 71% in cohort one

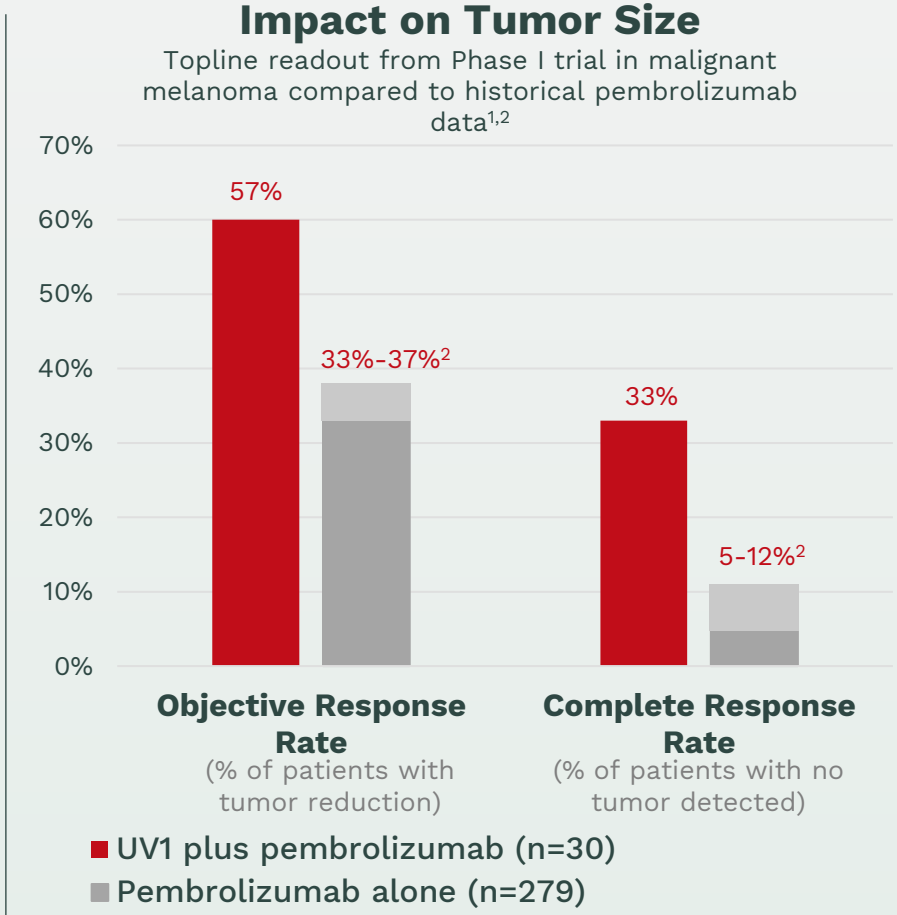
- The **Response Rates** for the 30 patients in cohort 1 and cohort 2 combined, as measured by iRECIST:
  - Complete response (CR) 10/30
  - Partial response (PR) 7/30

  } **Objective response rate (ORR) 57%**
  - Stable disease (SD) 2/30
  - Progressive disease (PD) 11/30

- **Median Progression Free Survival**
  - Cohort 1+2 combined: 18.9 months, as measured by iRECIST

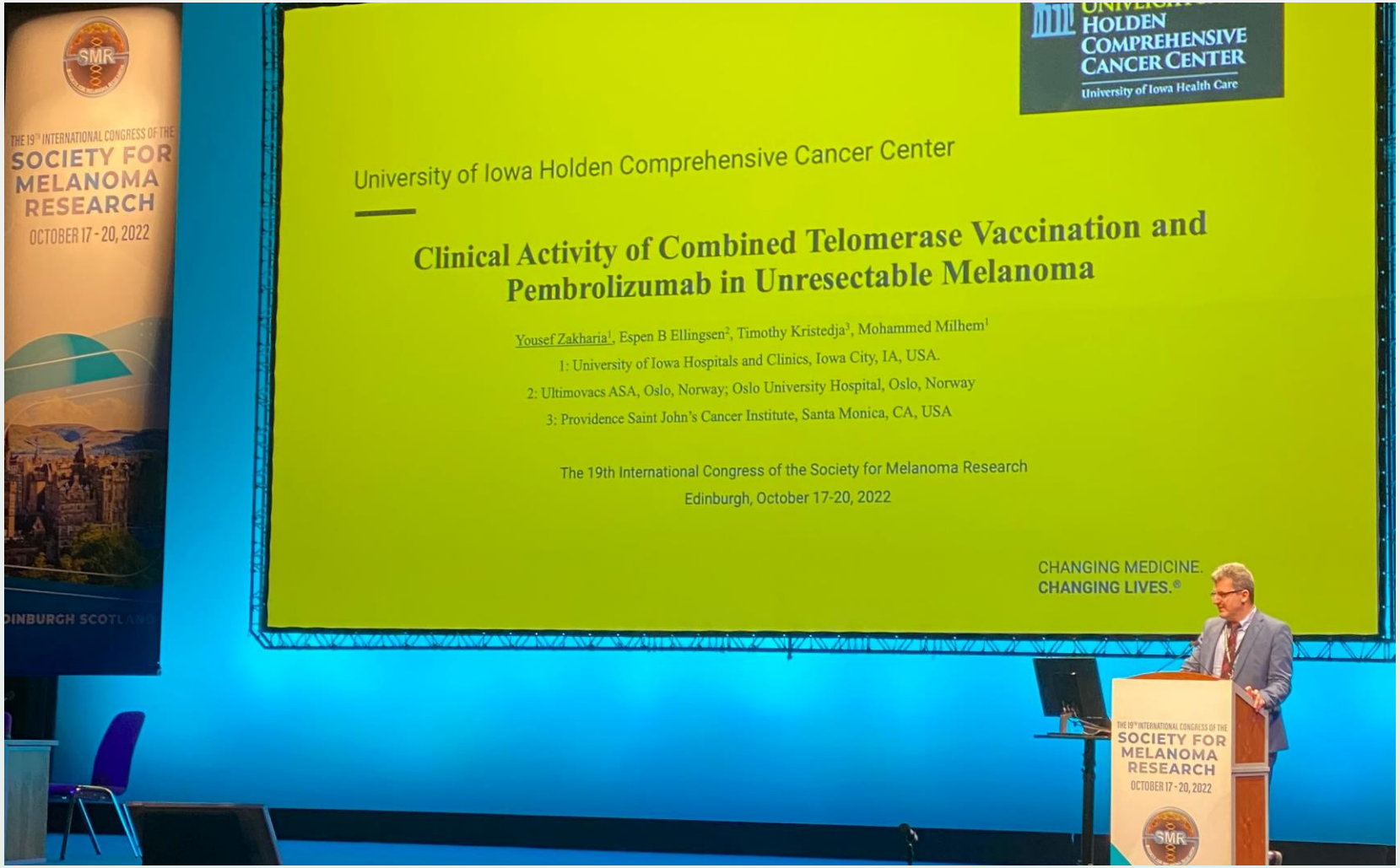
- **Overall Survival**
  - Cohort 1+2 combined after 12 months: 87%
  - Cohort 1+2 combined after 24 months: 73%
  - **Cohort 1 after 36 months: 71%**

- Patients will continue to be followed for long-term survival
- UV1 has demonstrated a good safety profile; no unexpected safety issues have been observed in the trial



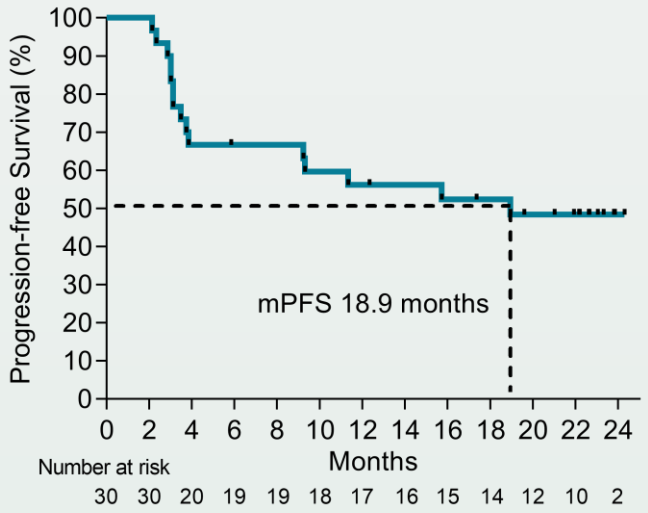

1. Not a head-to-head comparison, for reference only. Data from KEYNOTE-006 sub-set of patients is the reference trial for pembrolizumab in melanoma
2. Data from KEYNOTE-006 (Robert C, 2019), the pivotal study referred to in the Keytruda (pembrolizumab) package inserts.

# Biomarker data from the UV1-103 study presented at the International Congress of the Society for Melanoma Research by MD Yousef Zacharia

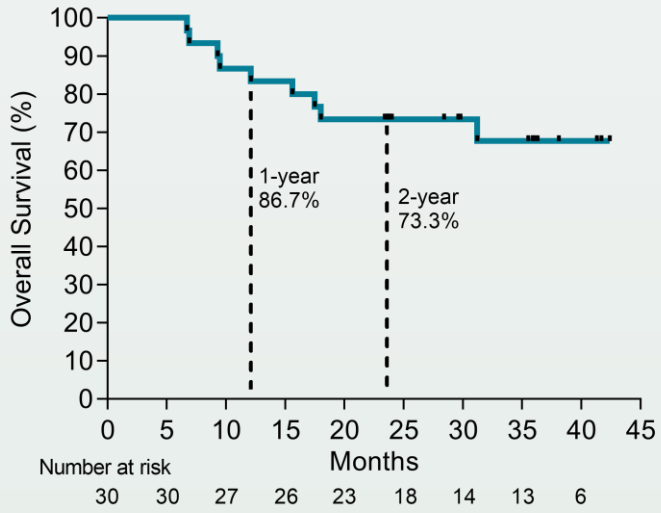


# The data shows promising progression-free and overall survival rates in the UV1-103 study

### Progression-free Survival (n=30)



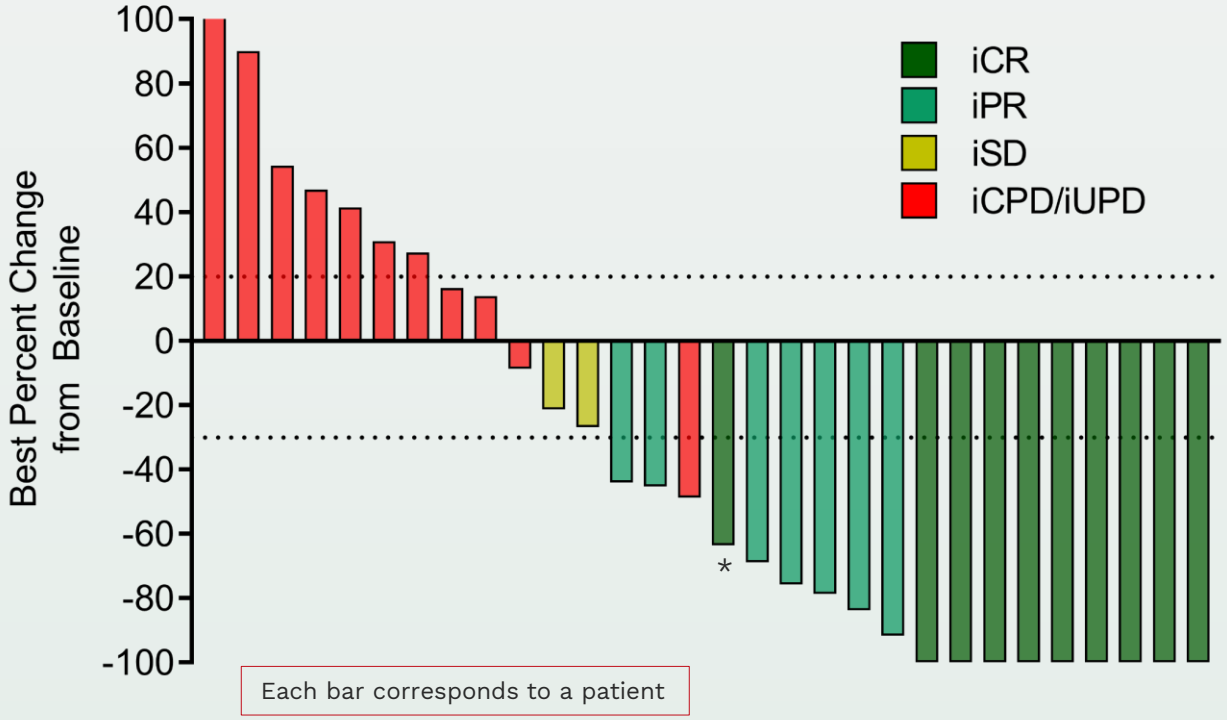

### Overall Survival (n=30)

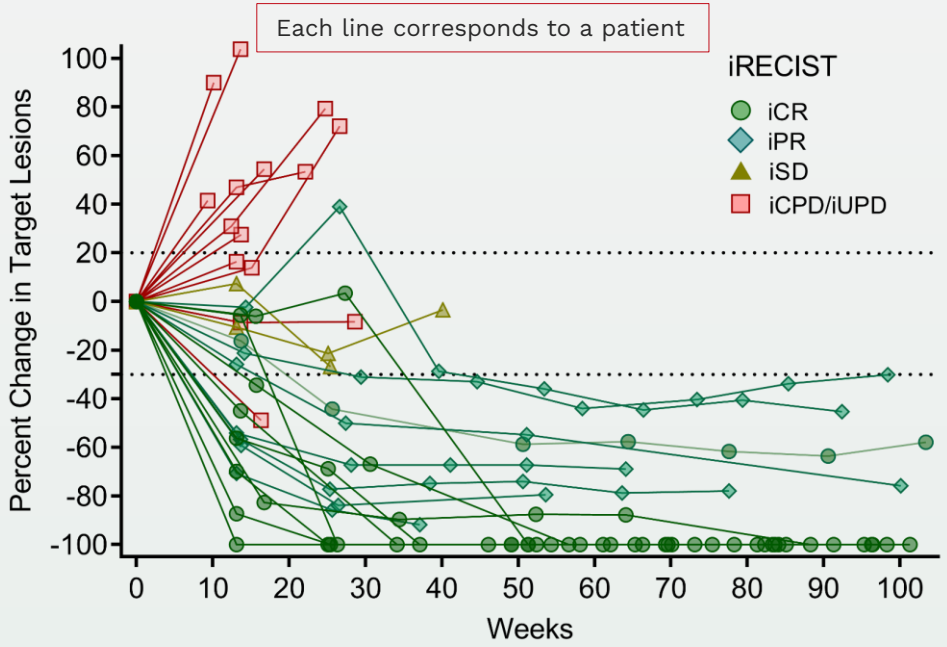



| Best Overall Response (iRECIST) | n | % |
|---|---|---|
| Objective Response Rate | 17 | 56.7 |
| • *Complete Response* | *10* | *33.3* |
| • *Partial Response* | *7* | *23.3* |
| Stable Disease | 2 | 6.7 |
| Confirmed/Unconfirmed Progressive Disease | 11 | 36.7 |

# UV1-103 biomarker data signals that clinical responses are not impacted by PD-L1 level when combining pembrolizumab with UV1

Potential to expand target patient population




| Population | ORR (%) | iCR (%) | iPR (%) |
|---|---|---|---|
| PD-L1 (≥1%) (n=8) | 4 (50.0%) | 3 (37.5%) | 1 (12.5%) |
| PD-L1 (<1%) (n=14) | 8 (57.1%) | 5 (35.7%) | 3 (21.4%) |
| Stage III B/C (n=11) | 8 (72.7%) | 5 (45.5%) | 3 (27.3%) |
| Stage IV (n=19) | 9 (47.4%) | 5 (26.3%) | 4 (21.1%) |

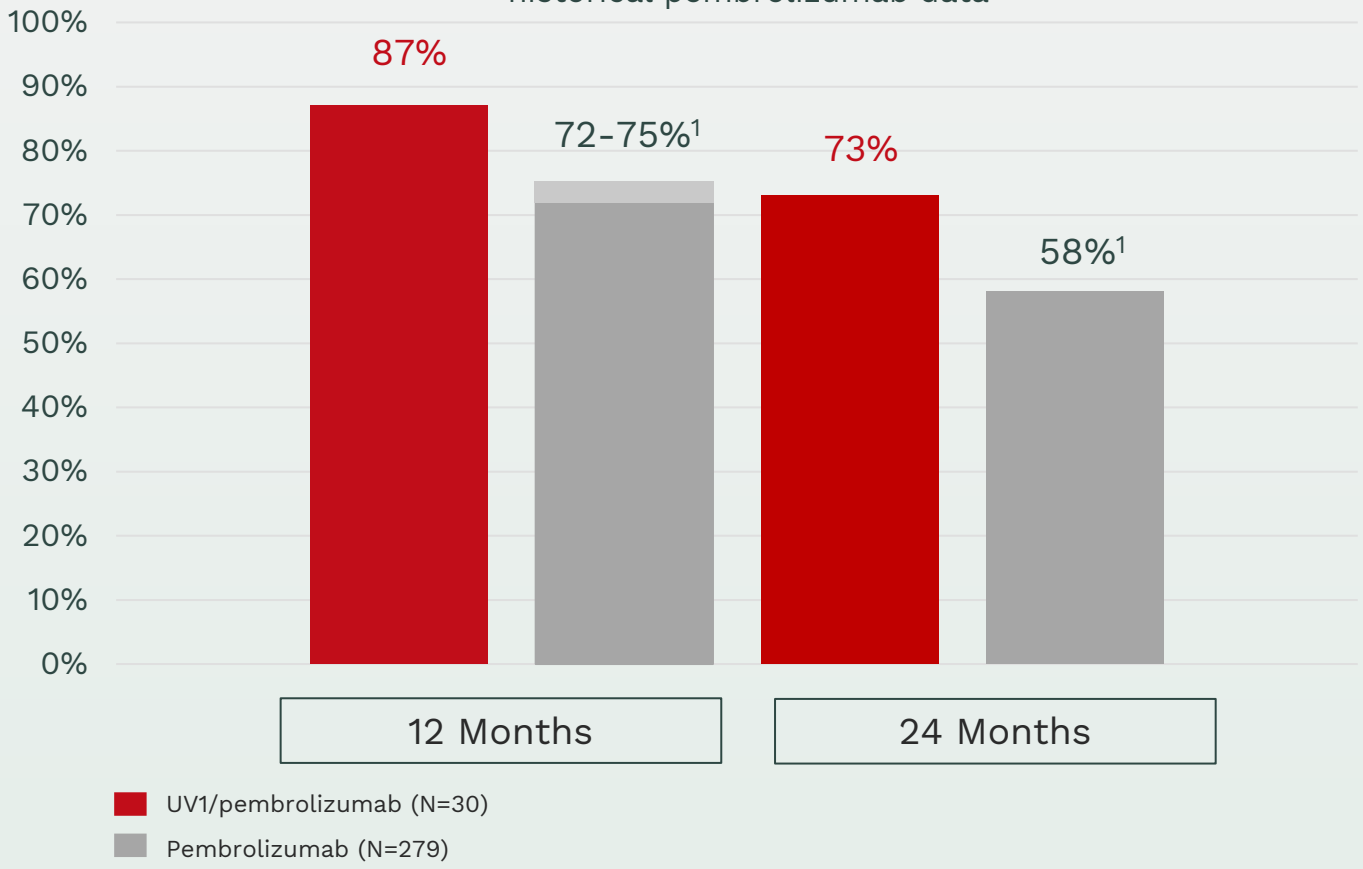
* Lymph node target lesion was reduced from 17.2 mm to 6.3 mm (-63% change). A lymph node size of <10 mm is considered normal, and a PET/CT-scan later confirmed no malignant activity. The patient is therefore considered an iCR according to iRECIST

PD-L1 staining with 22C3 pharmDx for Autostainer Link 48. PD-L1 positive defined as ≥1% of tumor cells

# UV1-103 results indicate encouraging OS & mPFS vs. historical pembrolizumab data in malignant melanoma

## Overall Survival at 12 and 24 months – All 30 patients

Topline readout from Phase I trial in malignant melanoma compared to historical pembrolizumab data[1]




## Median Progression Free Survival

**UV1 + pembrolizumab:**

- Cohort 1+2 combined: 18.9 months

**Pembrolizumab:**

- 5.5-11.6 months[1]

**OS for Cohort 1 after 36 months[1]:**

- UV1+pembrolizumab 71%
- Pembrolizumab 51%

1. Not a head-to-head comparison – for reference only. Keytruda package inserts and Robert C, Ribas A, Schachter J, et al. Pembrolizumab versus ipilimumab in advanced melanoma (KEYNOTE-006): post-hoc 5-year results from an open-label, multicentre, randomised, controlled, Phase 3 study. Lancet Oncol. 2019;20(9):1239-1251. doi:10.1016/S1470-2045(19)30388-2

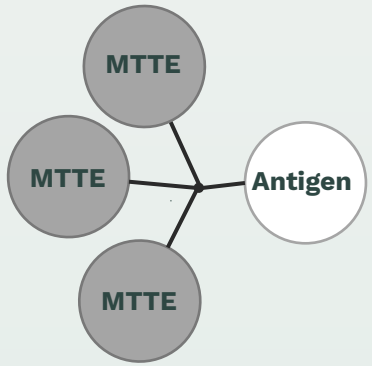
# The phase I TENDU study will provide information towards further development of new vaccine solutions based on the TET adjuvant technology platform

**Platform technology**

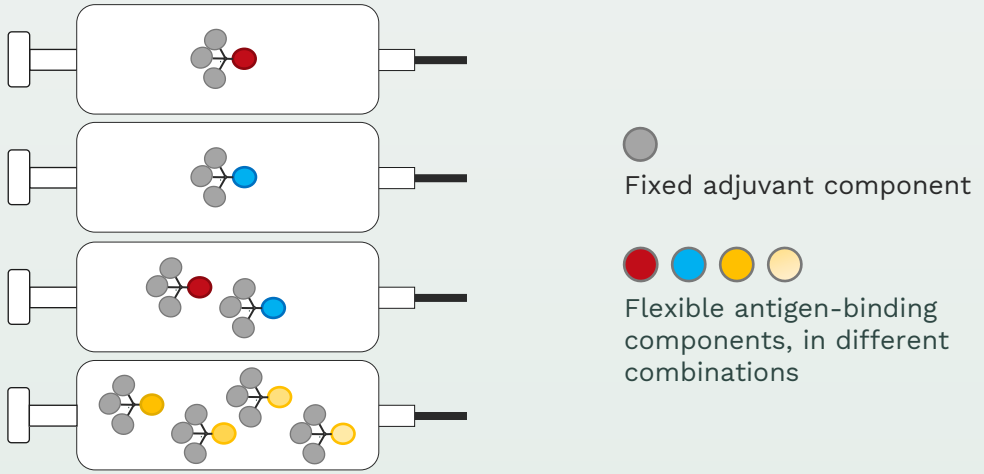
- **Expected benefits:** Improved safety profile, simplified administration, stronger immune response
- **Flexibility**: TET vaccines can be tailored to many types of cancer and infectious diseases, by coupling various antigens to the TET adjuvant

**Vaccine design**

- **Core element** is the vaccine adjuvant, a tetanus toxin peptide sequence MTTE (Minimal Tetanus Toxin Epitope), a B cell epitope
- **Molecule design:** the adjuvant (three identical MTTEs) and the tumor antigen are coupled to a central core and combined in the same molecule




*TET vaccine design (illustrative)*




*TET vaccine flexibility (illustrative)*

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# Key financials

## Key financials per Q3-2022 - Ultimovacs Group

| NOK (000) | Q3-21 | Q3-22 | YTD21 | YTD22 | FY21 |
|---|---|---|---|---|---|
| **Total revenues** | - | - | - | - | - |
| Payroll and payroll related expenses | 23 314 | 14 112 | 50 031 | 39 836 | 61 916 |
| External R&D and IPR expenses (incl. grants) | 16 031 | 24 743 | 52 631 | 55 740 | 88 169 |
| Other operating expenses (incl. depreciation) | 3 171 | 5 200 | 10 241 | 15 800 | 13 748 |
| **Total operating expenses** | **42 517** | **44 055** | **112 903** | **111 376** | **163 832** |
| **Operating profit (loss)** | **-42 517** | **-44 055** | **-112 903** | **-111 376** | **-163 832** |
| Net financial items | -791 | 5 752 | -668 | 14 097 | -890 |
| **Profit (loss) before tax** | **-43 308** | **-38 303** | **-113 570** | **-97 279** | **-164 722** |
| Net increase/(decrease) in cash and cash eq. | -32 880 | -29 726 | -90 751 | -113 289 | 137 106 |
| **Cash and cash equivalents at end of period** | **347 804** | **469 063** | **347 804** | **469 063** | **574 168** |
| Number of FTEs at end of period | 21 | 23 | 21 | 23 | 24 |

- Net cash of MNOK 469 by the end of Q3 2022

**Comments:**

***Payroll expenses***

- Total payroll expenses in Q3-22 and YTD22 were lower than previous year;
  - Regular salary costs were slightly higher in Q3-22 and YTD22 than the previous year (two more FTEs)
  - However, the decrease in total payroll expenses is mainly due to share option costs (including related social security tax accrual), which fluctuates with the company share price

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

- R&D costs were higher in Q3-22 and YTD22 compared to the same periods in 2021, primarily due to milestone payments in clinical trials, as well as higher CMC expenses this quarter.
- R&D costs are expected to increase with further progress in the phase II trials, CMC development and other R&D activities.

***Other operating expenses***

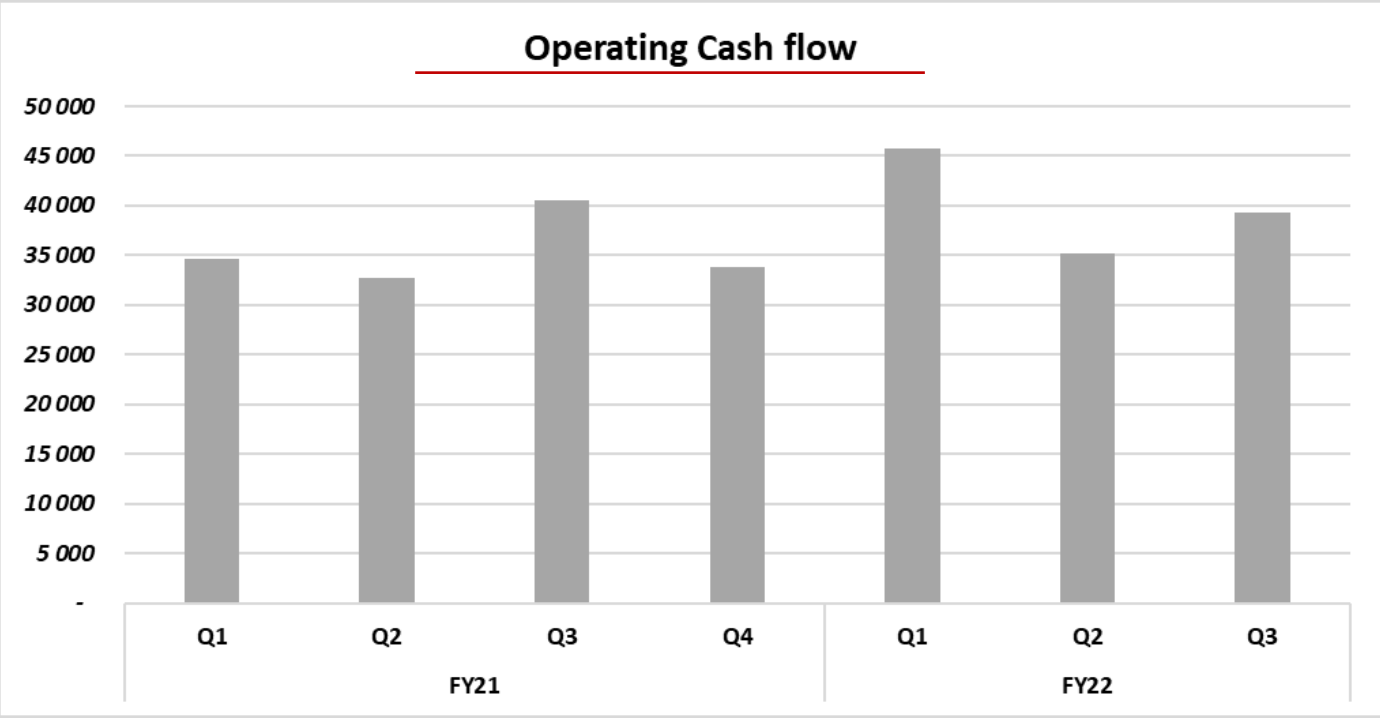
- Increase from the previous year primarily due to higher activity level (business development, travel and other)

***Net financial items***

- Net gain of MNOK 4.1 in Q3-22 and MNOK 9.8 YTD22 from EUR account and EUR/NOK future contracts

# Key financials – quarterly operating cash flow

*NOK (000) – Negative amounts*




Note: excluding incoming public grants

**Comments:**

- Operating cash flow is expected to increase from the current level, mainly due to expected higher R&D costs
- 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 Q3-2022 - Ultimovacs Group

| NOK (000) | Q1-21 | Q2-21 | Q3-21 | Q4-21 | Q1-22 | Q2-22 | Q3-22 |
|---|---|---|---|---|---|---|---|
| **Total revenues** | - | - | - | - | - | - | - |
| Payroll and payroll related expenses | 12 203 | 14 514 | 23 314 | 11 885 | 11 384 | 14 340 | 14 112 |
| External R&D and IPR expenses (incl. grants) | 16 012 | 20 588 | 16 031 | 35 538 | 14 725 | 16 272 | 24 743 |
| Other operating expenses (incl. depreciation) | 3 000 | 4 069 | 3 171 | 3 507 | 5 791 | 4 810 | 5 200 |
| **Total operating expenses** | **31 215** | **39 171** | **42 517** | **50 930** | **31 900** | **35 421** | **44 055** |
| **Operating profit (loss)** | **-31 215** | **-39 171** | **-42 517** | **-50 930** | **-31 900** | **-35 421** | **-44 055** |
| Net financial items | -2 582 | 2 706 | -791 | -222 | -4 699 | 13 045 | 5 752 |
| **Profit (loss) before tax** | **-33 798** | **-36 465** | **-43 308** | **-51 152** | **-36 600** | **-22 376** | **-38 303** |
| Net increase/(decrease) in cash and cash equivalents* | -28 213 | -29 657 | -32 880 | 227 856 | -44 507 | -31 837 | -29 726 |
| **Cash and cash equivalents at end of period** | **409 288** | **381 799** | **347 804** | **574 168** | **523 706** | **486 338** | **469 063** |
| Number of FTEs at end of period | 21 | 21 | 21 | 24 | 23 | 23 | 23 |

*not including effects of change in exchange rate

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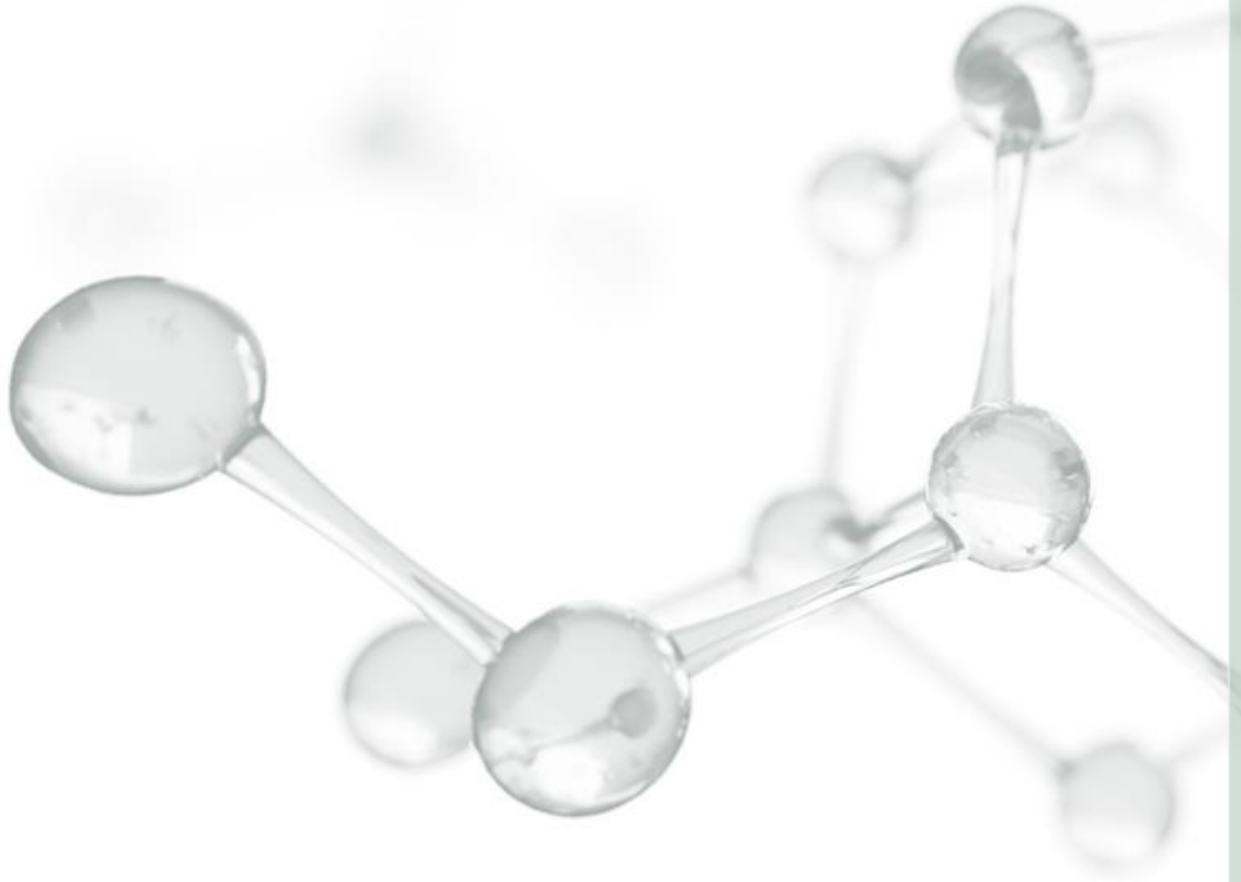

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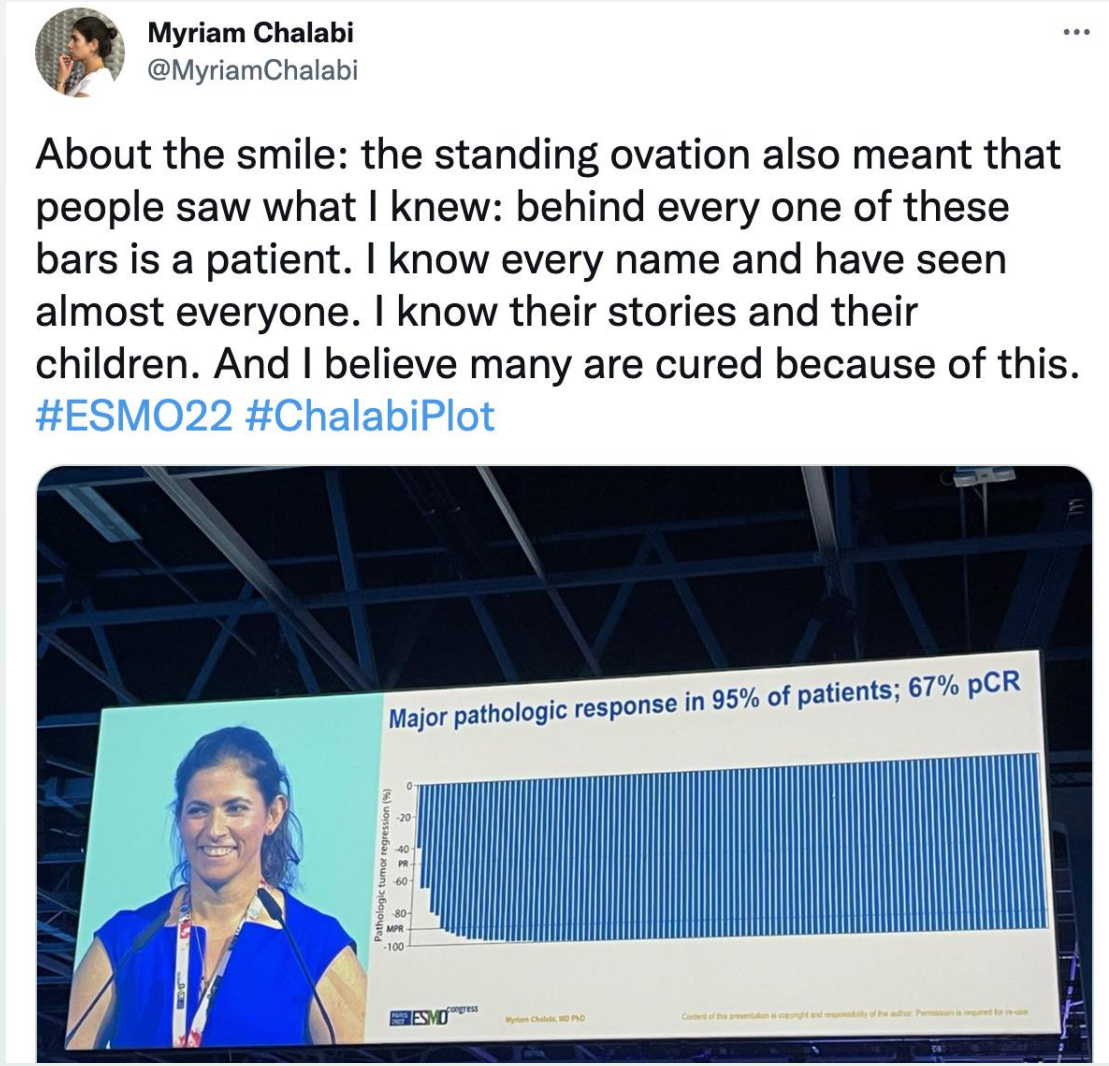
# Immuno-oncology industry highlights:

- Increased focus on neoadjuvant treatment across cancer indications at ESMO 2022
  - NICHE-2 (colon and rectal cancer)
  - SWOG S1801 (melanoma)
- Cancer vaccines gained strong momentum in October
  - Merck + Moderna deal
  - BioNTech expectations



# Expected news flow and milestones:
# Key value inflection points during the next 9-24 months

| UV1 | 2022 | 2023 | 2024 |
|---|---|---|---|
| Malignant melanoma | **Phase I, UV1–103** Q3: 2-yr OS update (all 30 patients)<br>**Phase I, UV1–103** Q4: Cohort 1, 3-yr OS update<br>**Phase II, INITIUM** Q2: Enrollment completed | **Phase II, INITIUM** H1: Topline results | |
| Malignant pleural mesothelioma | | **Phase II, NIPU** H1: Topline results | |
| Ovarian cancer | | **Phase II, DOVACC*** Topline results | |
| Head and neck cancer | | **Phase II, FOCUS*** Topline results | |
| Non-small cell lung cancer | **Phase II, LUNGVAC** Q3: First patient in | | **Phase II, LUNGVAC*** By end of 2024: Topline results |
| **TET** | | | |
| Prostate cancer | **Phase I, TENDU** Q3: Interim safety data | | |

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

# Summary

- The first two UV1 phase II trials, INITIUM and NIPU, on track to expected topline readout during H1 2023
- Overall good patient enrollment continues in Ultimovacs' clinical program
- Positive survival data in the UV1-103 trial: 36-month overall survival rate of 71% in cohort one
- Biomarker analyses from the UV1-103 trial reinforce confidence in broad applicability of UV1 in combination with anti-PD1 checkpoint inhibitors
- Strong cash position with expected financial runway to first half of 2024

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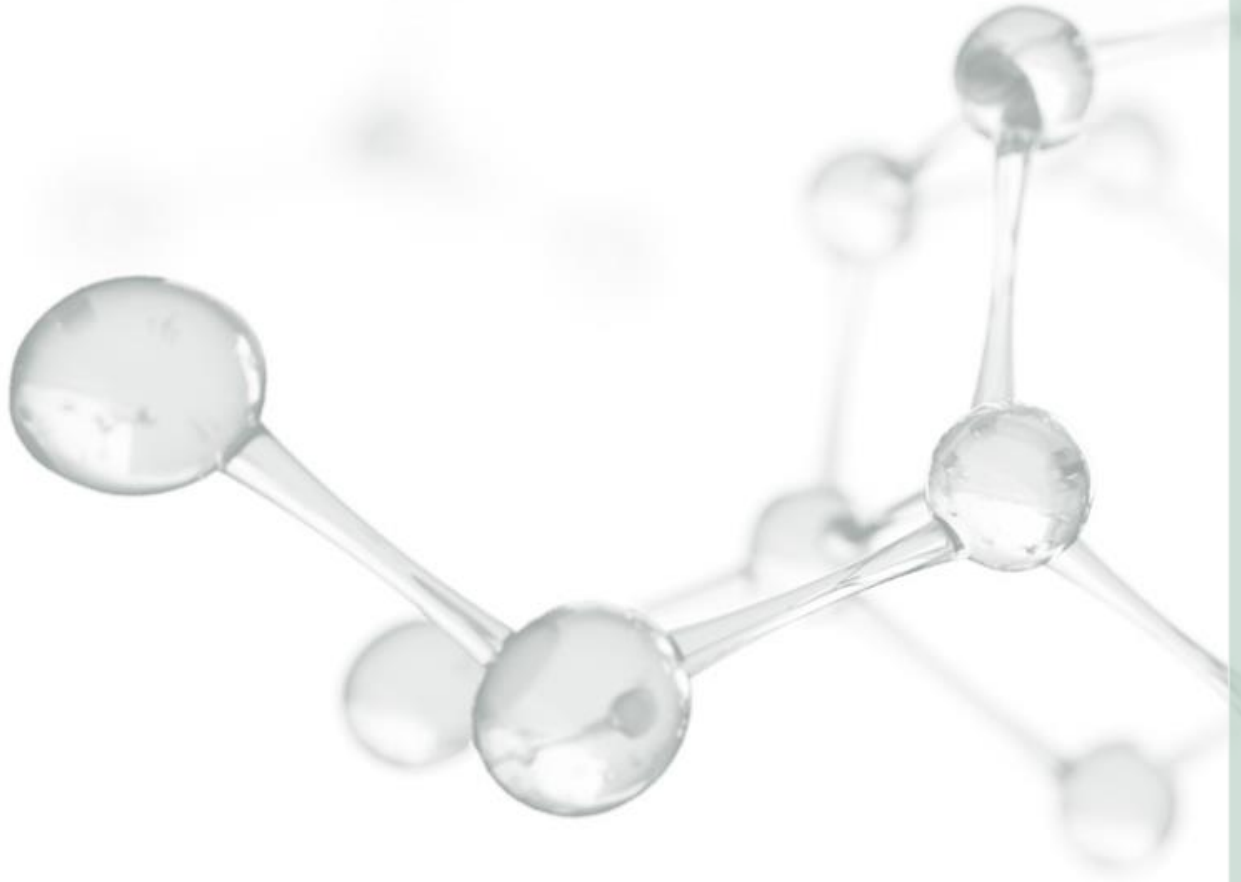

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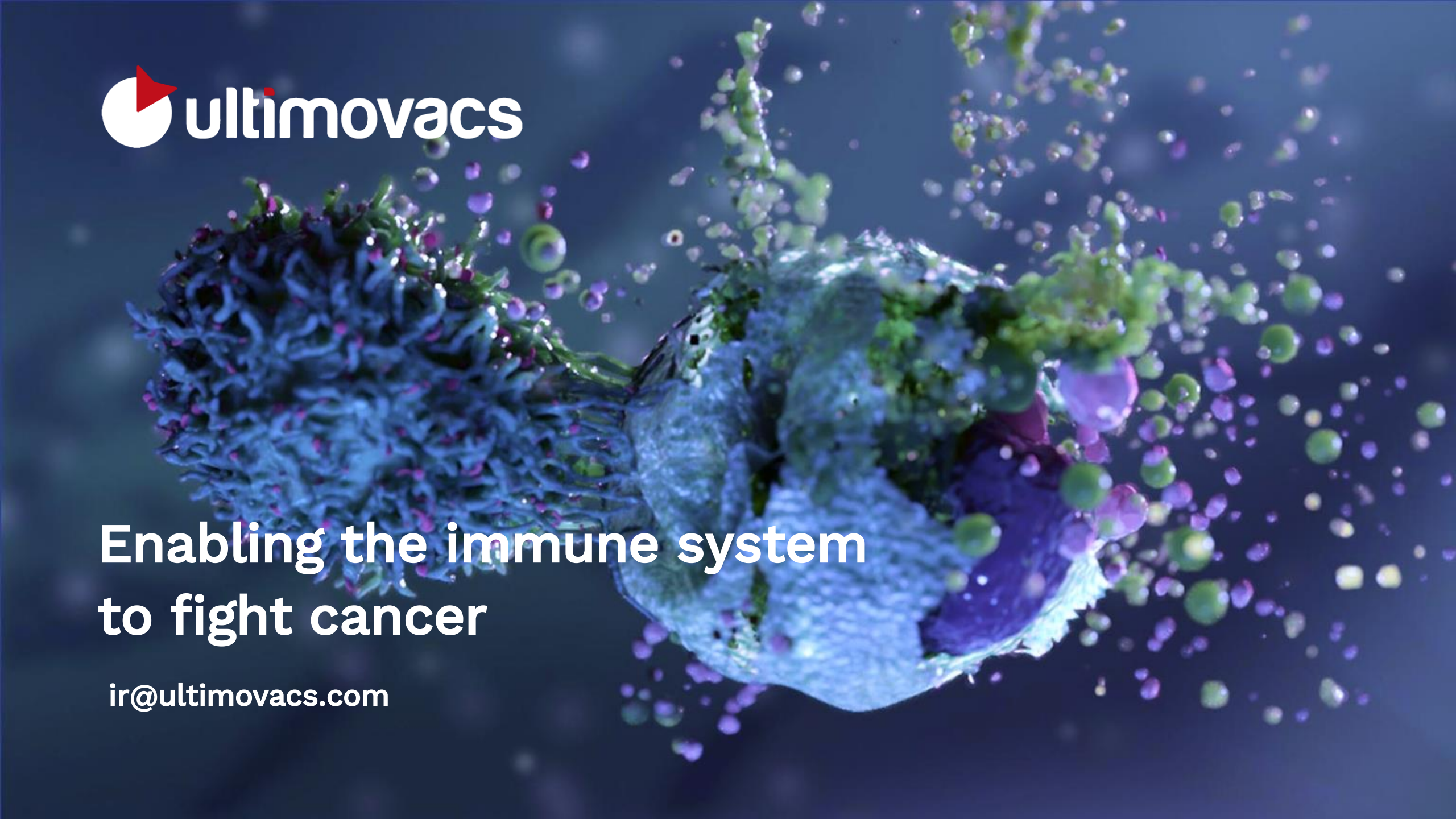
ultimovacs
Enabling the immune system
to fight cancer
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