Society for Immunotherapy of Cancer

Advances in Cancer Immunotherapy™ Webinar: Clinical Updates From ASCO20 Virtual

September 10, 2020

5:00-6:00 p.m. ET

Webinar Agenda

5:00-5:05 p.m. ET Overview: Welcome and Introductions

5:05-5:40 p.m. ET Presentation

5:40-5:55 p.m. ET Question and Answer Session

5:55-6:00 p.m. ET Closing Remarks

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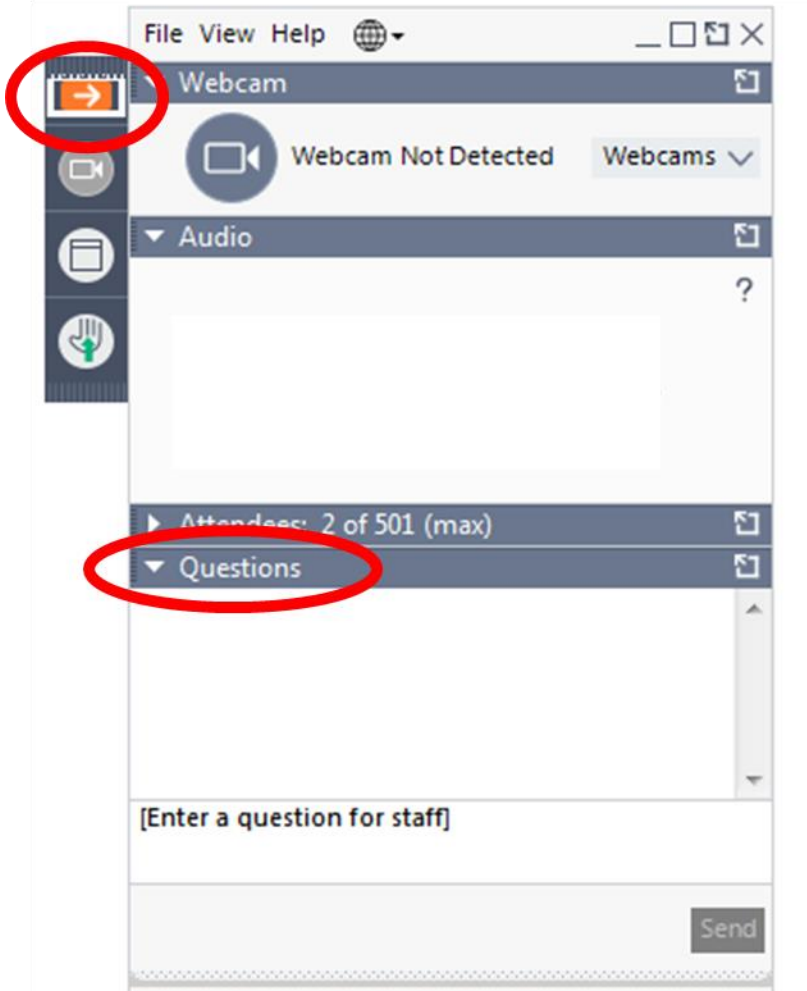
How to Submit Questions

Computer



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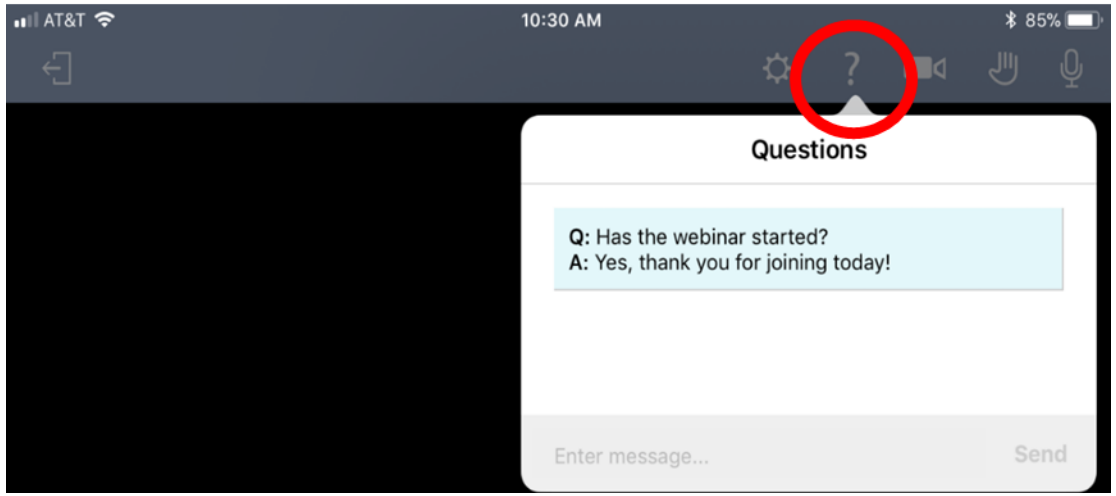
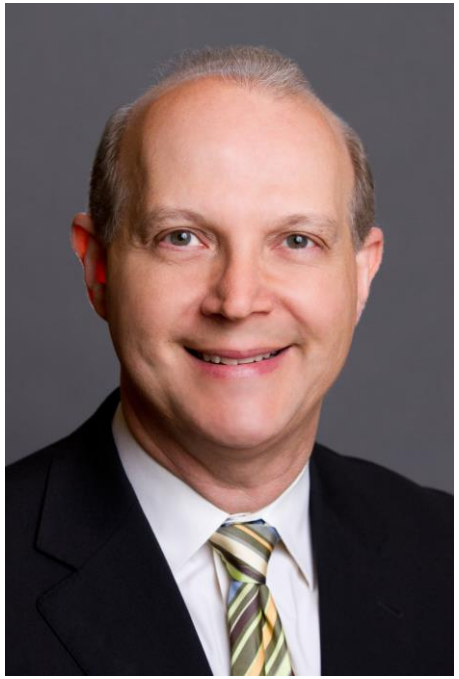


Webinar Faculty

Michael Atkins, MD –
Georgetown-Lombardi Comprehensive Cancer Center

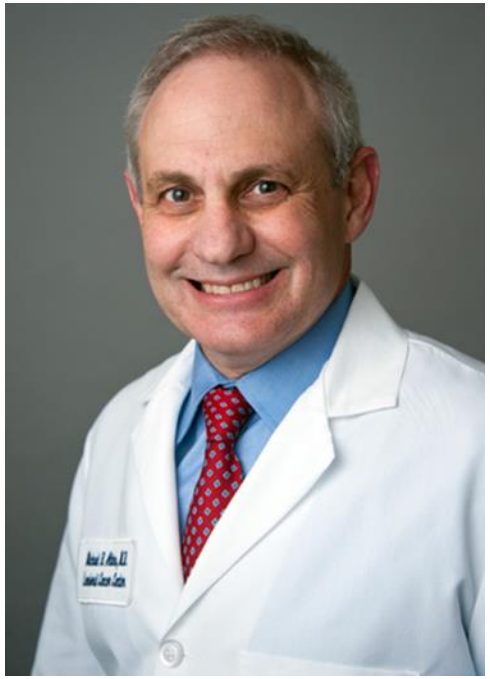
Shailender Bhatia, MD –
University of Washington

Stephan Grupp, MD, PhD –
University of Pennsylvania



Jose Lutzky, MD, FACP –
University of Miami, Sylvester Cancer Center

Michael Atkins, MD



- Deputy Director of Georgetown-Lombardi Comprehensive Cancer Center
- Scholl Professor and Vice Chair Department of Oncology and Medicine (Hematology/Oncology) at Georgetown University School of Medicine
- Research interests: Cancer immunotherapy, treatment of melanoma and renal cell carcinoma, predictive markers for response to biologic therapy, and antiangiogenic and targeted therapies

Learning objectives

Upon completion of this webinar, participants will be able to:

- Describe the latest advancements in combination and monotherapy treatments using immune checkpoint inhibitors for various cancers.
- Outline novel cell-based therapies under clinical investigation.
- Summarize current efforts for optimizing immunotherapy dosing and regimens.

Outline

- Renal cell carcinoma
- Melanoma
  - First-line treatments
  - Treatments after PD-1 failure
- Cellular therapies

Renal cell carcinoma

Dr. Atkins

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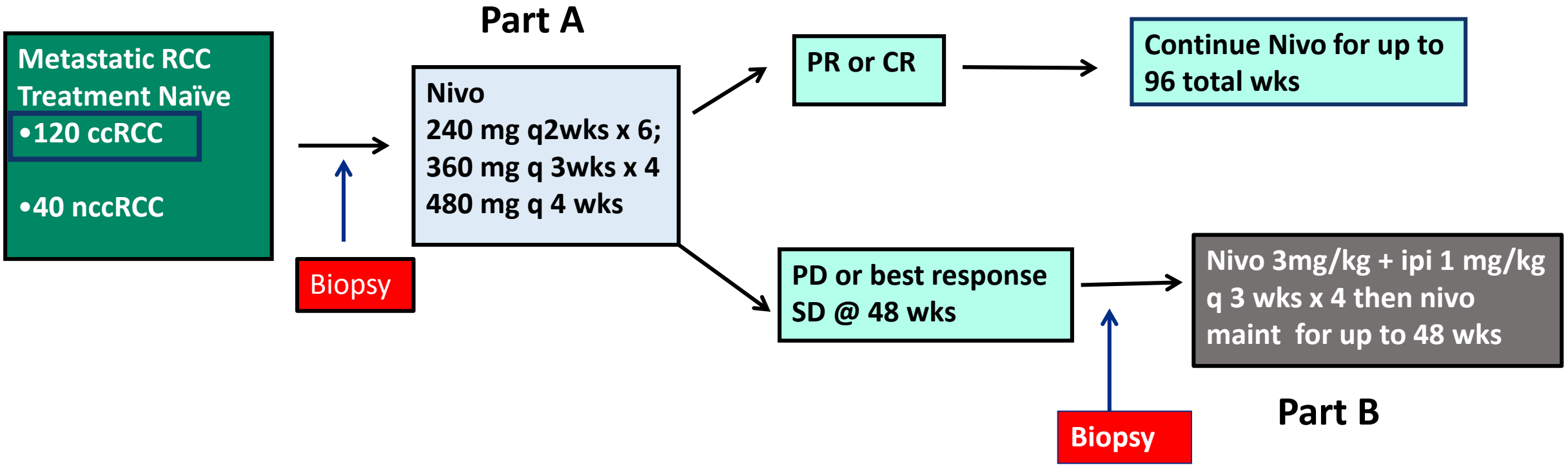
Phase II Study of Nivolumab and Salvage Nivolumab + Ipilimumab in Treatment-Naïve Patients with Advanced Renal Cell Carcinoma (HCRN GU16-260)

Michael B. Atkins[1], Opeyemi A. Jegede[2], Naomi B. Haas[3], David F. McDermott[4], Mehmet A. Bilen[5], Charles G. Drake[6], Jeffrey A. Sosman[7], Robert Alter[8], Elizabeth R. Plimack[9], Brian Rini[10], Michael Hurwitz[11], David Peace[12], Sabina Signoretti[13], Catherine J. Wu[2], Paul J. Catalano[2], Hans Hammers[14]

Study design



Extensive Biomarker studies in collaboration with the DFHCC
Kidney Cancer SPORE
DOD Translational Partnership Grant (Atkins, Wu)

Scans q12 weeks; Confirm response and PD;
Measurements by RECIST 1.1
Mandatory biopsies

Atkins, ASCO 2020.

Results – Nivo monotherapy: Part A

Best Response N (%)	IMDC Risk Category (N)			Total (N = 123) N (%)
	Favor (30) N (%)	Interm (80) N (%)	Poor (12) N (%)	
CR	4 (13.3)	3 (3.8)	0	7 (5.7)
PR*	11 (36.7)	17 (21.2)	3 (25)	32 (26.0)
SD	15 (50.0)	26 (32.5)	5 (42)	46 (37.4)
PD	0	34 (42.5)	4 (33)	38 (30.9)
ORR	15/30 (50)	20/80 (25)	3/12 (25)	39/123 (31.7)
(95% CI) %	(31.3,68.7)	(16.6, 35.1)		(23.6, 40.7)

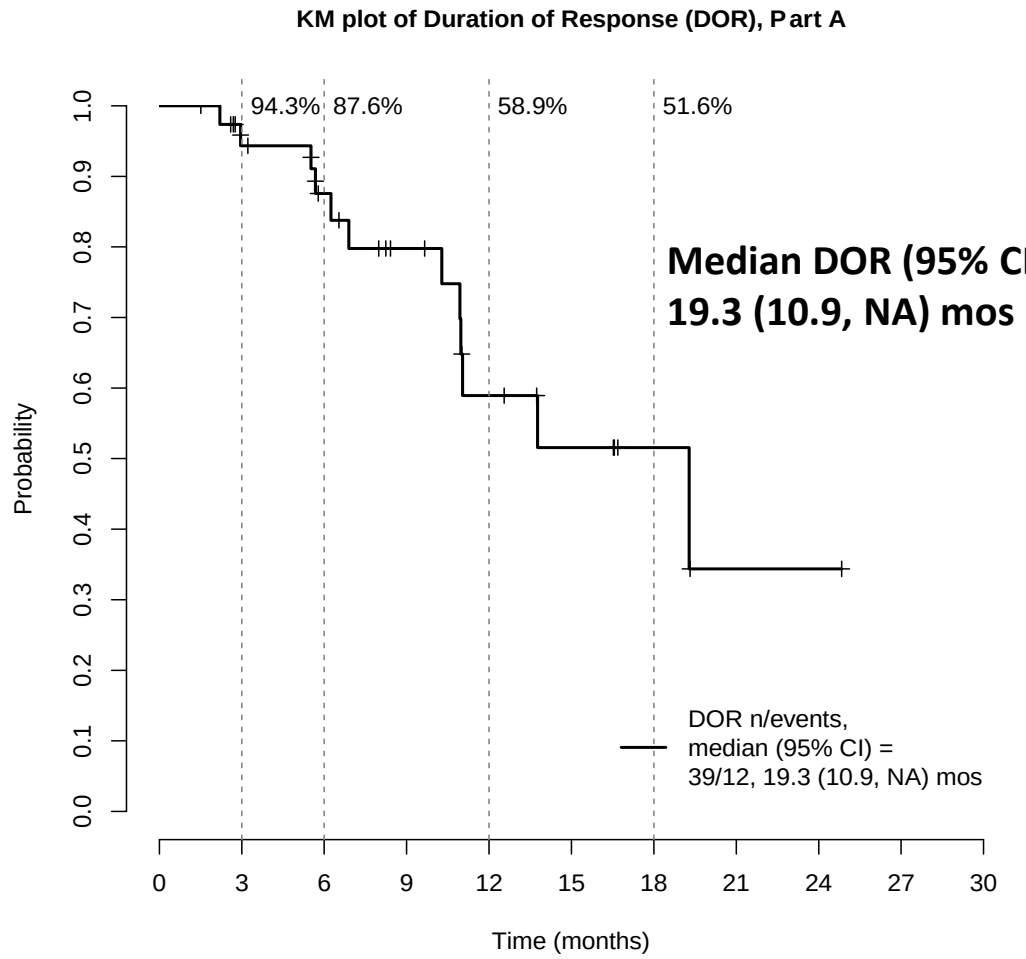
ORR: 39/123 = 31.7%
95% CI (23.6, 40.7%)

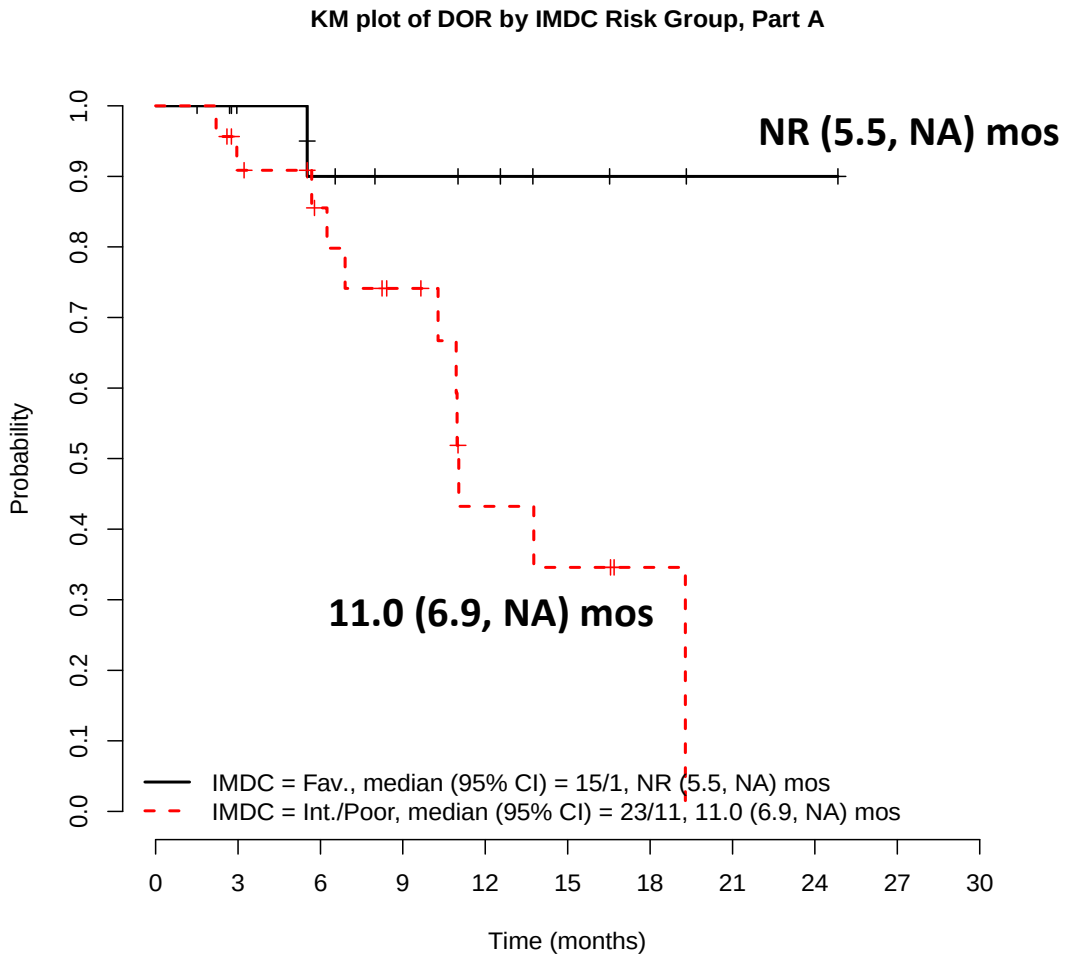
Sarcomatoid RCC ORR:
7/22 = 31.8% (all PRs)
95% CI (13.9, 54.9%)

*** 1 PR with missing IMDC Risk Category**

Atkins, ASCO 2020.

Results – Nivo monotherapy: Part A





Atkins, ASCO 2020.

Results – Nivo/Ipi salvage: Part B

Best Response N (%)	IMDC Risk Category (N=30)			Total N (%)
	Favor (4)	Interm (24)	Poor (2)	
CR	0	0	0	0
PR	2 (50)	2 (8.3)	0	4 (13.3)
SD	1 (25)	6 (25)	0	7 (23.3)
PD	1 (25)	16 (66.7)	2 (100)	19 (63.3)

ORR: 4/30 = 13.3%
95% CI (3.8, 30.7)

Atkins, ASCO 2020.

Conclusions

- Nivo monotherapy represents an alternative frontline approach
  - Particularly for the ipilimumab or VEGFR TKI averse
  - Possibly for those with IMDC favorable risk or maybe in the adjuvant setting.

- Nivo/Ipi likely preferred over nivo monotherapy
  - Particularly for Intermediate/Poor Risk patients and those with sarcomatoid RCC
  - Higher RR, longer PFS, longer DOR, more CRs

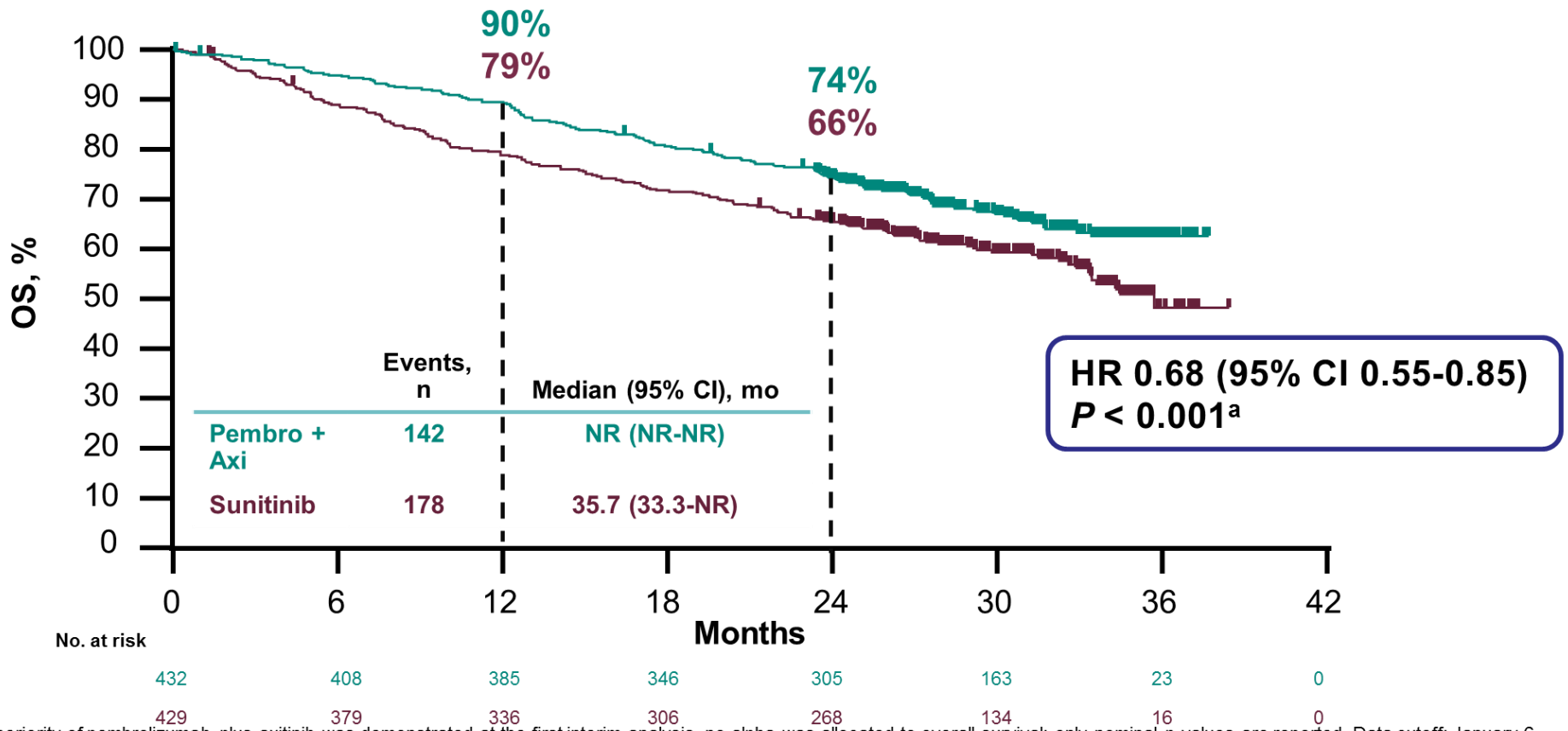
- BMS CM 209-8Y8 study will address this issue directly for IMDC intermediate and poor risk patients (Albiges, Atkins Co-PIs)

- Biologic predictors of response needed (studies ongoing)

Pembrolizumab Plus Axitinib Versus Sunitinib As First-Line Therapy For Advanced Renal Cell Carcinoma: Updated Analysis Of KEYNOTE-426

Elizabeth R. Plimack[1]; Brian I. Rini[2]; Viktor Stus[3]; Rustem Gafanov[4]; Tom Waddell[5]; Dmitry Nosov[6]; Frédéric Pouliot[7]; Denis Soulières[8]; Bohuslav Melichar[9]; Ihor Vynnychenko[10]; Sergio J. Azevedo[11]; Delphine Borchiellini[12]; Raymond S. McDermott[13]; Jens Bedke[14]; Satoshi Tamada[15]; Lina Yin[16]; Mei Chen[16]; L. Rhoda Molife[17]; Michael B. Atkins[18]; Thomas Powles[19]

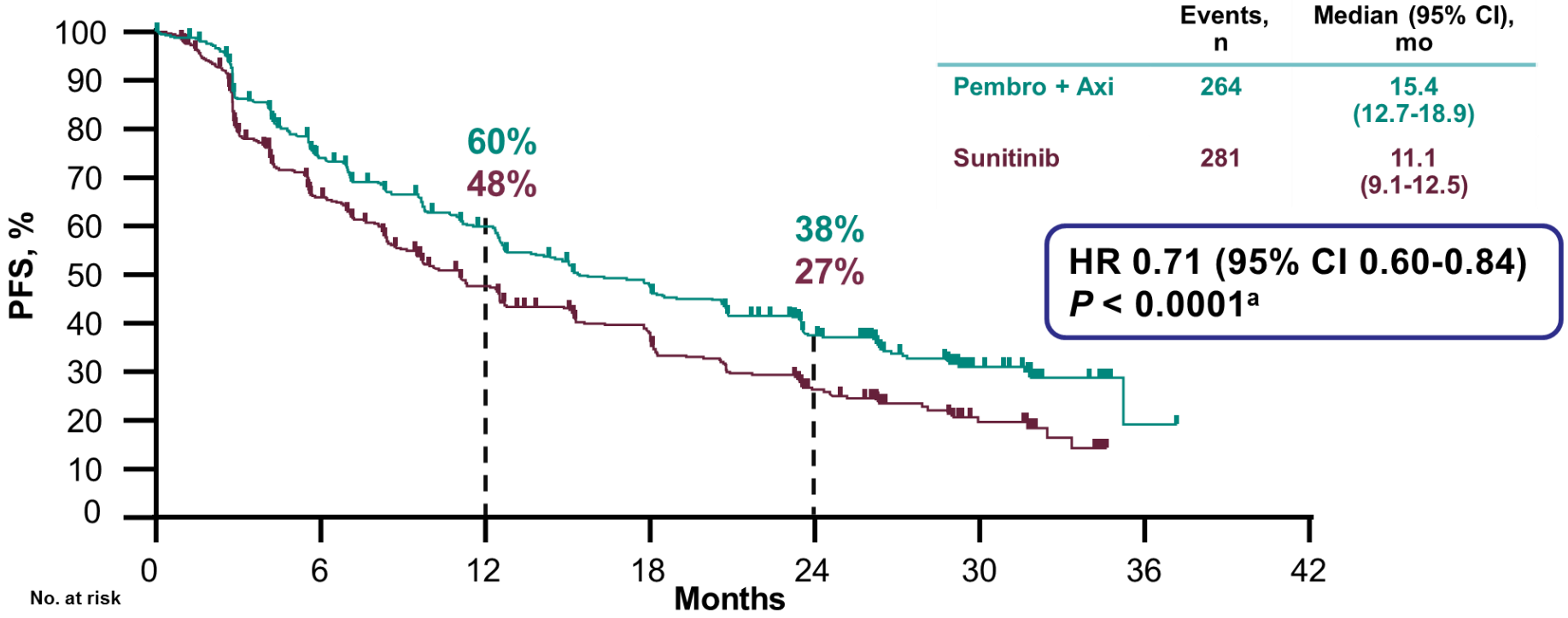
Results – OS in ITT population



[a]As superiority of pembrolizumab plus axitinib was demonstrated at the first interim analysis, no alpha was allocated to overall survival; only nominal p-values are reported. Data cutoff: January 6, 2020.

Plimack, ASCO 2020.

Results – PFS in ITT population



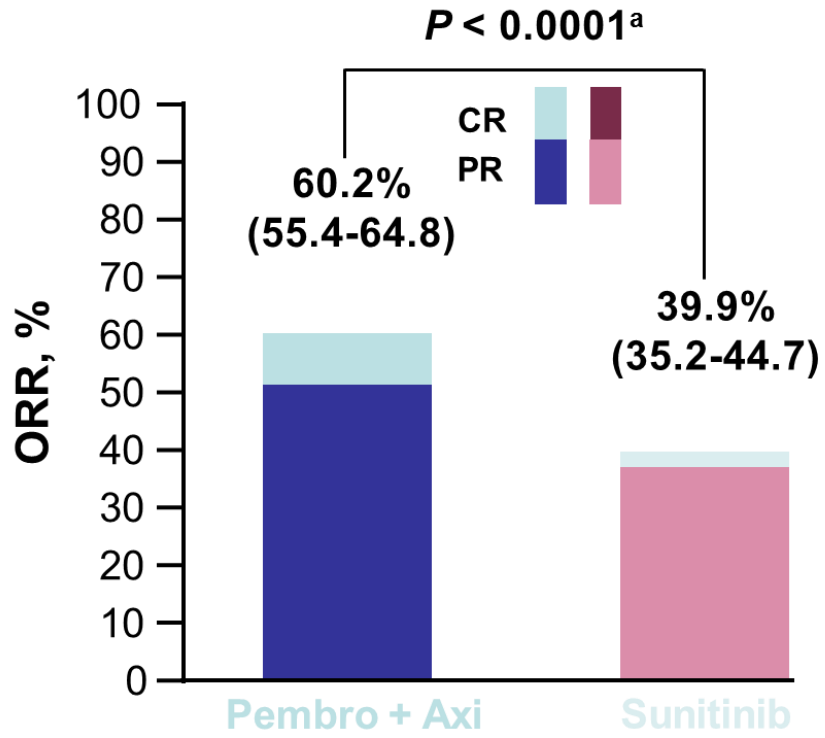
	Events, n	Median (95% CI), mo
Pembro + Axi	264	15.4 (12.7-18.9)
Sunitinib	281	11.1 (9.1-12.5)

HR 0.71 (95% CI 0.60-0.84)
***P* < 0.0001[a]**

[a]As superiority of pembrolizumab plus axitinib was demonstrated at the first interim analysis, no alpha was allocated to PFS; only nominal p-values are reported. Data cutoff: January 6, 2020.

Plimack, ASCO 2020.

Results – ORR in ITT population

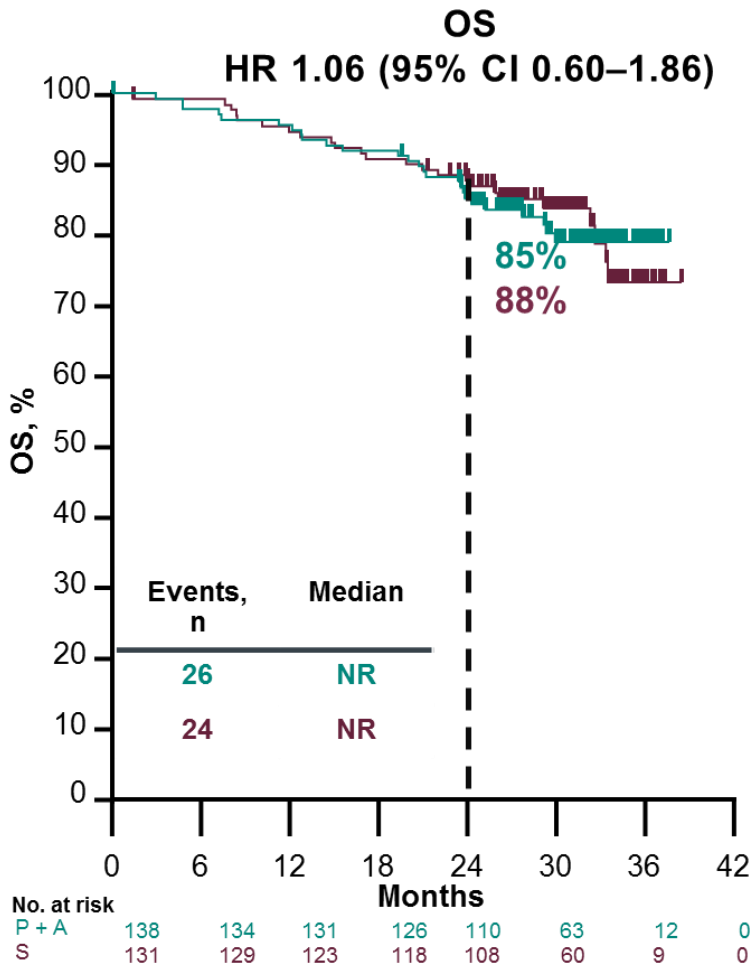


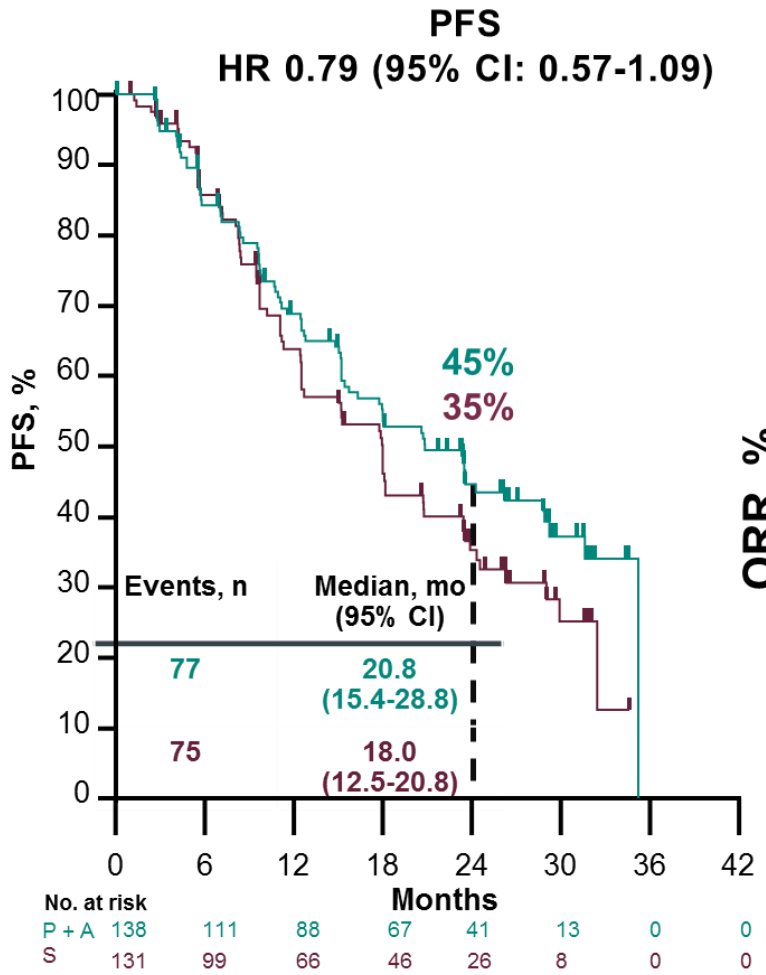
	Pembro + Axi n = 432	Sunitinib n = 429
Best Response, n (%)		
CR	38 (8.8)	13 (3.0)
PR	222 (51.4)	158 (36.8)
SD	100 (23.1)	150 (35.0)
PD	49 (11.3)	74 (17.2)
NE[b]	16 (3.7)	28 (6.5)
NA[c]	7 (1.6)	6 (1.4)
Median (range) duration of response, mo	23.5 (1.4+ to 34.5+)	15.9 (2.3 to 31.8+)

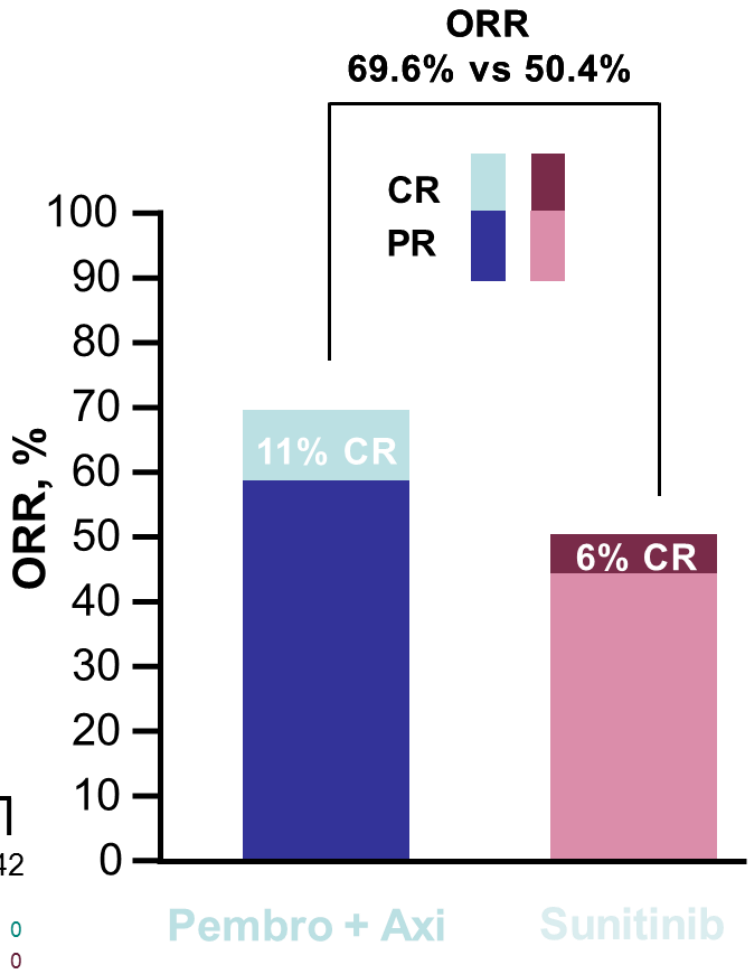
[a]As superiority of pembrolizumab plus axitinib was demonstrated at the first interim analysis, no alpha was allocated to confirmed objective response; only nominal p-values are reported. [b]Post-baseline assessment(s) available however not being evaluable (i.e., all post-baseline assessment(s) with insufficient data for assessment of response per RECIST 1.1. or CR/PR/SD <6 weeks from randomization). [c]No post-baseline assessment available for response evaluation; + indicates an ongoing response at time of last disease assessment. Data cutoff: January 6, 2020.

Plimack, ASCO 2020.

Results – Favorable risk patients



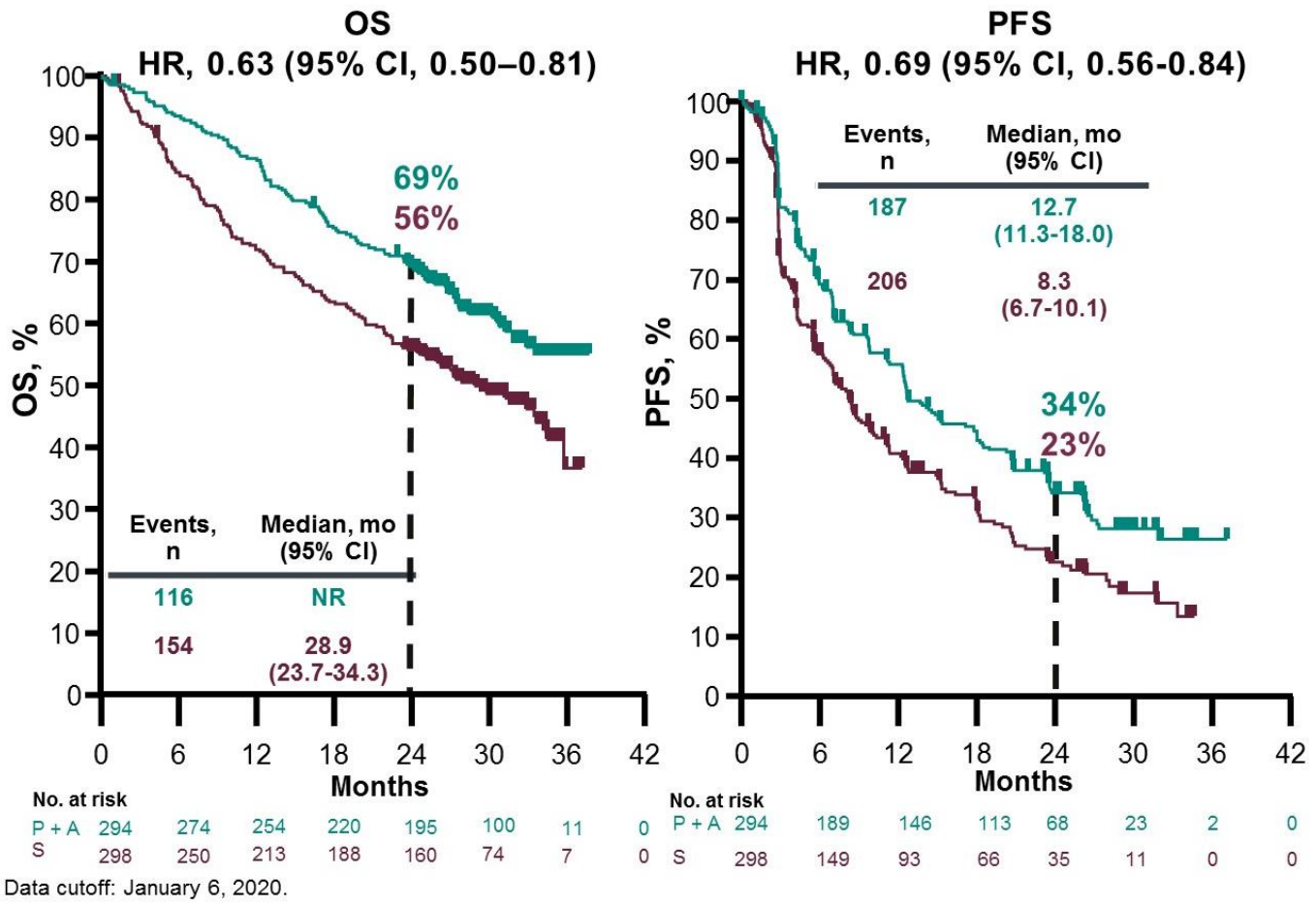


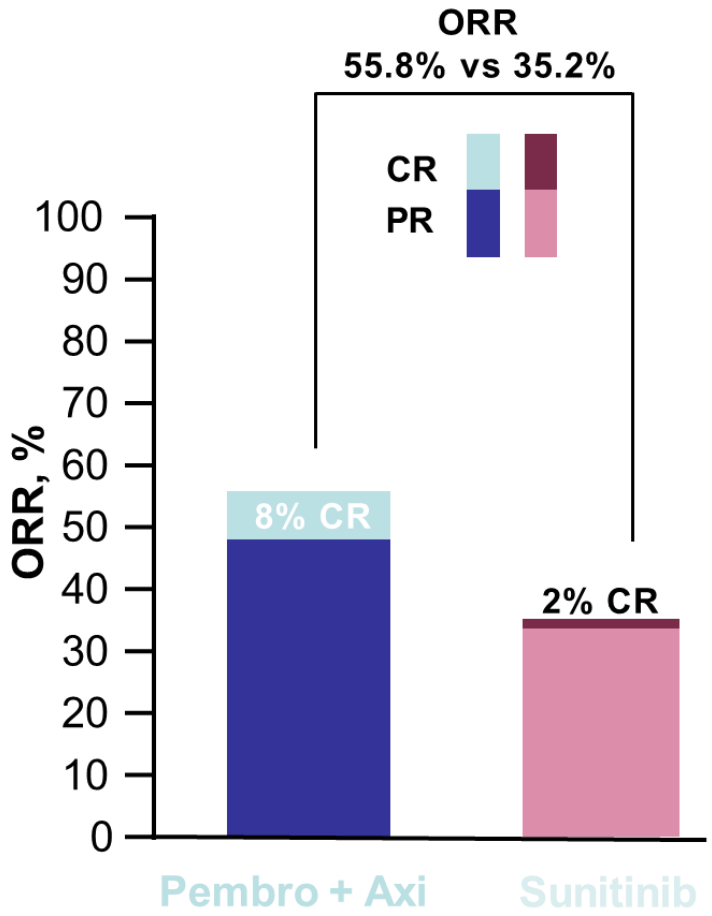


Data cutoff: January 6, 2020.

Plimack, ASCO 2020.

Results – intermediate/poor risk patients





Plimack, ASCO 2020.

Phase III TKI/IO-based combinations in RCC

Control	Comparator(s)	PFS (HR)	OS (HR)
Sunitinib	Axitinib + Pembrolizumab* 7 mos	Yes (0.69)	Yes (0.53)
	Axitinib + Pembrolizumab* 23 mos	Yes (0.71)	Yes (0.68)
Sunitinib	Bevacizumab + Atezolizumab	Yes (0.88)	TE (0.93)*
Sunitinib	Axitinib + Avelumab	Yes (0.69)	TE (0.78)
Sunitinib	Cabozantinib/Nivolumab 17 mos	Yes (0.51)	Yes (0.60)
Sunitinib	(Lenvatinib + Eve) *vs* Len/Pembro	TE	TE

Lenvatinib + pembrolizumab phase II

Parameter	Anti-PD-1/ PD-L1[b] (N = 104)	Anti-PD-1/PD-L1 and Anti-VEGF[c] (n = 68)	Nivolumab + Ipilimumab (n = 38)
ORR, % (95% CI)	55 (45–65)	59 (46–71)	47 (31–64)
Best objective response, %			
Partial response	55	59	47
Stable disease	36	31	42
Progressive disease	5	6	8
Not evaluable	5	4	3
Median duration of response, months (95% CI)	12 (9–18)	9 (7–17)	NR (7–NR)

Lee, ASCO 2020.

First-line therapy for RCC

- IO based doublets represent current SOC
  - No clear role for IMDC classification
  - VEGFR TKIs only indicated in patients who can't get IO
  - PD-L1 expression too inexact to select pts
- Nivo + ipi represents a current SOC for treatment naïve patients with intermediate and poor risk advanced RCC
  - Exclusion of good risk patients doesn't take into consideration IO endpoints durable response (TFS) possible in 30-35% of patients
- Anti-PD1 monotherapy may play a role in TKI/Ipi averse pts, particularly those with favorable risk

First-line therapy for RCC

- Anti-PD1/PD-L1 + anti-VEGF represents an alternative SOC
- Efficacy may relate to efficacy of TKI component/study design

  (bevacizumab < axitinib < cabozantinib < lenvatinib)/(early OS HR > late)
  - Axi/Pembro produces best OS HR (could be early reporting)
  - Cabo/Nivo results encouraging for stage of reporting
  - Len/Pembro promising 2nd line data; 1st line pending

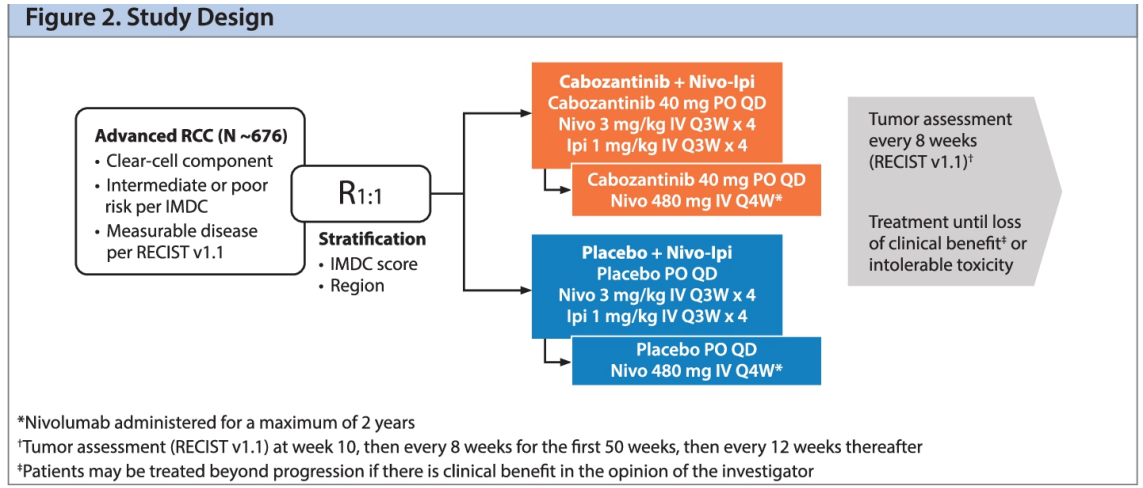
On the other hand

- Unclear if activity is synergistic or merely additive
- Expense and likely toxicity exceed sequential treatments
- Ability to produce durable TFS yet to be established

Future directions for RCC

- Ipi/Nivo vs. VEGF/PD-1 blockade?
  - Need longer followup and appropriate phase III trials with IO endpoints, standardized biomarkers, and universally available crossover to be able to make rational treatment decisions
  - Need biomarker studies to help us sort out who should get which therapy, rather than focusing on clinical variables
    - Biomarkers should be tied to IO endpoints

Cosmic-313



Shailender Bhatia, MD

- Associate Professor, Department of Medicine, Division of Medical Oncology
  University of Washington and Fred Hutchinson Cancer Research Center
- Attending Physician – Seattle Cancer Care Alliance
- Specialty: Skin Cancers (Melanoma, Merkel Cell Carcinoma), Immunotherapy, Intra-tumoral therapy, Targeted therapy

Melanoma studies - Front-line treatments

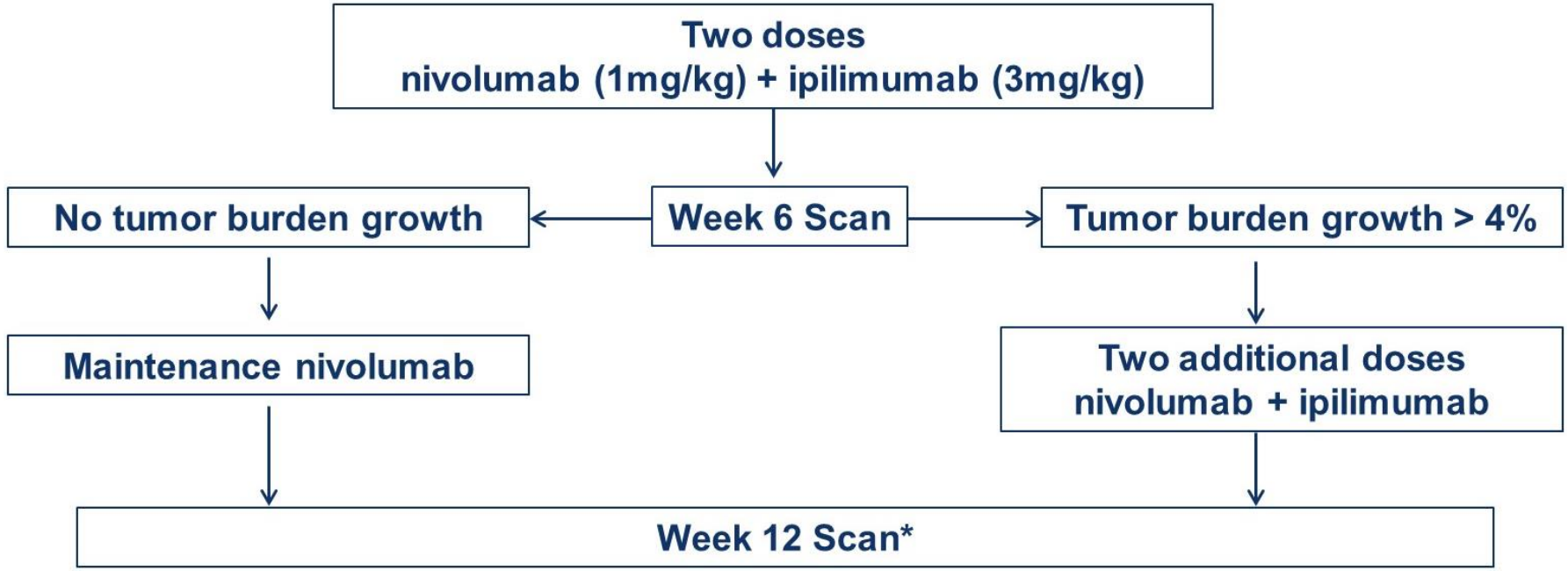
Dr. Bhatia

Study # 1

A phase II study to evaluate the need for >2 doses of nivolumab + ipilimumab combination immunotherapy in patients with unresectable stage III/IV melanoma

Michael A. Postow, *et al.*

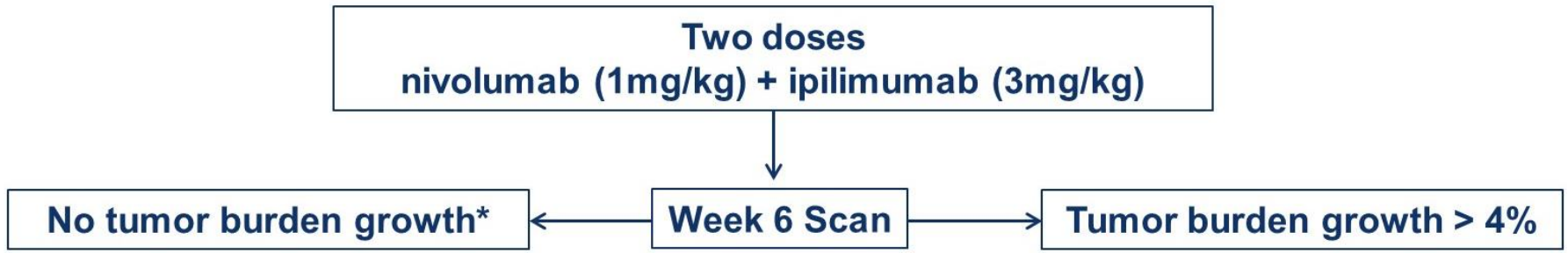
Study design



*If additional tumor growth was present, additional nivo + ipi was permitted

Postow, ASCO 2020.

Results



68%
(41/60)

*7 patients only had 1 total dose of nivo + ipi

32%
(19/60)

Among the 19, no patients had subsequent RECIST response**

**12/19 patients received ≥3 total doses of nivo + ipi

Postow, ASCO 2020.

Results

Response Rates (RECIST 1.1)

	Week 6 N (%; 95%CI)	Week 12* N (%; 95%CI)	BORR N (%; 95%CI)
Overall Response	21 (35%; 23-48)	29 (48%; 35-62)	34 (57%; 43-69)
CR	0 (0)	3 (5)	11 (18)
PR	21 (35)	26 (43)	23 (38)
SD	26 (43)	11 (18)	13 (22)
PD	13 (22)	18 (30)	13 (22)

*Two patients with unknown Week 12 responses were included in denominator

- **57% had grade 3-4 treatment-related adverse events**
- 3 patients died from treatment-related toxicity
  - Adrenal insufficiency & upper extremity DVT (3 doses)
  - Myocarditis (1 dose)

Postow, ASCO 2020.

My conclusions on Postow *et al* study

- An **early restaging scan at 6 weeks** is (somewhat) predictive of the final outcome.
- If major regression is seen at 6 weeks, an **early switch to maintenance therapy** is not entirely unreasonable (could potentially avoid IRAEs and hence, use of immunosuppression).
- If clear progression is seen at 6 weeks (especially PD that threatens clinical safety), this data may support **proactive switching to another approach** (such as BRAF-MEKi in BRAF mutant melanoma).
- Small N limits **generalizability** of results at this time.
- Another option to optimize Ipi-Nivo combination is reduced dose of Ipi (1 mg/kg)

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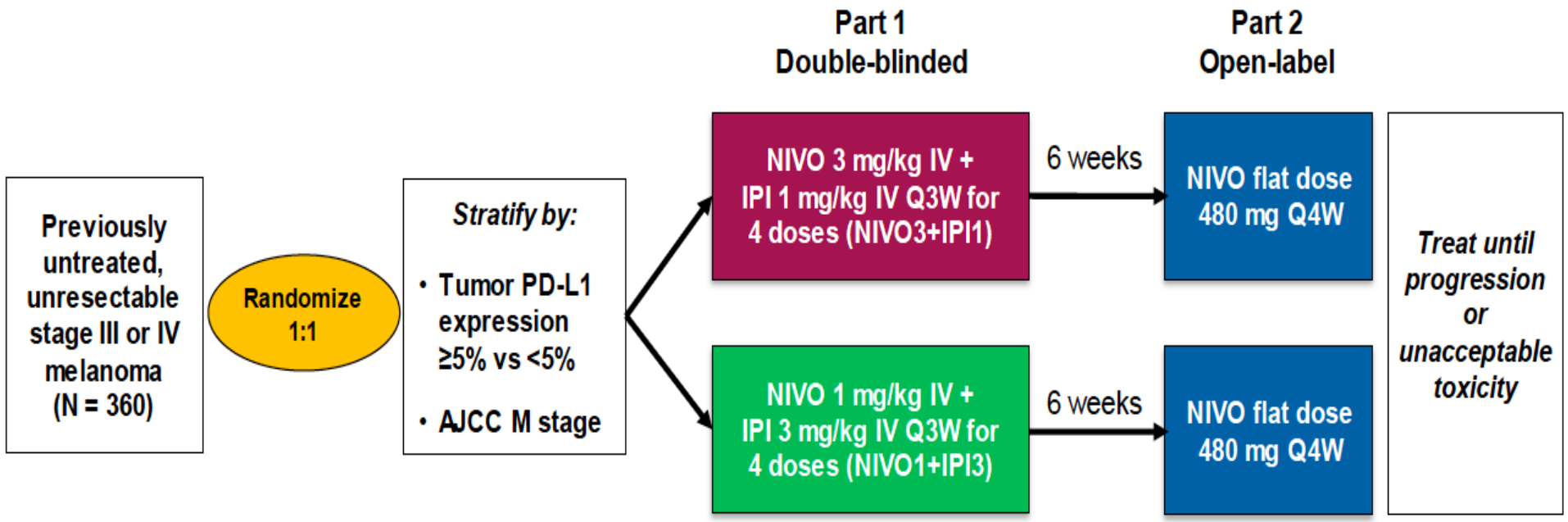
Evaluation of Two Dosing Regimens for Nivolumab in Combination With Ipilimumab in Patients With Advanced Melanoma: Results From the Phase IIIb/IV CheckMate 511 Trial

Celeste Lebbé, MD, PhD[1]; Nicolas Meyer, MD, PhD[2]; Laurent Mortier, MD, PhD[3]; Ivan Marquez-Rodas, MD, PhD[4]; Caroline Robert, MD, PhD[5]; Piotr Rutkowski, MD, PhD[6]; Alexander M. Menzies, MBBS, PhD[7], Thomas Eigentler, MD[8]; Paolo A. Ascierto, MD[9]; Michael Smylie, MD[10]; Dirk Schadendorf, MD[11,12]; Mazhar Ajaz, PhD, MRCP[13]; Inge Marie Svane, MD, PhD[14]; Rene Gonzalez, MD[15]; Linda Rollin, PhD[16]; Jennifer Lord-Bessen, PhD[16]; Abdel Saci, PhD[16]; Elena Grigoryeva, MD, PhD[16]; and Jacopo Pigozzo, MD[17]

Figure 1. CheckMate 511 study design



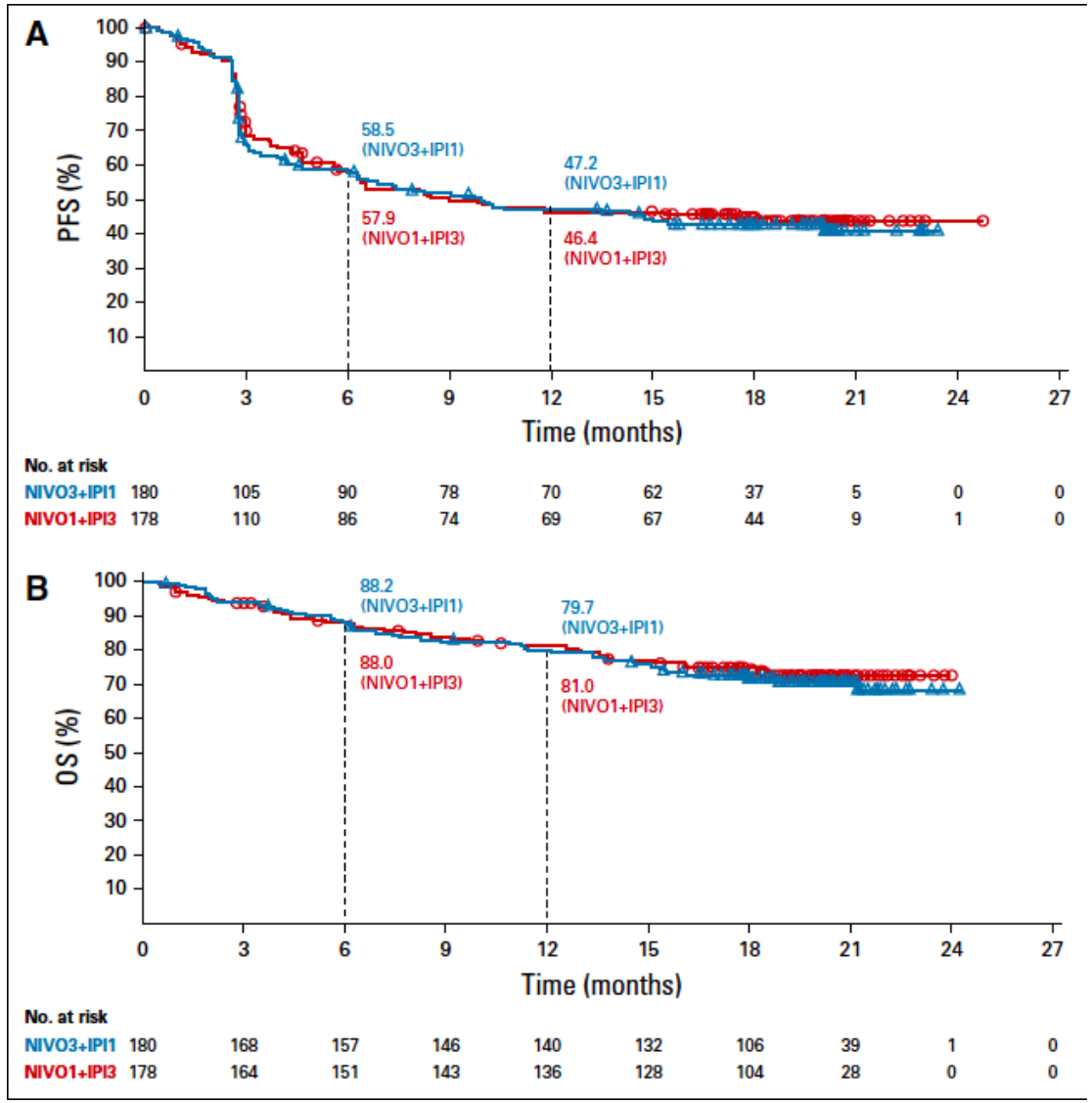

A
PFS (%)
100
90
80
70
60
50
40
30
20
10
0
3
6
9
12
15
18
21
24
27
Time (months)
58.5
(NIVO3+IPI1)
57.9
(NIVO1+IPI3)
47.2
(NIVO3+IPI1)
46.4
(NIVO1+IPI3)
No. at risk
NIVO3+IPI1 180 105 90 78 70 62 37 5 0 0
NIVO1+IPI3 178 110 86 74 69 67 44 9 1 0
B
OS (%)
Time (months)
88.2
(NIVO3+IPI1)
88.0
(NIVO1+IPI3)
79.7
(NIVO3+IPI1)
81.0
(NIVO1+IPI3)
No. at risk
NIVO3+IPI1 180 168 157 146 140 132 106 39 1 0
NIVO1+IPI3 178 164 151 143 136 128 104 28 0 0

Table 2. Safety summary[a]

	NIVO3+IPI1 (n = 180)	NIVO1+IPI3 (n = 178)
Rate of treatment-related grade 3-5 AEs, % (n/N) (95% CI)	**33.9%** (61/180) (27.0–41.3)	**48.3%** (86/178) (40.8–55.9)
Difference between treatment-related grade 3-5 AE rates (95% CI)	**-14.4%** (-24.5 to -4.3)	
***P* value**	**0.0059**	
Treatment-related AEs, %	85.6	93.8
Grade 3–4	33.3	48.3
Grade 5	0.6	0
All cause serious AEs, %	47.8	63.5
Grade 3–4	33.9	47.8
Grade 5	3.3	1.7
Treatment-related AEs leading to discontinuation, %	23.9	33.1
Grade 3–4	16.7	27.5
Grade 5	0.6	0

[a]Includes events reported between the first dose and 30 days after the last dose of study therapy

Study # 2

Atezolizumab, vemurafenib, and cobimetinib as first-line treatment for unresectable advanced *BRAF*^{V600} mutation-positive melanoma (IMspire150): primary analysis of the randomised, double-blind, placebo-controlled, phase 3 trial

Ralf Gutzmer, Daniil Stroyakovskiy, Helen Gogas, Caroline Robert, Karl Lewis, Svetlana Protsenko, Rodrigo P Pereira, Thomas Eigentler, Piotr Rutkowski, Lev Demidov, Georgy Moiseevich Manikhas, Yibing Yan, Kuan-Chieh Huang, Anne Uyei, Virginia McNally, Grant A McArthur, Paolo A Ascierto**

Lancet 2020; 395: 1835–44

Grant A. McArthur, *et al.,* AACR 2020.

Study design

- Previously untreated, advanced *BRAF*^{V600} mutation–positive melanoma
- ECOG PS 0 to 1
- Measurable disease by RECIST v1.1

Randomized 514 patients

Randomization stratified by:
- Geographic region and
- Centrally tested LDH level (≤ ULN versus > ULN)

R 1:1

	28-day doublet period; cycle 1		Triple combination period; cycle 2 onward
	Days 1–21	Days 22–28	28-day cycle
Arm 1	Vemurafenib 960 mg BID plus Cobimetinib 60 mg QD	Vemurafenib 720 mg BID plus vemurafenib placebo	Atezolizumab 840 mg on days 1 and 15 plus Vemurafenib 720 mg BID plus vemurafenib placebo BID plus Cobimetinib 60 mg QD on days 1–21
Arm 2	Vemurafenib 960 mg BID plus Cobimetinib 60 mg QD	Vemurafenib 960 mg BID	Atezolizumab placebo on days 1 and 15 plus Vemurafenib 960 mg BID plus Cobimetinib 60 mg QD on days 1–21

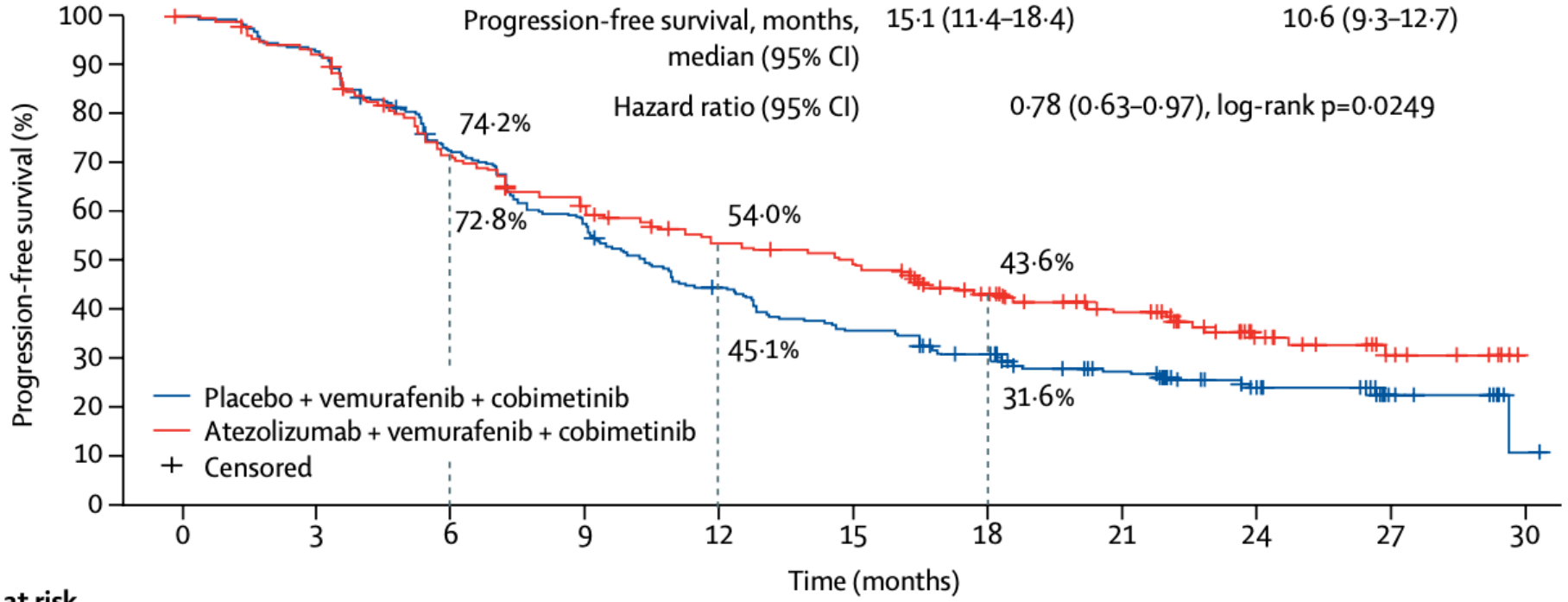
Primary endpoint
- Investigator-assessed PFS

Key secondary endpoints
- PFS assessed by an IRC
- Objective response (confirmed by observations at least 4 weeks apart)
- DOR
- OS

McArthur, AACR 2020.

Results – Investigator-assessed PFS

A



	Atezolizumab + vemurafenib + cobimetinib	Placebo + vemurafenib + cobimetinib
Progression-free survival, months, median (95% CI)	15·1 (11·4–18·4)	10·6 (9·3–12·7)
Hazard ratio (95% CI)	0·78 (0·63–0·97), log-rank p=0·0249	

Number at risk

Placebo + vemurafenib + cobimetinib	258	230	179	143	107	86	71	51	27	11	1
Atezolizumab + vemurafenib + cobimetinib	256	229	174	149	123	114	90	66	34	11	

Gutzmer R *et al*, Lancet 2020.

Results – ORR and Duration of response

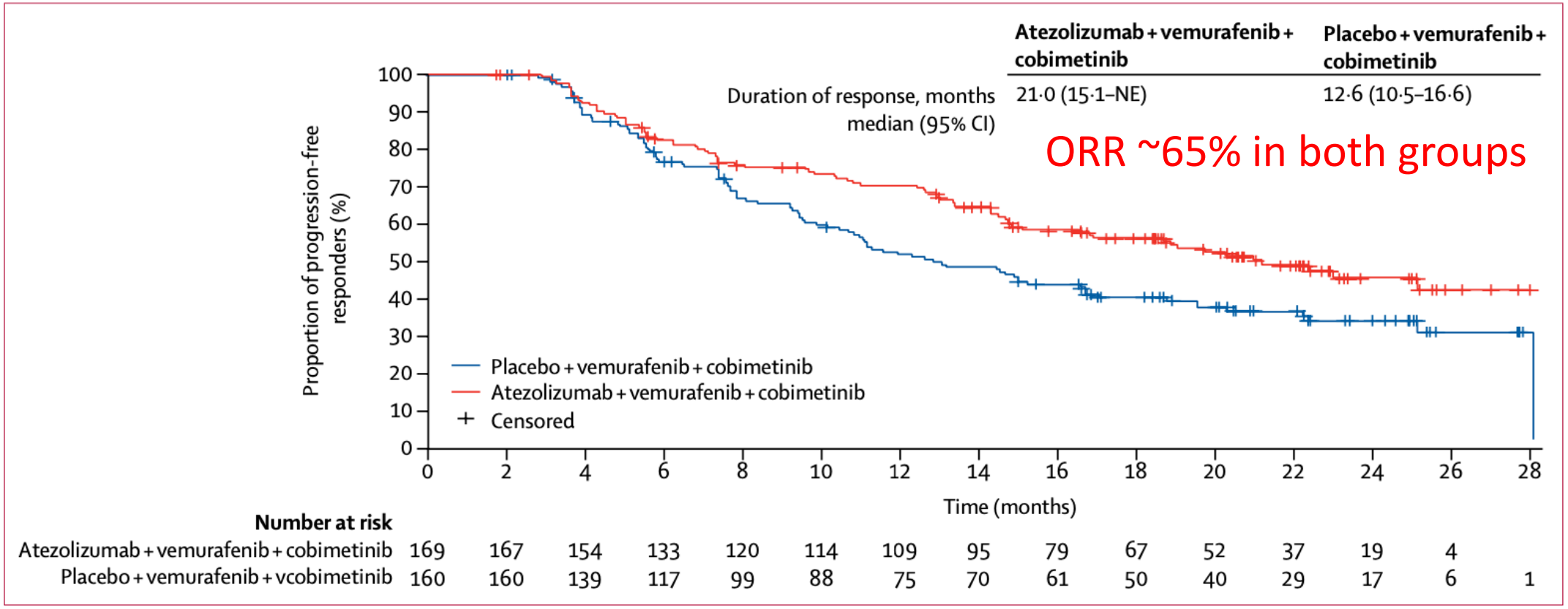
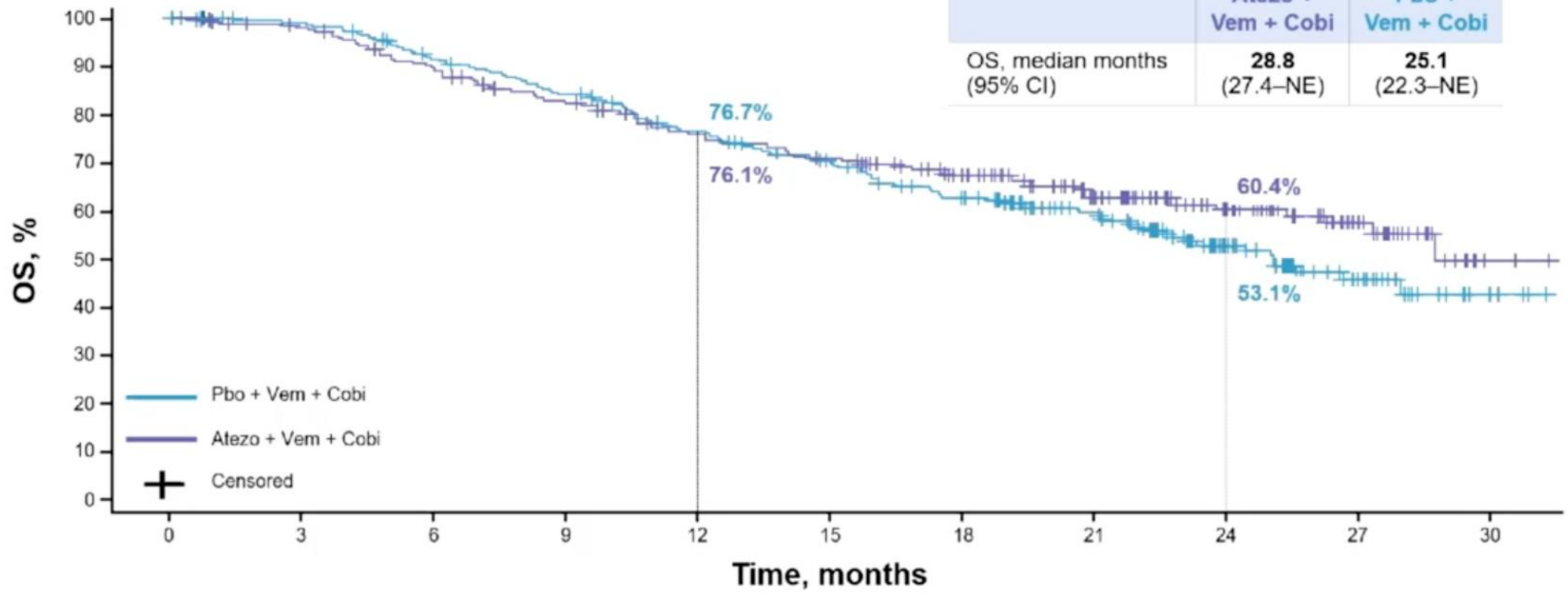


Figure 3: Kaplan-Meier estimate of duration of response in the intention-to-treat population
NE=not estimable.

Gutzmer R *et al*, Lancet 2020.

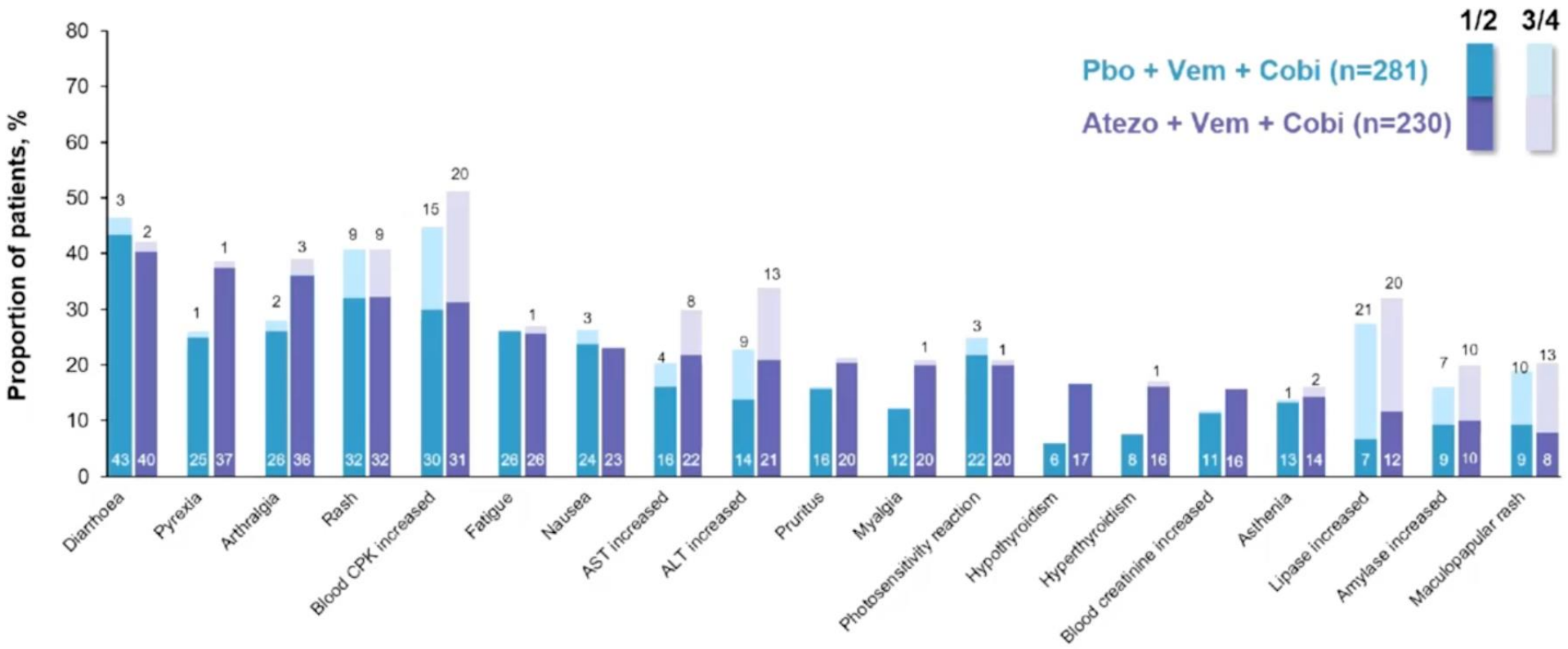
Results – Overall survival

	Atezo + Vem + Cobi	Pbo + Vem + Cobi
OS, median months (95% CI)	**28.8** (27.4–NE)	**25.1** (22.3–NE)



McArthur, AACR 2020.

Adverse events



IRAEs of special interest (requiring steroids) were 63% in A+V+C vs 51% in V+C

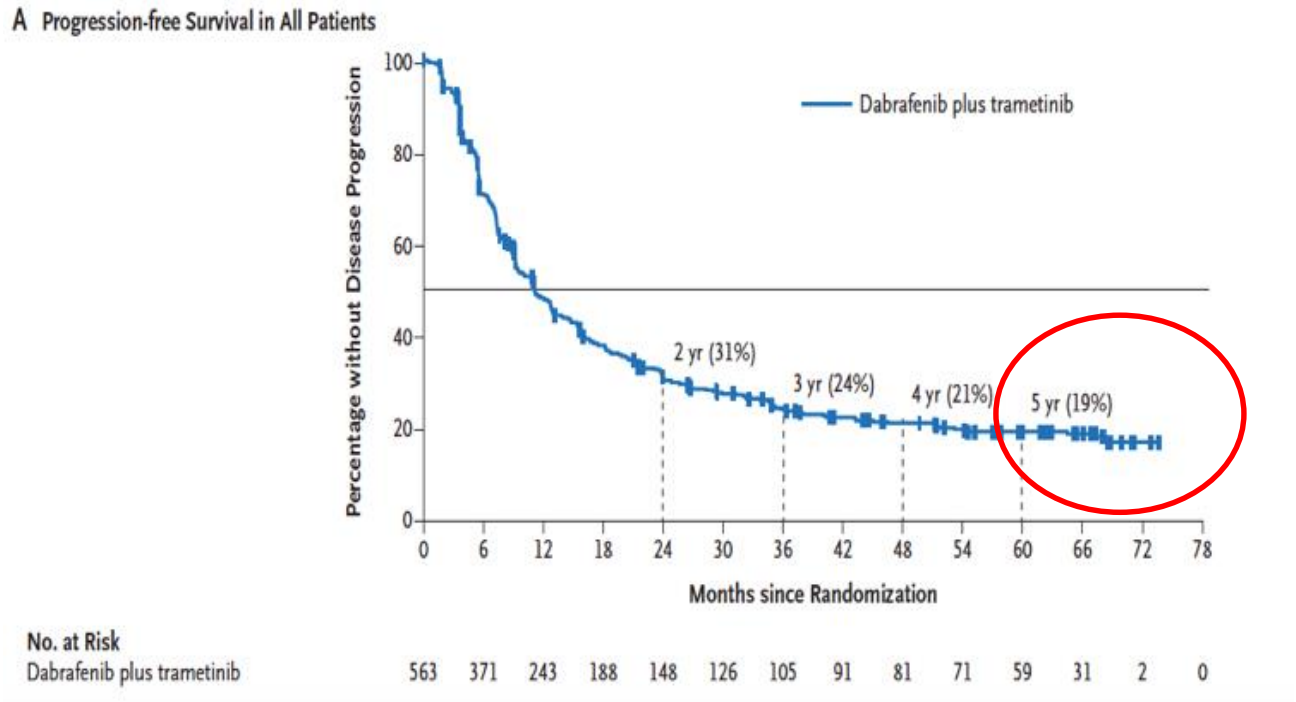
McArthur, AACR 2020. Gutzmer R *et al*, Lancet 2020.

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Five-Year Outcomes with Dabrafenib plus Trametinib in Metastatic Melanoma

C. Robert, J.J. Grob, D. Stroyakovskiy, B. Karaszewska, A. Hauschild, E. Levchenko, V. Chiarion Sileni, J. Schachter, C. Garbe, I. Bondarenko, H. Gogas, M. Mandalá, J.B.A.G. Haanen, C. Lebbé, A. Mackiewicz, P. Rutkowski, P.D. Nathan, A. Ribas, M.A. Davies, K.T. Flaherty, P. Burgess, M. Tan, E. Gasal, M. Voi, D. Schadendorf, and G.V. Long



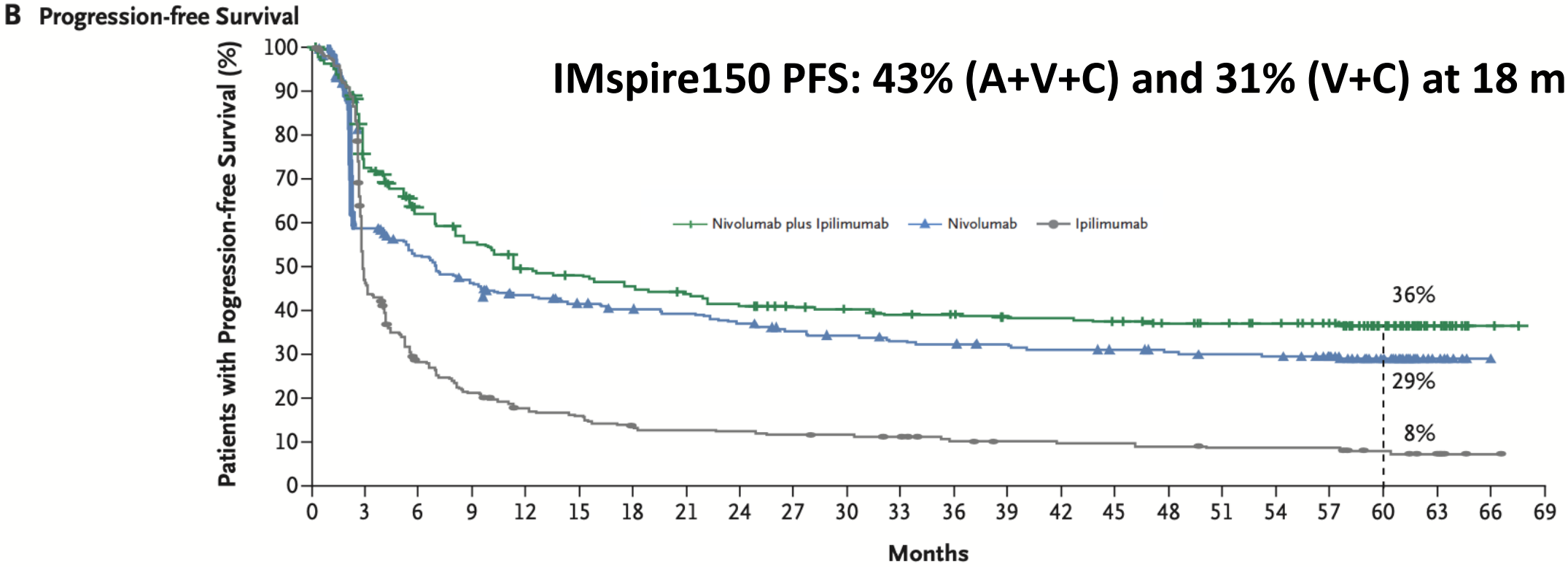
IMspire150: 32% at 18 months

88% (52/59) of patients, who were ongoing on trial and progression-free at 5-years, were **still receiving treatment (Dab or Tram or both).**

Five-Year Survival with Combined Nivolumab and Ipilimumab in Advanced Melanoma

J. Larkin, V. Chiarion-Sileni, R. Gonzalez, J.-J. Grob, P. Rutkowski, C.D. Lao,

IMspire150 PFS: 43% (A+V+C) and 31% (V+C) at 18 months

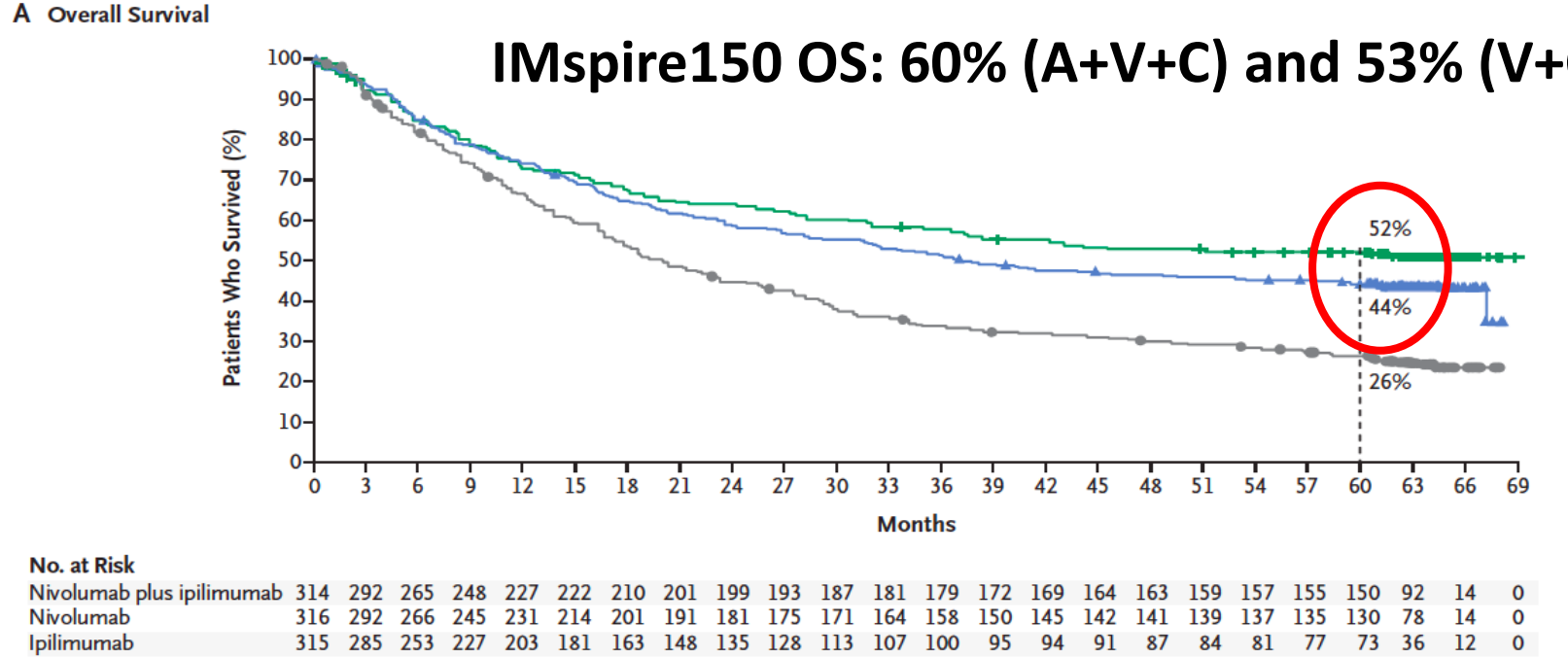


DOI: 10.1056/NEJMoa1910836

Five-Year Survival with Combined Nivolumab and Ipilimumab in Advanced Melanoma

J. Larkin, V. Chiarion-Sileni, R. Gonzalez, J.-J. Grob, P. Rutkowski, C.D. Lao,

IMspire150 OS: 60% (A+V+C) and 53% (V+C) at 24 months



No. at Risk																							
Nivolumab plus ipilimumab	314	292	265	248	227	222	210	201	199	193	187	181	179	172	169	164	163	159	157	155	150	92	14	0
Nivolumab	316	292	266	245	231	214	201	191	181	175	171	164	158	150	145	142	141	139	137	135	130	78	14	0
Ipilimumab	315	285	253	227	203	181	163	148	135	128	113	107	100	95	94	91	87	84	81	77	73	36	12	0

DOI: 10.1056/NEJMoa1910836

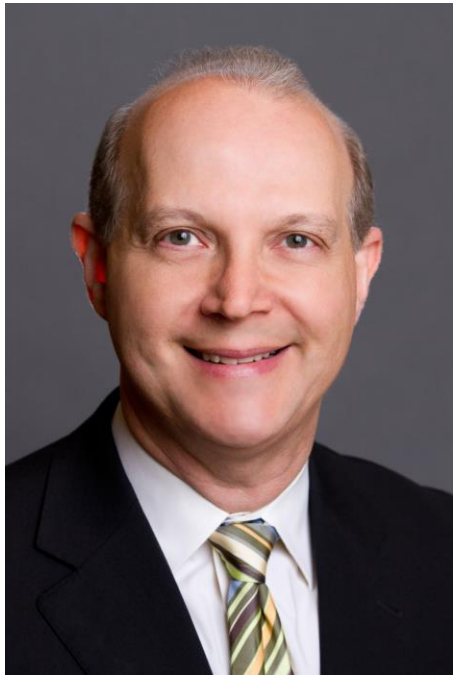
My Conclusions – Front-line melanoma

- Preliminary data from the IMspire 150 suggests significantly improved PFS with addition of atezolizumab to the vemu-cobi combination.
- PFS improvement appears to be clinically meaningful, although OS data will be more definitive towards superiority of the triple combo.
- Toxicity appears manageable (although rate of steroid use was higher than anticipated in both arms reflecting challenges of identifying the culprit medications).
- Lack of PD-1 monotherapy comparator limits widespread clinical application of this triple combination, since many clinicians would favor using immunotherapy (such as Ipi-Nivo) in frontline therapy of metastatic melanoma.
- In my practice, I will likely use this data to support the addition of PD-1/PD-L1 blockade in patients who are going to get BRAF-MEKi anyways.

Spartalizumab combo with Tafinlar + Mekinist fails in Phase III advanced melanoma study

Basel, August 22, 2020 — Novartis announced today that the Phase III COMBI-i study evaluating the investigational immunotherapy spartalizumab (PDR001), in combination with the targeted therapies Tafinlar® (dabrafenib) and Mekinist® (trametinib), did not meet its primary endpoint of investigator-assessed progression-free survival. The trial was conducted among untreated patients with unresectable (Stage IIIC) or metastatic (Stage IV) BRAF V600 mutation-positive cutaneous melanoma, compared to Tafinlar + Mekinist alone[3].

Jose Lutzky, MD, FACP



- Professor(pending), Department of Medicine, University of Miami Sylvester Comprehensive Cancer Center
- Director, Cutaneous Oncology
- Expertise: Melanoma, basal cell carcinoma, squamous cell carcinoma and Merkel cell carcinoma

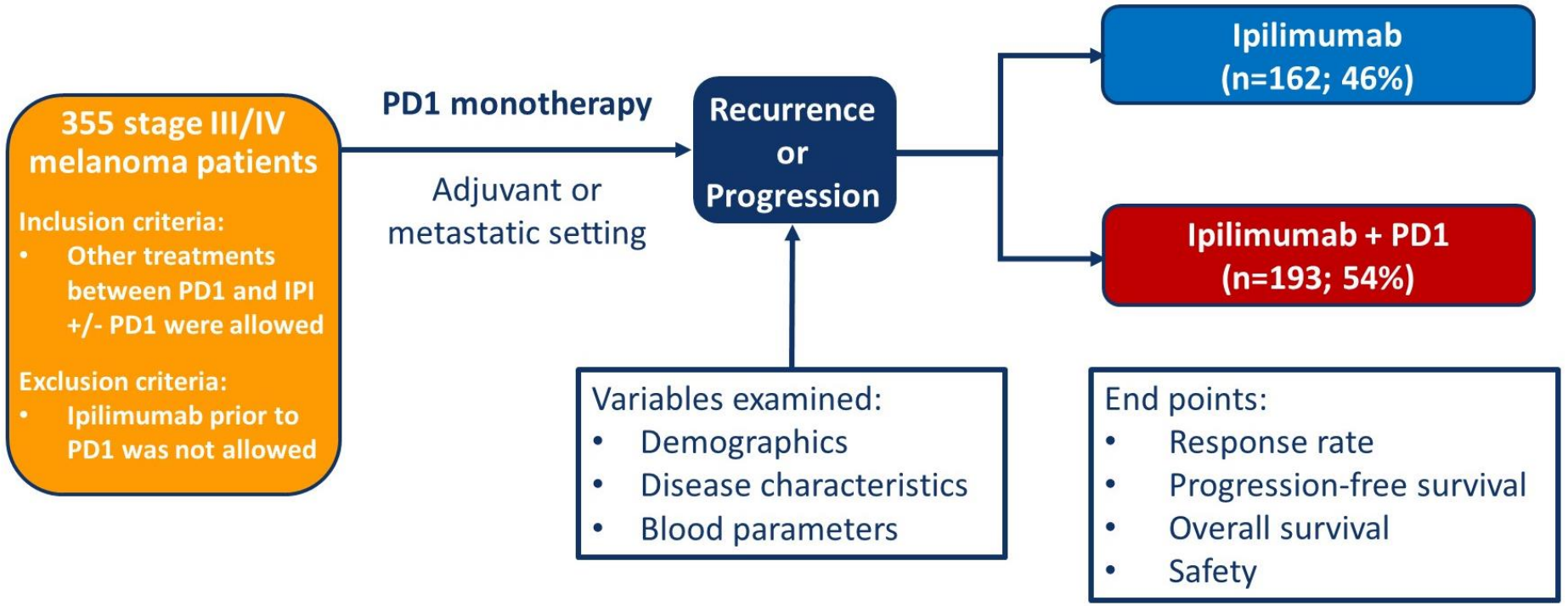
Melanoma studies – After PD-1 therapy

Dr. Lutzky

Ipilimumab (IPI) alone or in combination with anti-PD-1 (IPI+PD1) in patients (pts) with metastatic melanoma (MM) resistant to PD1 monotherapy

Ines Pires da Silva, *et al.*

Study design



Da Silva, ASCO 2020.

Results

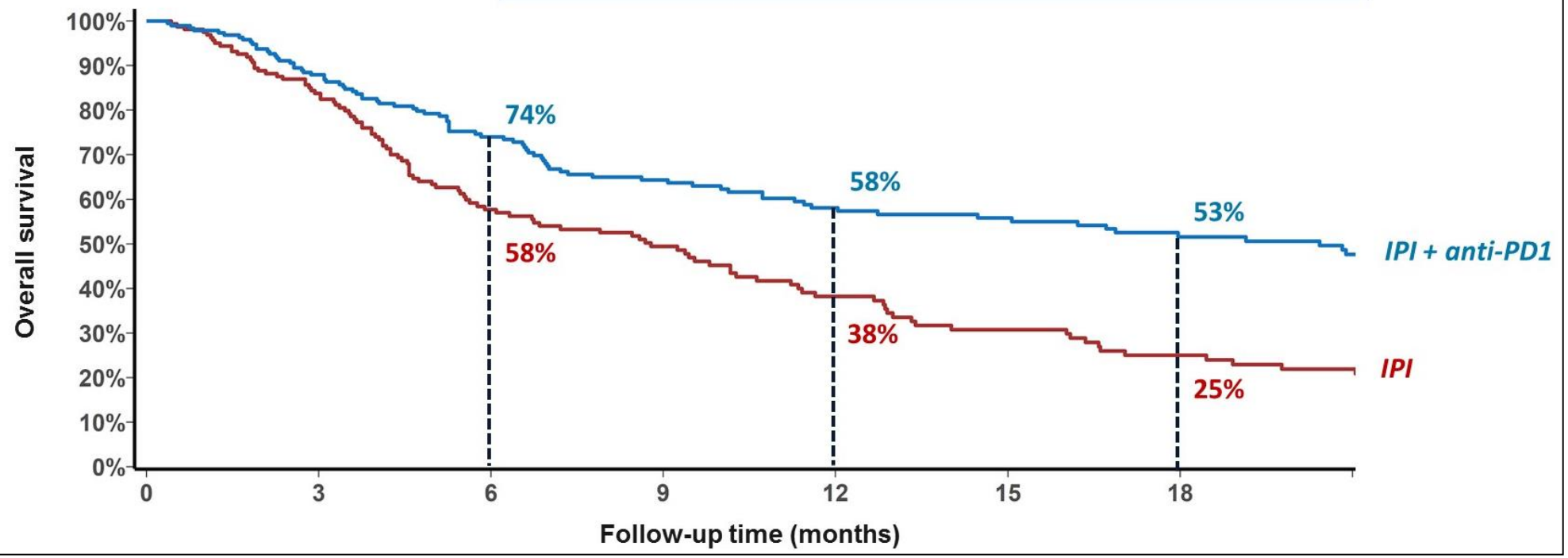
	IPI + PD1 (n=193)	IPI (n=162)	*p-value*
Objective Response Rate (%)	61 (32%)	21 (13%)	**0.0021**
Response			**0.0076**
Complete response (%)	21 (11%)	3 (2%)	
Partial response (%)	40 (21%)	18 (11%)	
Stable disease (%)	17 (9%)	23 (14%)	
Progressive disease (%)	115 (59%)	118 (73%)	
Rate of Disease Control (%)	78 (41%)	44 (27%)	0.0519
Response Duration (95% CI) - months	11.6 (9.4 – 15.5)	9.0 (4.4 – 13.7)	**0.0467**

Da Silva, ASCO 2020.

Results

Overall survival

	IPI + anti-PD1 (n=193)	IPI (n=162)	HR (95% CI) IPI + anti-PD1 over IPI	*p-value*
Median OS, months (95% CI)	20.4 (12.7, 34.8)	8.8 (6.1, 11.3)	0.51 (0.38, 0.67)	<0.0001



Da Silva, ASCO 2020.

Adverse events

High Grade Adverse Events (≥ G3)	IPI + PD1 (n=193)	IPI (n=162)	p-value
Total	59 (31%)	54 (33%)	0.6474
Rash	3 (2%)	2 (1%)	0.9999
Diarrhoea / colitis	23 (12%)	33 (20%)	0.0401
Increased ALT/AST level	24 (12%)	15 (9%)	0.3960
Dyspnea / pneumonitis	2 (1%)	1 (1%)	0.9999
Nephritis	-	1 (1%)	0.4579
Endocrinopathies	3 (2%)	2 (1%)	0.9999
Others	9 (5%)	5 (3%)	0.5869

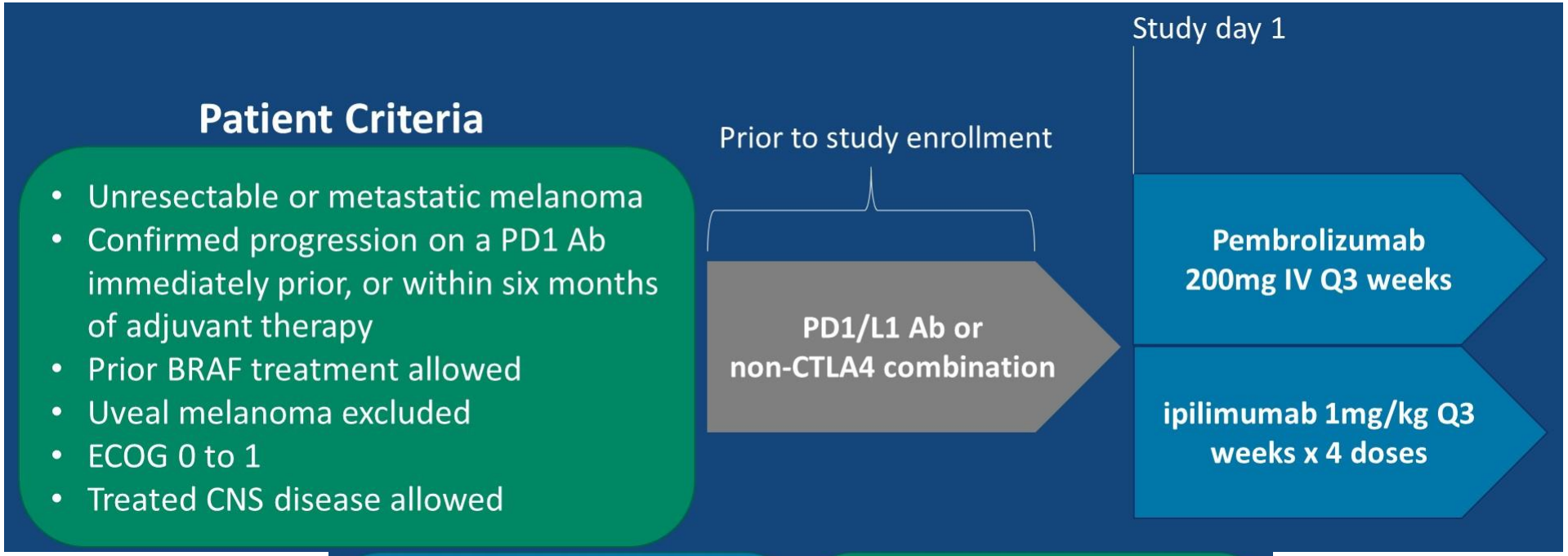
High grade (≥ G3) toxicity was not associated with response.

Da Silva, ASCO 2020.

Significant antitumor activity for low-dose ipilimumab (IPI) with pembrolizumab (PEMBRO) immediately following progression on PD1 Ab in melanoma (MEL) in a phase II trial

Daniel J. Olson, *et al.*

Study design



Primary Endpoint:
- Immune-related response per irRECIST

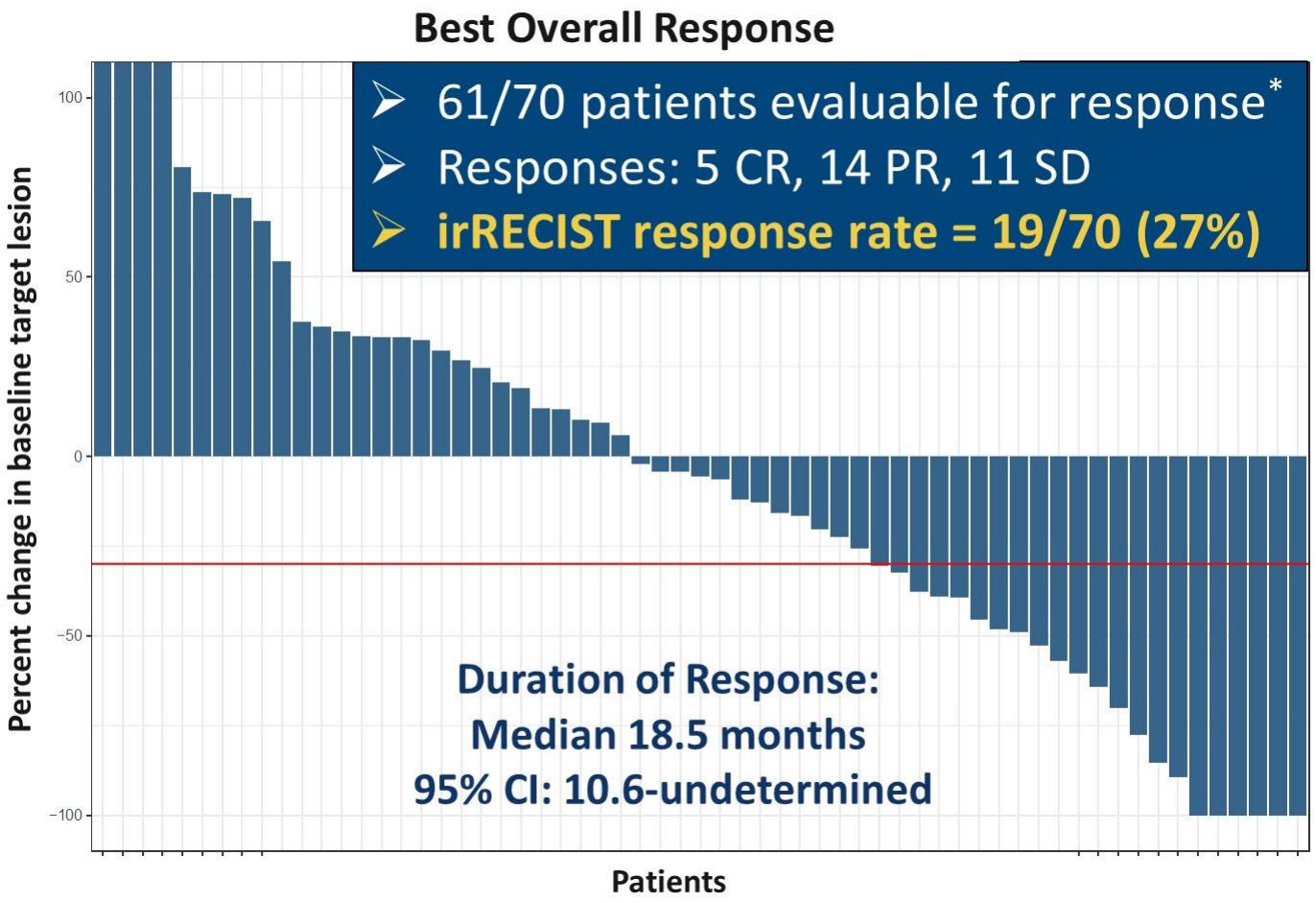
Secondary Endpoints:
- Safety
- Progression free survival
- Overall survival
- Biomarkers

Initial Study Design:
- Simon optimal two-stage design:
  - > 17% RR to expand trial
- 2018 Interim results: 10/22 responses

Total Study Enrollment
Trial expanded to 70 patients

Olson, ASCO 2020.

Results



Response after PD1 Ab adjuvant progression	Response in non-cutaneous melanoma
2/13 (15%)	1/8 (14%)

Response by BRAF Status		Response by PD-L1 Status*	
Mutant	4/19 (26%)	PD-L1 +	4/24 (17%)
Wild Type	15/48 (31%)	PD-L1 -	15/39 (38%)

Response by Liver or CNS disease	Response by elevated LDH
6/20 (30%)	8/19 (42%)

Olson, ASCO 2020.

Adverse events

Patients with toxicity at least possibly related to treatment - n (%)			
Grade 1	Grade 2	Grade 3	Grade 4
61/70 (87%)	40/70 (57%)	18/70 (26%)	1 (1%)

Possibly related toxicites occuring at > 10% of patients - n (%)	Grade 1	Grade 2	Grade 3
Pruritis	23 (33%)	5 (7%)	
Rash (maculo-papular, acneiform, papulopustular)	22 (31%)	3 (4%)	4 (6%)
Colitis/Diarrhea	21 (30%)	7 (10%)	6 (9%)
Fatigue	12 (17%)	11 (16%)	
Nausea	12 (17%)	5 (7%)	1 (1%)
Alanine/Aspartate aminotransferase increased	11 (16%)	3 (4%)	4 (6%)
Arthralgia	7 (10%)		
Anorexia	6 (9%)	8 (11%)	

Number of patients with ≥ grade 3 toxicity at least possibly related to study drug - n (%)*	Grade 3	Grade 4
Colitis/Diarrhea	6 (9%)	0
Rash (acneiform or maculopapular)	4 (6%)	0
AST and/or ALT elevation	4 (6%)	0
Lipase Elevation	2 (3%)	1 (1%)
Acute Kidney Injury	2 (3%)	0
Hyperglycemia	2 (3%)	0
Pancreatitis	1 (1%)	0
Skin and subcutaneous tissue disorders - Other, specify (vasculitis)	1 (1%)	0
Anemia	1 (1%)	0
Nausea	1 (1%)	0
Lymphocyte Count Decreased	1 (1%)	0
Lympocyte count increased	1 (1%)	0
Lung Infection	1 (1%)	0
Alkaline Phosphatase Elevation	1 (1%)	0

*Four patients experienced two grade 3+ toxicities; one patient experienced four

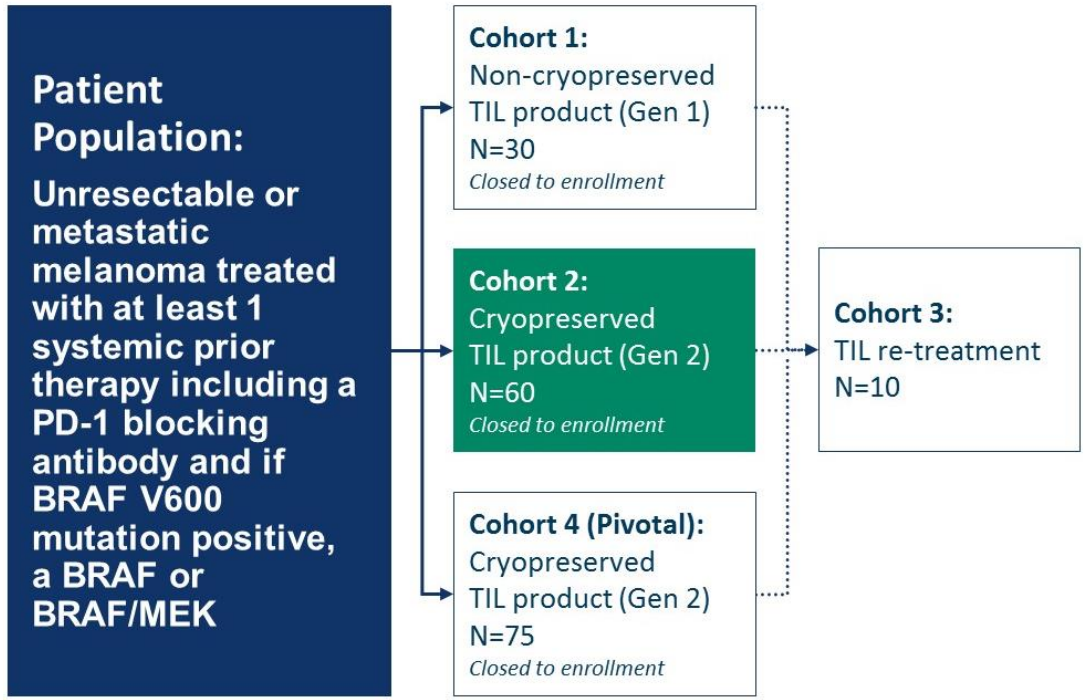
Median time to onset of all high-grade irAEs = 55 days

Olson, ASCO 2020.

Long-term follow up of lifleucel (LN-144) cryopreserved autologous tumor infiltrating lymphocyte therapy in patients with advanced melanoma progressed on prior therapies

Amod Sarnaik, *et al.*

Study design



Cohort 2 Endpoints:

- Primary: Efficacy defined as investigator-assessed Objective Response Rate (ORR) following RECIST 1.1
- Secondary: Safety and efficacy

Other Key Eligibility Criteria:

- One tumor lesion resectable for TIL generation (~1.5cm in diameter) and ≥ one tumor lesion as target for RECIST 1.1 assessment
- Age ≥ 18 years at the time of consent
- ECOG Performance Status of 0-1

Methods:

- Data Extract: 23 April 2020 for Cohort 2
- Cohort 2 Safety and Efficacy sets: 66 patients who underwent resection for the purpose of TIL generation and received lifileucel infusion

Sarnaik, ASCO 2020.

Results

RESPONSE	PATIENTS, N=66 n (%)
Objective Response Rate	**24 (36.4)**
Complete Response	2 (3.0)
Partial Response	22 (33.3)
Stable Disease	29 (43.9)
Progressive Disease	9 (13.6)
Non-Evaluable[(1)]	4 (6.1)
Disease Control Rate	53 (80.3)
Median Duration of Response	**Not Reached**
Min, Max (months)	2.2, 26.9+

- After a median study follow-up of 18.7 months, median DOR was still not reached (range 2.2, 26.9+)
- Response was seen regardless of location of tumor resected
- Mean number of TIL cells infused: 27.3 x 10^9

Sarnaik, ASCO 2020.

Adverse events

PREFERRED TERM	Cohort 2 (N=66)		
	Any Grade, n (%)	Grade 3/4, n (%)	Grade 5, n (%)
Number of patients reporting at least one Treatment-Emergent AE	66 (100)	64 (97.0)	2 (3.0)*
Thrombocytopenia	59 (89.4)	54 (81.8)	0
Chills	53 (80.3)	4 (6.1)	0
Anemia	45 (68.2)	37 (56.1)	0
Pyrexia	39 (59.1)	11 (16.7)	0
Neutropenia	37 (56.1)	26 (39.4)	0
Febrile neutropenia	36 (54.5)	36 (54.5)	0
Hypophosphatemia	30 (45.5)	23 (34.8)	0
Leukopenia	28 (42.4)	23 (34.8)	0
Fatigue	26 (39.4)	1 (1.5)	0
Hypotension	24 (36.4)	7 (10.6)	0
Lymphopenia	23 (34.8)	21 (31.8)	0
Tachycardia	23 (34.8)	1 (1.5)	0

Sarnaik, ASCO 2020.

Conclusions – Later-line melanoma

- Data presented at ASCO 2020 corroborates previous clinical reports suggesting that patients progressing or refractory to PD1 blockade may respond to ipilimumab alone or ipilimumab+PD1 Ab.
- Ipi/Nivo outcomes appear superior
- These responses are durable and the toxicity manageable.
- Still awaiting results of trial SWOG 1606: randomized ipi vs ipi/nivo after progression on PD1 Ab.

Conclusions – Later-line melanoma

- Adoptive cell therapy with TIL for patients resistant or refractory to CTLA-4/PD1 CPI and BRAF/MEKi(if BRAF V600 mutated) has resulted in a 36% RR with median DOR not reached at a median of 18.7 mos of follow up.

- While toxicity is significant, it can be managed with appropriate patient selection and physician experience.

Stephan Grupp, MD, PhD

- Chief, Cell Therapy and Transplant Section, Director of the Cancer Immunotherapy Program, and Medical Director of the Cell and Gene Therapy Laboratory
- Expertise: CAR and TCR T cell therapy, engineered cell therapies for nonmalignant disorders

Cellular therapy studies

Dr. Grupp

First-in-human data of ALLO-501 and ALLO-647 in relapsed/refractory large B-cell or follicular lymphoma (R/R LBCL/FL): ALPHA study

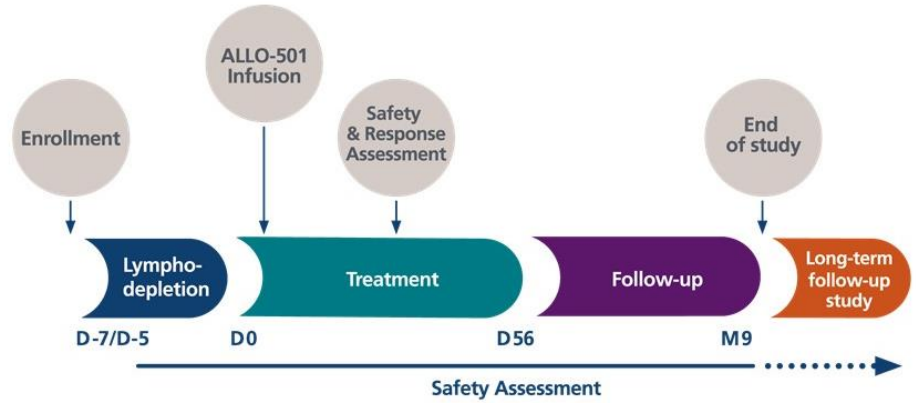
SS Neelapu, *et al.*

Study design

Primary Endpoints
- Safety and dose-limiting toxicity of ALLO-647/Flu/Cy followed by ALLO-501

Key Secondary Endpoints
- Overall response rate
- ALLO-501 cell kinetics
- ALLO-647 PK

Key Eligibility Criteria
- R/R LBCL or FL
- At least 2 prior lines of therapy, including an anti-CD20 monoclonal antibody
- ECOG 0 or 1
- Prior autologous CAR T allowed if tumor remains CD19+
- Patients with Donor Specific Antibodies and rituximab > 15ng/ml were excluded



	DL1	DL2	DL3
Cell Dose	40 x 10^6 CAR^+ T cells	120 x 10^6 CAR^+ T cells	360 x 10^6 CAR^+ T cells

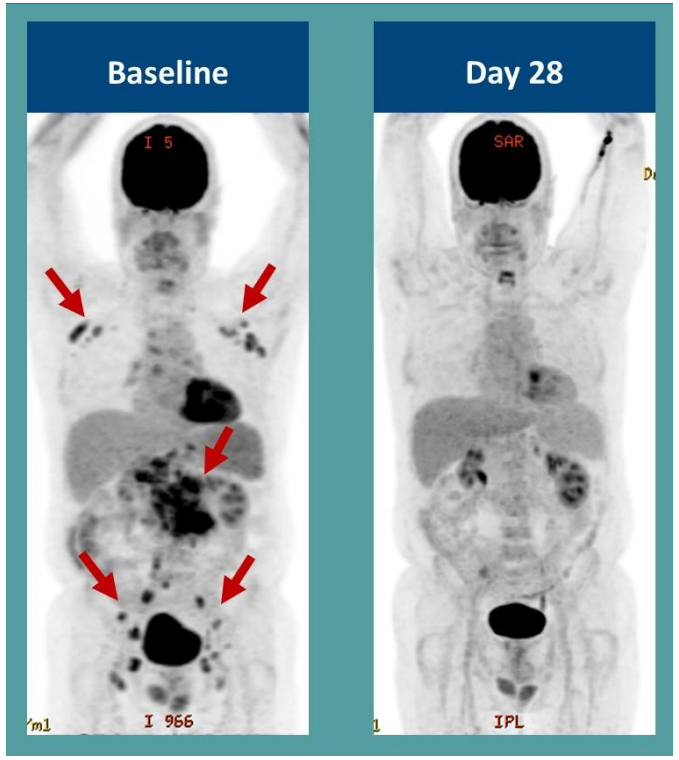
- Lymphodepletion Regimens
  - LD1: Flu/Cy and ALLO-647 13 mg/d x 3 days
  - LD2/LD3: Flu/Cy and ALLO-647 30 mg/d x 3 days (concomitant/staggered)

Neelapu, ASCO 2020.

Results

Cell Dose and LD regimen	39mg ALLO-647			ALL 39mg ALLO-647 (N = 11)	90mg ALLO-647		All 90mg ALLO-647 (N=8)	All Patients (N=19) Rate (95%CI)
	40 x 10^6 CAR+ cells (N=4)	120 x 10^6 CAR+ cells (N=4)	360 x 10^6 CAR+ cells (N=3)		120 x 10^6 CAR+ cells (N=6)	360 x 10^6 CAR+ cells (N=2)		
ORR, n (%)	3 (75%)	3 (75%)	1 (33%)	7 (64%)	4 (67%)	1 (50%)	5 (63%)	12/19 (63%) (38%, 84%)
CR , n (%)	1 (25%)	1 (25%)	1 (33%)	3 (27%)	4 (67%)	0 (0%)	4 (50%)	7/19 (37%) (16%, 62%)

Median follow-up time: 3.8 months (range: 0.7 - 6.1)



Neelapu, ASCO 2020.

Adverse events

AE of Interest ‡	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	All grades n (%)
Cytokine Release Syndrome *	2 (9%)	4 (18%)	1 (5%)	-	-	7 (32%)
ICANS *	-	-	-	-	-	-
Graft-versus-Host Disease	-	-	-	-	-	-
Infection	5 (23%)	4 (18%)	2 (9%)†	-	-	11 (50%)
Infusion Reaction #	1 (9%)	9 (41%)	1 (9%)	-	-	11 (50%)
Neutropenia	-	1 (5%)	7 (32%)	7 (32%)	-	15 (68%)

- No DLT, GvHD
- Manageable CRS
- ALLO-501 toxicity not dose-proportional
- Median duration of hospitalization from D0: 7 days

Serious Adverse Events (time to resolution) ‡

- **4 patients (18%):**
  - Gr2 pyrexia (2 days) and Gr2 CMV reactivation (6 days)
  - Gr3 rotavirus infection (15 days) and Gr3 hypokalemia (2 days)
  - Gr3 febrile neutropenia (2 days) and Gr3 hypotension (2 days)
  - Gr3 upper GI hemorrhage (<1 day) and Gr3 CMV reactivation (25 days)

* ASTCT Lee, 2019. ICANS: Immune Effector Cell-Associated Neurotoxicity Syndrome
† CMV reactivations and Rotavirus infection
# attributed to ALLO-647

‡ Number of patients with AE regardless of attribution unless otherwise indicated, occurring from the start of study drug up to subsequent anti-cancer therapy (for patients reporting more than one AE within a preferred term, only one AE with the maximum grade is reported).

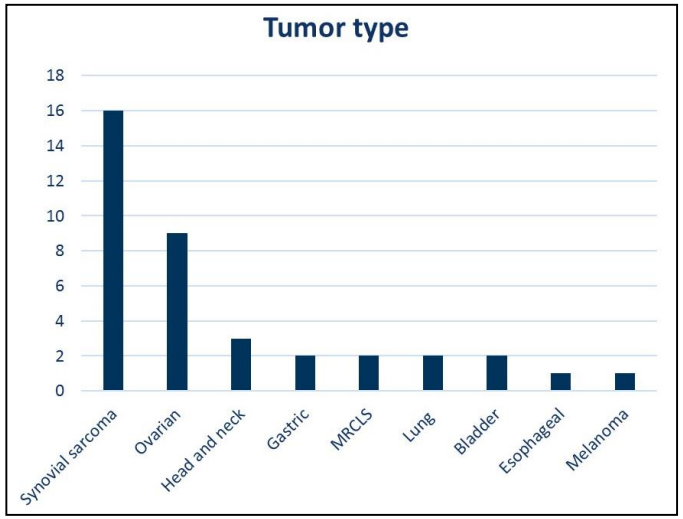
Data Cutoff Date: May 11, 2020

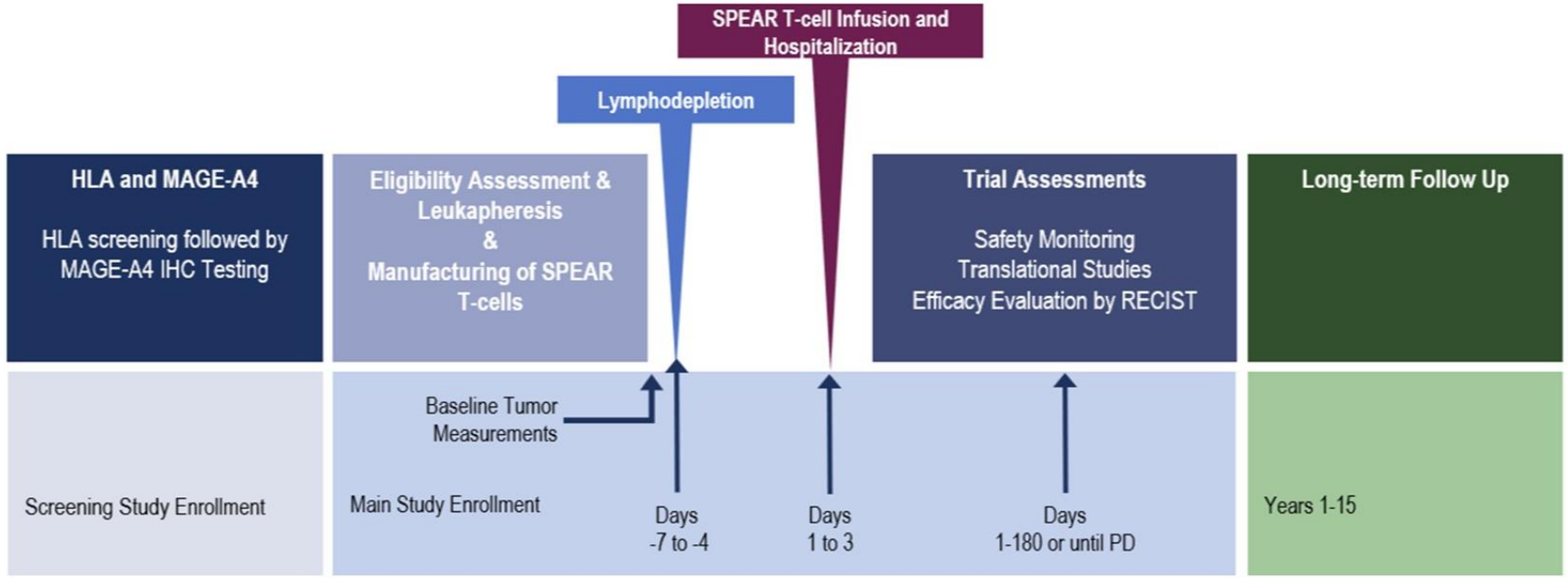
Neelapu, ASCO 2020.

Phase 1 dose escalation and expansion trial to assess safety and efficacy of ADP-A2M4 in advanced solid tumors

David S. Hong, *et al.*

Study design





Hong, ASCO 2020.

Adverse events

N=38; n (%)	Any grade	≥Grade 3
Patients with any AEs	37 (97.4)	37 (97.4)
Lymphopenia	37 (97.4)	37 (97.4)
Leukopenia	35 (92.1)	35 (92.1)
Neutropenia	35 (92.1)	34 (89.5)
Anemia	28 (73.7)	24 (63.2)
Fatigue	24 (63.2)	1 (2.6)
Nausea	23 (60.5)	0
Thrombocytopenia	23 (60.5)	18 (47.4%)
Pyrexia	22 (57.9)	0
CRS	19 (50.0)	2 (5.3)
Vomiting	19 (50.0)	1 (2.6)

N=38; n (%)	Any grade	≥Grade 3
Decreased appetite	16 (42.1)	2 (5.3)
Dyspnea	16 (42.1)	1 (2.6)
Diarrhea	14 (36.8)	0
Hypotension	14 (36.8)	4 (10.5)
Hypophosphatemia	13 (34.2)	11 (28.9)
Febrile neutropenia	12 (31.6)	12 (31.6)
Hyponatremia	12 (31.6)	8 (21.1)
Sinus tachycardia	12 (31.6)	0
Abdominal pain	10 (26.3)	1 (2.6)
Arthralgia	10 (26.3)	2 (5.3)
Rash	10 (26.3)	5 (13.2)

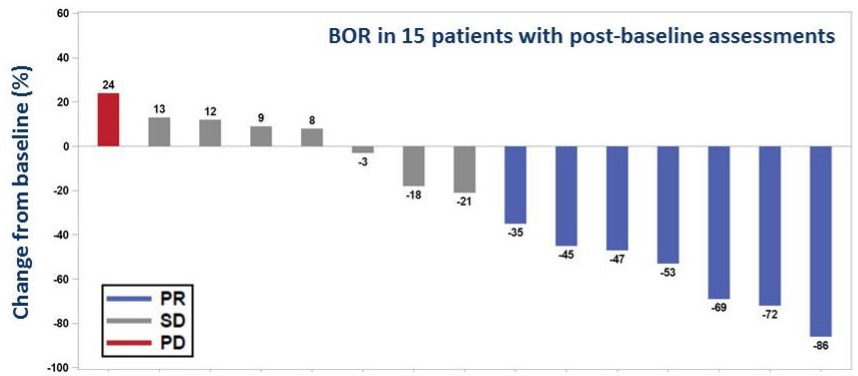
N=38	Related SAE; n (%)
Patients with any related SAEs	13 (34.2)
CRS	9 (23.7)
Pyrexia	2 (5.3)
Aplastic anemia	1 (2.6)
Pancytopenia	1 (2.6)
Cerebrovascular accident	1 (2.6)
Neurotoxicity	1 (2.6)
Encephalopathy	1 (2.6)
Rash	1 (2.6)
Sepsis	1 (2.6)
ALT/AST/Alk Phos increased	1 (2.6)
Arrhythmia	1 (2.6)

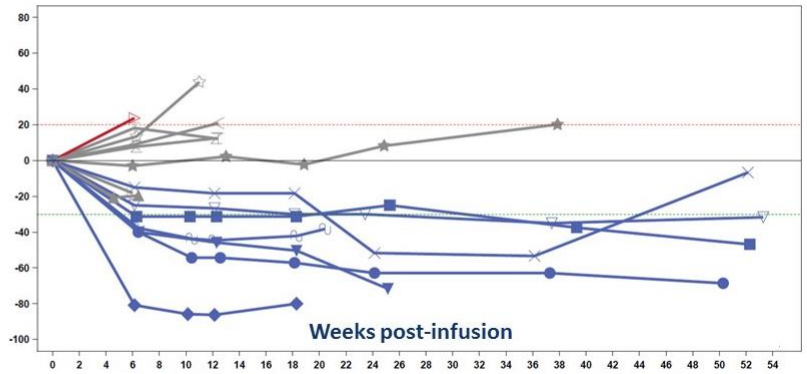
Hong, ASCO 2020.

Results

	Overall	Synovial sarcoma	Non-sarcoma	Head & neck	Lung
n	38[1]	16	22	3	2
BOR partial response (%)	9 (23.7)	7 (43.8)	2 (9.1)	1 (33.3)	1 (50.0)
BOR stable disease (%)	18 (47.4)	7 (43.8)	11 (50.0)	1 (33.3)	0
BOR progressive disease (%)	7 (18.4)	1 (6.3)	6 (27.3)	1 (33.3)	1 (50.0)
Unknown or missing (%)	4 (10.5)	1 (6.3)	3 (13.6)	0	0
ORR (%)	23.7	43.8	9.1	33.3	50.0

Synovial sarcoma cohort





Hong, ASCO 2020.

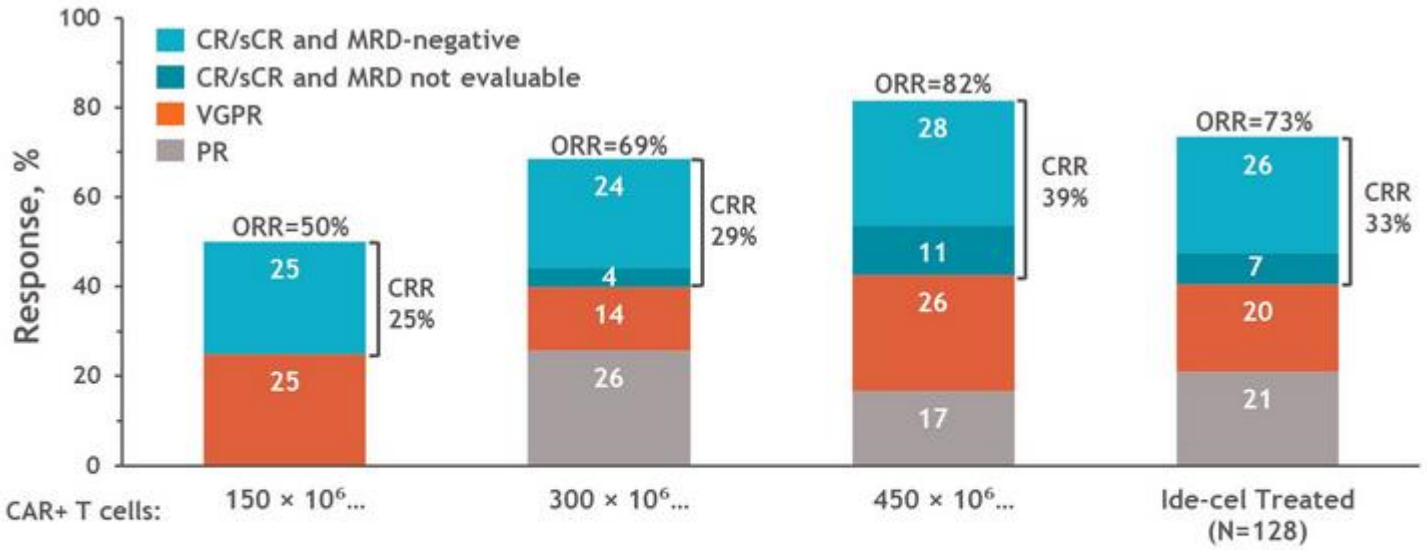
Multiple myeloma studies

- Idecabtagene vicleucel (ide-cel; bb2121), a BCMA-targeted CAR T-cell therapy, in patients with relapsed and refractory multiple myeloma (RRMM): Initial KarMMa results – Nikhil Munshi, *et al*
- Orvacabtagene autoleucel (orva-cel), a B-cell maturation antigen (BCMA)-directed CAR T cell therapy for patients (pts) with relapsed/refractory multiple myeloma (RRMM): update of the phase 1/2 EVOLVE study (NCT03430011) – Sham Mailankody, *et al*
- Update of CARTITUDE-1: A phase Ib/II study of JNJ-4528, a B-cell maturation antigen (BCMA)-directed CAR-T-cell therapy, in relapsed/refractory multiple myeloma – Jesus Berdeja, *et al*

Trial comparison

Trial	Phase	Agent	Patient population	Primary endpoint
KarMMa	2	Ide-cel: anti-BCMA, 4-1BB, CD3ζ	R/R MM with ≥3 prior therapies	ORR
EVOLVE	1/2	Orva-cel: anti-BCMA, 4-1BB, CD3ζ	R/R MM with ≥3 prior therapies	1: safety/RP2D 2: ORR at RP2D
CARTITUDE-1	1b/2	JNJ-4528: two anti-BCMA, 4-1BB, CD3ζ	R/R MM with ≥3 prior therapies	1b: safety and confirm RP2D 2: efficacy

KarMMa results



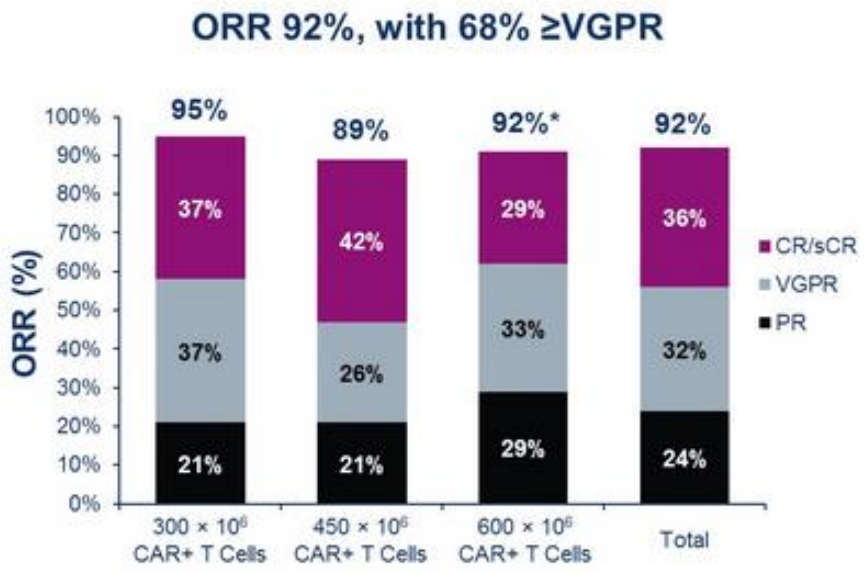
- Primary (ORR >50%) and key secondary (CRR >10%) endpoints met in the ide-cel treated population
  - *ORR of 73% (95% CI, 65.8–81.1; P<0.0001*)*
  - *CRR (CR/sCR) of 33% (95% CI, 24.7–40.9; P<0.0001)*
- Median time to first response of 1.0 mo (range, 0.5–8.8); median time to CR of 2.8 mo (range, 1.0–11.8)
- Median follow-up of 13.3 mo across target dose levels

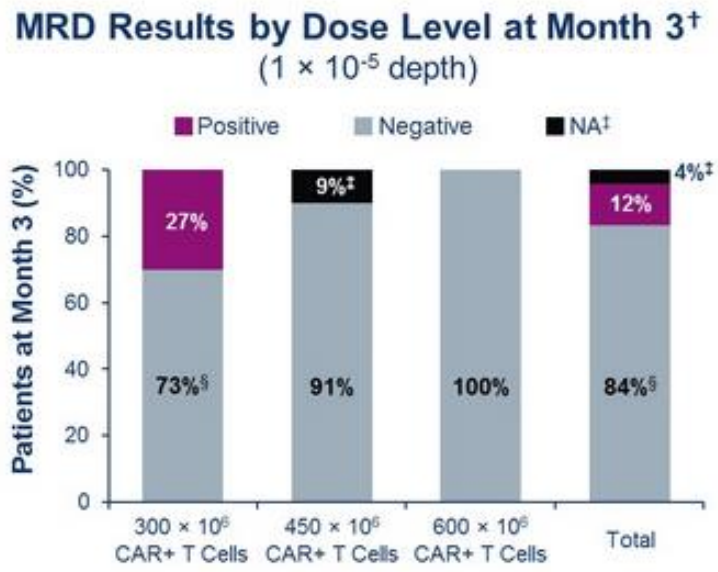
Target Dose, × 10^6 CAR+ T cells	150 (n=4)	300 (n=70)	450 (n=54)	Ide-cel Treated (N=128)
≥1 CRS event, n (%)	2 (50)	53 (76)	52 (96)	107 (84)
Max. grade (Lee Criteria)*				
1/2	2 (50)	49 (70)	49 (91)	100 (78)
3	0	2 (3)	3 (6)	5 (4)
4	0	1 (1)	0	1 (<1)
5	0	1 (1)	0	1 (<1)
Median onset, d (range)	7 (2–12)	2 (1–12)	1 (1–10)	1 (1–12)
Median duration, d (range)	5 (3–7)	4 (2–28)	7 (1–63)	5 (1–63)
Tocilizumab, n (%)	1 (25)	30 (43)	36 (67)	67 (52)
Corticosteroids, n (%)	0	7 (10)	12 (22)	19 (15)

Target Dose, × 10^6 CAR+ T cells	150 (n=4)	300 (n=70)	450 (n=54)	Ide-cel Treated (N=128)
≥1 NT event, n (%)	0	12 (17)	11 (20)	23 (18)
Max. grade (CTCAE)*				
1	0	7 (10)	5 (9)	12 (9)
2	0	4 (6)	3 (6)	7 (5)
3	0	1 (1)	3 (6)	4 (3)
Median onset, d (range)	NA	3 (1–10)	2 (1–5)	2 (1–10)
Median duration, d (range)	NA	3 (2–26)	5 (1–22)	3 (1–26)
Tocilizumab, n (%)	NA	0	3 (6)	3 (2)
Corticosteroids, n (%)	NA	2 (3)	8 (15)	10 (8)

Munshi, ASCO 2020.

EVOLVE results

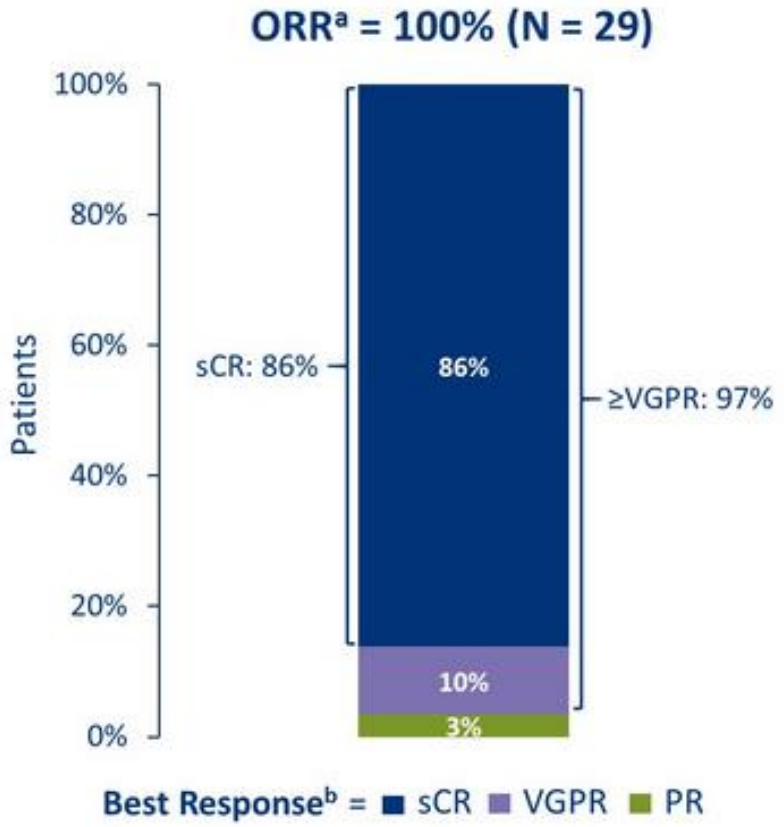




	300 × 10⁶ CAR+ T Cells (n=19)	450 × 10⁶ CAR+ T Cells (n=19)	600 × 10⁶ CAR+ T Cells (n=24)	Total (N=62)
Any SAE, n (%)	**4 (21)**	**5 (26)**	**8 (33)**	**17 (27)**
AEs of special interest grade ≥3, n (%)				
Neutropenia	15 (79)	19 (100)	22 (92)	56 (90)
Anemia	8 (42)	8 (42)	14 (58)	30 (48)
Thrombocytopenia	6 (32)	10 (53)	13 (54)	29 (47)
Infections	3 (16)	4 (21)	1 (4)	8 (13)
Cytokine release syndrome (CRS)	0	1 (5)	1 (4)	2 (3)
Neurological events (NE)	1 (5)	1 (5)	0	2 (3)
MAS/HLH	0	2 (11)	1 (4)	3 (5)

Mailankody, ASCO 2020.

CARTITUDE-1 results



	N = 29	
CAR-T-associated AEs, n (%)	All Grade	Grade ≥3
Cytokine release syndrome (CRS)[a]	27 (93)	2 (7)
Neurotoxicity consistent with ICANS[b]	3 (10)[c]	1 (3)

Timing and management of CRS

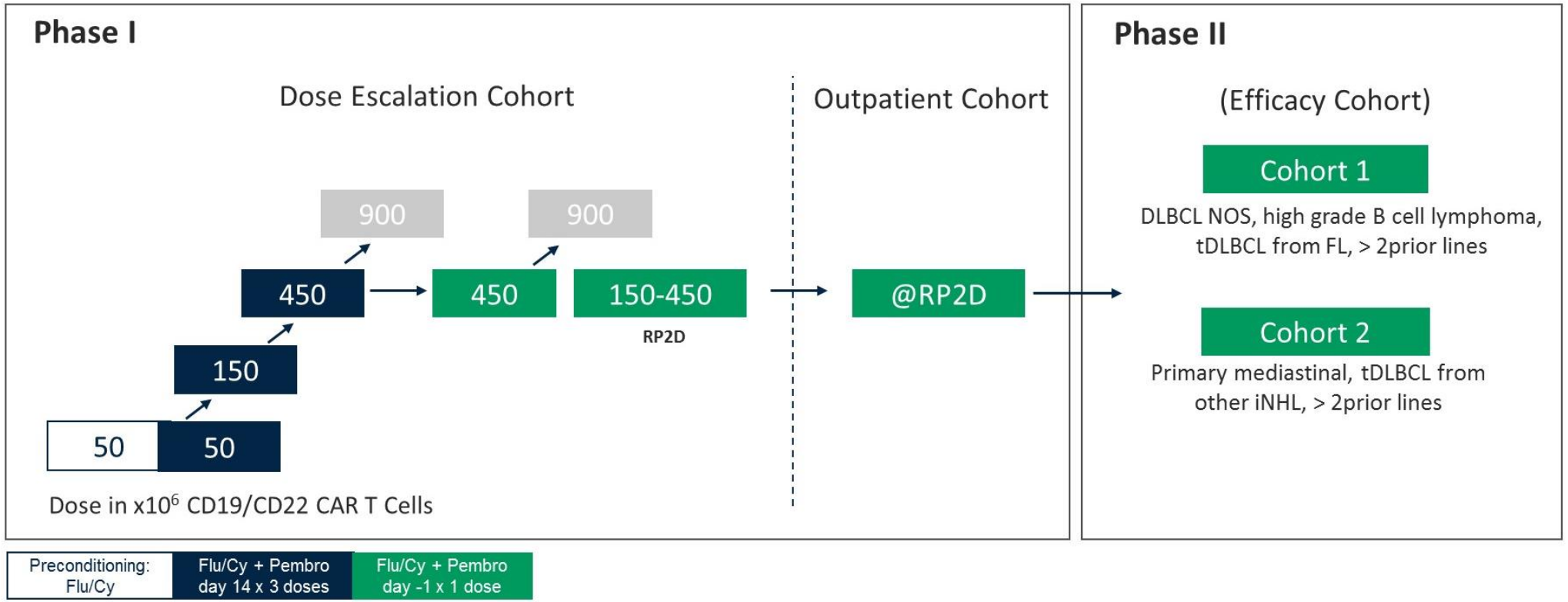
- Median time to onset of CRS = 7 days (2 – 12)
- Median duration of CRS = 4 days (2 – 64)
- 23 (79%) patients were given tocilizumab
- 6 (21%) patients each were given anakinra or corticosteroids

Berdeja, ASCO 2020.

Phase 1/2 study of AUTO3, the first bicistronic chimeric antigen receptor (CAR) targeting CD19 and CD22, followed by anti-PD1 in patients with relapsed/refractory (r/r) diffuse large B cell lymphoma (DLBCL): results of safety cohorts of the ALEXANDER study

Aravind Ramakrishnan, *et al*.

Study design



Ramakrishnan, ASCO 2020.

Adverse events

AEs (Total N = 23)	All Grades N (%)	Grades 3 & 4 N (%)
Neutropenia	20 (87%)	20 (87%)
Thrombocytopenia	15 (65%)	13 (57%)
Anaemia	13 (57%)	11 (48%)
Cytokine release syndrome	9 (39%)	0
Fever	9 (39%)	0
Constipation	7 (30%)	0
Fatigue	6 (26%)	0

	50 x10^6 AUTO3 no pem (N=4)	50 x10^6 AUTO3 D14 pem (N=3)	150 x10^6 AUTO3 D14 pem (N=4)	450 x10^6 AUTO3 D14 pem (N=4)	450 x10^6 AUTO3 D -1 pem (N=4#)	150-450 x 10^6 AUTO3 D-1 pem RP2D (N=4)	Total (N=23)
Grade 1 CRS	1	0	1	1	2	1	6 (26.1%)
Grade 2 CRS	0	0	1	1	0	1	3 (13%)
≥ Grade 3 CRS	0	0*	0	0	0	0	0

	50 x10^6 AUTO3 no pem (N=4)	50 x10^6 AUTO3 D14 pem (N=3)	150 x10^6 AUTO3 D14 pem (N=4)	450 x10^6 AUTO3 D14 pem (N=4)	450 x10^6 AUTO3 D -1 pem (N=4#)	150-450 x 10^6 AUTO3 D-1 pem RP2D (N=4)	Total (N=23)
All grades NT	1	0	0	0	0	0	1 (4.3%)
≥ Grade 3 NT	1	0	0	0	0	0	1 (4.3%)

Ramakrishnan, ASCO 2020.

Results

Dose level ≥ 150 x 10^6 day -1 pembro appears promising

	50 x 10^6 No pem (N=4)	50 x 10^6 D14 pem (N=3)	150 x 10^6 D14 pem (N=4)	450 x 10^6 D14 pem (N=4)	450 x 10^6 D-1 pem (N=4)	150-450 x 10^6 D-1 pem RP2D (N=4)
CR	1	1	2	2	2	3
PR	1	1	0	1	0	1
PD	2	0	2	1	2**	0
NE	0	1*	0	0	0	0

- All Dose Levels (N=23): ORR 65%, CRR 48%
  - ≥ 150 x 10^6 (N=16): ORR 69%, CRR 56%
  - ≥ 150 x 10^6, Day -1 pem (N=8): ORR 75%, CRR 63%

* NE because baseline PET negative disease, **Includes one patient that received only 125 x 10^6 and NE per protocol

Ramakrishnan, ASCO 2020.

Cellular therapy conclusions

- 2 FDA approved products, with more to come soon
- Myeloma – multiple products, excellent response rates with manageable toxicity, but the big question will be durability
- Allo/off the shelf products are feasible, with comparable response rates to auto CAR T in NHL. Looking good in the short term.
  - Too soon to know about durability
  - Lot to lot variability is an open question that will require larger Ns
  - Will reinfusion and/or further engineering to extend persistence be necessary?
- Checkpoint Rx with CAR T can be safe and may improve efficacy in NHL
- Early evidence for solid tumor activity in TCR Ts. NY-ESO and now MAGE A4
  - Still limited to HLA-A2
- Things are moving forward

Other impactful studies from ASCO 2020

- Pembrolizumab versus chemotherapy for microsatellite instability-high/mismatch repair deficient metastatic colorectal cancer: The phase 3 KEYNOTE-177 study – Thierry André, *et al.*
- Durvalumab and tremelimumab in combination with FOLFOX in first line RAS-mutated, microsatellite-stable metastatic colorectal cancer: Results of the first intermediate analysis of the phase IB/II MEDITREME trial - Francois Ghiringhelli, *et al.*
- CITYSCAPE: Primary analysis of a randomized, double-blind, phase II study of the anti-TIGIT antibody tiragolumab plus atezolizumab versus placebo plus atezolizumab as 1L treatment in patients with PD-L1-selected NSCLC - Delvys Rodriguez-Abreu, *et al.*
- Maintenance avelumab + best supportive care (BSC) versus BSC alone after platinum-based first-line chemotherapy in advanced urothelial carcinoma: JAVELIN Bladder 100 phase III results – Thomas Powles, *et al.*

ASCO 2020 trends

- Immunotherapy combinations and sequencing becoming important questions
- Many studies are investigating optimal dosing regimens
- Standard-of-care is rapidly changing for many cancers
- While early-stage data are promising, we need to wait for final OS results to determine true advantages of novel immunotherapies

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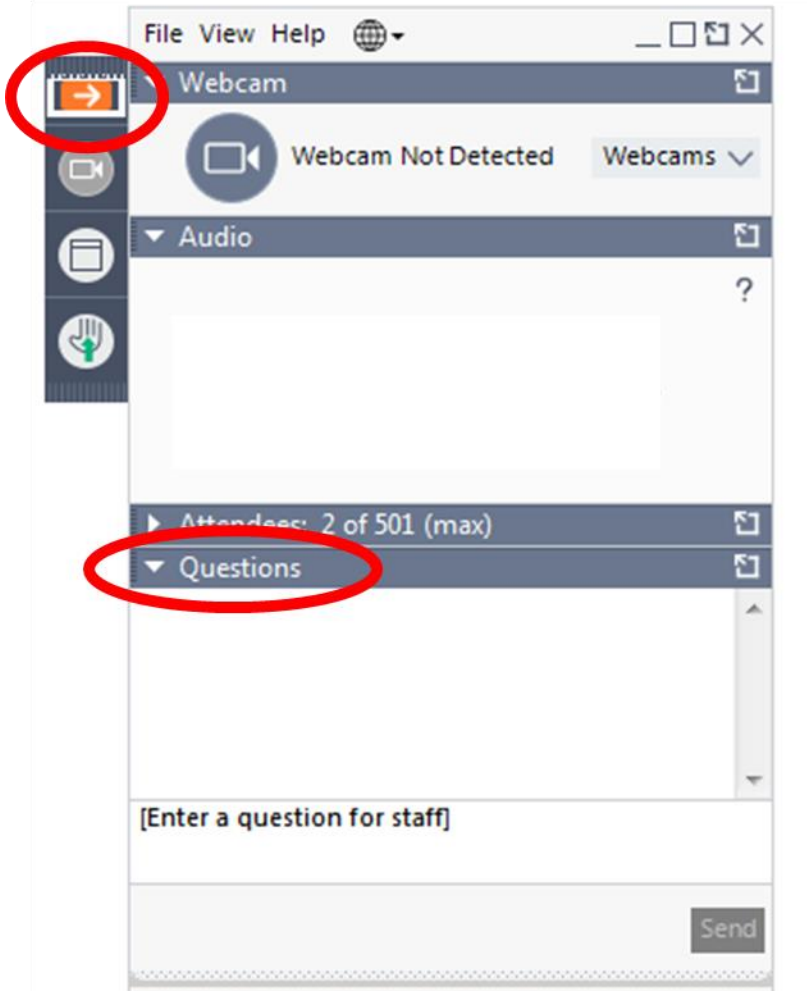
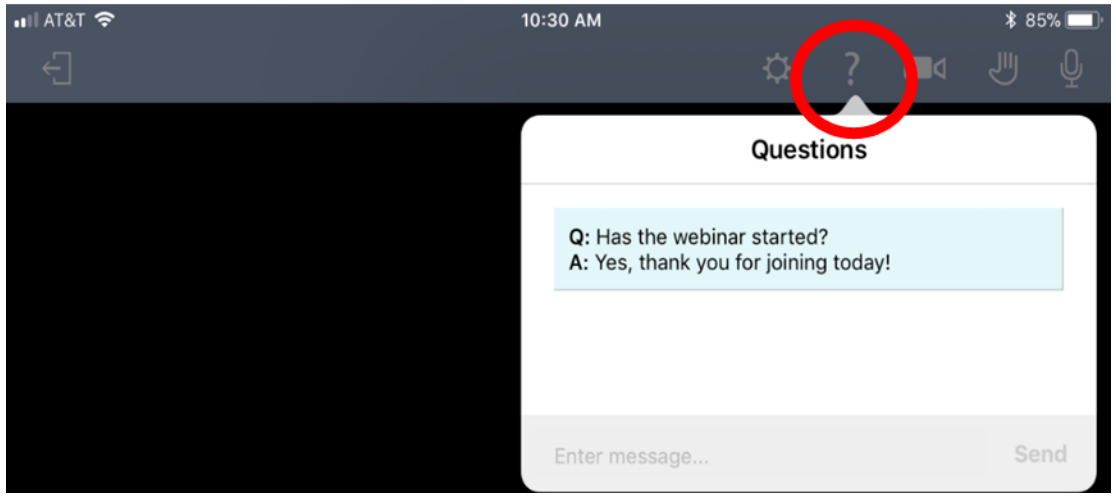
How to Submit Questions

Computer



Mobile Phone



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