



Results from NIPU Phase II trial

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Principal Investigator NIPU trial: Professor Åslaug Helland MD, PhD

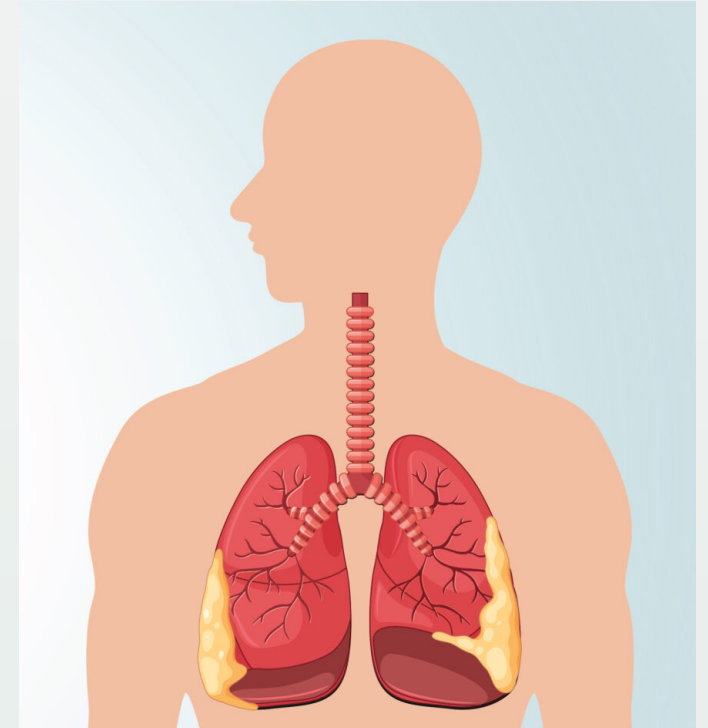
- Åslaug Helland, MD, PhD, is Research Director at the OECl-accredited Oslo Comprehensive Cancer Centre. She is an oncologist by training, with expertise in thoracic oncology.
- She is also Professor at the University of Oslo, Institute of Clinical Medicine. She is director of the national research centre for clinical cancer research, MATRIX, and she leads the national centre for lung cancer research funded by the Norwegian Cancer Society.
- She leads the research group “Translational research on solid tumours” at the Institute for Cancer Research, Norwegian Radium Hospital (NRH), Oslo, focusing on translational studies on solid tumours, with a special interest in lung cancers and pancreatic cancers.
- She furthermore leads several clinical and translational studies in lung cancer; the DART trial, the NIPU trial, and the IMPRESS-Norway study.
- Åslaug Helland was awarded King Olav Vs cancer research honorary prize in 2023.

Agenda

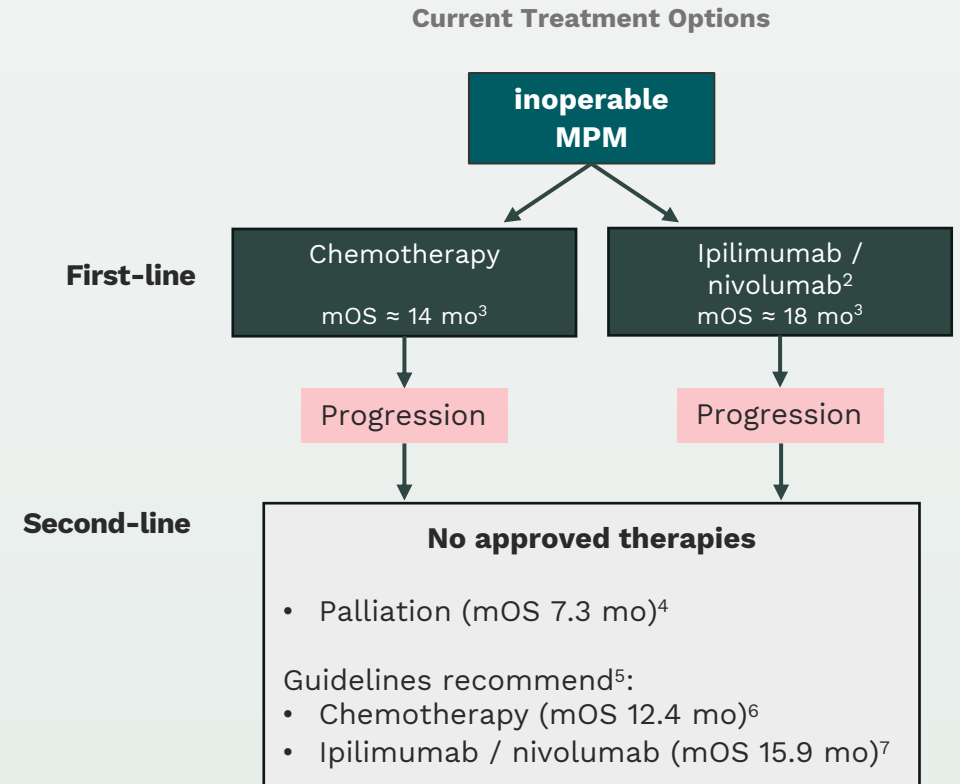
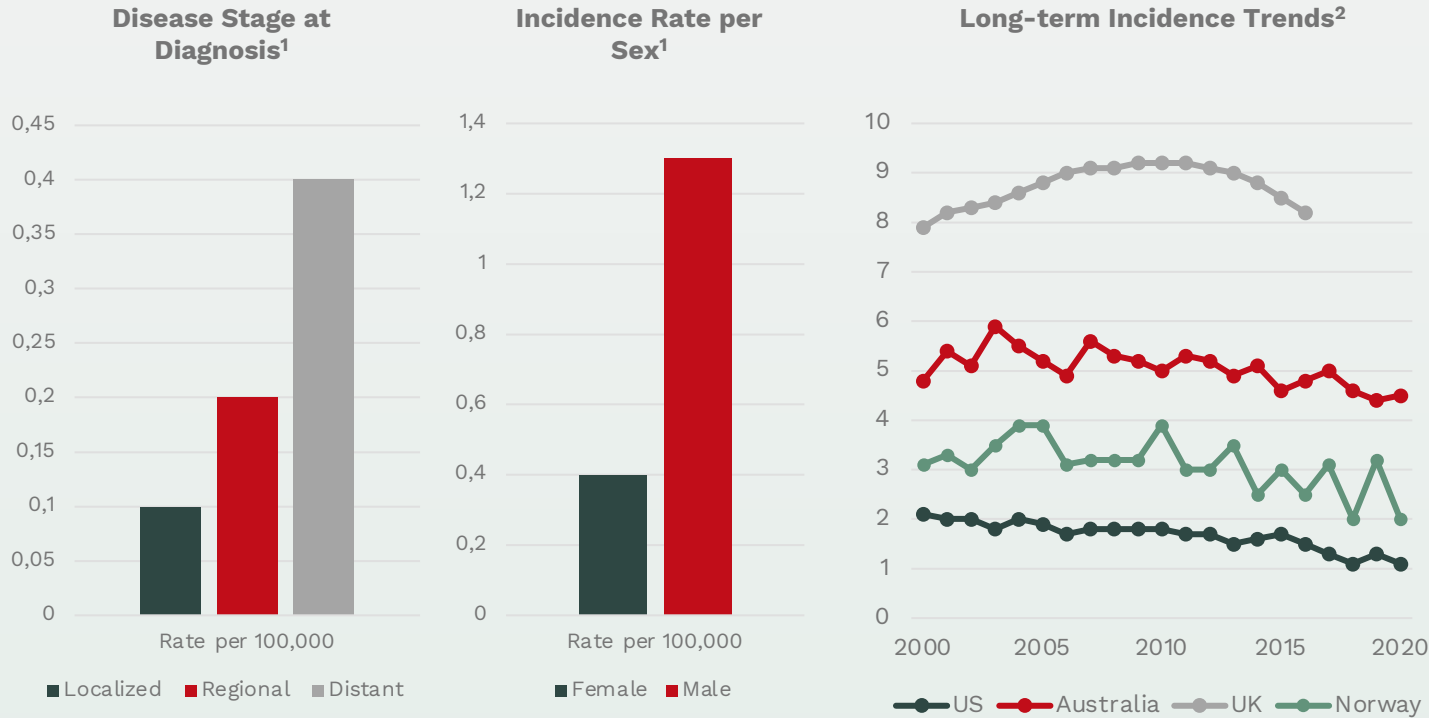
- Welcome and introduction
- Principle Investigator, Professor Åslaug Helland MD PhD
 - About malignant mesothelioma
 - Incidence and treatment options
 - Study rationale
 - Trial design
 - Patient baseline characteristics
 - PFS (BICR and Local)
 - ORR and OS
 - Conclusions
 - Q&A
- Ultimovacs team
 - Future of UV1 in mesothelioma
 - Next steps for Ultimovacs
 - Q&A

About Malignant Pleural Mesothelioma (MPM)

- Cancerous disease arising from the mesothelial cells lining the lungs
- Commonly associated with asbestos exposure
- Long latency period, can take up to 50 yrs before symptoms appear
- Often diagnosed at a late stage due to diffuse symptoms
- MPM holds a poor prognosis and is a disease with few treatment options
 - 5-year relative survival rates range from 7-24% in advanced and localized disease, respectively¹



Malignant Pleural Mesothelioma (MPM) – incidents and treatment options



1: US population (SEER)

2: Rate per 100,000 males. SEER Incidence Data; Cancer Research UK; Australian Institute of Health and Welfare; Kreftregisteret

3: Approved by EMA and FDA, but not reimbursed in all Western countries (including Norway)

4: Baas et al (2021)

5: Maio et al (2017)

6: Whichever was not used in first-line treatment - NCCN Clinical Practice Guidelines in Oncology - Mesothelioma: Pleural

7: Popat et al (2020)

8: Scherpereel et al (2019)

Study rationale NIPU

- Expression of telomerase in MPM
- Limited checkpoint inhibitor (CPI) efficacy – need for an improvement
 - Rationale for combining a vaccine with checkpoint inhibition to improve efficacy
- Phase I trials of UV1 demonstrate good safety profile and robust immune response induction

NIPU – Trial design

- **Eligible patients:**

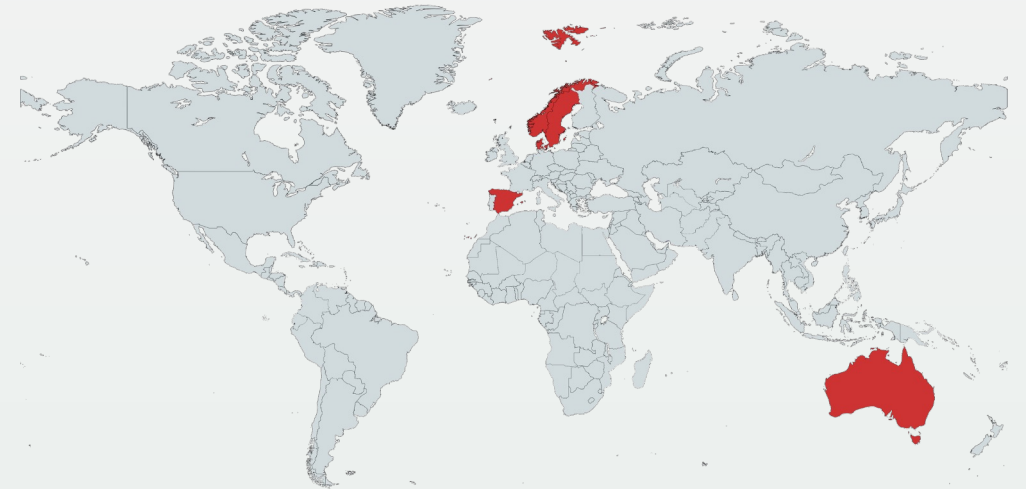
- Inoperable malignant pleural mesothelioma
- Age \geq 18 yrs
- ECOG Status 0-1
- Measurable disease according to mRECIST
- Adequate organ function
- Previously treated with first-line chemotherapy

- **Primary Endpoint**

- Progression-free survival (PFS) per Blinded Independent Central Review (BICR)
- Target HR 0.6, Power 80%, 1-sided alpha 0.1
- Event-driven design: Read-out when 69 PFS events occurs

- **Secondary Endpoints**

- Overall survival (OS)
- Objective response rate (ORR, per BICR)
- Safety



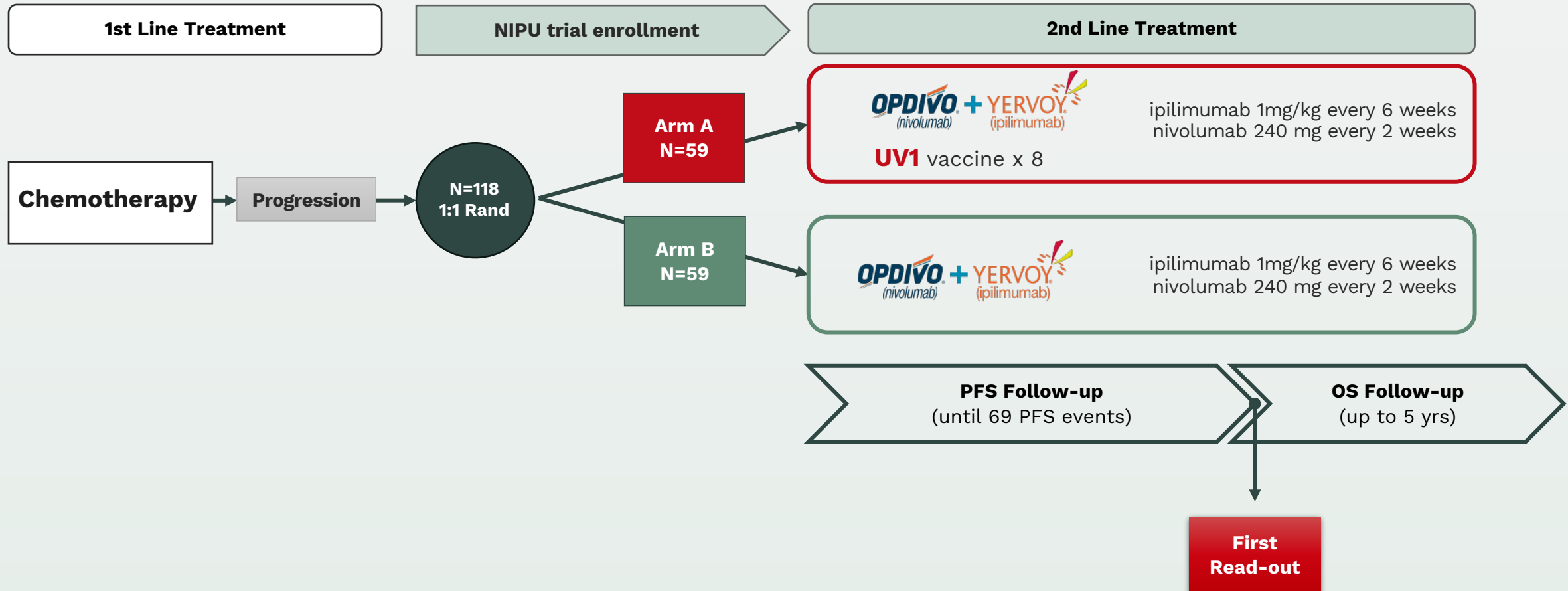
Sponsor:  OSLO UNIVERSITY HOSPITAL | 

Collaborators and drug supply:

 Bristol Myers Squibb

 **ultimovacs**

NIPU – Trial design



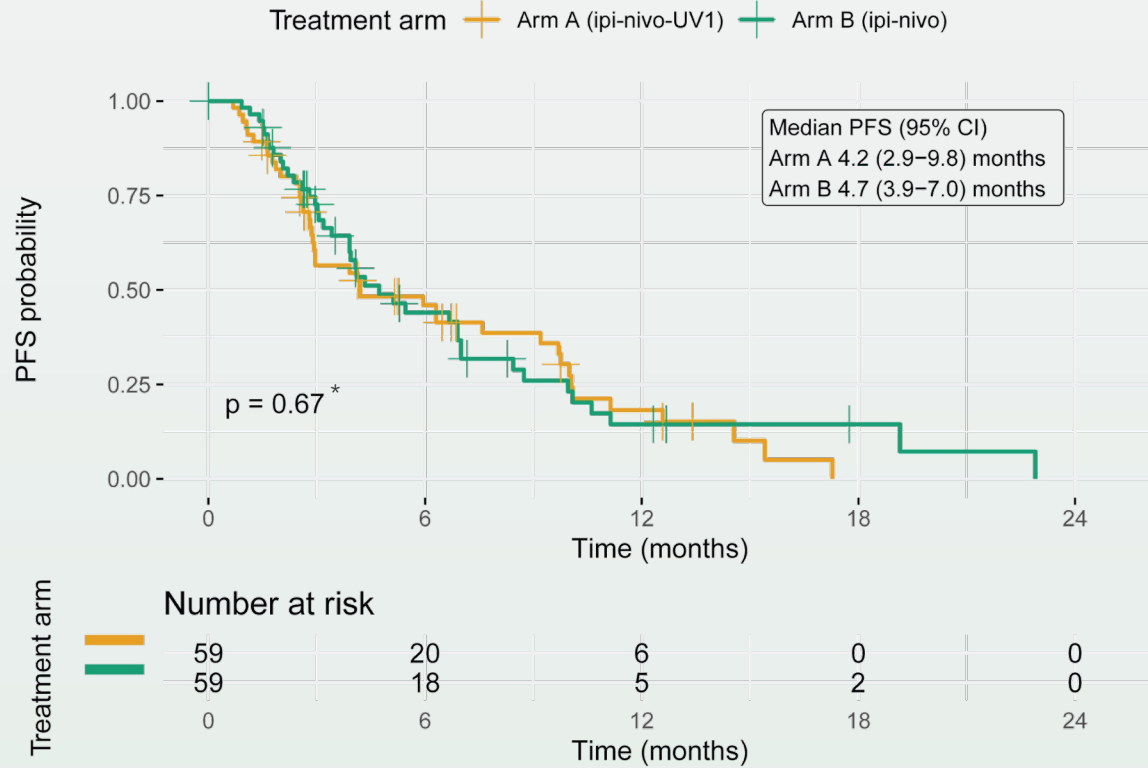
NIPU – Patient baseline demographics



	Arm A (N=59)	Arm B (N=59)	Total (N=118)
Sex			
Female	14 (23.7%)	12 (20.3%)	26 (22.0%)
Male	45 (76.3%)	47 (79.7%)	92 (78.0%)
Age			
Median	71.0	72.0	71.0
Range	39.0 - 79.0	42.0 - 83.0	39.0 - 83.0
ECOG			
0	17 (28.8%)	18 (30.5%)	35 (29.7%)
1	42 (71.2%)	41 (69.5%)	83 (70.3%)
Histology			
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 (0.0%)	1 (0.8%)
Unknown	4 (6.8%)	1 (1.7%)	5 (4.2%)
PD-L1(%)			
<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%)

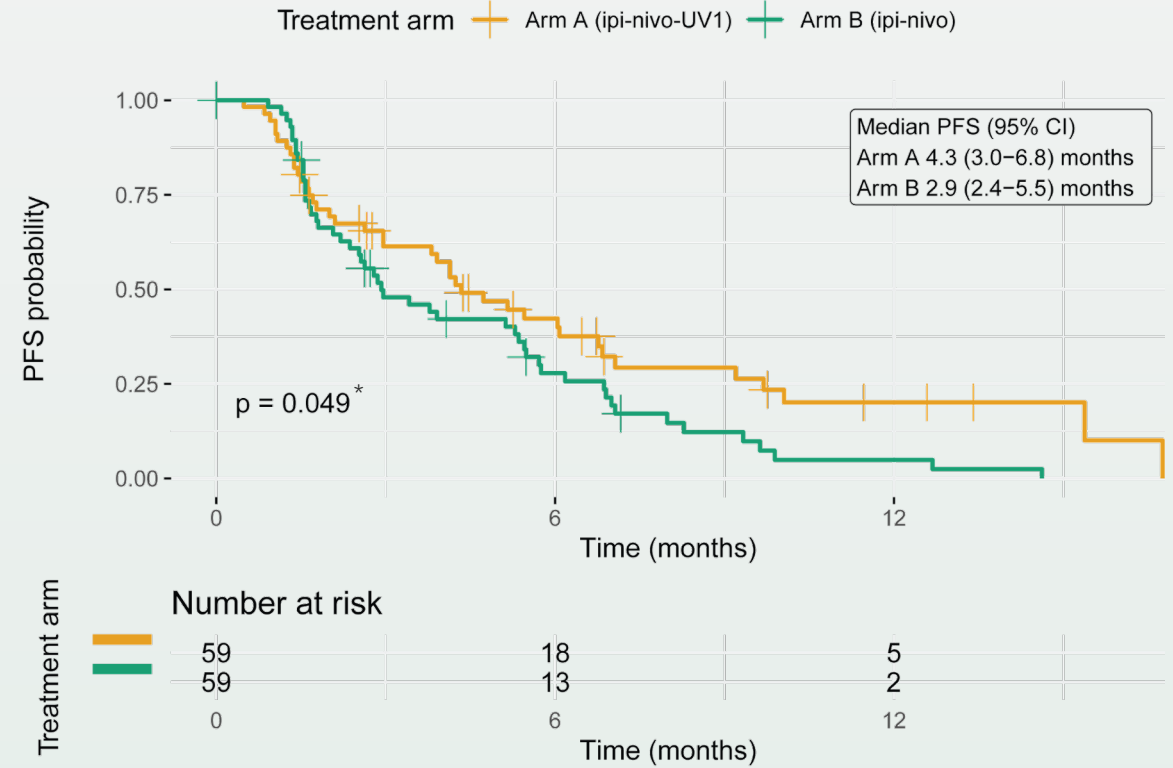
Progression-free survival reported by BICR and Investigator Assessment

Blinded Independent Central Review (BICR)



Progression-free Survival based on BICR[†]
 HR = 1.01 (80% CI 0.75–1.36, 1-sided p value = 0.4895)

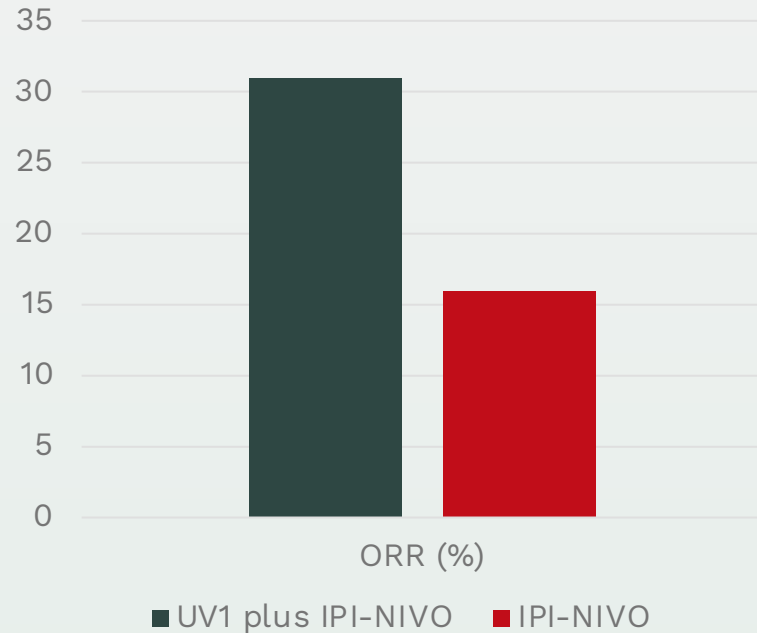
Investigator Assessment



Progression-free Survival based on Investigator Assessment
 HR = 0.60 (80% CI 0.45–0.81, 1-sided p value = 0.0125)

Near doubling of ORR and clinically meaningful prolonged survival

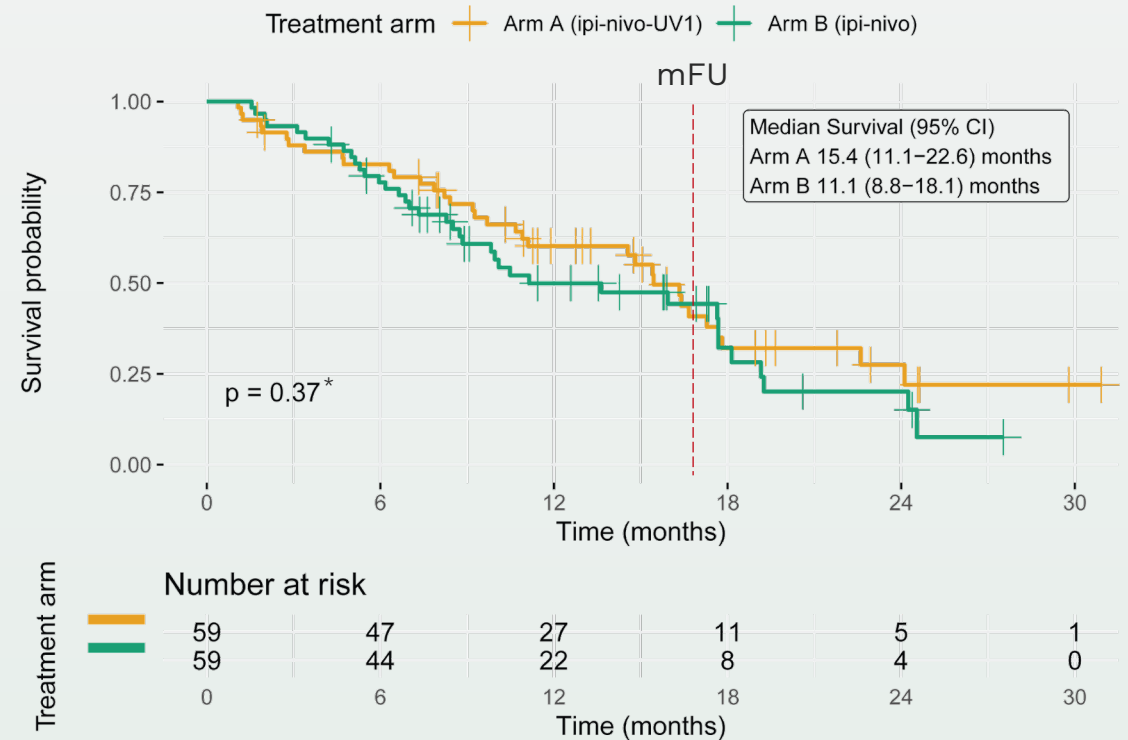
Objective Response Rates (per BICR)



Objective Response Rate (per BICR)

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

Overall Survival



Overall Survival†

UV1 plus IPI-NIVO improved overall survival (OS), reducing the risk of death by 27% (HR=0.73 [80% CI, 0.53-1.00], 1-sided p value = 0.0985), with a median OS of 15.4 months (95% CI, 11.1-22.6) versus 11.1 months (95% CI, 8.8-18.1) for IPI-NIVO alone.

No Additional Toxicity with UV1 plus NIVO-IPI

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

- Patients with serious adverse events: 36 (61.0%) vs 35 (59.3%)

Conclusion

- Meaningful prolonged survival warrants further investigations with combined ipi-nivo and UV1 vaccine in patients with malignant pleural mesothelioma

- Q&A

Comments from Ultimovacs Management

- The future of UV1 in mesothelioma
- Next steps for Ultimovacs
- Q&A



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