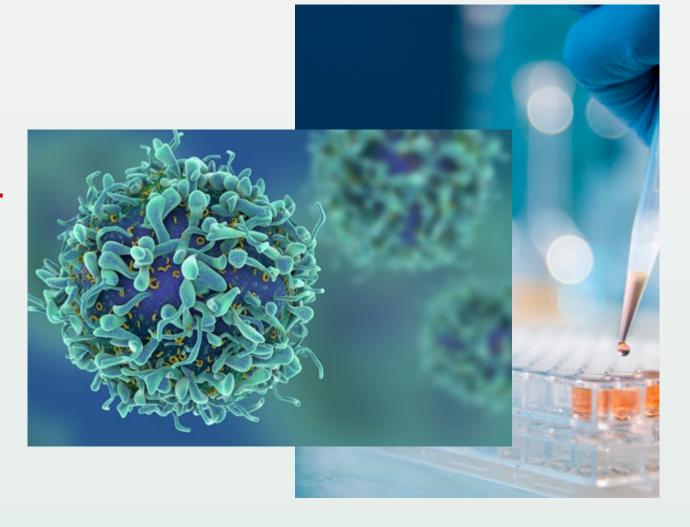


# Enabling the immune system to fight cancer

# Fourth quarter 2020 presentation

17 February 2021

Carlos de Sousa, CEO Jens Bjørheim, CMO Hans Vassgård Eid, CFO



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Intellectual Property Rights (IPR)



## Highlights Q4 2020

### UV1 Phase II program extended from two to four trials – more than 500 patients to be enrolled

- The DOVACC trial:
  - Collaboration study with NSGO-CTU, ENGOT and AstraZeneca
  - Ovarian cancer
  - UV1, durvalumab and Olaparib
  - 184 patients
- The FOCUS trial:
  - Collaboration with University Medicine Halle, Germany
  - Head and neck cancer
  - UV1 and pembrolizumab
  - 75 patients



### Highlights Q4 2020 (cont.)

### Ongoing patient recruitment in the INITIUM and NIPU trials

- INITIUM: 24 out of 154 patients enrolled (12 enrolled as of Q3 2020)
- NIPU: 18 out of 118 patients enrolled (6 enrolled as of Q3 2020)

### **Covid-19 impact**

- The Company is actively monitoring the COVID-19 pandemic regarding patient enrollment in its Phase II clinical trials and continues to implement activities to minimize the impact
- The longer-term effect of the pandemic on the biotech industry and the general ability to conduct clinical trials is still uncertain



# Highlights Q4 2020 (cont.)

### Read-out of 5-year overall survival in two Phase I trials

- Safety confirmed
- Encouraging signals of long-term survival benefit

### **New Chief Business Officer position**

Ton Berkien joined as Chief Business Officer from December 2020



# Highlights Q4 2020 (cont.)

### Paper published in "Frontiers in Immunology"

• Based on positive long-term follow-up data from UV1 Phase I trial in non-small cell lung cancer

### Significant public grants obtained for Phase II trials

 Public grants of up to MNOK 26 obtained from Innovation Norway and the Norwegian Research Council to support the DOVACC and FOCUS Phase II trials



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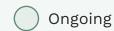


# Broad Development Pipeline: more than 500 patients in Phase II

	Indication	Clinical trial information	Preclinical	Phase I	Phase II	Phase III	Partner/Collaboration
	Prostate cancer	Conducted at OUS, 22 patients. Completed in 2015					Oslo University Hospital
	Non-small cell lung cancer (NSCLC)	Conducted at OUS, 18 patients. Completed in 2016					Oslo University Hospital
	Metastatic malignant melanoma	Conducted at OUS, 12 patients. UV1 in combination with Ipilimumab. Completed in 2016					Oslo University Hospital
	Metastatic malignant melanoma	First line phase I trial with combination UV1/pembrolizumab). 30 patients, enrolment completed in Aug-20					
UV1	Metastatic malignant melanoma	INITIUM: Phase II proof of concept trial (first line metastatic malignant melanoma with triple combination ipilimumab/nivolumab/UV1) 154 patients					
	Mesothelioma	NIPU: 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)
	Ovarian cancer	<b>DOVACC</b> : Phase II proof of concept trial (randomized, second line maintenance in ovarian cancer with combination durvalumab/Olaparib/UV1) 184 patients					AstraZeneca and NSGO/ENGOT
	Head and Neck cancer	<b>FOCUS:</b> Phase II proof of concept trial (first line head and neck cancer with combination pembrolizumab/UV1) 75 patients					University Medicine Halle (Saale) / Martin-Luther-University
тет	Prostate cancer	<b>TENDU:</b> phase I study to assess the safety of the TET platform					
TET	Various	First-in-class cancer vaccine solutions based on the TET-platform technology					







### DOVACC and FOCUS are newly initiated Phase II trials

#### **DOVACC**

- Randomized Phase II second maintenance trial in BRCA negative ovarian cancer patients
- Sponsored by NSGO/ENGOT in collaboration with Astra Zeneca
- 184 patients in >40 sites in approximately 10 European countries
- FPFV in H1 2021
- Topline results expected 2023

Maintenance treatment of 2<sup>nd</sup> BRCA negative ovarian cancer patients. Stratification: HRD and PDL1 (n=184)

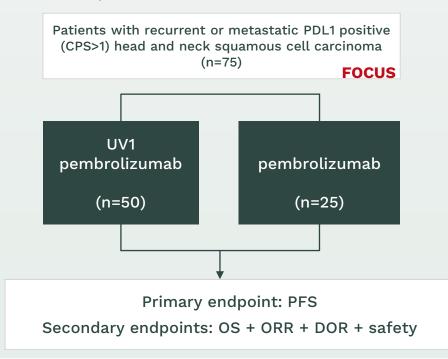
DOVACC

A olaparib olaparib durvalumab (n=46)

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

#### **FOCUS**

- Randomized phase II trial in patients with recurrent or metastatic PDL1 positive head and neck cancer
- Sponsored by Halle University Hospital network
- 75 patients in 10 sites in Germany
- FPFV in 2021
- Topline results expected 2023

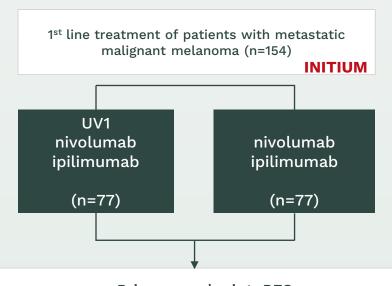




### INITIUM and NIPU are ongoing Phase II trials

#### INITIUM

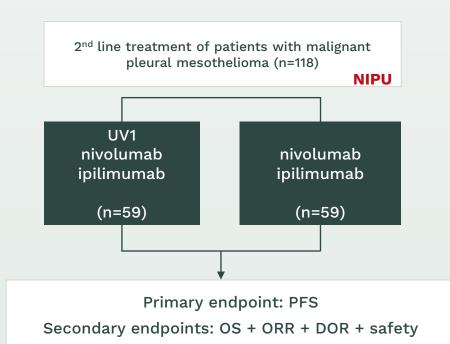
- Randomized Phase II trial in 1st line treatment of patients with metastatic malignant melanoma
- Ultimovacs sponsored study
- 154 patients in 40 sites in Norway, Belgium, UK and USA
- FPFV in June 2020
- Topline results expected H2 2022
- 24 patients enrolled as of 16 February 2021 (vs. 12 after Q3 2020)

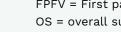


Primary endpoint: PFS Secondary endpoints: OS + ORR + DOR + safety

#### NIPU

- Randomized Phase II trial in 2<sup>nd</sup> line malignant pleural mesothelioma
- Sponsored by Oslo University Hospital in collaboration with BMS
- 118 patients in 6 sites in Norway, Sweden, Denmark, Spain and Australia
- FPFV in June 2020
- Topline results expected H2 2022
- 18 patients enrolled as of 16 February 2021 (vs. 6 after Q3 2020)





## Three Phase I trials are completed with 5-year follow-up

**Good safety profile** and **signals of clinical efficacy** observed (compared to historical controls)

Clinical Trial <sup>1</sup>	Ultimovacs Trials			Historical Comparison⁵			
	Overall Survival (OS) - Year 5²	Median OS (months)	Median PFS (months)³	Overall Survival (OS) - Year 5	Median OS (months)	Median PFS (months)	
Prostate (n=22)	50%	61.8	n.a.⁴	Revelant historical control not available	36-42	n.a.	
NSCLC (n=18)	33%	28.2	10.7	Below 5%	~12	3 - 4	
Malignant Melanoma (n=12)	50%	Will be > 54 months	6.7	~ 20%	~16	3.5 - 4	

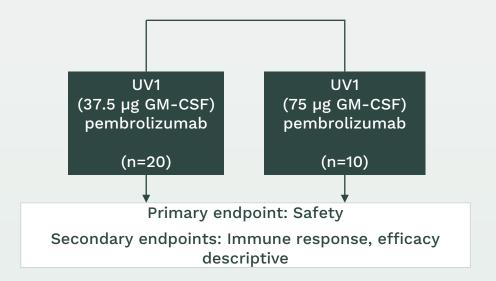
# Q4 2020 results

- 1. Prostate: (EudraCT No. 2021-002411-26) NSCLC: (EudraCT No. 2012-001852-20) Malignant melanoma: (EudraCT No. 2013-005582-39)
- 2. Note that some patients have received other treatments upon progression, and this is likely to affect survival
- 3. Median Progression-Free Survival
- 4. 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
- 5. References to historical comparisons:
  - Prostate: Fizazi K et al. Lancet Oncol. 2019; 20: 686-700.
  - NSCLC: Cortot AB et al. Eur J Cancer. 2020; 131: 27-36
  - Malignant melanoma: Robert C et al. Lancet Oncol. 2019; 20: 1239-1251.



# Ongoing Phase I trial in first line malignant melanoma patients in combination with pembrolizumab

- Ultimovacs sponsored study running in the US
- Patient enrolment completed Q3 2020
- Cohort 1
  - 20 patients
  - 1 year follow up in Sep-2020:
    - Overall survival (OS) rate was 85%
    - Median Progression-Free Survival (mPFS) was not yet reached
    - A historical comparison\*, demonstrated a 68% OS at 12 months and a mPFS of 11.6 months.
  - 2 year follow up in Q4 2021
- Cohort 2
  - 10 patients
  - LPFV on 18 August 2020
  - 1 year follow up in Q4 2021





### The TET-platform and the TENDU trial

### The TET-platform (Tetanus-Epitope Targeting)

- Next-generation vaccine technology expanding Ultimovacs' product pipeline
- Promising approach to strengthen and increase T cell responses against cancer-specific peptides by combining antigens and the vaccine adjuvant in the same molecule
- Expected beneficial safety profile and simplified administration
- The platform generates new, first-in-class cancer vaccine candidates that harness the preexisting antibody response against tetanus resulting from standard tetanus vaccination
- These vaccine candidates can be tailored to many types of cancer



# The TET-platform and the TENDU trial (cont,)

#### The TENDU Phase I trial

- This trial will investigate a prostate cancer specific vaccine based on the TET technology
- The TENDU trial will be conducted at Oslo University Hospital
- 9-12 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
- First patient is expected in Q1 2021



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### Financial position

- Total cash end of Q4 2020 amounted to MNOK 441
- As expected, the negative cash-flow from operations has increased significantly in FY20, due to the ramp-up of the R&D activities with the initiation the Phase II trials
- However, the increase in R&D costs in Q4 / 2020 is lower than previously guided due to certain delays of initial costs in clinical trials
- A significant increase in R&D costs should be expected in 2021 with the increase in patient inclusion
  in ongoing studies (INITIUM and NIPU) and start-up of the new Phase II trials (DOVACC and FOCUS),
  as well as start-up of the TENDU Phase I trial
- 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



# Key financials

### **Key financials per Q4-2020 - Ultimovacs Group**

NOK (000)	Q4-19	Q4-20	FY19	FY20
Total revenues	-	-	-	-
Payroll and payroll related expenses	8 686	14 662	20 160	50 989
External R&D and IPR expenses (incl. grants)	16 598	7 537	32 938	60 870
Other operating expenses (incl. depreciation)	2 550	3 390	13 119	12 287
Total operating expenses	27 833	25 588	66 217	124 146
Operating profit (loss)	-27 833	-25 588	-66 217	-124 146
Net financial items	2 470	1 007	5 051	3 594
Profit (loss) before tax	-25 363	-24 582	-61 166	-120 552
Net increase/(decrease) in cash and cash eq.	-12 440	-12 524	284 332	42 058
Cash and cash equivalents at end of period	399 607	440 925	399 607	440 925
Number of FTEs at end of period	17	19	17	19

- Cash flow
- YTD-20 includes increase in cash from share issue of net MNOK 152.9, and YTD-19 includes cash from IPO of net MNOK 344.5

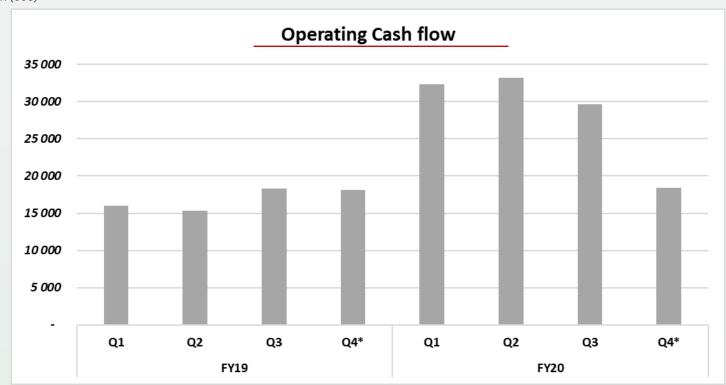
#### **Comments:**

- Payroll expenses
- Higher cost in Q4/FY20 than same periods previous year due to:
  - 2 more FTEs in 2020 and higher share-option costs
  - severance pay liability of MNOK 5.0 recognized in the P&L related to the resignation of the former CEO (FY)
  - liability of MNOK 10.2 related to employees' synthetic shares was reversed in June 2019 (FY)
- External R&D and IPR expenses
- Higher R&D costs in FY20 primarily due to the start-up of clinical trials
  - Start-up fees
  - Site set-up / openings and patient inclusion
- Low invoicing from trials and CMC in Q4-20, while Q4-19 had large up-front invoices related to INITIUM
- Other operating expenses
- Approximately at the same level as the previous year, both for Q4 and full year



# Key financials – operating cash flow

NOK (000)



<sup>\*</sup> Q4-19/20 are adjusted (increased) by MNOK 5 to exclude the receival of public grants from Skattefunn. No other adjustments made.

#### **Comments:**

- Following relatively stable operating cash flow per quarter in FY19, the negative cash flow has increased significantly in 2020 due to higher R&D activities (as planned)
- A further increase in operating costs related to R&D should be expected in 2021 with the initiation of the two new phase II trials, increased patient recruitment, start-up of TENDU and other R&D costs



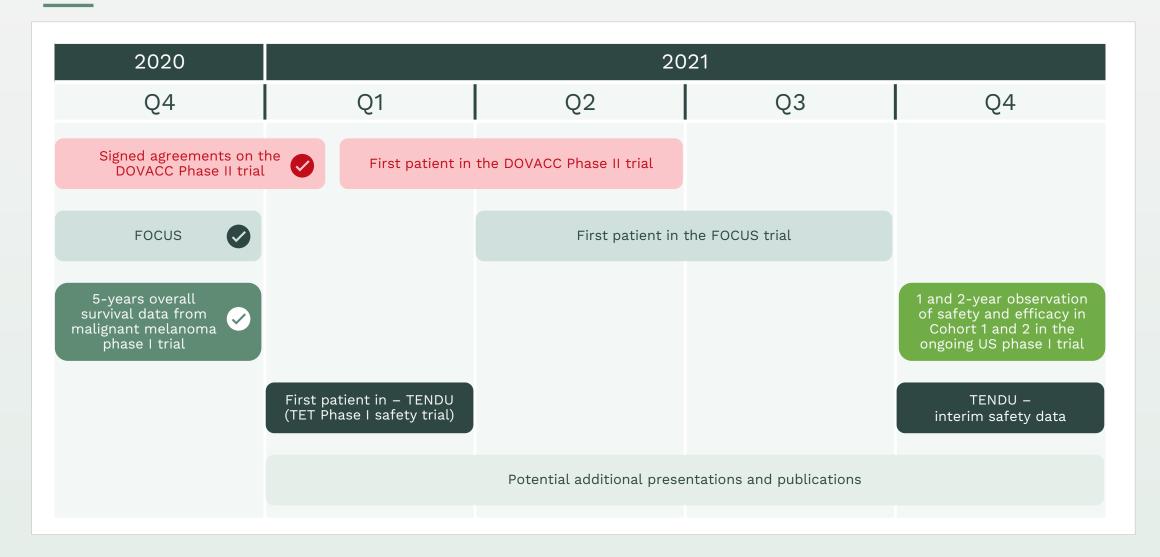
# Key financials – quarterly overview

# Key financials per Q4-2020 - Ultimovacs Group

NOK (000)	Q1-19	Q2-19	Q3-19	Q4-19	Q1-20	Q2-20	Q3-20	Q4-20
Total revenues	-	-	-	-	-	-	-	-
Payroll and payroll related expenses	7 538	-4 717	8 653	8 686	10 015	13 197	13 115	14 662
External R&D and IPR expenses (incl. grants)	4 665	4 909	6 766	16 598	18 089	19 938	15 307	7 537
Other operating expenses (incl. depreciation)	2 766	3 905	3 898	2 550	3 155	3 048	2 695	3 390
Total operating expenses	14 970	4 096	19 317	27 833	31 259	36 183	31 116	25 588
Operating profit (loss)	-14 970	-4 096	-19 317	-27 833	-31 259	-36 183	-31 116	-25 588
Net financial items	247	252	2 082	2 470	922	1 274	391	1 007
Profit (loss) before tax	-14 723	-3 844	-17 235	-25 363	-30 337	-34 909	-30 725	-24 582
Net increase/(decrease) in cash and cash	-16 110	346 740	-33 858	-12 440	-31 479	115 247	-29 186	-12 524
Cash and cash equivalents at end of perio	99 352	446 041	412 025	399 607	367 686	483 159	453 523	440 925
Number of FTEs at end of period	16	17	17	17	19	19	19	19



### Recent and expected newsflow 2020-2021

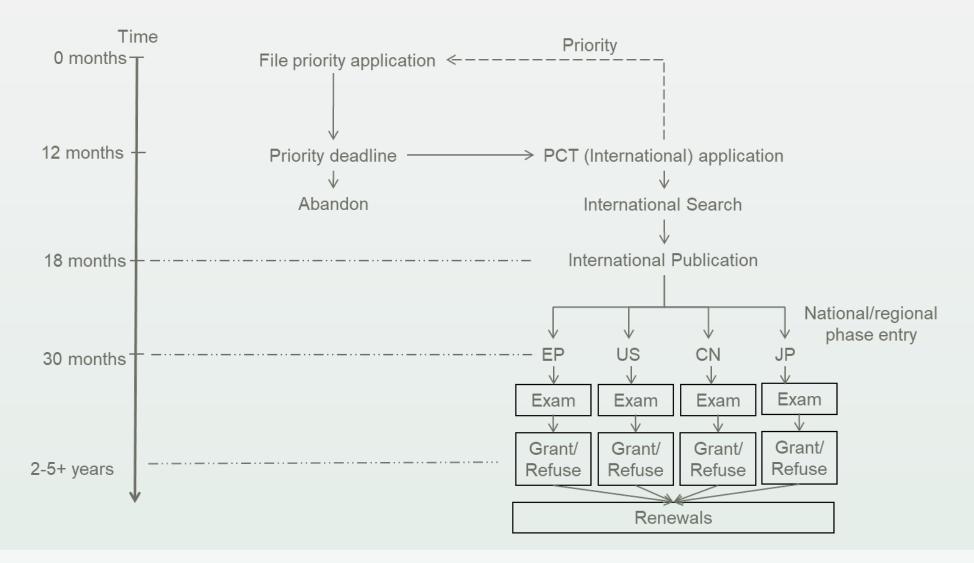




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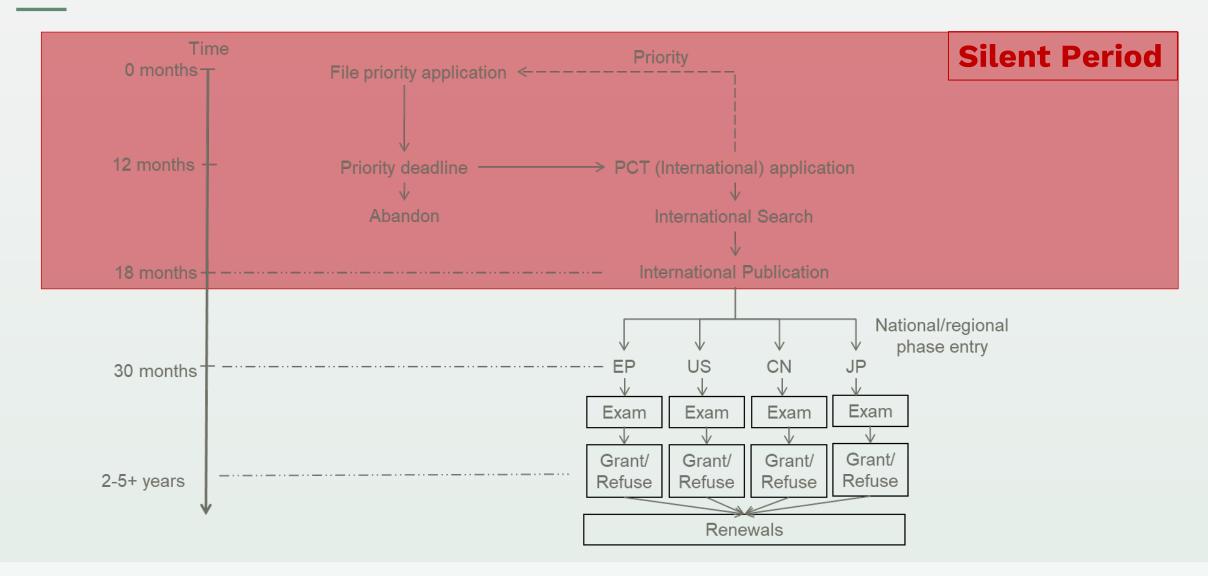


### General patent application process





### General patent application process





# Rights protecting pharmaceutical products in the EU

#### **Patents**

- 20 year duration
- Extension terms on patents: up to **5 additional years** via Supplementary Protection Certificates (SPC) **(+0.5 years** via paediatric extension (PED))

#### **Regulatory Data Protection**

- 8 years of protection of data filed in support of a marketing authorization (MA) application for a new active substance
- + 2 years of market exclusivity
- + 1 additional year of market exclusivity for "new indications"

#### **Orphan Drug Market Exclusivity**

- 10 years once MA obtained
- + 2 years for completion of the Paediatric Investigation Plan (PIP)



### Rights protecting biological products in the US

#### **Patents**

- 20 years from filing
- Extension terms on patents:
  - Patent term extension (PTE) to compensate for delays caused by FDA
    - Up to 5 years or up to 14 years from FDA approval
       (+ 0.5 years via paediatric exclusivity (PED))

### **Regulatory Data Protection**

- 4 years of data protection no application for biosimilar license may be submitted (+0.5 years via PED)
- 12 years of market exclusivity (+ 0.5 years via PED)

### **Orphan Drug Market Exclusivity**

• 7 years of market exclusivity once BLA obtained (+ 0.5 years via PED)



### Eligible subject matter

### With a focus on Europe

- Examples of potentially patentable inventions include:
  - New chemical entities, compositions, formulations, combinations (i.e. compositions of matter)
  - 1st medical use, 2nd and subsequent medical uses
  - Dosage regimes
  - Ex vivo diagnostic methods
  - Methods of making, process intermediates
- Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are not patentable
- In contrast, in other jurisdictions, such as the US, methods of treatment are patentable
- For example, the granted European UV1 patent includes various <u>product claims</u> (i.e. compositions of matter) as well as medical use claims (i.e. the product <u>for use in medicine</u> as well as the product <u>for use in the treatment or prophylaxis of cancer)</u>



# Options to extend patent terms

### **Europe**

- Supplementary Protection Certificate (SPC)
  - Up to 5 additional years via SPC (additional 6 months via paediatric extension)
  - Aim of SPCs is to compensate the patentee for the patent term "lost" while obtaining regulatory approval

### **USA**

- Patent Term Extension (PTE)
  - Allows patent owners to recover some of the term of the patent lost while waiting for pre-market government approval



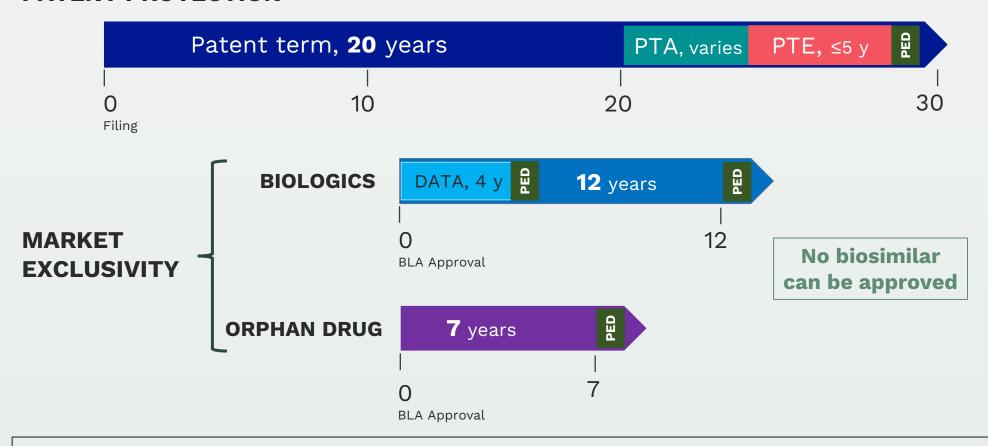
# Main UV1 patent (as example)

Patent / patent application	Priority date	Status	Area covered	Geographic area	Expiry date (unextended)	Expiry date (extended)	Assignee
EP10250265.5	16 Feb 2010	Granted/ pending	UV1 composition of matter, the nucleic acid sequences coding for the vaccine peptides, as well as use of the vaccine for treatment of cancer.	South-Korea, India, China and Hong Kong.	2031	Up until 15 February 2036 via a Supplementary Protection Certificate (SPC) in Europe or via Patent Term Extension (PTE) in the USA.	Ultimovacs



### Summary of exclusivities in the US

#### PATENT PROTECTION



Product manufacturing process know-how is additional protection



# Key take-aways from Q4 report

- UV1 Phase II program extended from two to four trials more than 500 patients to be enrolled
- Patient recruitment in the INITIUM and NIPU trials is proceeding despite COVID-19 challenge
- Read-out of 5-year overall survival in two Phase I trials shows encouraging results
- A Chief Business Officer joins the team to amplify Business Development activities
- Publication in "Frontiers in Immunology" supports our goal of recognition by medical community
- Significant and valuable public grants (up to MNOK 26) support our efforts to develop new treatment alternatives for cancer patients



# Q&A





### Enabling the immune system to fight cancer

### For questions

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