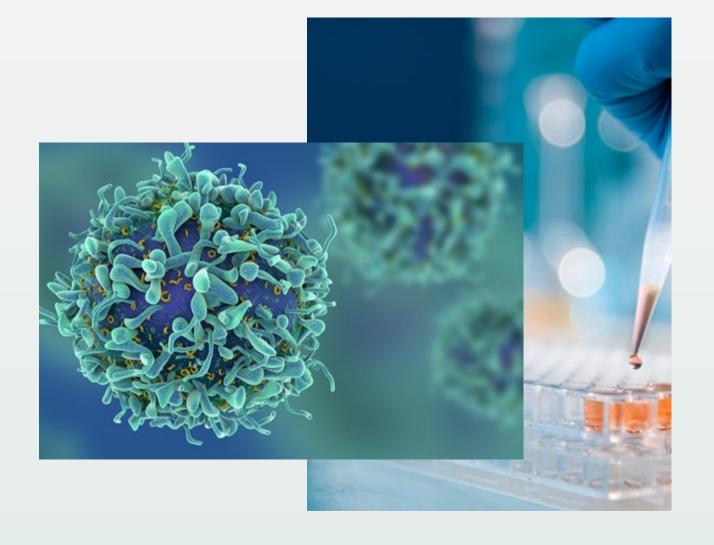


# UV1: Encouraging Safety & Efficacy in Melanoma

Supports our Broad Phase II Combination Program in Solid Tumors

**ASCO Update, May 2021** 



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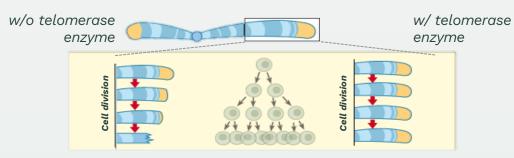
# ASCO UV1 Efficacy and Safety Data Supports Broad Phase II Program

- UV1, a novel immune-stimulatory vaccine, is being evaluated in a Phase I/II Trial in Advanced Malignant Melanoma patients in combination with the standard of care pembrolizumab
- Interim data from this trial are being presented at the ASCO conference, June 4-8th
- Key results from 1<sup>st</sup> study cohort (20 patients) in 21-month follow up show that UV1 when used in combination with pembrolizumab:
  - is safe and well tolerated
  - helps shrink melanoma tumors more than pembrolizumab monotherapy alone
  - helps patients with melanoma live longer versus pembrolizumab monotherapy alone
- Supports our broad Phase II combination program with checkpoint inhibitors
- Broad Combination Potential for UV1 in multiple cancer types
  - Clinical data opens the door to future collaborations in combination therapy
  - UV1 is uniquely positioned in Phase II trials with 4 out of the top 5 CPI's, and enrolling >500 patients



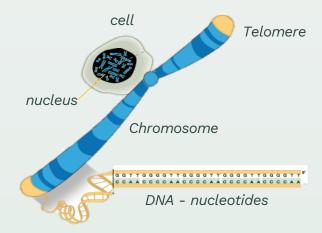
## Telomerase (hTERT) is an Ideal Target Antigen in Cancer Immunotherapy

# Telomerase preserves telomers in cancer cells



Normal cell = normal cell death and replacement

Cancer cell = Unlimited, uncontrolled cell division



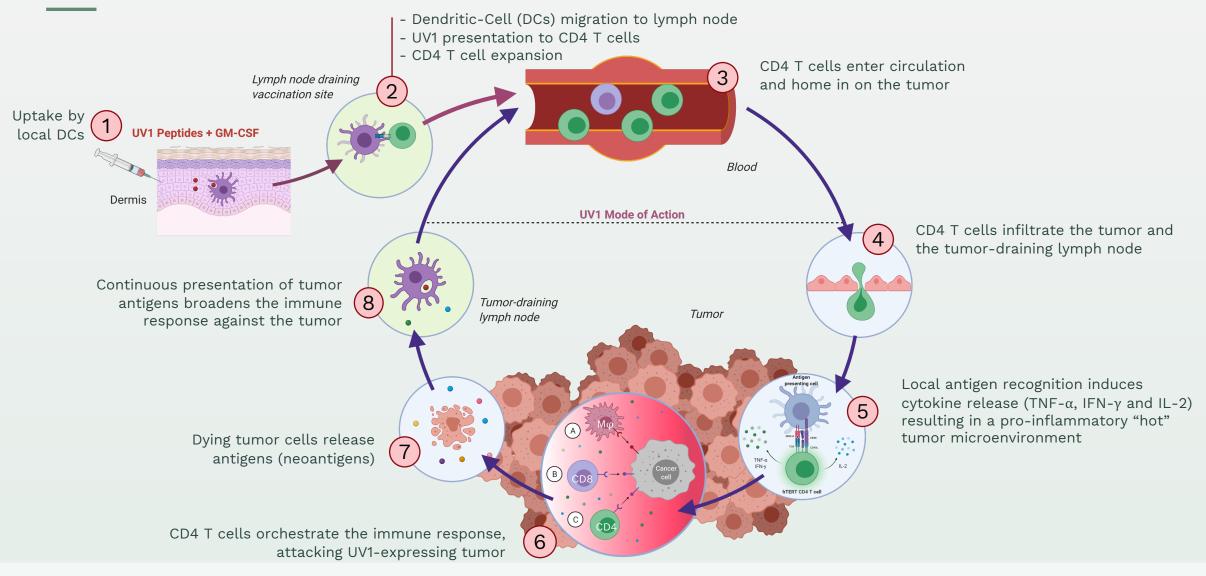
Telomerase is a universal target: 85-90% of cancer cells express hTERT

Telomerase is an essential target: Tumor cells are dependent on expressing hTERT

- Most normal cells are telomerase-negative
- Telomerase's function and relevance for tumor is well known and documented
- Telomerase is present in cancer stem cells and therefore also in all tumor cells
- Telomerase is essential for unlimited growth and immortality
- Telomerase is also essential for tumor spread



# UV1 Activates hTERT Specific CD4-helper T Lymphocytes





# UV1 Works Synergistically with Check Point Inhibitors (CPIs)

UV1 activates, educates and expands the patient's immune cells, killing the cancer cells

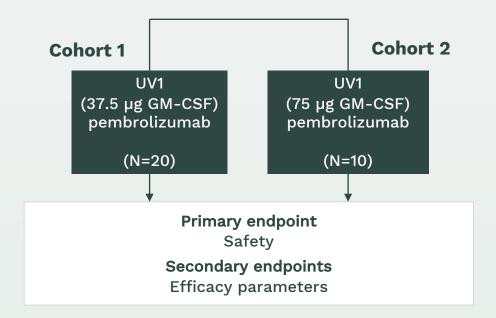


CPIs, e.g., pembrolizumab and nivolumab, block important cancer cells' defense mechanisms against the patient's immune cells.



# UV1/pembrolizumab Phase I Design in First Line Advanced Malignant Melanoma

- Ultimovacs sponsored study running in the U.S.
- Enrollment of all 30 patients completed in Q3 2020
- ASCO 2021 update: 21-month follow-up of cohort 1





# Demographics: Comparable to Pembrolizumab Registrational Trial

Total of 20 patients without earlier treatment for advanced malignant melanoma were included in cohort 1

Male / Female	13 / 7
Median Age (Range)	70 (31-82)
ECOG 0 / 1	15 / 5
Stage IIIb, IIIc, IV	2 / 8 / 10
Elevated LDH	5
UV1 / GM-CSF Doses (# of Patients)	8 doses (17)
	7 doses (2)
	6 doses (1)

ECOG: performance status scale developed by the Eastern Cooperative Oncology Group (ECOG)
LDH: lactate dehydrogenase. The lactate dehydrogenase (LDH) test, looks for signs of damage to the body's tissues
GM-CSF: adjuvant used in vaccines



### UV1 is Safe and Well Tolerated

- Safety profile manageable, and as expected for a PD1 antibody (e.g., pembrolizumab) except injection site reactions which are related to the vaccine
- The major adverse events reported were grade 1 (48%) and grade 2 (41%)\*
- Main adverse events were fatigue (8%), injection site reactions (5%), diarrhea
   (4%) and pyrexia (3%)\*



# **Key Efficacy Results**

- All patients have been observed a minimum of 18 months
- Median observation time is 21 months as of May 2021
- Responses as measured:
  - complete response (CR) 6/20
  - partial response (PR) 6/20
  - stable disease (SD) 1/20
  - progressive disease (PD) 7/20

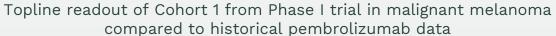
**Objective Response Rate (ORR) 60%** 

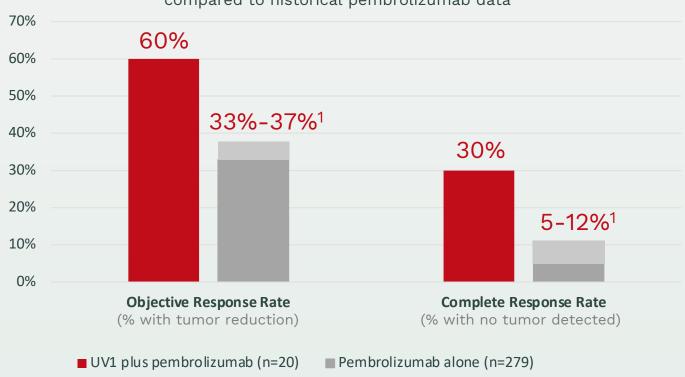
- Median Progression Free Survival (mPFS): 18.9 months
- Overall Survival (OS): 80%
- Median Overall Survival (mOS): not yet reached\*



# UV1 added to pembrolizumab clearly improves Response Rate compared with pembrolizumab alone







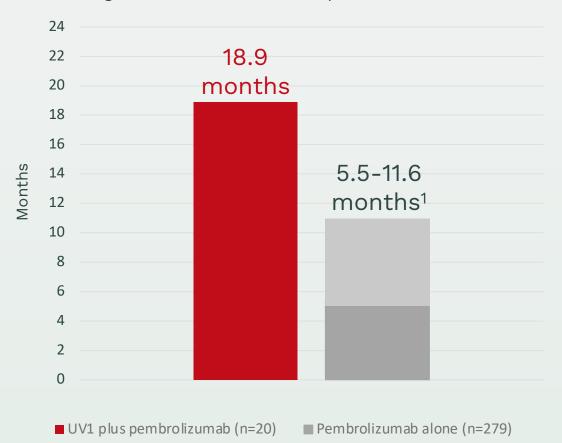
<sup>&</sup>lt;sup>1</sup> Data from KEYNOTE-006 (Robert C, 2019). KEYNOTE-006 is the pivotal study referred to in the Keytruda (pembrolizumab) package inserts. Data from Robert C (2019) is a post-hoc non-planned analysis UV1/pembrolizumab phase I/II trial measured by iRECIST KEYNOTE-006 was measured by RECIST 1.1.



# UV1 added to pembrolizumab helps patients with melanoma live longer compared with pembrolizumab alone

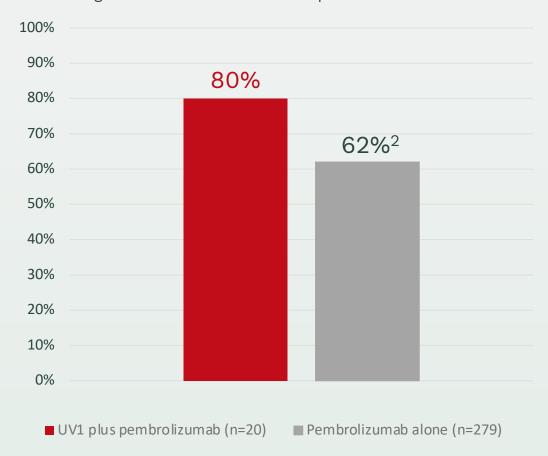
#### **Median Progression Free Survival**

Topline readout of Cohort 1 from Phase 1 trial in malignant melanoma vs historic pembrolizumab data



#### **Overall Survival at 18 months**

Topline readout of Cohort 1 from Phase 1 trial in malignant melanoma vs historic pembrolizumab data



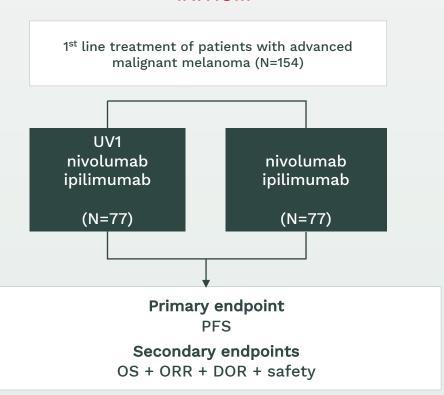


<sup>&</sup>lt;sup>2</sup> Visual reading from KEYNOTE-006 Kaplan Meyer graph at 18 months

# Next Steps for UV1 in Advanced Malignant Melanoma

- ASCO presentation and poster, June 4-8
  - Cohort 1: 21 months follow up
- Phase I combination trial with pembrolizumab
  - Cohort 1: 2 year follow up in Q4 2021
  - Cohort 2: 1 year follow up in Q4 2021
- INITIUM Phase II combination trial with nivolumab and ipilimumab in advanced malignant melanoma
  - Enrollment ongoing since June 2020
  - 154 patients in 40 sites in 4 countries (US, UK, Belgium and Norway)

#### INITIUM





# Data Supports our Broad Phase II Pipeline in >500 Patients

	Indication	Clinical trial information	Pre- clinical	Phase I	Phase II	Phase III	Partner / Collaboration
	First line metastatic malignant melanoma	With pembrolizumab 30 patients					Oslo University Hospital
	First line metastatic malignant melanoma	With ipilimumab & nivolumab 154 patients			INITIUM		
UV1	Second line mesothelioma	With ipilimumab & nivolumab 118 patients			NIPU		Bristol-Myers Squibb
	Second line ovarian cancer	With durvalumab & olaparib 184 patients			DOVACC		AstraZeneca  ENGOT  European Network of  Gynacological Trial groups
	First line head and neck cancer	With pembrolizumab 75 patients			Focus		Martin-Luther University Halle network

Note: UV1 Phase II development is supported by good safety profile and signals of clinical efficacy observed in three Phase 1 trials with 5 year follow up in 52 patients in prostate, NSCLC and malignant melanoma



# The Commercial Potential and Key Market Players



# Immuno-oncology is the fastest growing pharmaceutical segment

#### IMMUNO-ONCOLOGY IN BRIEF

Immuno-Oncology is designed to help the body's own immune system fight cancer by either activating the immune system against cancer cells or by suppressing factors that limit the immune system's ability to kill cancer cells such as checkpoint inhibitors

FDA APPROVED CHECKPOINT INHIBITORS\*



2014



2014

2016



2017



2017



TOTAL MARKET SIZE 2019

\$24bn

TOTAL MARKET SIZE 2026e

\$67bn

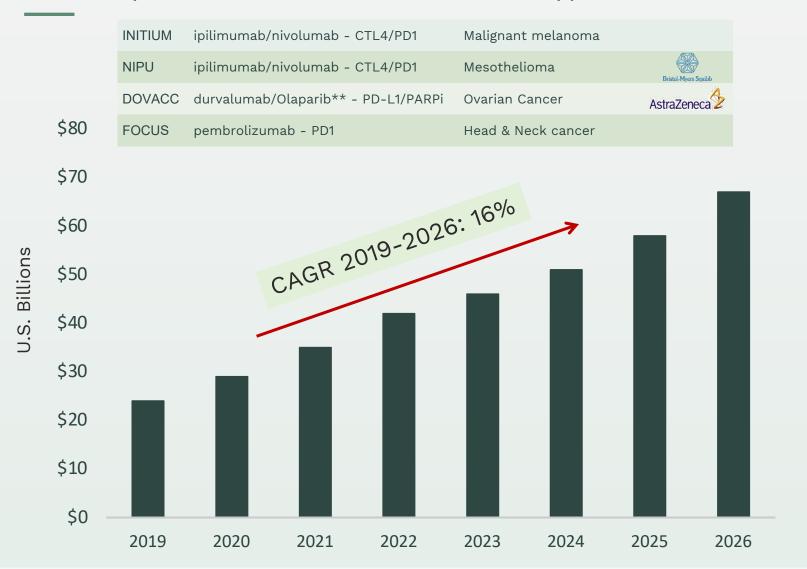
CAGR 2019-2026e

16%



### UV1 Uniquely Positioned in Phase II trials with 4 out of the top 5 CPI's\*

Partnerships with BMS and AstraZeneca validate approach



#### Marketed CPI's

- 1. Pembrolizumab (Keytruda®)
- 2. Nivolumab (Opdivo®)
- 3. Atezolizumab (Tecentriq®)
- 4. Ipilimumab (Yervoy®)
- 5. Durvalumab (Imfinzi®)
- 6. Cemiplimab (Libtayo®)
- 7. Sintilimab (Tyvyt®)
- 8. Avelumab (Bavencio®)



\*CPI: Checkpoint Inhibitor
\*\* PARP inhibitor

# Broad Combination Potential for UV1 in multiple cancer types<sup>1</sup>

Clinical data opens the door to future collaborations in combination therapy

















	Keytruda®	Opdivo®	Imfinzi®	Tecentriq®	Bavencio®	Yervoy®	Lynparza®
(As per January 2021)	pembrolizumab	nivolumab	durvalumab	atezolizumab	avelumab	ipilimumab	olaparib <sup>2</sup>
Malignant melanoma							
NSCLC							
HNSCC							
Mesothelioma						Nivo + Ipi	
Ovarian							
Prostate							
SCLC							
Renal						Nivo + Ipi	
Urothelial							
MSI-high							
Gastric							
Cervical							
Hepatocellular							
Merkel cell							
Hodgkins							
Large B-cell							
Breast							
Pancreatic							
Esophageal							
Endometrial							
Cutaneous squamous cell							
Colon							





<sup>2</sup> PARP inhibitor

# **Exciting Times Ahead**

- Excellent safety and efficacy data being presented at ASCO on the melanoma study in combination with pembrolizumab
- New data to be presented in Q4 2021, including first results from 2<sup>nd</sup> cohort
- Ambitious and broad Phase II plan progressing
  - Patient enrollment to continue in the INITIUM and NIPU studies
  - Patient enrollment in the DOVACC and FOCUS studies to start soon
- We keep regular discussions with Pharma and Biotech companies while preparing for future program collaboration
- 4 June 2021 at 15.00 CET: ASCO Release of Poster presentation





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