Ultimovacs webcast presentation

NIPU Phase II trial results elaborated
INITIUM update on timeline for readout
October 31, 2023

Carlos de Sousa, CEO
Jens Bjørheim, CMO

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Agenda

- Introduction and key take-aways
- NIPU results
- INITIUM update
- Summary and Q&A

Introduction and key take-aways

Introduction and key take-aways

NIPU results

- Malignant Pleural Mesothelioma ("MPM") is one of the most challenging cancers to treat
- Based on data from recent trials, KOLs and regulatory authorities both recognize that PFS is a poor endpoint in MPM, and that overall survival (OS) remains the gold standard and hence the primary endpoint in phase 3 trials
- NIPU results show OS benefit of UV1 plus IPI-NIVO vs. IPI-NIVO
- Trial investigators recommend to advance UV1 to the next phase of development; this view is supported by Ultimovacs

INITIUM update

- The amendment, as communicated in the press release this morning, is implemented as it is taking longer than anticipated for the patients in the INITIUM study to experience cancer progression or death.
- The study protocol for INITIUM has been amended based on a minimum of 18-month follow-up of all evaluable patients. The amendment will maintain statistics integrity and is based on response from the FDA and other regulatory authorities.
- The amendment enables analysis starting in mid-January 2024. Topline readout of the INITIUM trial is expected approximately two to three months later.

NIPU results

NIPU is an investigator-initiated trial run by highly experienced and well-reputed investigators throughout Scandinavia, Australia and Spain

Investigators:

- **Åslaug Helland**, Dept of Oncology, Oslo University Hospital, Oslo, Norway
- **Anna Nowak**, National Centre for Asbestos-Related Diseases, University of Western Australia
- **Oscar Grundberg**, Thoracic Oncology Center, Karolinska University Hospital, Stockholm, Sweden
- **Weronika Szejniuki**, Clinical Cancer Research Center & Department of Oncology, Aalborg University Hospital, Aalborg, Denmark
- **Jens Benn Sørensen**, Department of Oncology, Rigshospitalet, Copenhagen University Hospital, Copenhagen, Denmark
- **Susana Cedres**, Vall d'Hebron Institute of Oncology, Hospital Universitari Vall d'Hebron, Barcelona, Spain

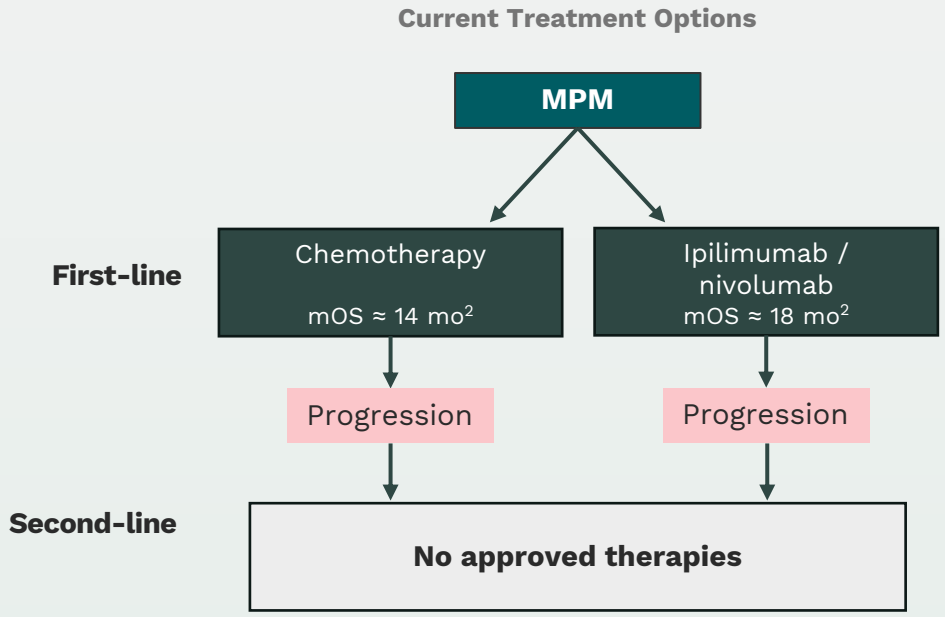
Sponsor: OSLO UNIVERSITY HOSPITAL

Collaborators and drug supply:

Bristol Myers Squibb ultimovacs

Malignant Pleural Mesothelioma (MPM) – One of the Most Challenging Cancers to Treat

- Most patients:
  - Are diagnosed with advanced disease
  - Have poor prognosis and few therapeutic options
  - Do not have surgery as an option
- Chemotherapy has been the Standard of Care (SoC) for the past 20 years
- Ipilimumab and nivolumab (IPI-NIVO) was approved in 1st line treatment by regulatory authorities in 2020/2021[1]
- Despite current improvement in SoC, patients with MPM remain an underserved population with a high unmet medical need



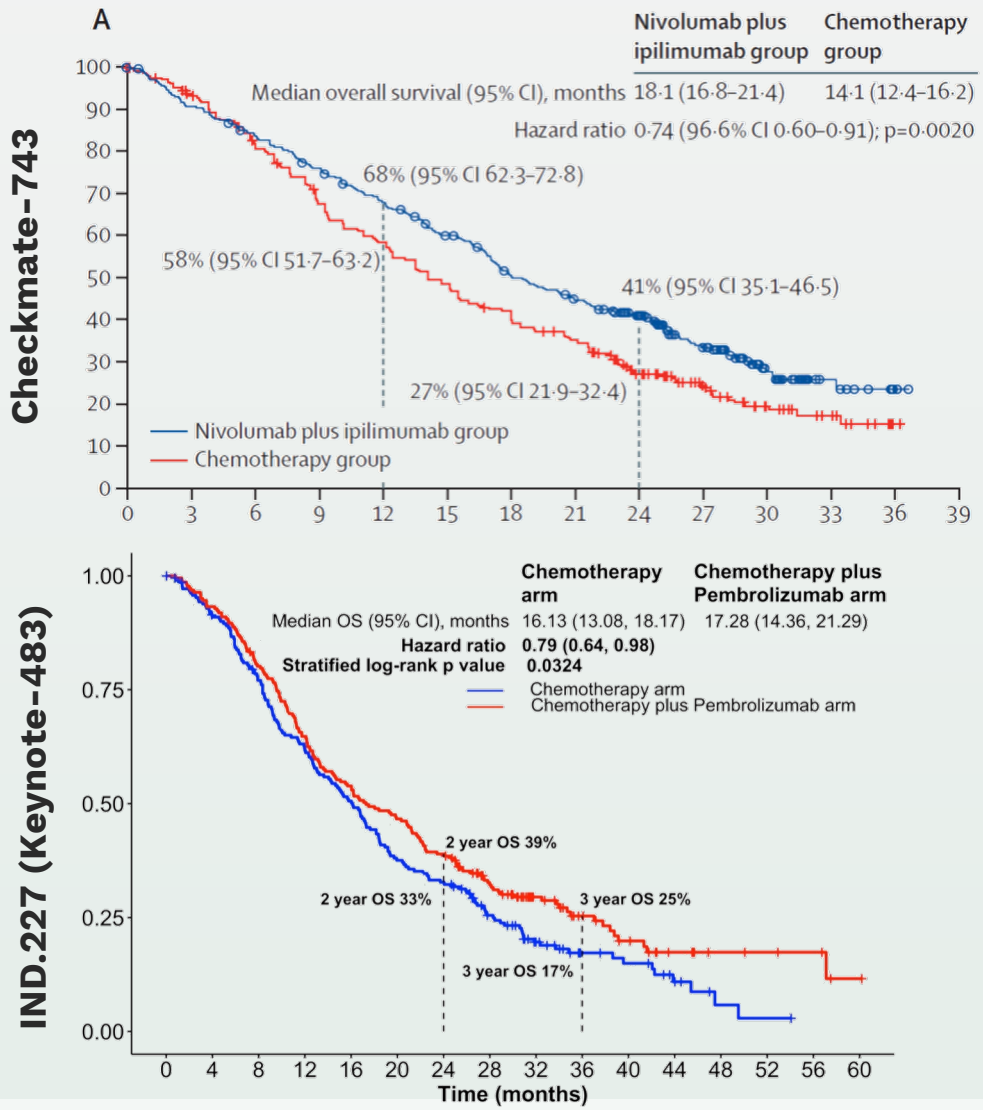
1: Approved by EMA and FDA, but not reimbursed in most EU countries (including Norway)
2: Baas et al (2021)

Overall Survival is the Gold Standard Endpoint in Cancer Trials

Overall survival (OS) in first-line MPM trials with checkpoint inhibitors

- CheckMate-743 trial[1]
  - IPI-NIVO versus chemotherapy
  - **No difference in PFS, but:**
  - **26% reduction in risk of death** with IPI-NIVO
    - HR=0.74 [96.6% CI, 0.60-0.91]
- IND-227 (Keynote-483) trial[2]
  - PEMBRO plus chemotherapy versus chemotherapy
  - **No difference in PFS, but:**
  - **21% reduction in risk of death** with PEMBRO-chemo
    - HR=0.79 [95% CI, 0.64-0.98]

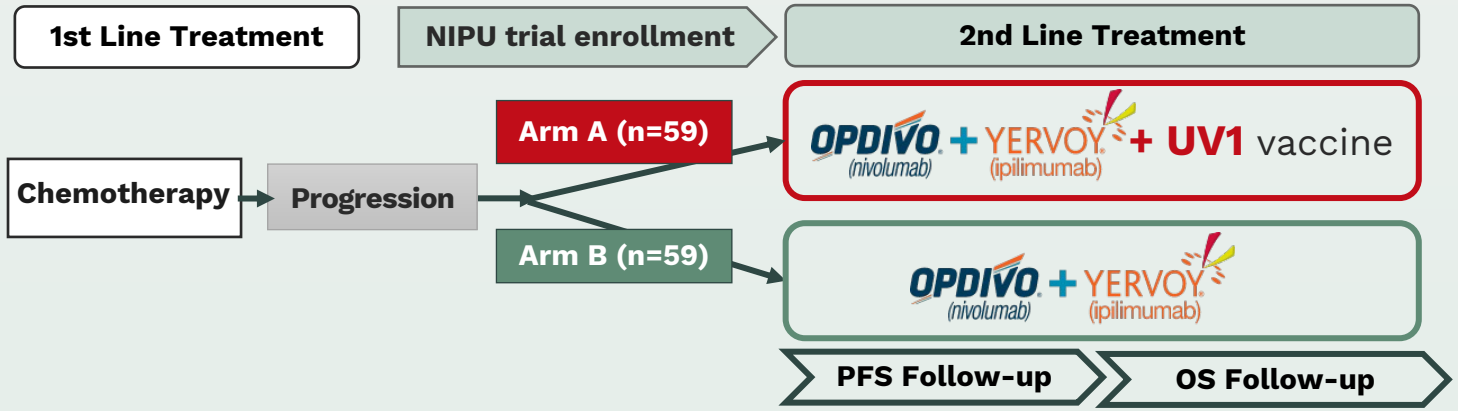
OS improvements in MPM remain modest even in first-line treatment with new immunotherapies. This level of improvement is nevertheless considered clinically relevant in MPM.



1: Baas et al (2021)
2: Chu et al, Presented at ASCO 2023

NIPU – First Randomized Trial in MPM Designed to Investigate the Impact of UV1 Vaccination on Top of Checkpoint Inhibitors

- At the time of study initiation, the only 1st line SoC was chemotherapy and IPI-NIVO was not approved
- Standard study design for a phase II study
- **Primary Endpoint**
  - Progression-free survival (PFS) per Blinded Independent Central Review (BICR)
    - Measured using a multivariate Hazard Ratio (HR)
    - Standard phase II statistics: Power 80%, 1-sided alpha 0.1 (HR < 0.736)
- **Secondary Endpoints**
  - Overall survival (OS)
    - Measured using a multivariate Hazard Ratio (HR), analyzed the same way as primary endpoint
  - Objective response rate (ORR) per BICR
  - Safety



Helland et al. Presented at ESMO 2023 (LBA99)

The NIPU baseline demographics is relatively balanced

OPDIVO (nivolumab) + YERVOY (ipilimumab) **UV1** vaccine

OPDIVO (nivolumab) + YERVOY (ipilimumab)

		UV1 plus IPI-NIVO (n=59)	IPI-NIVO (n=59)	Total (N=118)
Sex – n (%)	Female	14 (23.7)	12 (20.3)	26 (22.0)
	Male	45 (76.3)	47 (79.7)	92 (78.0)
Age	Median	71	72	71
	Range	39-79	42-83	39-83
ECOG – n (%)	0	17 (28.8)	18 (30.5)	35 (29.7)
	1	42 (71.2)	41 (69.5)	83 (70.3)
Histology – n (%)	Epithelioid	44 (74.6)	47 (79.7)	91 (77.1)
	Sarcomatoid	5 (8.5)	4 (6.8)	9 (7.6)
	Biphasic	5 (8.5)	7 (11.9)	12 (10.2)
	Rhabdoid	1 (1.7)	0 (0)	1 (0.8)
	Unknown	4 (6.8)	1 (1.7)	5 (4.2)
PD-L1 – n (%)	<1	31 (52.5)	32 (54.2)	63 (53.4)
	1-49	6 (10.2)	4 (6.8)	10 (8.5)
	≥50	2 (3.4)	4 (6.8)	6 (5.1)
	Unknown	20 (33.9)	19 (32.2)	39 (33.1)

Helland et al. Presented at ESMO 2023 (LBA99)

UV1 Maintains an Excellent Safety Profile in the NIPU study

The addition of UV1 to IPI-NIVO was safe and did not noticeably increase occurrences of serious adverse events

- In the NIPU trial, the percentage of patients with serious adverse events was similar in both arms
  - UV1 plus IPI-NIVO: 36 patients (61.0%)
  - IPI-NIVO: 35 patients (59.3%)

NIPU Results Show Survival Benefit of UV1 plus IPI-NIVO

Overall survival (OS)

- 27% reduction in risk of death with the addition of UV1 to IPI-NIVO
  - HR=0.73 (80% CI, 0.53-1.00, 1-sided p value = 0.0985)
- Median OS 15.4 months with UV1 plus IPI-NIVO versus 11.1 months with IPI-NIVO

HR is the key efficacy measure

Objective response rate (ORR)

- UV1 plus IPI-NIVO: 31%
- IPI-NIVO: 16%
- Odds Ratio 2.44 (80% CI, 1.35-4.49, 1-sided p value = 0.028)

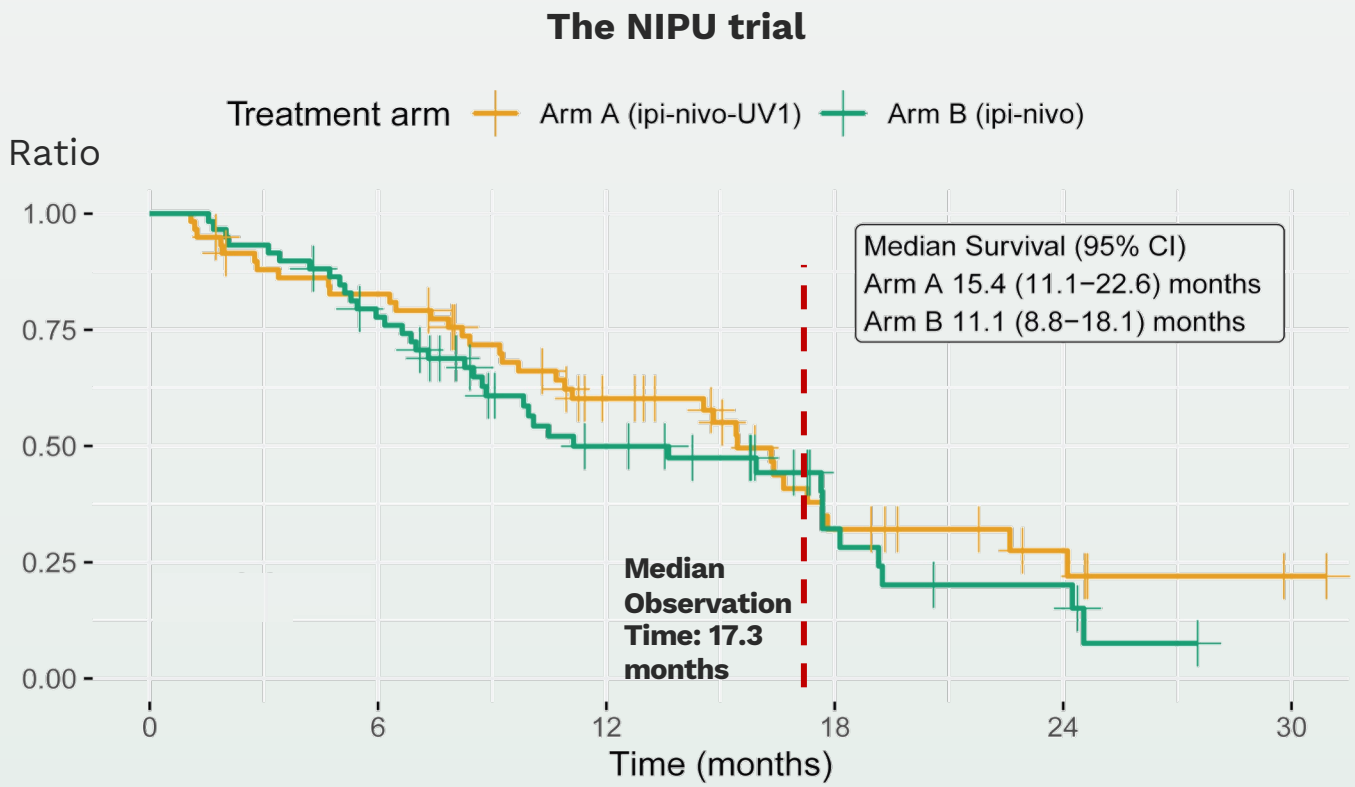
Progression-free survival (PFS)

- Primary endpoint
- PFS BICR (central review)
  - HR = 1.01 (80% CI 0.75-1.36, 1-sided p value = 0.4895)
  - Median PFS 4.2 months with UV1 plus IPI-NIVO versus 4.7 months with IPI-NIVO
- PFS local review
  - HR = 0.60 (80% CI 0.45-0.81, 1-sided p value = 0.0125)
  - Median PFS 4.3 months with UV1 plus IPI-NIVO versus 2.9 months with IPI-NIVO

Helland et al. Presented at ESMO 2023 (LBA99). 80% CI is standard in Phase II clinical trials.

Current Survival Data Signals an OS Benefit when Adding UV1 Vaccination to IPI-NIVO as Measured by HR Based on the Multivariate Analysis (1:2)

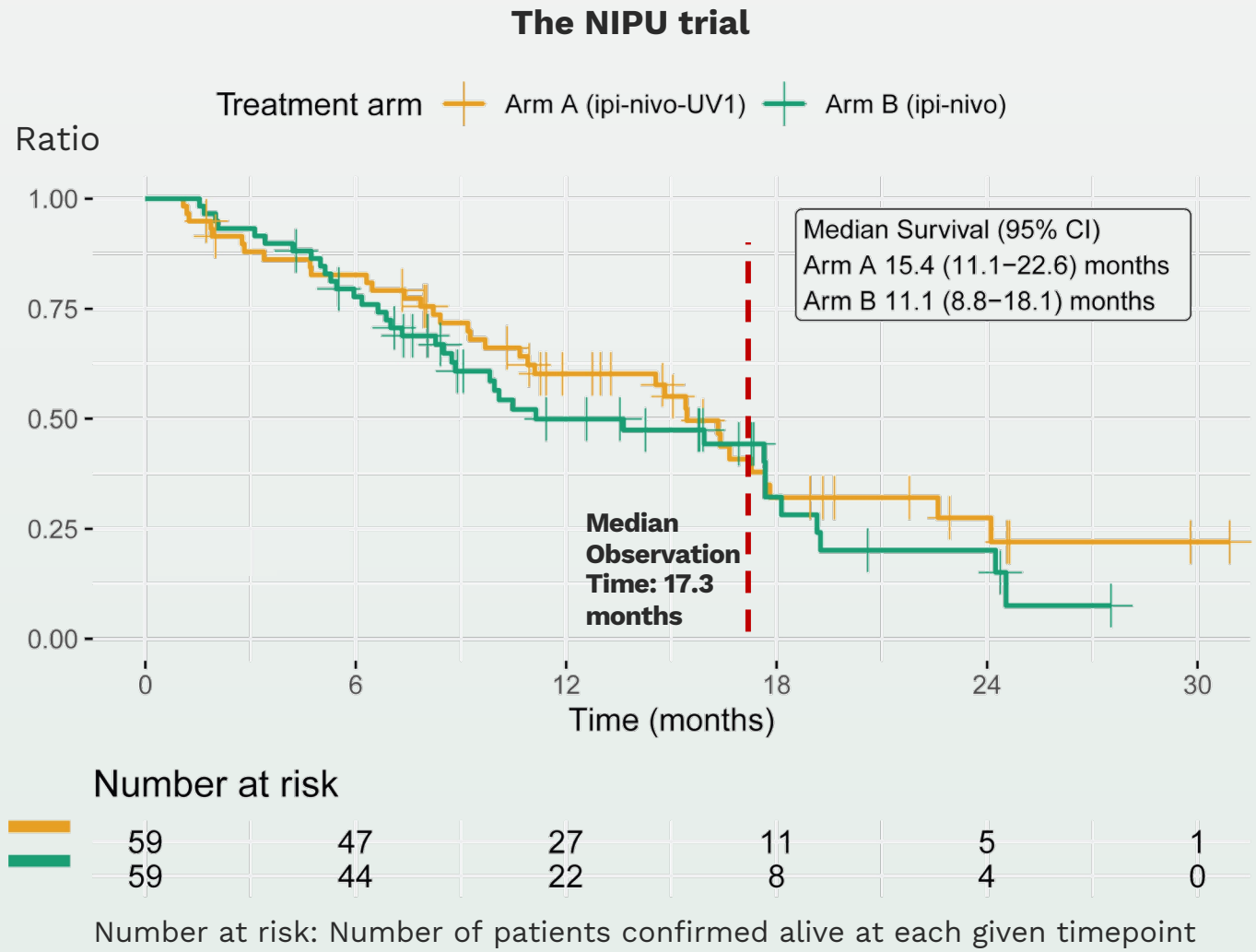
- The Kaplan-Meier diagram shows the percentage of patients alive in either study arm over time
- The current data has a median observation time of 17.3 months
- Median observation time exceeds median overall survival for the patients – appropriate time point for first OS read-out
- To assess long-term OS benefit, the patients must be followed further
- HR is a multivariate analysis, including differences in histology between study arms, - the standard efficacy measure in clinical trials
- Kaplan-Meier diagram and the associated logrank test* is a univariate analysis, not accounting for such differences, and not part of the predefined NIPU endpoints



*P value based on logrank test 0.37

Current Survival Data Signals an OS Benefit when Adding UV1 Vaccination to IPI-NIVO as Measured by HR Based on the Multivariate Analysis (2:2)

- The median observation time (mOT) is important to know prior to review of lines. In this figure the mOT is marked with a vertical line at 17.3 months.
- The curves are crossing around 17 months. The data in this area and beyond need to mature further before conclusions are drawn.
- The «number at risk» is the number of patients confirmed alive at each given timepoint*.
- The further to the right, the fewer patients, and the less certainty around the data. The certainty around the data will improve with increased observation time.
- **The key efficacy measure, the HR, is calculated from the aggregated area between the two arms and shows a 27% reduction in risk of death with the addition of UV1 to IPI-NIVO.**



* The reason for patients not being confirmed alive can be that the patient have passed away, dropped out of the study or have not yet reached the given timepoint.

Next Steps

- Ultimovacs management agrees with the trial investigators' recommendation to advance UV1 to the next phase of development
- Ultimovacs will:
  - Carefully evaluate the current results from NIPU together with more detailed analyses as well as more updated data as it matures
  - Discuss with regulatory authorities and Key Opinion Leaders how these results should define the optimal way forward into a phase III trial
  - Complete a market analysis as a basis for a possible decision to move into a UV1 Phase III trial in mesothelioma

INITIUM update

INITIUM update (today's announcement)

- Since it is taking longer than anticipated for the patients in the INITIUM study to experience cancer progression, the study protocol for INITIUM has been amended to enable data analysis to start in mid-January 2024, at which time:
  - the last enrolled patient has been followed up for 18 months
  - the patients will have a mean follow-up time of approximately 24 months

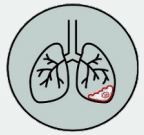
- The FDA has not raised any objections to the protocol amendment, which was also approved by two regulatory bodies in Europe. We expect approval from the remaining European country soon.

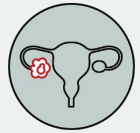
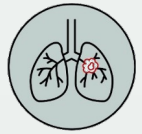
- Topline readout of the trial is expected approximately two to three months after mid-January 2024.

Summary and Q&A

UV1 Clinical Program Consists of Five Randomized Phase II Trials

- The NIPU trial is the first of five randomized UV1 Phase II trials, each playing an important role in expanding our understanding of UV1's potential. Mesothelioma, with its notoriously aggressive nature, was a demanding initial target.



Trial design	1 NIPU	2 INITIUM	3 FOCUS	4 DOVACC	5 LUNGVAC
CPI combination	Ipilimumab + nivolumab	Ipilimumab + nivolumab	Pembrolizumab	Durvalumab + olaparib	Cemiplimab
Indication	Second line mesothelioma	First line malignant melanoma	First line head and neck cancer	Second line ovarian cancer	First line non-small cell lung cancer
Timeline	2020 – 2023	2020 – 2023	2021 – 2023	2021 – 2023	2022 – 2024
Expected topline results	**Announced October 2023**	**H1 2024**	**H2 2024**	H2 2024[1]	H2 2025[1]
No. of patients	N=118	N=156	N=75	N=184	N=138

1. DOVACC and LUNGVAC: Readout estimates will be updated with the Q4 2023 report

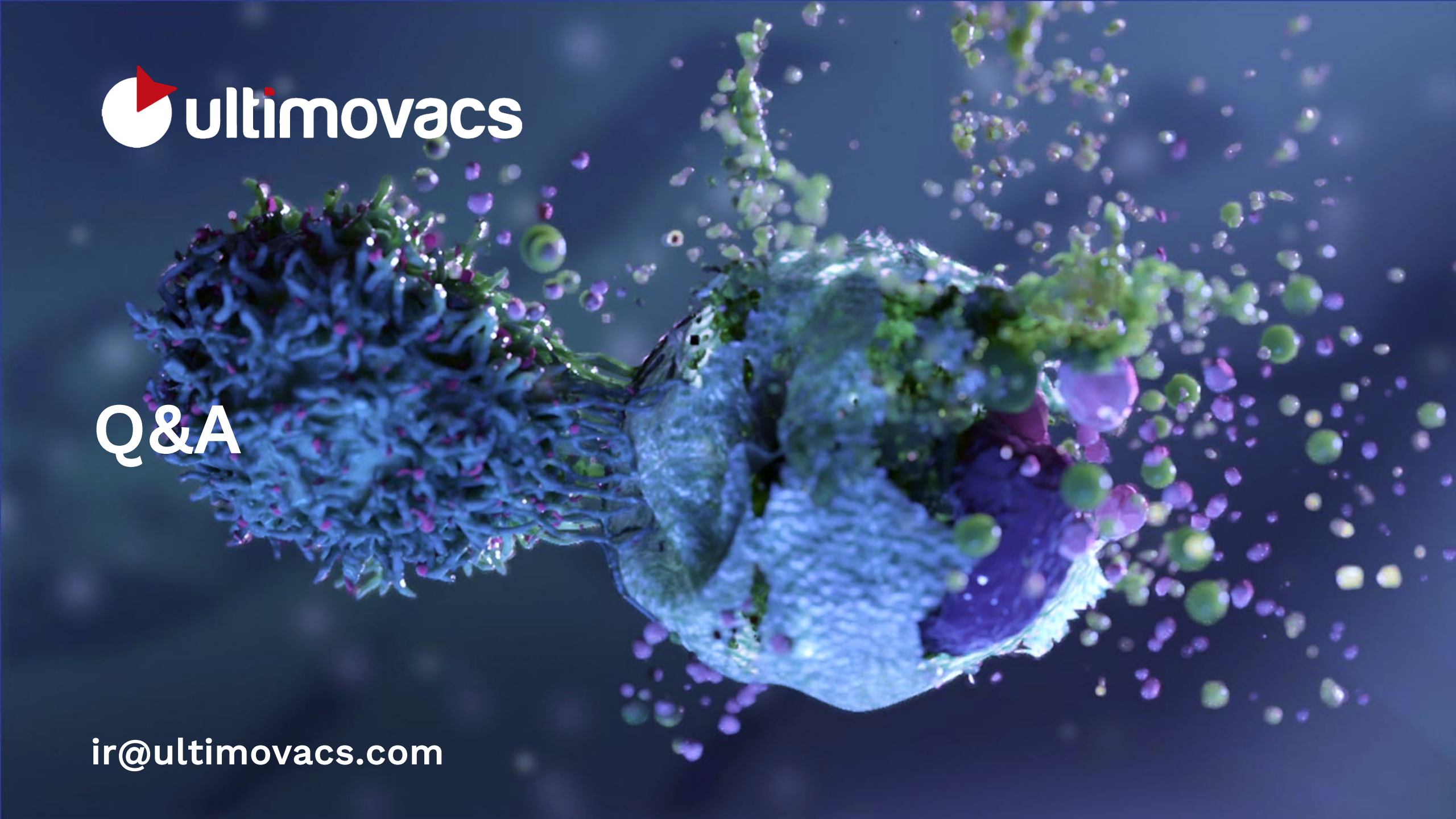
Summary

NIPU results

- NIPU results show benefit of UV1 plus IPI-NIVO in overall survival, the gold standard efficacy measure in cancer treatment for regulatory authorities
- Based on the positive findings, the trial investigators recommend to advance UV1 to the next phase of development. This view is supported by Ultimovacs
- Ultimovacs will discuss with regulatory authorities and Key Opinion Leaders how these results could define an optimal way forward into a Phase III trial

INITIUM update

- Since it is taking longer than anticipated for the patients in the INITIUM study to experience cancer progression, the study protocol for INITIUM has been amended to secure readout of the trial approximately two to three months after mid-January 2024.


ultimovacs
Q&A
ir@ultimovacs.com