# ultimovacs

Activating the immune system to fight cancer

## Second quarter 2020 presentation

21 August 2020

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- The Phase II INITIUM trial (metastatic malignant melanoma): three patients enrolled
- > The Phase II NIPU trial (mesothelioma): **four** patients enrolled
- The ongoing Phase I trial in malignant melanoma, is fully recruited as of this week (30 patients). No unexpected safety issues have been observed to date.
- The Covid-19 pandemic has so far had limited impact regarding site openings and patient inclusion. The longer-term effect on the biotech industry and the general ability to conduct clinical trials is still uncertain.



- A third Phase II clinical trial was announced in May 2020:
  - Collaboration with a non-specified large pharma company and a leading European oncology clinical trial group
  - UV1 will be evaluated in a new indication and a new combination
  - More information is planned to be disclosed in Q3 2020
- The 3 Phase II trials will enroll more than 400 patients in total
- Significantly oversubscribed private placement in May 2020, gross proceeds of MNOK 160
- Carlos de Sousa appointed new CEO of Ultimovacs ASA effective 1 June 2020



## Broad Development Pipeline

Platform / andidate	Indication	Clinical trial information	Preclinical	Phase I	Phase II	Phase III	Partner / Collaboration
UV1	Prostate	Conducted at OUS, 22 patients. Completed in 2015					
	Non-small cell lung cancer (NSCLC)	Conducted at OUS, 18 patients. Completed in 2016					
	Metastatic malignant melanoma	Conducted at OUS, 12 patients. UV1 in combination with Ipilimumab. Completed in 2016					
	Metastatic malignant melanoma	First line phase I trial with combination UV1/pembrolizumab). 30 patients, enrolment completed in Aug-20					
	Metastatic malignant melanoma	INITIUM: Phase II proof of concept trial (first line metastatic malignant melanoma with triple combination ipilimumab/nivolumab/UV1) 154 patients					
	Mesothelioma	<b>NIPU:</b> Phase II proof of concept trial (second line mesothelioma with triple combination ipilimumab/nivolumab/UV1) 118 patients					Bristol Myers Squibb and Oslo University Hospital (OUS)
	Undisclosed	Phase II trial – new combination in new indication					To be disclosed
TET	Prostate	<b>Project TENDU:</b> phase I study to assess the safety of the TET platform.					
	Various	First-in-class cancer vaccine solutions based on the TET-platform technology					

## Ultimovacs – Extensive Development Plan

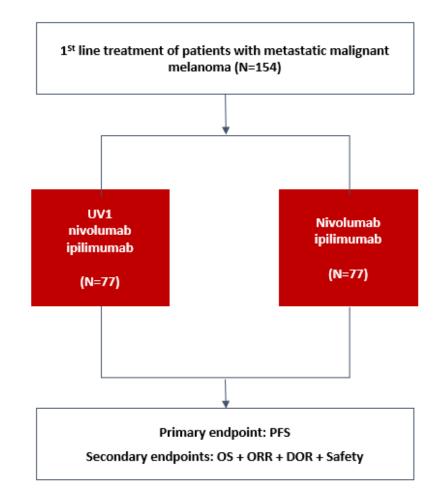
	2018	2019	2020	2021	2022	2023
Ultimovacs sponsored UV1	Phase I tria	l (first line metastatic maligi combination UV1/pembro	lizumab) INITIUM: Phase II proo	of of concept trial (first line t ple combination ipilimumal	metastatic malignant b/nivolumab/UV1)	
Collaboration UV1			NIPU: Phase II proof o triple com	of concept trial (second line bination ipilimumab/nivolu Phase II co	e mesothelioma with mab/UV1) Ilaboration trial	
TET technology			TET preclinical TE	NDU: TET phase I trial		



## Highlights – Q2 2020: Clinical trial update

# The INITIUM trial (randomized phase II trial in malignant melanoma)

- UV1 will be given in combination with the CTLA-4 checkpoint inhibitor ipilimumab and the PD-1 checkpoint inhibitor nivolumab
- 154 patients in total
- The trial will be run in the US and Europe (including Norway)
- Lead investigator is Dr. Steven O'Day at John Wayne Cancer Institute, Los Angeles, USA
- Appr. 40 sites (hospitals) will be activated during this year
- Sites are opened both in Europe and the US
- Three patients enrolled as of 20 August 2020

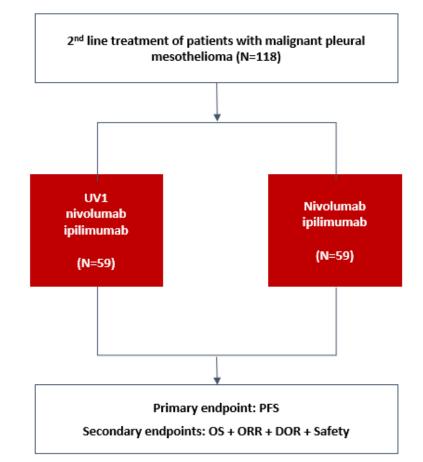




## Highlights – Q2 2020: Clinical trial update (cont.)

# The NIPU trial (randomized phase II trial in malignant pleural mesothelioma)

- UV1 will be given in combination with the CTLA-4 checkpoint inhibitor ipilimumab and the PD-1 checkpoint inhibitor nivolumab
- 118 patients in total
- Lead investigator is Dr. Åslaug Helland at Oslo University Hospital, Norway
- The trial will be run at 7 sites (hospitals) in the Scandinavian countries, Spain and Australia.
- Four patients enrolled as of 20 August 2020





## Highlights – Q2 2020: Clinical trial update (cont.)

#### A third Phase II clinical trial – non-disclosed indication

- In May 2020, Ultimovacs announced the collaboration with a leading big pharma company and a European oncology clinical trial group to evaluate the Company's universal cancer vaccine, UV1, in an additional randomized, multi-center Phase II clinical trial.
- This third Phase II clinical trial will evaluate UV1 in a new cancer indication in combination with indication-specific standard of care cancer therapies different from those to be tested in the INITIUM and NIPU trials.
- In the collaboration, Ultimovacs will supply UV1 and the big pharma company will supply its proprietary cancer treatment to the clinical trial group which will sponsor the trial.
- Final agreements are planned to be signed in Q3 2020
- First patient is expected to be enrolled in the study around year end 2020 with the read-out of primary endpoints anticipated during 2023



## Highlights – Q2 2020: Clinical trial update (cont.)

#### Ongoing US based phase I trial study in malignant melanoma

- UV1 is given in combination with the PD-1 checkpoint inhibitor pembrolizumab
- > The trial is now fully enrolled
- Cohort 1 safety pembrolizumab/UV1 20 patients
  - In September 2020, all patients in cohort 1 will have 1-year observation time. Safety and efficacy data from this cohort will be presented at an international medical conference H1 2021, top-line results will be presented in Q4 2020.

#### Cohort 2 – dose finding GM-CSF – 10 patients

- > This cohort is used to investigate an increased dosage of the adjuvant GM-CSF
- > All of these 10 additional patients are now enrolled
- During Q3 2021, all patients in cohort 1 will have 2-years observation time and all patients in cohort 2 will have 1-year observation time. These patients will be followed for safety and efficacy.
- No unexpected safety issues related to UV1 have been observed to date



## Highlights – Q2 2020: Results from the completed trials – in followup phase

		Over	Median OS	mPFS <sup>2</sup>			
Clinical trial⁵	Year 1	Year 2	Year 3	Year 4	Year 5	(months)	(months)
Prostate (n=22)	95 %	86 %	73 %	55 %	50 %	61.8	n.a. <sup>3</sup>
NSCLC (n=18)	72 %	50 %	44 %	39 %	Q4-20	28.2	10.7⁴
Malignant Melanoma (n=12)	75 %	75 %	67 %	50 %	Q1-21	Will be more than 48 months	6.7

1. Note that some patients have received other treatments upon progression and this is likely to affect survival

2. Median Progression-Free Survival

3. PFS (Progression-Free Survival) not possible to measure in the prostate cancer trial. Instead, patients are followed on PSA measurements. As of today, 8 patients have normalized PSA levels. (For definition of PSA, please see Glossary at the end of this report)

4. mPFS updated after database revision (previously reported as 12.3 months)

5. Prostate: (EudraCT No. 2012-002411-26) NSCLC: (EudraCT No. 2012-001852-20) MM: (EudraCT No. 2013-005582-39)

#### Most recent update on overall survival data:

- Prostate cancer trial mOS reached at 61.8 months
- Even though any comparison should be done with care, the mOS for a similar population in the LATITUDE trial\* receiving anti androgen treatment only was 36.5 months



## Highlights – Q2 2020: The TET-platform and TENDU

#### The TET platform

- In July 2018, Ultimovacs acquired the former immunotherapy technology business of Immuneed AB
- The core technology is the proprietary and patent-protected Tetanus-Epitope Targetingplatform (the 'TET-platform'), a promising approach to strengthen and increase T cell responses against cancer peptides
- Ultimovacs is therefore pursuing the development of new first-in-class cancer vaccine solutions based on the TET-platform technology
- Vaccines are generally used together with an adjuvant to enhance the response of the immune system to the vaccine antigens
- The TET-platform represents such a new adjuvant. With this technology the antigens and adjuvant are part of the same molecule. The technology is based on the immune system's response to the tetanus bacteria following vaccination against tetanus
- A generic adjuvant technology for peptide-based vaccines, not limited to cancer vaccines



## Highlights – Q2 2020: The TET-platform and TENDU (cont.)

#### TENDU Phase I clinical trial to test the safety of the TET technology

- Ultimovacs is now preparing for a Phase I trial to test the TET technology in prostate-cancer patients. Expected to start before the end of this year
- > The main objective is to assess the safety of the TET technology
- In this first study, the TET technology will be applied together with prostate cancer specific antigens. This project is named TENDU
- Pending confirmation of the safety of the TET technology and further pre-clinical development, the ambition is to identify TET-based cancer vaccine candidates to move into clinical development



## **Financial position**

- Significantly oversubscribed private placement in May 2020
  - ► Share issue done 'at market' NOK 38.90 per share
  - Gross proceeds of MNOK 160, net proceeds of MNOK 153
- Total cash end of Q2 2020 amounted to MNOK 482
- Based on current development plan and timeline, the existing funding is expected to last through the read-out of primary endpoints in the Phase II trials in 2022 and 2023
- The negative cash-flow from operations has increased significantly in Q1 and Q2 2020 due to the ramp-up of the R&D activities with the initiation the Phase II trials. A further increase should be expected in 2H 2020



### Key financials per Q2-2020 - Ultimovacs Group

				-	
NOK (000)	Q2-19	Q2-20	YTD-19	YTD-20	FY19
Total revenues	0	0	0	0	0
Payroll and payroll related expenses	-4 717	13 197	2 821	23 212	20 160
External R&D and IPR expenses (incl. grants)	4 909	19 938	9 574	38 027	32 938
Other operating expenses (incl. depreciation)	3 905	3 048	6 671	6 203	13 119
Total operating expenses	4 096	36 183	19 066	67 442	66 217
Operating profit (loss)	-4 096	-36 183	-19 066	-67 442	-66 217
Net financial items	252	1 274	499	2 196	5 051
Profit (loss) before tax	-3 844	-34 909	-18 568	-65 245	-61 166
Net increase/(decrease) in cash and cash eq.	346 740	115 247	330 630	83 768	284 332
Cash and cash equivalents at end of period	446 041	483 159	446 041	483 159	399 607
Number of FTEs at end of period	17	19			17

#### Cash

Q2-20 includes increase in cash from share issue/IPO (net MNOK 152.9). Without this element, net decrease in cash would have been MNOK 37.8 (including a milestone payment of MNOK 5.0 for the purchase of the UV1 technology)

#### Comments:

#### **Payroll expenses**

- Higher cost in Q2/YTD-20 than same periods prior year due to:
  - 2 more FTEs in 2020
  - severance pay liability of MNOK 5.0 recognised in the P&L related to the resignation of the former CEO
  - Iability of MNOK 10.2 related to employees' synthetic shares was reversed in June 2019

#### External R&D and IPR expenses

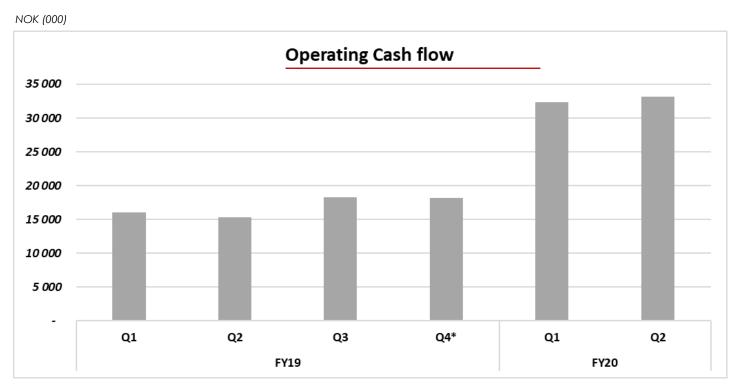
- Higher R&D costs in Q2/YTD-20 primarily due to the start-up of the NIPU and INITIUM clinical trials
  - Up-front start-up fees
  - Site set-up / openings and patient inclusion

#### Other operating expenses

Approximately at the same level as the same quarter in the previous year



## Key financials – operating cash flow



\* Q4-19 is adjusted (increased) with MNOK 5 due to exclude the receival of public grants from Skattefunn. No other adjustments made.

#### Comments:

- Following relatively stable operating cash flow per quarter, the cash burn has increased significantly in 2020 due to higher R&D activities (as planned)
- A further increase in operating costs should be expected in 2H 2020
- Increase of personnel expenses during this period due to number of FTEs going from 10 early 2018 to 19 now
- Cash flows related to the 2019 IPO and the 2020 share issue are not included in the operating cash-flow

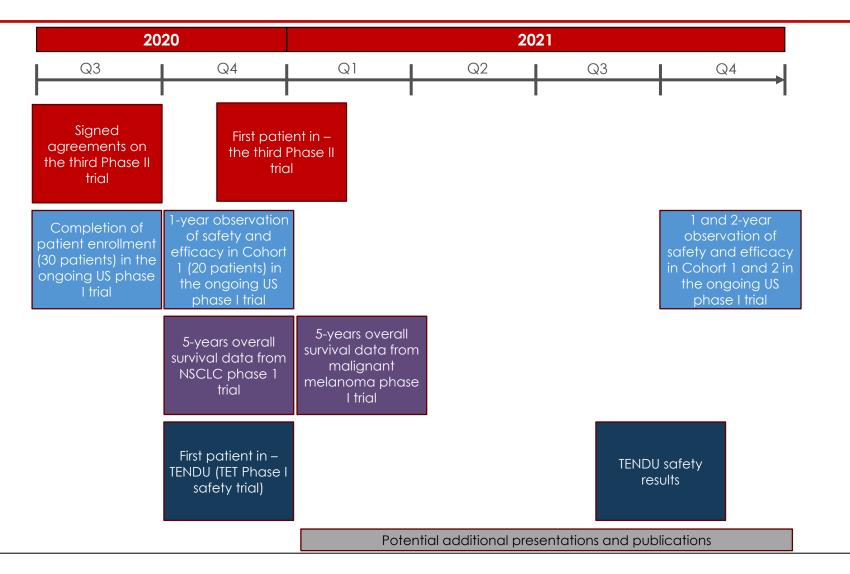


## Key financials per Q2-2020 - Ultimovacs Group

NOK (000)	Q1-19	Q2-19	Q3-19	Q4-19	Q1-20	Q2-20
Total revenues	0	0	0	0	0	0
Payroll and payroll related expenses	7 538	-4 717	8 653	8 686	10 015	13 197
External R&D and IPR expenses (incl. grants)	4 665	4 909	6 766	16 598	18 089	19 938
Other operating expenses (incl. depreciation)	2 766	3 905	3 898	2 550	3 155	3 048
Total operating expenses	14 970	4 096	19 317	27 833	31 259	36 183
Operating profit (loss)	-14 970	-4 096	-19 317	-27 833	-31 259	-36 183
Net financial items	247	252	2 082	2 470	922	1 274
Profit (loss) before tax	-14 723	-3 844	-17 235	-25 363	-30 337	-34 909
Net increase/(decrease) in cash and cash eq.	-16 110	346 740	-33 858	-12 440	-31 479	115 247
Cash and cash equivalents at end of period	99 352	446 041	412 025	399 607	367 686	483 159
Number of FTEs at end of period	16	17	17	17	19	19



## Expected newsflow 2020-2021





## Key take-aways and outlook

Universal vaccine technology (UV1 and TET) broadly applicable in different cancer types and in different therapeutic combinations Good safety profile and early positive signals of clinical efficacy Broad Phase II development program – 3 trials with more than 400 Strong platform for further patients (on top of the 82 patients in Phase I) development Validation through collaboration with large pharma companies and oncology specialist groups Strong shareholder base and good cash position with funding through read-out of Phase II primary endpoints Experienced team with strong execution skills and good track-record Focus on execution Ultimovacs is continuously monitoring the Covid-19 situation in order to minimize its impact on the development activities Increase visibility among investors, scientific community and potential More active partners both domestically and internationally communication

Multiple near-term milestones and news flow



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