Advances in Cancer Immunotherapy™ Webinar: Clinical Updates from ESMO Congress 2019

Friday, February 28, 2020

1:00-2:00 p.m. EST

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Webinar Agenda

1:00-1:05 p.m. EST Overview: Welcome and Introductions

1:05-1:40 p.m. EST Presentation

1:40-1:55 p.m. EST Question and Answer Session

1:55-2:00 p.m. EST Closing Remarks

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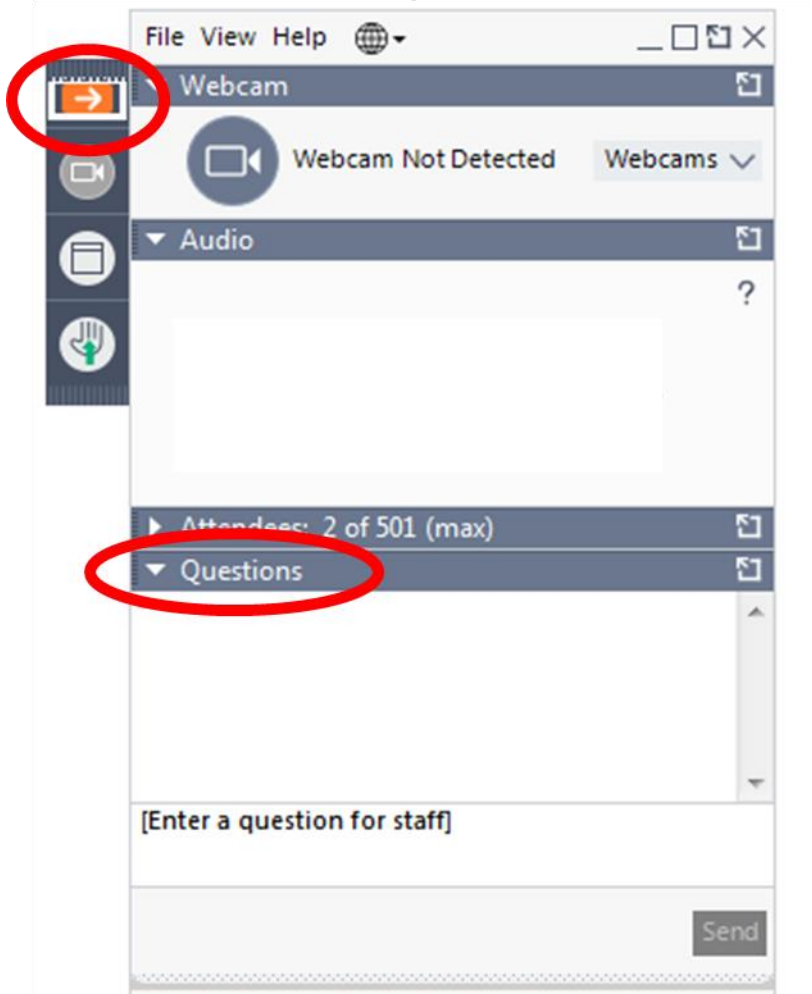
How to Submit Questions

Computer



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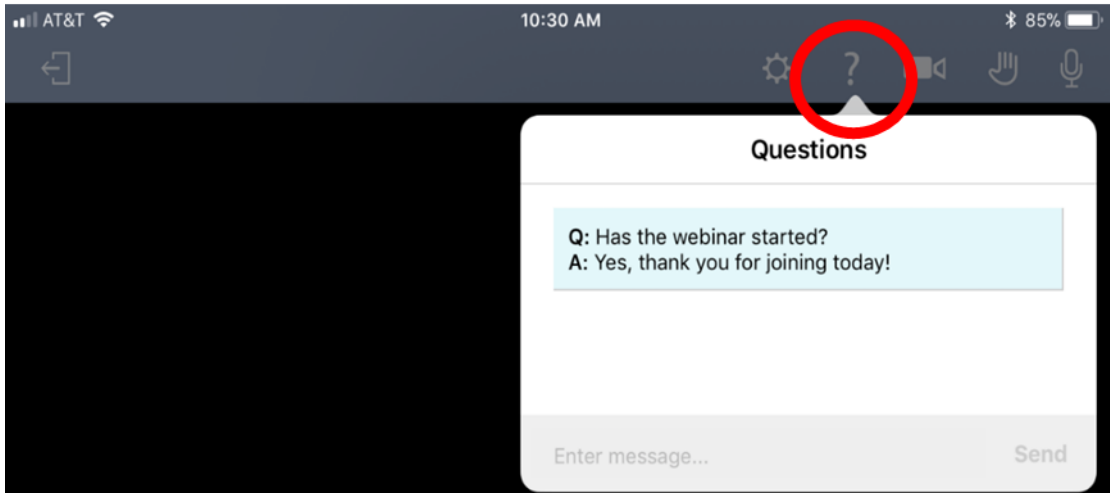

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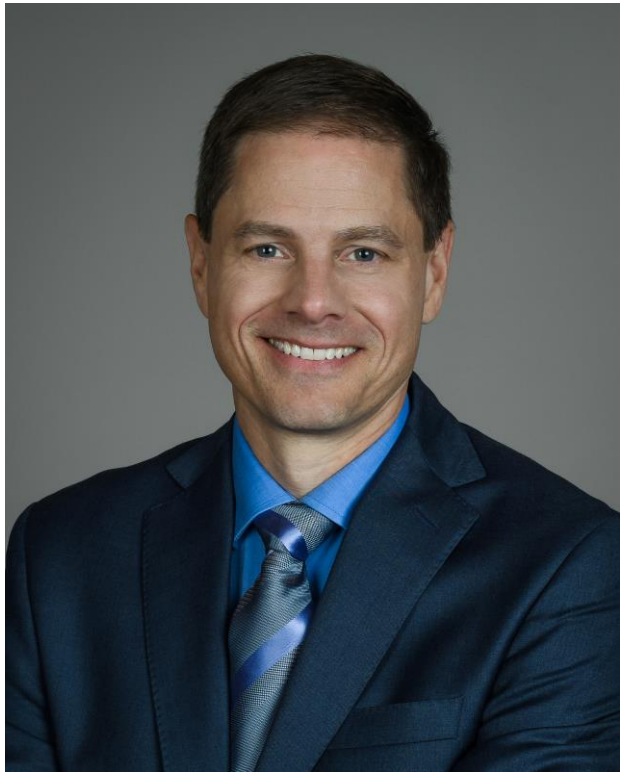
Webinar Faculty

Leora Horn, MD –
Vanderbilt University Medical Center

Amanda Kirane, MD –
UC Davis Comprehensive Cancer Center



Brian Rini, MD –
Vanderbilt University Medical Center

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Learning Objectives

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

- Describe advances in immune checkpoint inhibitor therapies for highly immunotherapy-responsive cancers including melanoma, non-small cell lung cancer, and renal cell carcinoma
- Outline the application of immune checkpoint inhibitor therapies for less-explored indications, such as in triple-negative breast cancer and hepatocellular carcinoma
- Explain the rationale behind and implications of current combination immunotherapy studies

Genitourinary malignancies

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Tailored ImmunoTherapy Approach with Nivolumab in advanced Renal Cell Carcinoma (TITAN-RCC)

Marc-Oliver Grimm[1], Manuela Schmidinger[2], Ignacio Duran[3], Giovanni Schinzari[4], Emilio Esteban[5], Marc Schmitz[6], Ulrike Schumacher[7], Gustavo Baretton[8], Philippe Barthelemy[9], Bohuslav Melichar[10], Natalie Charnley[11], Dirk Schrijvers[12], Laurence Albiges[13]

[1]Urology Department, Universitätsklinikum Jena, Jena, Germany; [2]Department of Internal Medicine I, Vienna General Hospital (AKH) - Medizinische Universität Wien, Vienna, Austria; [3] Hospital Universitario Marques de Valdecilla, IDIVAL, Santander, Spain; [4]Policlinico Universitario A. Gemelli, Università Cattolica del Sacro Cuore, Rome, Italy; [5]Departamento de Oncología Médica, Hospital Universitario Central de Asturias, Oviedo, Spain; [6]Institut für Immunologie, Medizinische Fakultät Carl Gustav Carus der TU Dresden, Dresden, Germany; [7]Center for Clinical Studies, Universitätsklinikum Jena, Jena, Germany; [8]Institut für Pathologie, Universitätsklinik Carl Gustav Carus, Dresden, Germany; [9]Medical Oncology Department, C.H.U. Strasbourg-Nouvel Hopital Civil, Strasbourg, France; [10]Oncology, University Hospital Olomouc, Olomouc, Czech Republic; [11]Cancer Services, Royal Preston Hospital-Lancashire Teaching Hospitals NHS Foundation Trust, Preston, United Kingdom; [12]Medical Oncology, Ziekenhuisnetwerk Antwerpen-Middelheim, Antwerp, Belgium; [13]Medical Oncology, Institut Gustave Roussy, Villejuif, France

Study Design

Tailored **I**mmuno**T**herapy **A**pproach with **N**ivolumab in **RCC** (**TITAN-RCC**)

TITAN

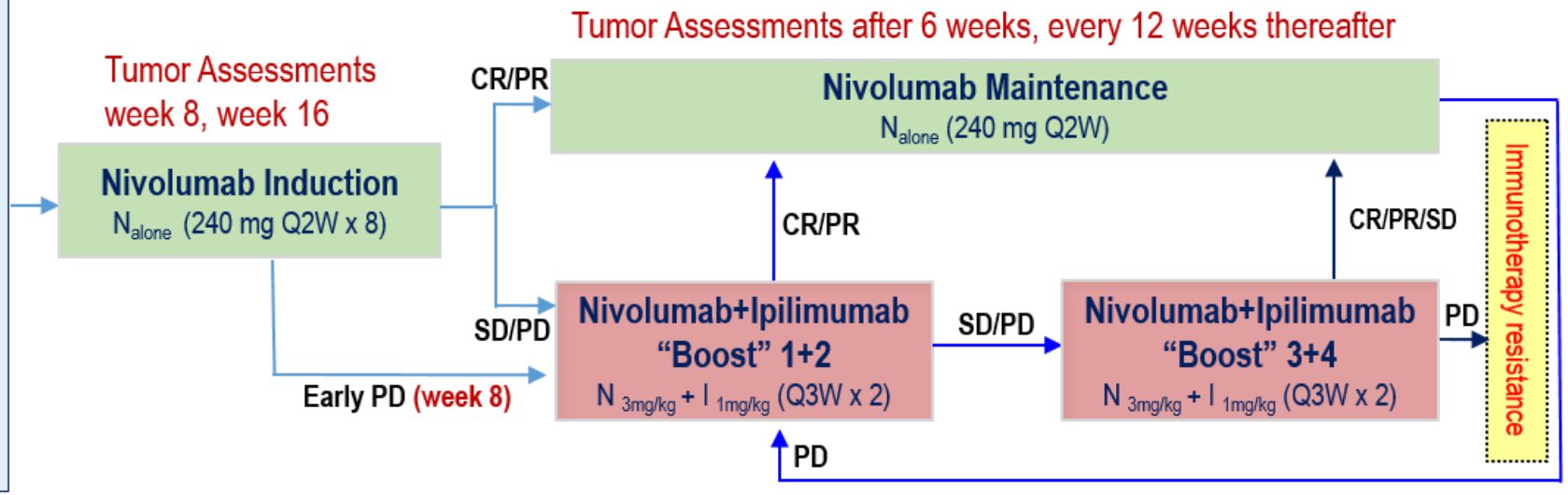
EudraCT number: 2016-002307-26

n=200

Key Inclusion Criteria

- Metastatic/locally advanced RCC, histologically confirmed
- Clear cell component
- Intermediate/high risk by IMDC
- Untreated or pretreated with 1 prior TKI (⇨ 1st or 2nd line*)
- Measurable disease as per RECIST v1.1
- KPS ≥ 70
- Evaluable tumor sample for PD-L1 expression (Dako PD-L1 IHC 28-8 pharmDx antibody, central lab)

* Independent cohorts



Primary endpoint: Overall Response Rate (ORR)
Secondary endpoints: PFS, OS, RR after Nivo+Ipi "Boosts"
Safety (TRAE), QoL (FKSI-19)

IMDC: International Metastatic Renal Cell Carcinoma Database Consortium
(Heng DY, *et al*. Lancet Oncol 2013; 14:141-8)

Results

	1L (n=108)		2L (n=99)		Total (n=207)	
	N_{alone} #	N ± N+I †	N_{alone} #	N ± N+I †	N_{alone} #	N ± N+I †
ORR (BOR), n (%)	31 (**28.7**)	40 (**37.0**)	18 (**18.2**)	28 (**28.3**)	49 (**22.7**)	68 (**32.9**)
Complete response, n (%)	2 (**1.9**)	2 (**1.9**)	**0**	4 (**4.0**)	2 (**1.0**)	6 (**2.9**)
Partial response, n (%)	29 (**26.9**)	38 (**35.2**)	18 (**18.2**)	24 (**24.2**)	47 (**22.7**)	62 (**30.0**)
Stable disease, n (%)	26 (**24.1**)	26 (24.1)	23 (**23.2**)	25 (**25.3**)	49 (**23.7**)	51 (**24.6**)
Progressive disease, n (%)	13 (**12.0**)	38 (**35.2**)	16 (**16.2**)	43 (**43.4**)	29 (**14.0**)	81 (**39.6**)
Early Progressive disease / 'Boost' Week 8, n (%)	22 (**20.4**)		26 (**26.3**)		48 (**23.2**)	
Not evaluable *, n (%)	16 (**14.8**)	4 (**3.7**)	16 (**16.2**)	3 (**3.0**)	32 (**15.5**)	7 (**3.4**)

- 64.3% of all patients (133/207) received at least one ‚boost' cycle

* i.e. including patients with early end of study, e.g. due to death or due to treatment-related adverse event (TRAE);
# Confirmed overall assessment at week 16; † BOR, Best Overall Response

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Phase 2 study of lenvatinib plus pembrolizumab for disease progression after PD-1/PD-L1 immune checkpoint inhibitor in metastatic clear cell renal cell carcinoma (mccRCC): results of an interim analysis

Chung-Han Lee[1], Amishi Y. Shah[2], Vicky Makker[1], Matthew Taylor[3], David Shaffer[4], James J. Hsieh[5], Allen L. Cohn[6], Chris DiSimone[7], Alvaro Pinto Marin[8], Drew Rasco[9], Sara Gunnestad Ribe[10], Donald A. Richards[11], Daniel E. Stepan*, Corina E. Dutcus[12], Jane Wu[12], Emmett V. Schmidt[13], Rodolfo Perini[13], Robert Motzer[1]

*[1]Memorial Sloan Kettering Cancer Center, New York, NY, USA; [2]MD Anderson Cancer Center, University of Texas, Houston, TX, USA; [3]Oregon Health and Science University; Portland, OR, USA; [4]New York Oncology Hematology, Albany, NY, USA; [5]Washington University School of Medicine, St. Louis, MO, USA; [6]Rocky Mountain Cancer Center, Denver, CO, USA; [7]Arizona Oncology Associates, Tucson, AZ, USA; [8]Hospital Universitario La Paz, Madrid, Spain; [9]South Texas Accelerated Research Therapeutics, San Antonio, TX, USA; [10]Sorlandet Hospital, Kristiansand, Norway; [11]Texas Oncology, US Oncology Research, Tyler, TX, USA; [12]Eisai Inc., Woodcliff Lake, NJ, USA; [13]Merck & Co. Inc., Kenilworth, NJ, USA. *Formerly of Eisai Inc.*

Study Design & Methods

Study Design for the Phase 2 RCC Cohort

Key Inclusion Criteria

- mcc RCC
- Measurable disease per irRECIST
- ≤ 2 Prior systemic therapies
- ECOG performance status of 0 or 1
- Life expectancy ≥ 12 weeks

Study Treatment

Lenvatinib
20 mg/day PO
+
Pembrolizumab
200 mg/3 weeks IV

Primary End Point[a]

- Objective response rate as of Week 24

Key Secondary End Points

- Objective response rate
- Progression-free survival
- Duration of response
- Safety and tolerability

- This per-protocol interim analysis of the phase 2 portion of a multicenter, open-label, phase 1b/2 study (NCT02501096) included patients from the RCC cohort (N=33) who had demonstrated disease progression after prior anti-PD-1/PD-L1 therapy

[a]Per irRECIST, by investigator assessment.
ECOG, Eastern Cooperative Oncology Group; irRECIST, immune-related Response Evaluation Criteria In Solid Tumors; IV, intravenously; mcc RCC, metastatic clear cell renal cell carcinoma; PD-1, programmed death receptor-1; PD-L1, programmed death-ligand 1; PO, by mouth; RCC, renal cell carcinoma.

Summary of Tumor Response per Investigator Assessment (Full Analysis Set)

Parameter	irRECIST [a] (N = 33)
BOR, n (%)	
PR	21 (64)
SD	10 (30)
NE	2 (6)

Parameter	irRECIST [a] (N = 33)
ORR,[b] n (%), [95% CI]	21 (64) [45–80]
$ORR_{Week\ 24}$,[b,c] n (%), [95% CI]	20 (61) [42–77]
DOR, months	
Median (95% CI)	9.1 (6.1–NE)
TTR among responders, months	
Median, range	1.6 (1.1–14.0)

[a]Data were identical per RECIST v1.1 which allowed up to 10 target lesions to be selected (up to 5 per organ).
[b]The proportion of CR + PR; Responses were confirmed ≥ 4 weeks after initial response.
[c]Summarizes all tumor assessments up to week 24 provided the patients did not start a new anticancer therapy.
BOR, best overall response; CI, confidence interval; CR + PR, complete response + partial response; DOR, duration of response; irRECIST, immune-related Response Evaluation Criteria In Solid Tumors; NE, not evaluable; ORR, objective response rate; PR, partial response; RECIST v1.1, Response Evaluation Criteria In Solid Tumors version 1.1; SD, stable disease; TTR, time to response.

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EV-103: Initial results of enfortumab vedotin plus pembrolizumab for locally advanced or metastatic urothelial carcinoma

Christopher J Hoimes[1], Jonathan E. Rosenberg[2], Sandy Srinivas[3], Daniel P. Petrylak[4], Matthew I Milowsky[5], Jamie R. Merchan[6], Mehmet A. Bilen[7], Shilpa Gupta[8], Anne-Sophie Carret[9], Nancy Yuan[9], Amal Melhem-Bertrandt[10], Thomas W. Flaig[11]

[1]Case Western Reserve University/University Hospitals Seidman Center, Cleveland, OH; [2]Memorial Sloan Kettering Cancer Center and Weill Cornell Medical College, New York, NY; [3]Stanford University Medical Center, Stanford, CA; [4]Yale Cancer Center, New Haven, CT; [5]University of North Carolina, Lineberger Comprehensive Cancer Center, Chapel Hill, NC; [6]University of Miami, Miami, FL; [7]Winship Cancer Institute of Emory University, Atlanta, GA; [8]University of Minnesota Masonic Cancer Center, Minneapolis, MN; [9]Seattle Genetics, Inc., Bothell, WA; [10]Astellas Pharma, Inc., Northbrook, IL; [11]University of Colorado Comprehensive Cancer Center, Aurora, CO

Study Design

ENFORTUMAB VEDOTIN + PEMBROLIZUMAB COHORTS

EV 1.25 mg/kg + pembrolizumab (200 mg) in 1L la/mUC patients

Patient Population

Locally Advanced or Metastatic Urothelial Cancer (la/mUC)

Dose Escalation[1]
EV 1.25 mg/kg + pembro

cis-ineligible 1L

(n=5)

Dose Expansion Cohort A
EV + pembro

cis-ineligible 1L

(n=40)

Dosing: EV days 1 and 8 of 3-wk cycle to align with pembro (day 1 of 3-wk cycle)

EV exposure: Comparable to EV monotherapy on 4-wk schedule (EV Days 1, 8, and 15)[2]

Primary endpoints: AEs, lab abnormalities

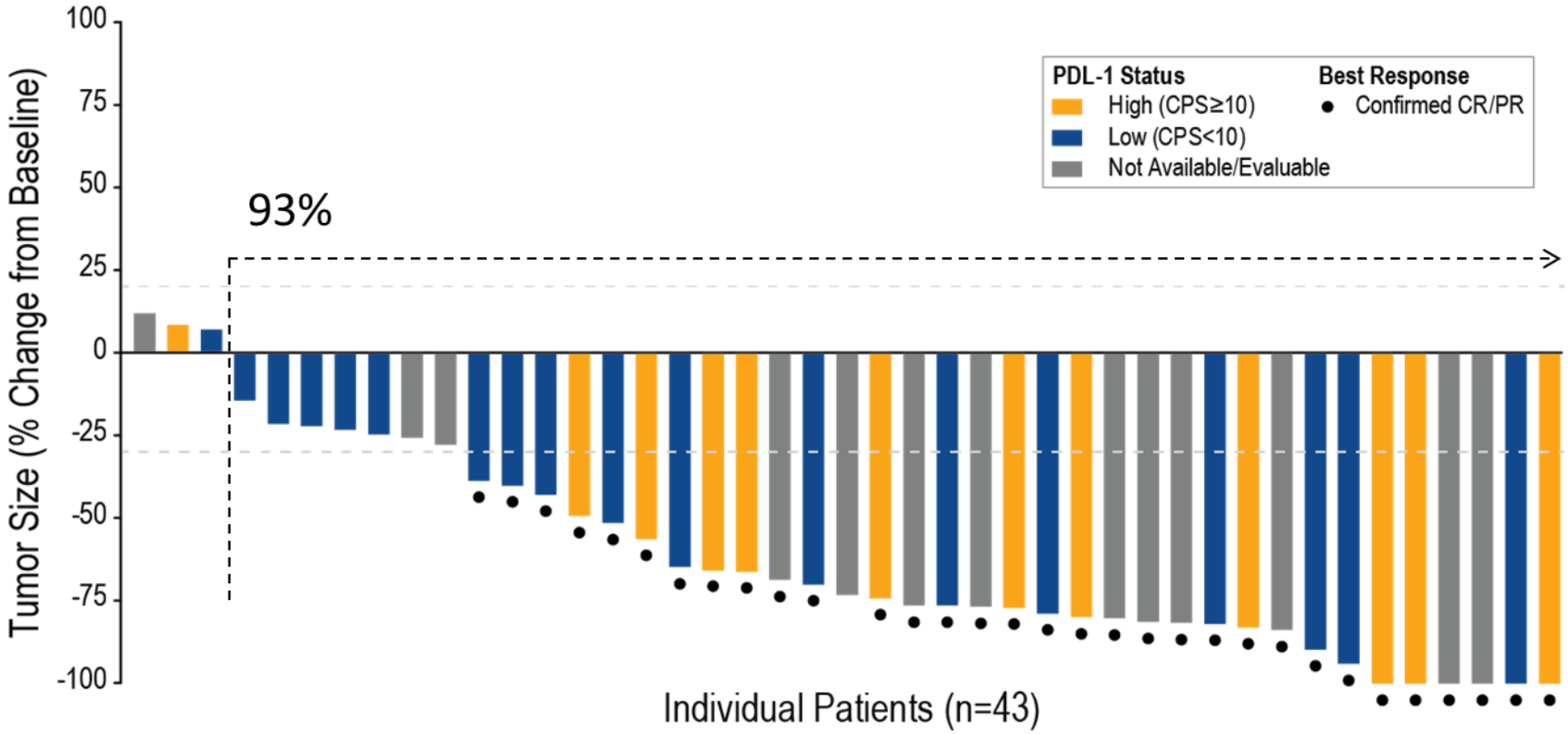
Key secondary endpoints: DLTs, ORR, DCR, DOR, OS

[1] Not included in the current analysis: three 1L patients treated with EV 1 mg/kg + pembro 200 mg and two 2L patients treated with EV 1.25 mg/kg + pembro 200 mg

[2] Rosenberg et al. *J Clin Oncol. Epub July* 2019

Results

MAXIMUM PERCENT REDUCTION FROM BASELINE IN SUM OF DIAMETERS OF TARGET LESIONS PER INVESTIGATOR



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IMvigor130: a phase III study of atezolizumab with or without platinum-based chemotherapy in previously untreated metastatic urothelial carcinoma

Enrique Grande,[1] Matthew D Galsky,[2] José Ángel Arranz Arija,[3] Maria De Santis,[4] Ian D Davis,[5] Ugo De Giorgi,[6] Marina Mencinger,[7] Eiji Kikuchi,[8] Xavier García-del-Muro,[9] Mahmut Gumus,[10] Mustafa Özgüroğlu,[11] Arash Rezazadeh Kalebasty,[12] Se Hoon Park,[13] Boris Alekseev,[14] Fabio Augusto Schutz,[15] Jian-Ri Li,[16] Almut Mecke,[17] Sanjeev Mariathasan,[18] AnnChristine Thåström,[18] Aristotelis Bamias[19]

[1]MD Anderson Cancer Center Madrid, Madrid, Spain; [2]Icahn School of Medicine at Mount Sinai/Tisch Cancer Institute, New York, NY, USA; [3]Hospital General Universitario Gregorio Marañón, Madrid, Spain; [4]Charité University Hospital, Berlin, Germany, and Department of Urology, Medical University, Vienna, Austria; [5]Eastern Health/Monash University, Melbourne, Australia; [6]Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori (IRST), IRCCS, Meldola, Italy; [7]Institute of Oncology Ljubljana, Ljubljana, Slovenia; [8]Keio University, Tokyo, Japan; [9]Catalan Institute of Oncology, IDIBELL, University of Barcelona, Barcelona, Spain; [10]Istanbul Medeniyet University, Goztepe Research Hospital, Istanbul, Turkey; [11]Istanbul University-Cerrahpaşa, Cerrahpasa School of Medicine, Istanbul, Turkey; [12]Norton Cancer Institute, Louisville, KY, USA; [13]Sungkyunkwan University Samsung Medical Center, Seoul, Korea; [14]P. Herzen Oncology Research Institute, Moscow, Russia; [15] Beneficência Portuguesa de São Paulo, São Paulo, Brazil; [16]Taichung Veterans General Hospital/Hungkuang University, Taichung, Taiwan; [17]F. Hoffmann-La Roche Ltd, Basel, Switzerland; [18]Genentech, Inc., South San Francisco, CA, USA; [19]National and Kapodistrian University of Athens, Athens, Greece

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Study Design

- Locally advanced or mUC
- No prior systemic therapy in the metastatic setting
- ECOG PS ≤ 2
- 1L platinum-eligible
- N = 1200
- Randomised 1:1:1

→ **Arm A**
Atezo + plt/gem

→ **Arm B**
Atezo monotherapy[a]

→ **Arm C**
Placebo + plt/gem

Stratification factors:
- PD-L1 IC status (IC0 vs IC1 vs IC2/3)
- Bajorin risk factor score including KPS < 80% vs ≥ 80% and presence of visceral metastases (0 vs 1 vs 2 ± patients with liver metastases)
- Investigator choice of plt/gem (gem + carbo or gem + cis)

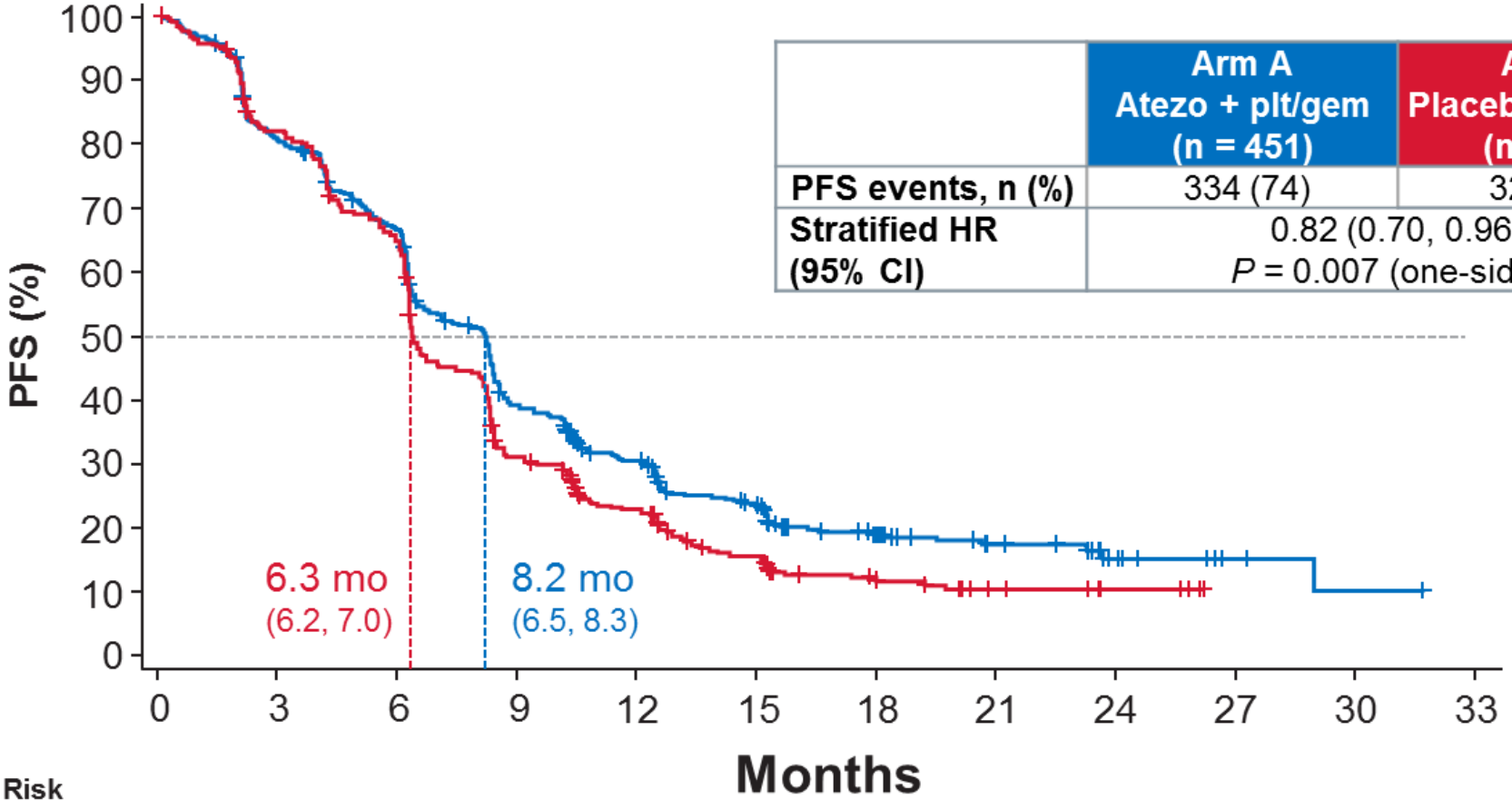
Co-primary endpoints:
- INV-assessed PFS[b] and OS (Arm A vs C)
- OS (Arm B vs C, hierarchical approach)

Key secondary endpoints:
- INV-ORR[b] and DOR
- PFS[b] and OS (Arm B vs C; PD-L1 IC2/3 subgroup)
- Safety

[a] The first 129 patients were randomized 2:1 to Arm A and Arm C per initial study design; Arm B enrolled later. PD-L1 status was unblinded in the final protocol amendment per IMDC recommendation, such that IC0/1 patients received atezo + plt/gem and IC2/3 patients received atezo monotherapy (n = 6).

[b] per RECIST 1.1.

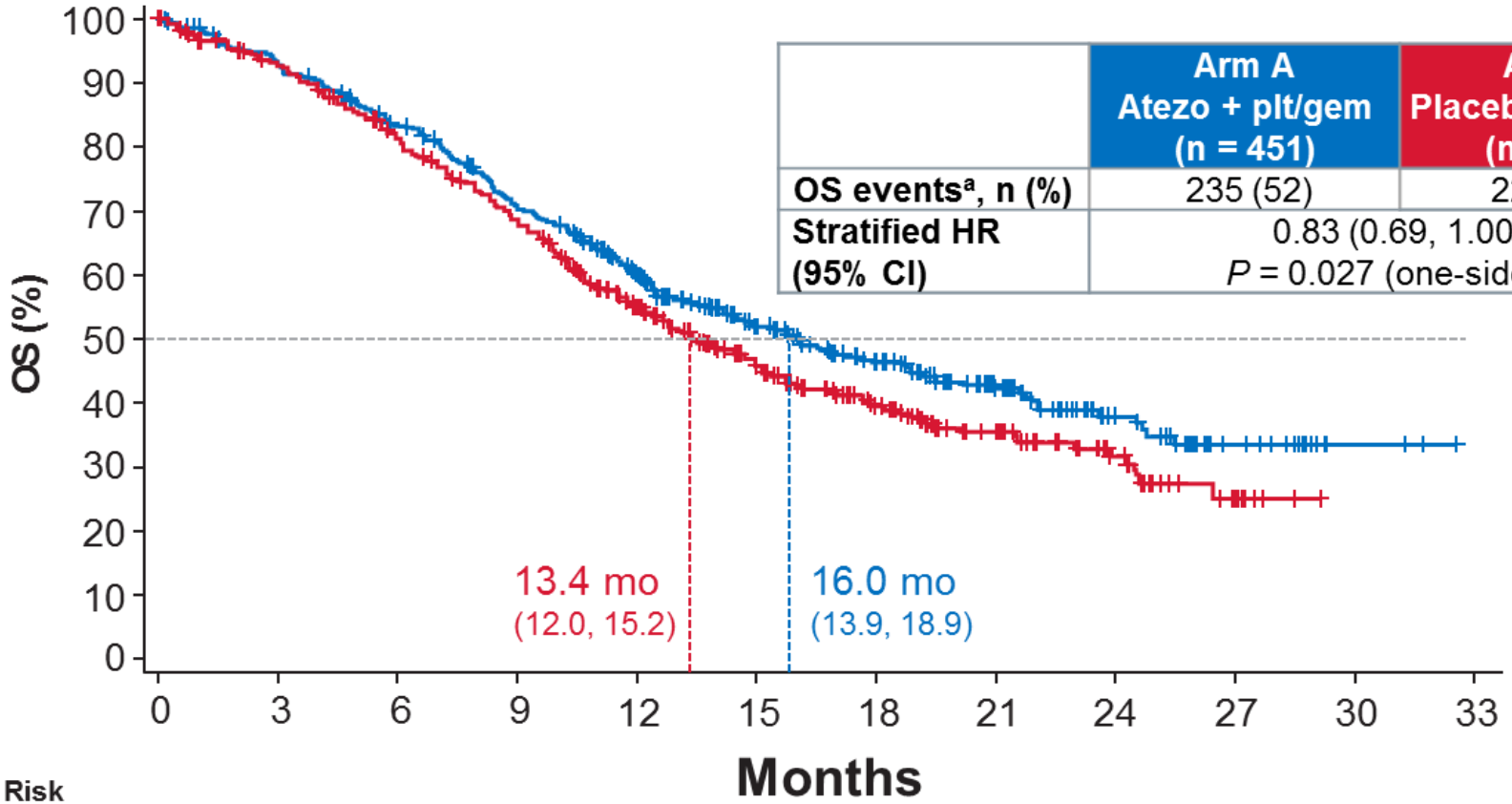
Results – Final PFS: ITT (Arm A vs C)



	Arm A Atezo + plt/gem (n = 451)	Arm C Placebo + plt/gem (n = 400)
PFS events, n (%)	334 (74)	326 (82)
Stratified HR (95% CI)	0.82 (0.70, 0.96) *P* = 0.007 (one-sided)	

NE, not estimable. Data cutoff 31 May 2019; median follow-up 11.8 months.

Results – Interim OS: ITT



	Arm A Atezo + plt/gem (n = 451)	Arm C Placebo + plt/gem (n = 400)
OS events[a], n (%)	235 (52)	228 (57)
Stratified HR (95% CI)	0.83 (0.69, 1.00) *P* = 0.027 (one-sided)[b]	

No. at Risk												
Atezo + plt/gem	451	408	360	301	229	163	117	72	36	16	3	NE
Placebo + plt/gem	400	359	308	255	182	123	79	49	25	8	NE	NE

Data cutoff 31 May 2019; median follow-up 11.8 months. [a] 5% of patents from Arm A and 20% of patients from Arm C crossed over to non-protocol immunotherapy.
[b] Did not cross the interim efficacy boundary of 0.007 per the O'Brien-Fleming method.

Melanoma

SITC-0319-285

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5-year survival outcomes of the CheckMate 067 phase 3 trial of nivolumab plus ipilimumab (NIVO+IPI) combination therapy in advanced melanoma

James Larkin,[1] Vanna Chiarion-Sileni,[2] Rene Gonzalez,[3] Jean-Jacques Grob,[4] Piotr Rutkowski,[5] Christopher D. Lao,[6] C. Lance Cowey,[7] Dirk Schadendorf,[8] John Wagstaff,[9] Reinhard Dummer,[10] Pier F. Ferrucci,[11] Michael Smylie,[12] David Hogg,[13] Andrew Hill,[14] Ivan Márquez-Rodas,[15] John Haanen,[16] Jasmine I. Rizzo,[17] Agnes Balogh,[17] Andriy Moshyk,[17] F. Stephen Hodi,[18*] Jedd Wolchok[19*]

[1]The Royal Marsden NHS Foundation Trust, London, UK; [2]Oncology Institute of Veneto IRCCS, Padua, Italy; [3]University of Colorado Cancer Center, Aurora, CO, USA; [4]Aix-Marseille University, APHM Hospital, Marseille, France; [5]Maria Sklodowska-Curie Institute - Oncology Center, Warsaw, Poland; [6]University of Michigan, Ann Arbor, MI, USA; [7]Texas Oncology-Baylor Charles A. Sammons Cancer Center, Dallas, TX, USA; [8]Department of Dermatology, University of Essen, Essen, Germany; & German Cancer Consortium, Heidelberg, Germany; [9]The College of Medicine, Swansea University, Swansea, UK; [10]Universitäts Spital, Zurich, Switzerland; [11]European Institute of Oncology, Milan, Italy; [12]Cross Cancer Institute, Alberta, Canada; [13]Princess Margaret Cancer Centre, Toronto, ON, Canada; [14]Tasman Oncology Research, QLD, Australia; [15]General University Hospital Gregorio Marañon, Madrid, Spain; [16]The Netherlands Cancer Institute, Amsterdam, The Netherlands; [17]Bristol-Myers Squibb, Princeton, NJ; USA, [18]Dana-Farber Cancer Institute, Boston, MA; USA, [19]Memorial Sloan Kettering Cancer Center and Weill Cornell Medical College, New York, NY, USA

*Contributed equally.

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CheckMate 067: Study Design

5-year follow up of a randomized, double-blind, phase 3 study to compare NIVO+IPI or NIVO alone with IPI alone[a]

Unresectable or metatastic melanoma
- **Previously untreated**
- **945 patients**

R 1:1:1

Stratify by:
- ***BRAF* status**
- **AJCC M stage**
- **Tumor PD-L1 expression < 5% versus ≥ 5%**

n = 314 → **NIVO 1 mg/kg + IPI 3 mg/kg Q3W for 4 doses then NIVO 3 mg/kg Q2W**

n = 316 → **NIVO 3 mg/kg Q2W + IPI-matched placebo**

n = 315 → **IPI 3 mg/kg Q3W for 4 doses + NIVO-matched placebo**

Treat until progression or unacceptable toxicity

Co-primary endpoints[a] were PFS and OS in the NIVO-containing arms versus IPI alone

Database lock: July 2, 2019; minimum follow-up of 60 months for all patients

NCT01844505

[a]The study was not powered for a comparison between NIVO+IPI and NIVO.AJCC, American Joint Committee on Cancer.

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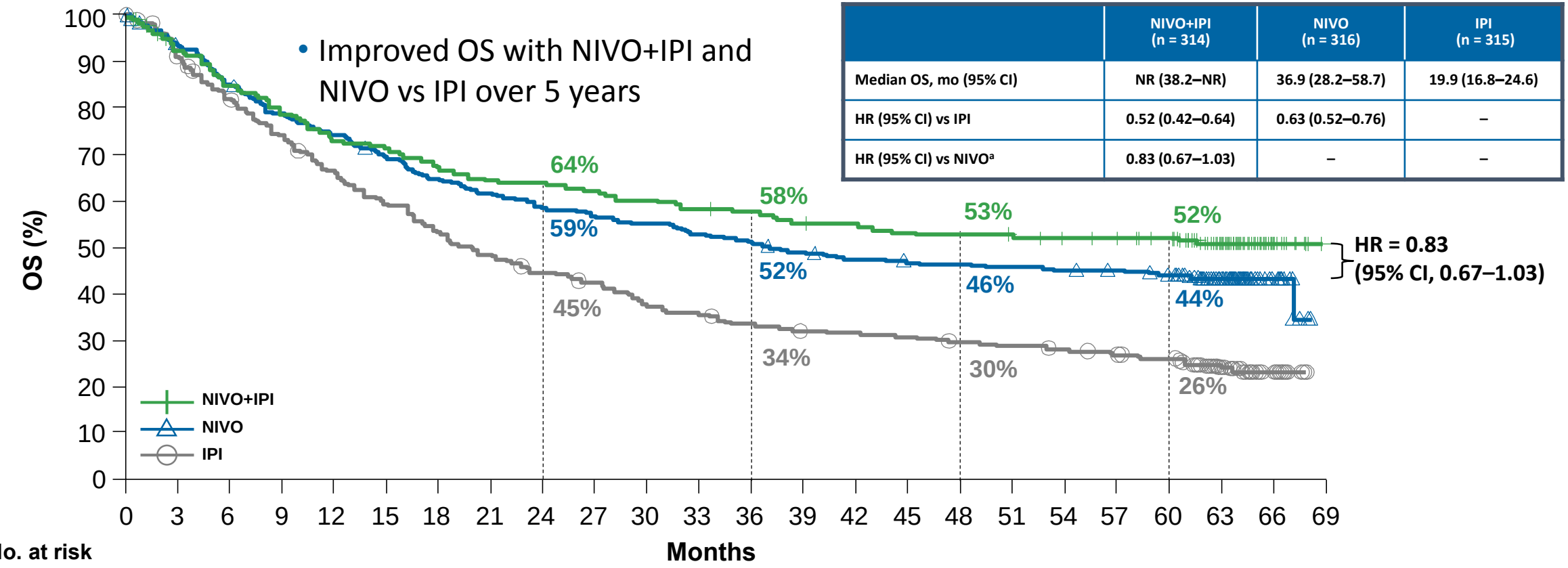
Overall Survival

- Improved OS with NIVO+IPI and NIVO vs IPI over 5 years

	NIVO+IPI (n = 314)	NIVO (n = 316)	IPI (n = 315)
Median OS, mo (95% CI)	NR (38.2–NR)	36.9 (28.2–58.7)	19.9 (16.8–24.6)
HR (95% CI) vs IPI	0.52 (0.42–0.64)	0.63 (0.52–0.76)	–
HR (95% CI) vs NIVO[a]	0.83 (0.67–1.03)	–	–



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

[a]Descriptive analysis. 1. Larkin J, et al. Oral presentation at the AACR Annual Meeting; April 1–5, 2017; Washington DC, USA. Abstract CT075; 2. Wolchok JD, et al. *N Engl J Med* 2017;377:1345–1356; 2. Hodi FS, et al. *Lancet Oncol* 2018;19:1480–1492.

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Primary 2-year (yr) results of a phase 2, multicenter, randomized, open-label trial of efficacy and safety for talimogene laherparepvec (T-VEC) neoadjuvant (neo) treatment (tx) plus surgery (surg) vs surg in patients (pts) with resectable stage IIIB-IVM1a melanoma

Reinhard Dummer,[1] David E Gyorki,[2] John Hyngstrom,[3] Adam Berger,[4] Robert Conry,[5] Lev Demidov,[6] Anjali Sharma,[7] Sheryl A Treichel,[7] Kevin Gorski,[8] Abraham Anderson,[7] Mark Faries,[9] Merrick I Ross[10]

[1]University Hospital of Zurich, Zurich, Switzerland; [2]Olivia Newton-John Cancer Centre, Austin Health, Melbourne, Australia; [3]University of Utah Huntsman Cancer Institute, Salt Lake City, UT; [4]Thomas Jefferson University Hospitals, Philadelphia, PA; [5]University of Alabama School of Medicine, Birmingham, AL; [6]N.N. Blokhin Russian Cancer Research Center, Moscow, Russia; [7]Amgen Inc., Thousand Oaks, CA; [8]Amgen Inc., San Francisco, CA; [9]John Wayne Cancer Institute, Santa Monica, CA; [10]University of Texas MD Anderson Cancer Center, Houston, TX

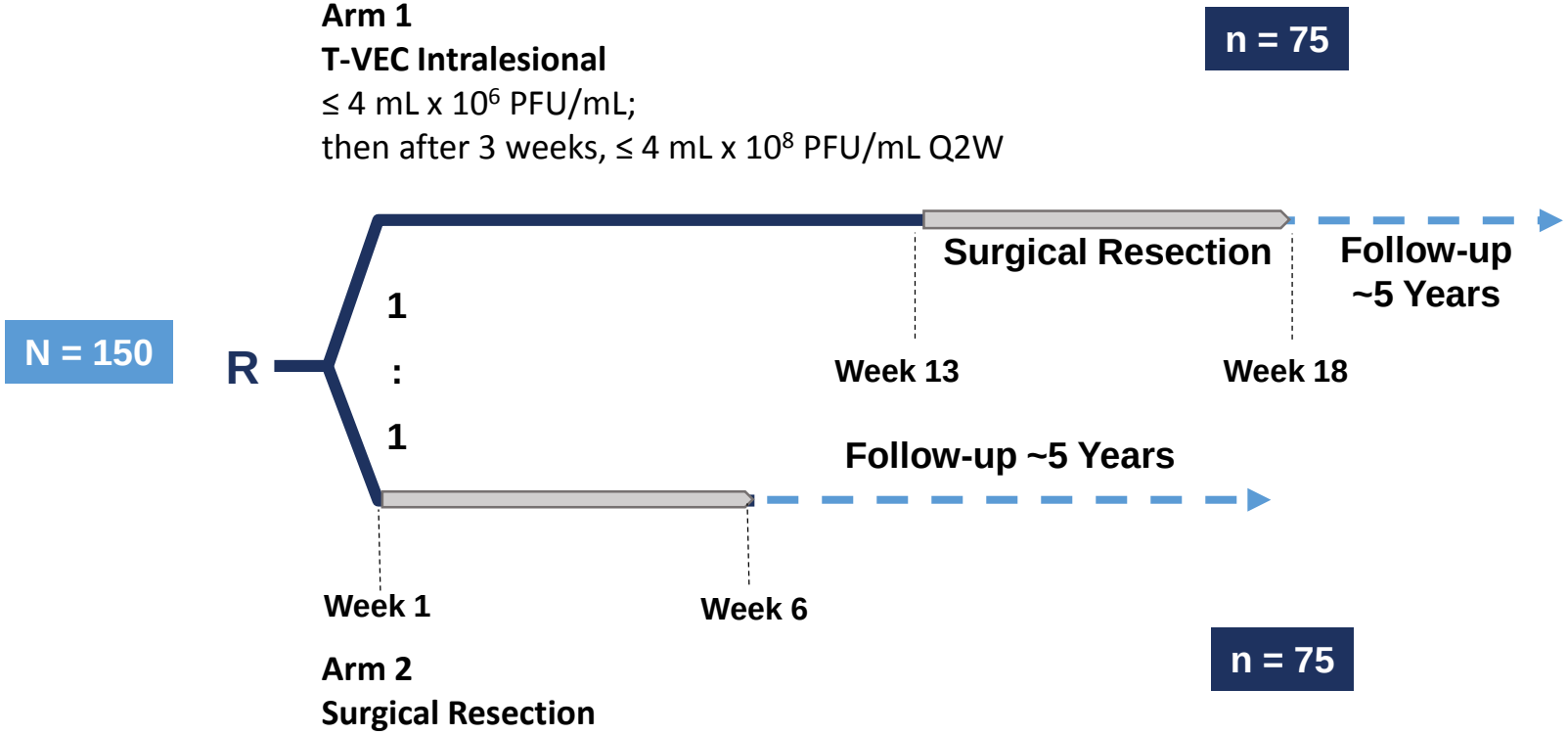
Methods#

Resectable Stage IIIB–IVM1a[6] Melanoma

- Injectable and measurable
- LDH ≤ 1.5 x ULN for IIIB/C and ≤ 1 x ULN for IVM1a
- ECOG PS 0 or 1
- Prior treatment completed ≥ 3 months prior

Stratification:

- Disease stage
- Planned adjuvant therapy

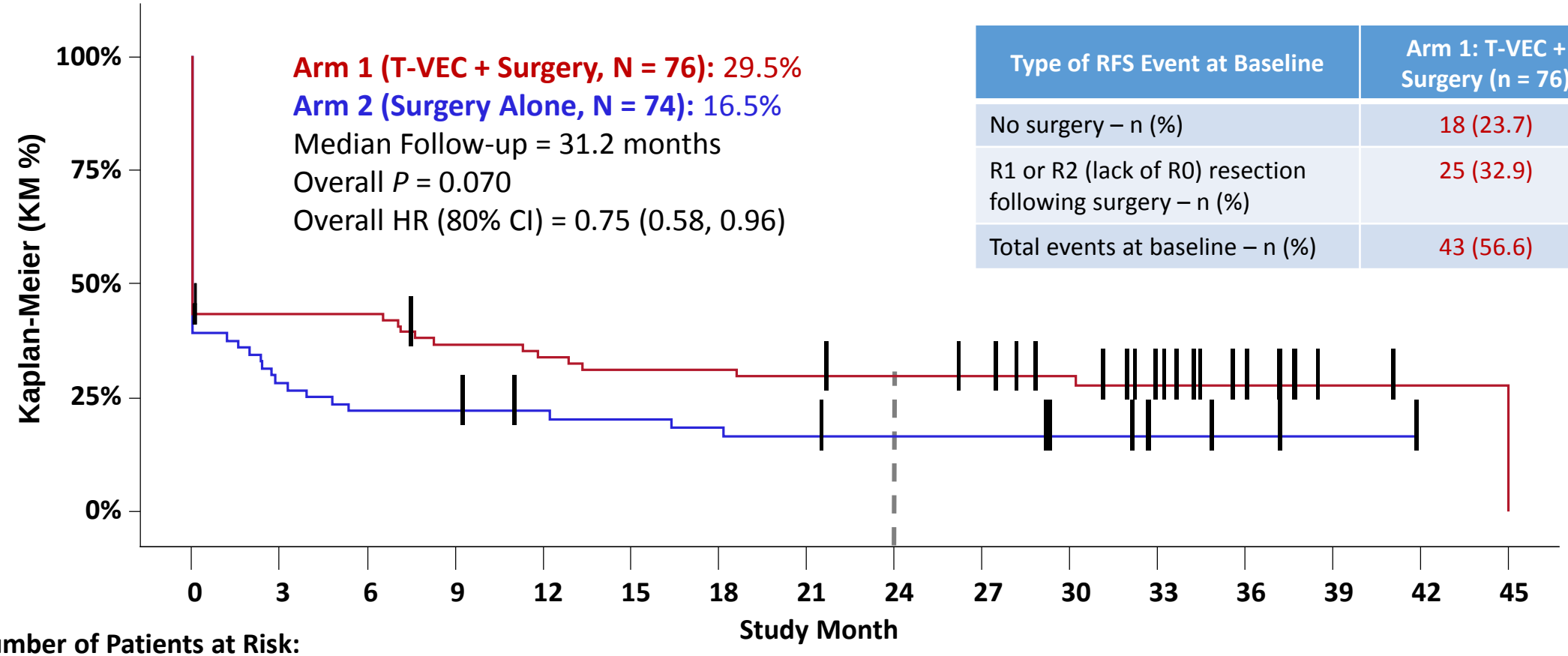


Primary Endpoint:	RFS
Key Secondary Endpoints:	RFS,* overall survival (OS),* overall tumor response (in Arm 1 only), pathological complete response (in Arm 1 only), rates of histopathological tumor-free (R0) surgical resection, local RFS, regional RFS, distant metastases-free survival, safety
Exploratory Endpoints:	Analyses of tumor tissue biomarkers and correlations with clinical outcomes for T-VEC

*RFS and OS at 2 years, 3 years, and 5 years.
LDH, lactate dehydrogenase; ULN, upper limit of normal; PFU, plaque forming units.
#Dummer R, et al. Presented at: ASCO 2019; Chicago, IL. Abstract 9520. **7.** AJCC Cancer Staging Manual, 7th Edition. 2015.

NCT02211131

2-Year RFS (Per Protocol)



Type of RFS Event at Baseline	Arm 1: T-VEC + Surgery (n = 76)	Arm 2: Surgery Alone (n = 74)
No surgery – n (%)	18 (23.7)	4 (5.4)
R1 or R2 (lack of R0) resection following surgery – n (%)	25 (32.9)	41 (55.4)
Total events at baseline – n (%)	43 (56.6)	45 (60.8)

ITT Analysis Set: 150 patients enrolled and randomized

Number of Patients at Risk:

Surgery Alone	74	18	14	14	12	11	10	9	8	8	6	4	2	1	0
T-VEC + Surgery	76	32	32	26	24	22	22	21	20	19	16	11	5	2	1	0

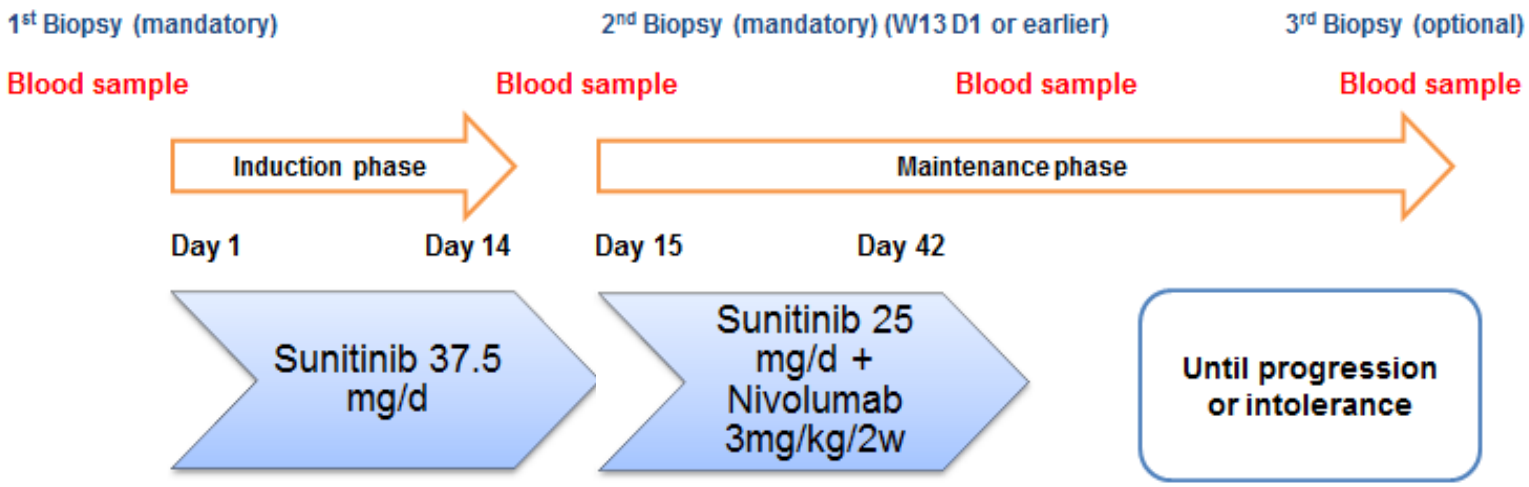
Sarcoma

IMMUNOSARC: A collaborative Spanish (GEIS) and Italian (ISG) sarcoma groups phase I/II trial of sunitinib plus nivolumab in advanced soft tissue and bone sarcomas: Results of the phase II-soft-tissue sarcoma cohort

J. Martin Broto[1,2], N. Hindi[1,2], G. Grignani[3], J. Martinez Trufero[4], A. Redondo[5], C. Valverde[6], A. Lopez Pousa[7], S. Stacchiotti[8], E. Palmerini[9], E. De Alava[1], D. Moura[2], H. Perez Vega[1], P. Collini[8], I. Otero[10], P. Ledesma[11], E. Marchesi[12], L. D'Ambrosio[3], J.A. Lopez Martin[10]

[1]HU Virgen del Rocio, Sevilla, ES, [2] Instituto de Biomedicina de Sevilla, Sevilla, ES, [3] Istituto di Candiolo - FPO - IRCCS, Candiolo, IT, [4] HU Miguel Servet, Zaragoza, ES, [5] HU La Paz, Madrid, ES, [6] Vall d'Hebron University Hospital, Barcelona, ES, [7] Hospital de la Santa Creu i Sant Pau, Barcelona, ES, [8] Istituto Nazionale dei Tumori di Milano - Fondazione IRCCS, Milan, IT, [9] IRCCS Istituto Ortopedico Rizzoli, Bologna, IT, IT, [10] HU Doce de Octubre, Madrid, ES, [11] Sofpromed, [12] Italian Sarcoma Group, Bologna, IT

Design



NCT03277924

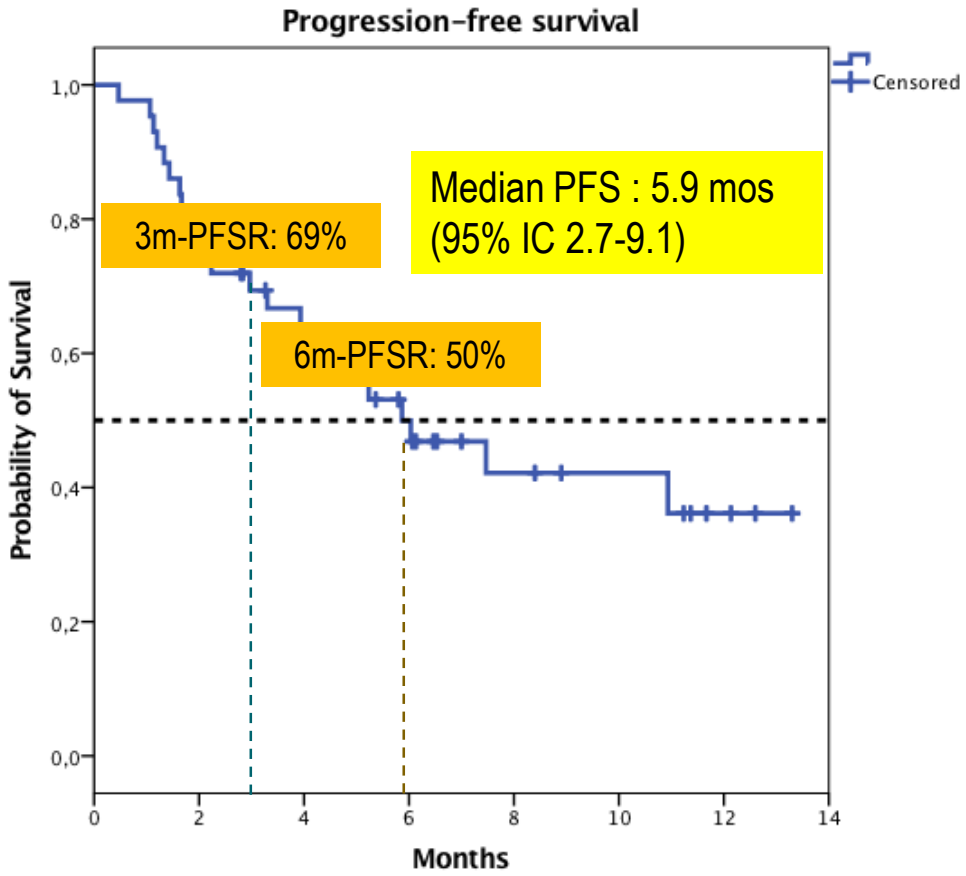
PRIMARY END-POINT:

- Progression-free survival rate (PFSR) at 6 months (RECIST)
- H0: 5%, H1: 15%, α error: 0.05, ß: 0.1.

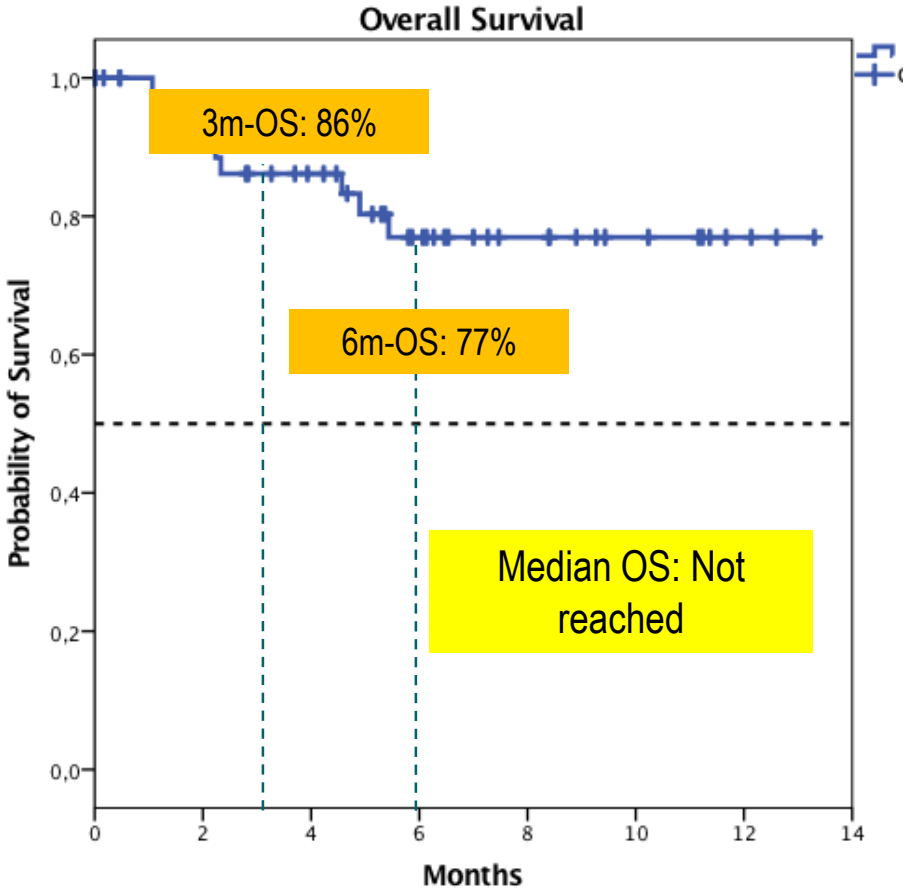
SECONDARY END-POINTS:

- Overall survival (OS)
- Overall response rate (ORR) by RECIST and CHOI
- Toxicity
- Translational research

Results



Number at risk 43 31 23 16 9 7 3 0



Number at risk 50 41 32 21 13 8 3 0

Hepatocellular carcinoma

SITC-0319-285

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CheckMate 459: A Randomized, Multi-Center Phase 3 Study of Nivolumab (NIVO) vs Sorafenib (SOR) as First-Line (1L) Treatment in Patients (pts) With Advanced Hepatocellular Carcinoma (aHCC)

Thomas Yau,[1] Joong-Won Park,[2] Richard S. Finn,[3] Ann-Lii Cheng,[4] Philippe Mathurin,[5] Julien Edeline,[6] Masatoshi Kudo,[7] Kwang-Hyub Han,[8] James J. Harding,[9] Philippe Merle,[10] Oliver Rosmorduc,[11] Lucjan Wyrwicz,[12] Eckart Schott,[13] Su Pin Choo,[14] Robin Kate Kelley,[15] Damir Begic,[16] Gong Chen,[16] Jaclyn Neely,[16] Jeffrey Anderson,[16] Bruno Sangro[17]

[1]University of Hong Kong, Hong Kong, China; [2]Center for Liver Cancer, National Cancer Center, Goyang, South Korea; [3]Geffen School of Medicine, UCLA, Los Angeles, CA, USA; [4]National Taiwan University Hospital, Taipei, Taiwan; [5]Centre Hospitalo-Universitaire Claude Huriez, Service d'Hépatologie, Lille, France; [6]Medical Oncology, Centre Eugène Marquis, Rennes, France; [7]Kindai University Faculty of Medicine, Osaka, Japan; [8]Severance Hospital, Yonsei University, Seoul, South Korea; [9]Department of Medicine, Memorial Sloan Kettering Cancer Center, New York, NY, USA; [10]Hepatology Unit, Croix-Rousse Hospital, Lyon, France; [11]Assistance Publique Hôpitaux de Paris, Hôpital Pitié-Salpétrière – Université Pierre et Marie Curie, Paris, France; [12]M. Sklodowska-Curie Memorial Cancer Center and Institute of Oncology, Warsaw, Poland; [13]Helios Klinikum Emil von Behring GmbH, Klinik für Innere Medizin II, Berlin, Germany; [14]National Cancer Centre Singapore, Singapore; [15]UCSF Helen Diller Family Comprehensive Cancer Center, San Francisco, CA, USA; [16]Bristol-Myers Squibb, Princeton, NJ, USA; [17]Clinica Universidad de Navarra and CIBEREHD, Pamplona, Spain

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Checkmate 459 Study Design

NCT02576509

Key eligibility criteria
- Histologically confirmed advanced HCC not eligible for surgical and/or LRT; or progressive disease after surgical and/or LRT
- Child-Pugh class A
- ECOG PS 0 or 1
- Systemic therapy naive

Stratification factors
- Etiology (HCV vs non-HCV)
- Vascular invasion and/or extrahepatic spread (present vs absent)
- Geography (Asia vs non-Asia)

R 1:1

N = 743

Nivolumab
240 mg IV Q2W
n = 371

Sorafenib
400 mg po BID
n = 372

Unacceptable toxicity or disease progression

Objectives
- Primary – OS
- Secondary – ORR, PFS, efficacy by PD-L1 status
- Exploratory – HRQoL using FACT-Hep

- **Patient randomization:** January 2016–May 2017
- **Database lock:** June 2019

BID, twice daily; ECOG PS, Eastern Cooperative Oncology Group performance status; FACT-Hep, Functional Assessment of Cancer Therapy - Hepatobiliary Cancer; HCV, hepatitis C virus; HRQoL, health-related quality of life; IV, intravenous; LRT, loco-regional therapy; ORR, objective response rate; PD-L1, programmed death ligand 1; PFS, progression-free survival; po, oral; R, randomization.

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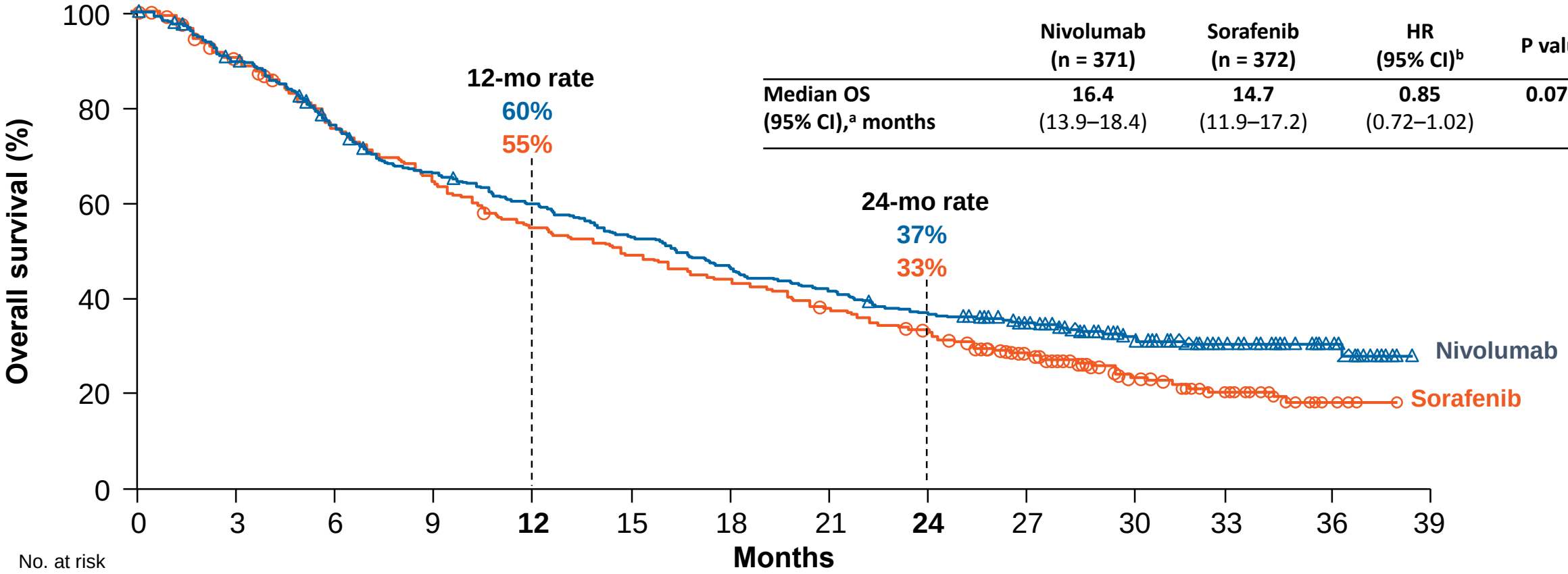
Overall Survival



	Nivolumab (n = 371)	Sorafenib (n = 372)	HR (95% CI)[b]	P value[c]
Median OS (95% CI),[a] months	**16.4** (13.9–18.4)	**14.7** (11.9–17.2)	**0.85** (0.72–1.02)	**0.0752**

No. at risk														
Nivolumab	371	326	271	235	211	187	165	146	129	104	63	39	17	0
Sorafenib	372	328	274	232	196	174	155	133	115	80	47	30	7	0

[a]Based on Kaplan–Meier estimates; [b]Stratified Cox proportional hazards model. HR is nivolumab over sorafenib; [c]*P* value from log-rank test; final OS boundary: 0.0419 for a 2-sided nominal *P* value. HR, hazard ratio.

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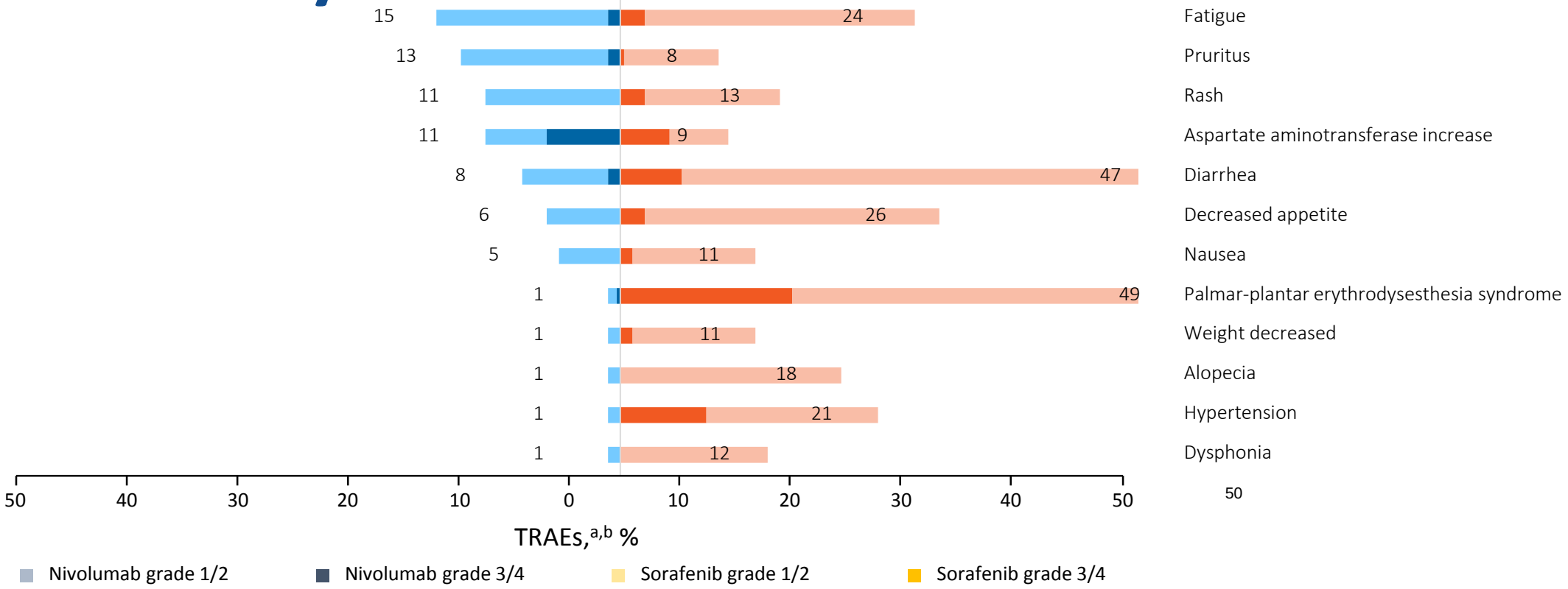
Summary of Treatment-Related Adverse Events



- Nivolumab demonstrated an improved safety profile compared with sorafenib, with fewer grade 3/4 TRAEs and TRAEs leading to discontinuation versus sorafenib
  - Grade 3/4 TRAEs were reported in 81 patients (22%) in the nivolumab arm and 179 patients (49%) in the sorafenib arm

[a]Events occurring in > 10% of patients in either treatment arm. Includes events reported between first dose and 30 days after last dose of study therapy; data labels represent rates of any-grade events; [b]One grade 5 event was reported in the nivolumab arm (cerebrovascular event), and 1 was reported in the sorafenib arm (hepatic failure). TRAE, treatment-related adverse event.

Lung cancer

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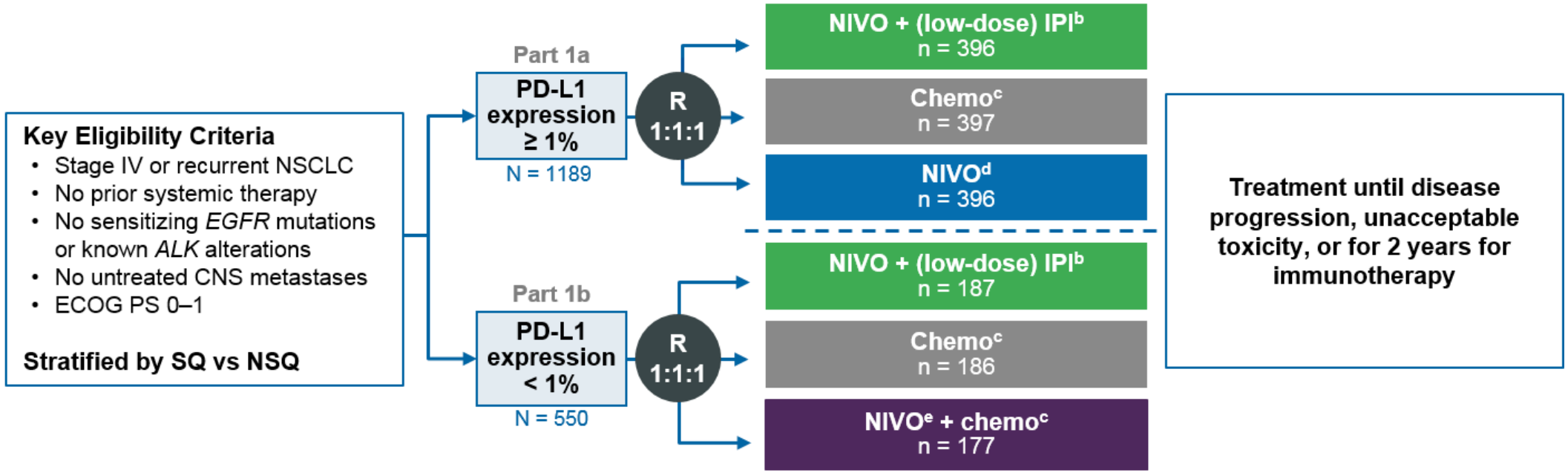
Nivolumab (NIVO) + low-dose ipilimumab (IPI) vs platinum-doublet chemotherapy (chemo) as first-line (1L) treatment (tx) for advanced non-small cell lung cancer (NSCLC): CheckMate 227 Part 1 final analysis

Solange Peters,[1] Suresh Ramalingam,[2] Luis Paz-Ares,[3] Reyes Bernabe Caro,[4] Bogdan Zurawski,[5] Sang-We Kim,[6] Aurelia Alexandru,[7] Lorena Lupinacci,[8] Emmanuel de la Mora Jimenez,[9] Hiroshi Sakai,[10] István Albert,[11] Alain Vergnenegre,[12] Martin Reck,[13] Hossein Borghaei,[14] Julie R. Brahmer,[15] Kenneth O'Byrne,[16] William J. Geese,[17] Prabhu Bhagavatheeswaran,[17] Faith E. Nathan,[17] Matthew D. Hellmann[18]

[1]Centre hospitalier universitaire Vaudois (CHUV), Lausanne University, Lausanne, Switzerland; [2]Winship Cancer Institute, Emory University, Atlanta, GA, USA; [3]Hospital Universitario Doce de Octubre, CNIO, Universidad Complutense & CiberOnc, Madrid, Spain; [4]Hospital Universitario Virgen Del Rocio, Seville, Spain; [5]Ambulatorium Chemioterapii, Bydgoszcz, Poland; [6]Asan Medical Center, Seoul, Republic of Korea; [7]Institute Of Oncology "Prof. Dr. Alexandru Trestioreanu" Bucha, Bucharest, Romania; [8]Hospital Italiano De Buenos Aires, Buenos Aires, Argentina; [9]Instituto Jalisciense De Cancerología, Guadalajara, Jalisco, Mexico; [10]Saitama Cancer Center, Saitama, Japan; [11]Matrai Gyogyintezet, Matrahaza, Hungary; [12]Limoges University Hospital, Limoges, France; [13]Lung Clinic Grosshansdorf, German Center for Lung Research, Grosshansdorf, Germany; [14]Fox Chase Cancer Center, Philadelphia, PA, USA; [15]Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore, MD, USA; [16]Princess Alexandra Hospital, Brisbane, Queensland, Australia;[17]Bristol-Myers Squibb, Princeton, NJ, USA; [18]Memorial Sloan-Kettering Cancer Center, New York, NY, USA

Study Design



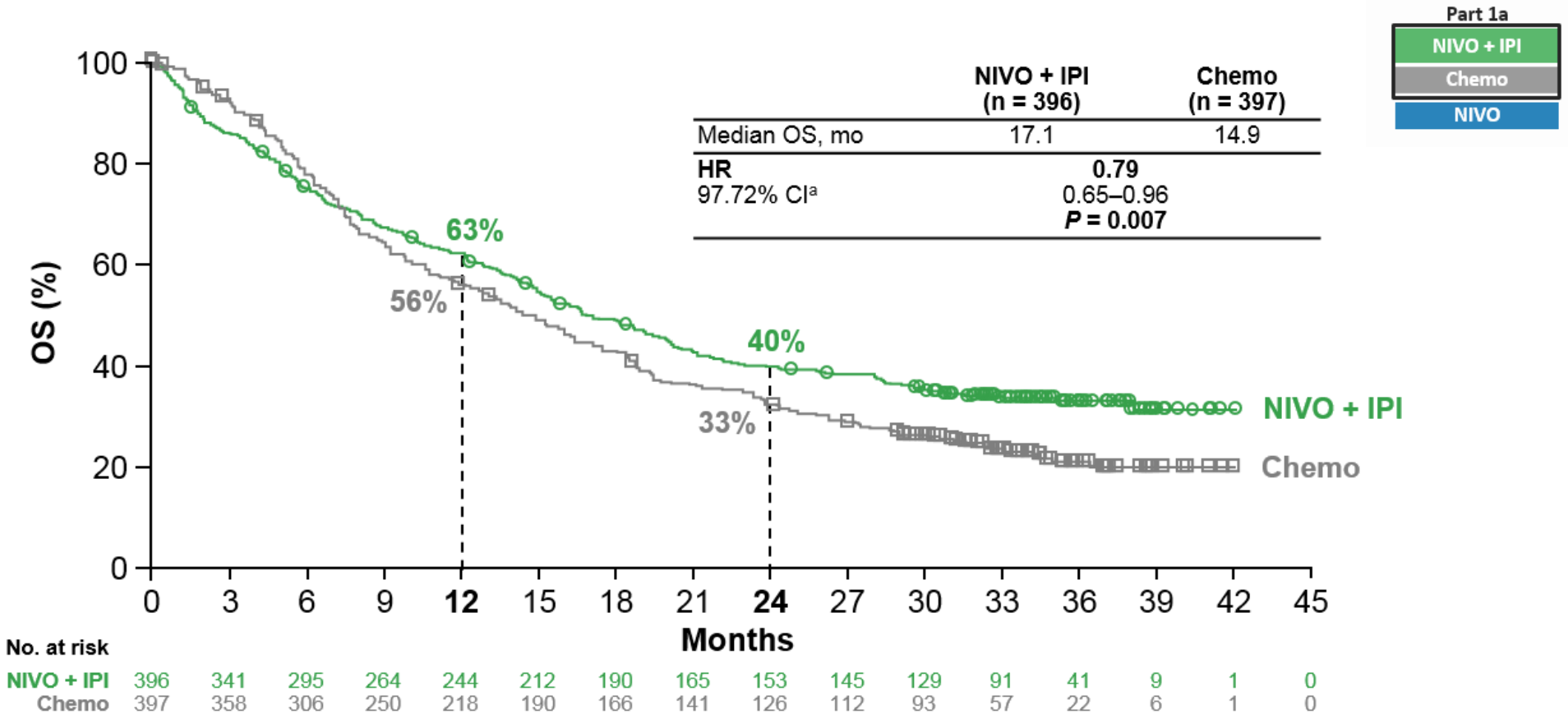
Independent co-primary endpoints: NIVO + IPI vs chemo
- PFS in high TMB (≥10 mut/Mb) population[f]
- OS in PD-L1 ≥ 1% population[g]

Secondary endpoints (PD-L1 hierarchy):
- PFS: **NIVO + chemo vs chemo** in PD-L1 < 1%
- OS: **NIVO + chemo vs chemo** in PD-L1 < 1%
- OS: **NIVO vs chemo** in PD-L1 ≥ 50%

Database lock: July 2, 2019; **minimum follow-up for primary endpoint: 29.3 months**

[a]NCT02477826; [b]NIVO (3 mg/kg Q2W) + IPI (1 mg/kg Q6W); [c]**NSQ:** pemetrexed + cisplatin or carboplatin, Q3W for ≤ 4 cycles, with optional pemetrexed maintenance following chemo or NIVO + pemetrexed maintenance following NIVO + chemo; **SQ:** gemcitabine + cisplatin, or gemcitabine + carboplatin, Q3W for ≤ 4 cycles; [d]NIVO (240 mg Q2W); [e]NIVO (360 mg Q3W); [f]TMB primary endpoint analysis conducted at January 24, 2018 database lock in subset of patients randomized to NIVO + IPI or chemo; alpha allocated was 0.025; [g]Alpha allocated was 0.025 overall (0.023 for final analysis)

Results



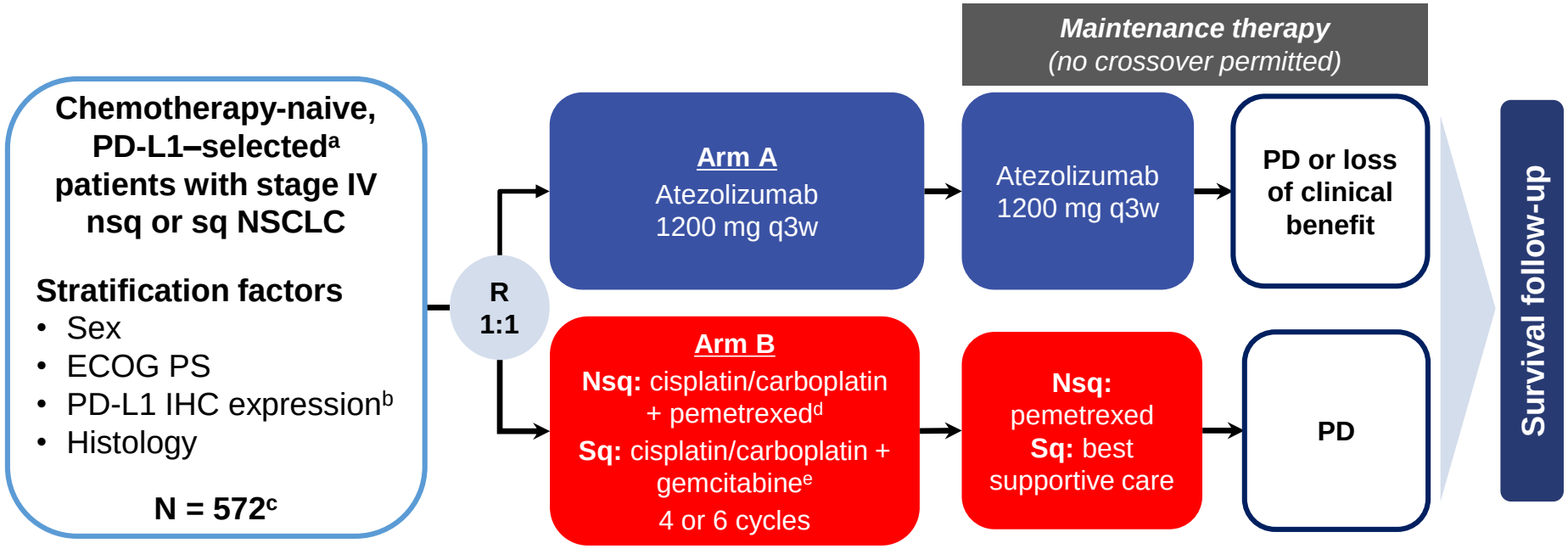
Minimum follow-up for primary endpoint: 29.3 months.
NIVO + IPI dosage was NIVO (3 mg/kg Q2W) + IPI (1 mg/kg Q6W). Subsequent systemic therapy was received by 35% of patients in the NIVO + IPI arm and 54% of patients in the chemo arm; subsequent immunotherapy was received by 6% and 43%, respectively.
[a]95% CI, 0.67–0.94.

IMpower110: Interim OS Analysis of a Phase III Study of Atezolizumab (atezo) vs Platinum-Based Chemotherapy (chemo) as 1L Treatment (tx) in PD-L1–selected NSCLC

David R Spigel,[1] Filippo De Marinis,[2] Giuseppe Giaccone,[3] Niels Reinmuth,[4] Alain Vergnenegre,[5] Carlos Henrique Barrios,[6] Masahiro Morise,[7] Enriqueta Felip,[8] Zoran Andric,[9] Sarayut Geater,[10] Mustafa Özgüroğlu,[11] Simonetta Mocci,[12] Mark McCleland,[12] Ida Enquist,[12] Kim Komatsubara,[12] Yu Deng,[12] Hiroshi Kuriki,[12] Xiaohui Wen,[12] Jacek Jassem,[13] Roy S Herbst[14]

[1]Sarah Cannon Research Institute, Nashville, TN, USA; [2]European Institute of Oncology, Milan, Italy; [3]Weill Cornell Medical Center, New York, NY, USA; [4]Asklepios Lung Clinic, Munich-Gauting, Germany; [5]Centro de Pesquisa Clínica, Hospital São Lucas, Porto Alegre, Brazil; [6]PUCRS School of Medicine, Porto Alegre, Brazil; [7]Nagoya University Graduate School of Medicine, Aichi, Japan; [8]Vall d'Hebron University Hospital, Barcelona, Spain; [9]Clinical Hospital Center Bezanijska Kosa, Belgrade, Serbia; [10]Prince of Songkla University – Hat Yai, Songkhla, Thailand; [11]Istanbul University-Cerrahpaşa, Cerrahpaşa School of Medicine, Istanbul, Turkey; [12]Genentech, Inc., South San Francisco, CA, USA; [13]Medical University of Gdansk, Gdansk, Poland; [14]Yale School of Medicine, New Haven, CT

IMpower110 Study Design

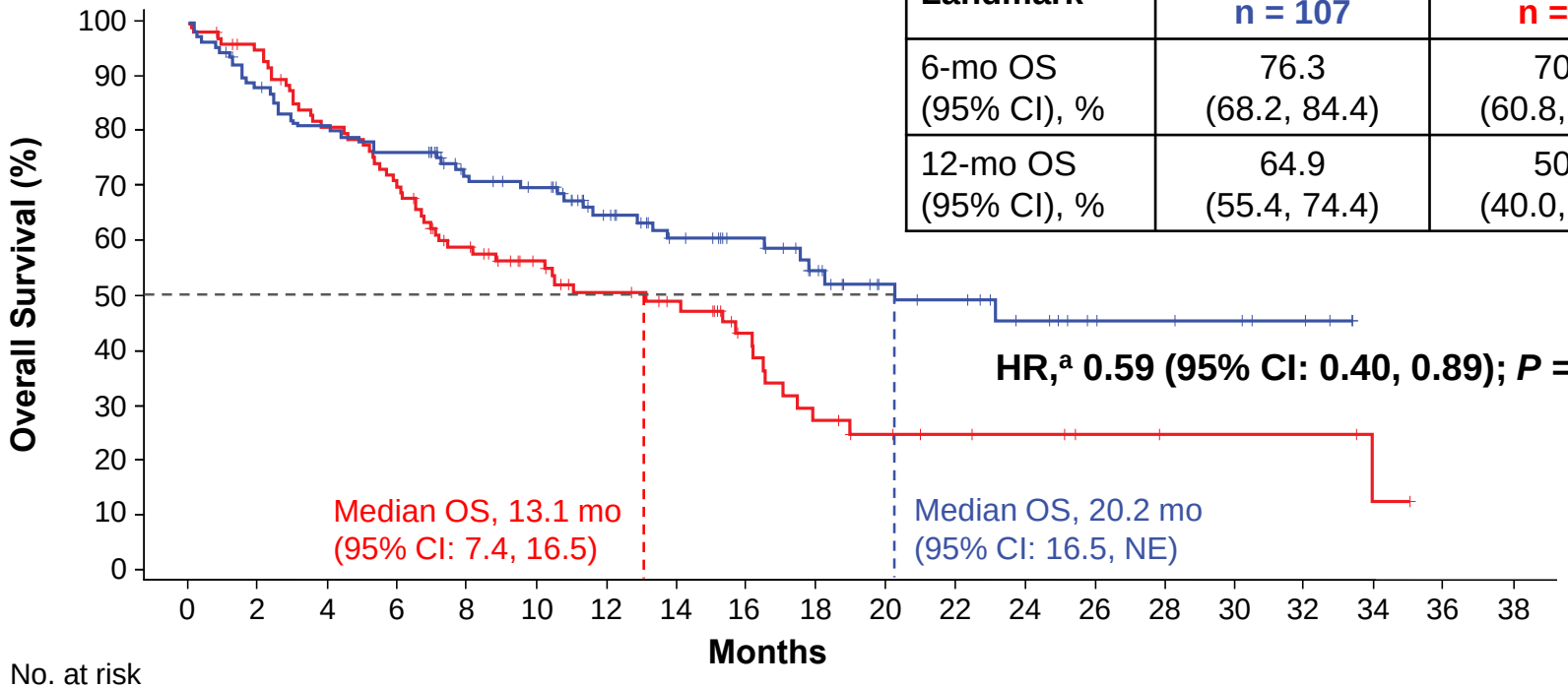


- Primary endpoint: OS in WT population[f]
- Key secondary endpoints: investigator-assessed PFS, ORR and DOR (per RECIST version 1.1)

IC, tumour-infiltrating immune cells; IHC, immunohistochemistry; nsq, non-squamous; PD, progressive disease; q3w, every 3 weeks; R, randomised; sq, squamous; TC, tumour cells; WT, wild-type. [a] PD-L1 expression (VENTANA SP142 IHC assay) ≥ 1% on TC or IC. [b] TC1/2/3 and any IC vs TC0 and IC1/2/3. [c] 554 patients in the WT population. [d] Cisplatin 75 mg/m^2 or carboplatin area under the curve (AUC) 6 + pemetrexed 500 mg/m^2 IV q3w. [e] Cisplatin 75 mg/m^2 + gemcitabine 1250 mg/m^2 or carboplatin AUC 5 + gemcitabine 1000 mg/m^2 IV q3w. [f] WT population excludes patients with *EGFR*+ and/or *ALK*+ NSCLC.

Results: OS – TC3 or IC3 WT

Landmark	Arm A (atezo) n = 107	Arm B (chemo) n = 98
6-mo OS (95% CI), %	76.3 (68.2, 84.4)	70.1 (60.8, 79.4)
12-mo OS (95% CI), %	64.9 (55.4, 74.4)	50.6 (40.0, 61.3)

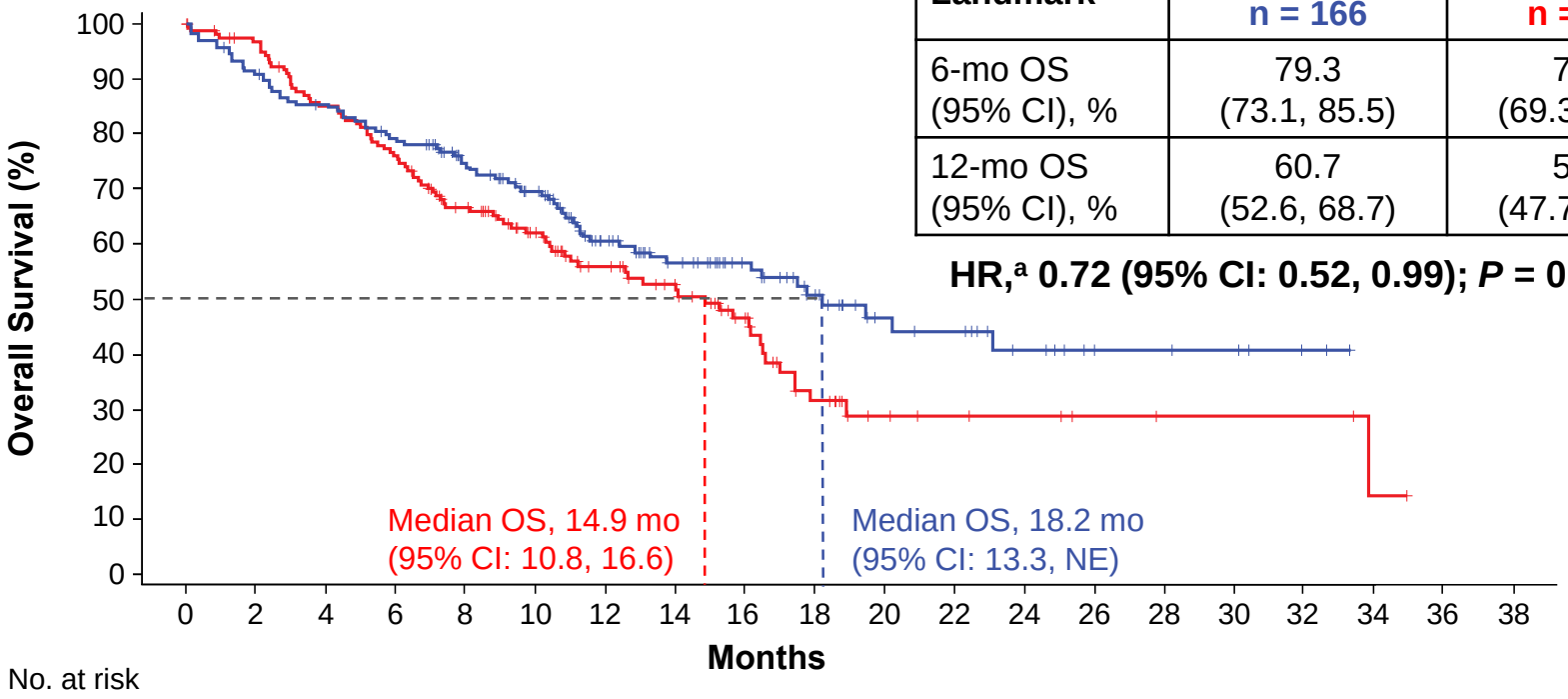


No. at risk

Atezolizumab	107	94	85	80	66	61	48	40	34	25	18	16	11	7	6	5	2	
Chemotherapy	98	89	75	65	50	40	33	28	19	12	9	7	6	4	3	3	3	1

NE, not estimable. [a] Stratified. [b] Stratified log-rank.
Data cutoff: 10 September 2018.

Results: OS – TC2/3 or IC2/3 WT



Landmark	Arm A (atezo) n = 166	Arm B (chemo) n = 162
6-mo OS (95% CI), %	79.3 (73.1, 85.5)	76.1 (69.3, 82.8)
12-mo OS (95% CI), %	60.7 (52.6, 68.7)	56.0 (47.7, 64.3)

HR,[a] 0.72 (95% CI: 0.52, 0.99); *P* = 0.0416[b,c]

No. at risk

Atezolizumab	166	151	139	128	108	92	66	54	42	30	19	17	11	7	6	5	2	
Chemotherapy	162	150	131	117	95	75	57	46	32	17	9	7	6	4	3	3	3	1

[a] Stratified. [b] Stratified log-rank. [c] Not crossing the pre-specified alpha boundary. Data cutoff: 10 September 2018.

Society for Immunotherapy of Cancer

KRAS mutation status and efficacy in KEYNOTE-189: Pembrolizumab plus chemotherapy vs placebo plus chemotherapy as first-line therapy for metastatic nonsquamous NSCLC

S. Gadgeel[1], D. Rodriguez-Abreu[2], E. Felip[3], E. Esteban[4], G. Speranza[5], M. Reck[6], R. Hui[7], M. Boyer[8], E.B. Garon[9], H. Horinouchi[10], R. Cristescu[11], D. Aurora-Garg[11], J. Lunceford[11], J. Kobie[11], M. Ayers[11], B. Piperdi[11], M.C. Pietanza[11], M.C. Garassino[12]

[1] Oncology, Karmanos Cancer Institute (currently at University of Michigan), 48201 - Detroit/US; [2] Medical Oncology, Complejo Hospitalario Universitario Insular Materno-Infantil de Gran Canaria, Universidad de Las Palmas de Gran Canaria, Gran Canaria/ES; [3] Medical Oncology Department, Vall d'Hebron University Hospital, 8035 - Barcelona/ES; [4] Medical Oncology, Hospital Universitario Central de Asturias, 33011 - Oviedo/ES; [5] Oncology, Centre integré de cancérologie de la Montérégie, Université de Sherbrooke, Greenfield Park/CA; [6] Thoracic Oncology, LungenClinic, Airway Research Center North, German Center for Lung Research, 22927 - Grosshansdorf/DE; [7] Medical Oncology, Westmead Hospital and University of Sydney, 2145 - Westmead/AU; [8] Medical Oncology, Chris O'Brien Lifehouse, Camperdown/AU; [9] Medicine; Division Of Heme/onc, David Geffen School of Medicine at UCLA, 90404 - Los Angeles/US; [10] Oncology, National Cancer Center Hospital, 104-0045 - Tokyo/JP; [11] Oncology, Merck & Co., Inc., 07033 - Kenilworth/US; [12] Medical Oncology, Fondazione IRCCS Istituto Nazionale dei Tumori, Milan/IT

Methods

KEYNOTE-189 (NCT02578680)[1]

- Phase 3, double-blind trial
- 2:1 randomization to pembrolizumab + pemetrexed + platinum or placebo + pemetrexed + platinum

Association of *KRAS* Mutations with Outcomes

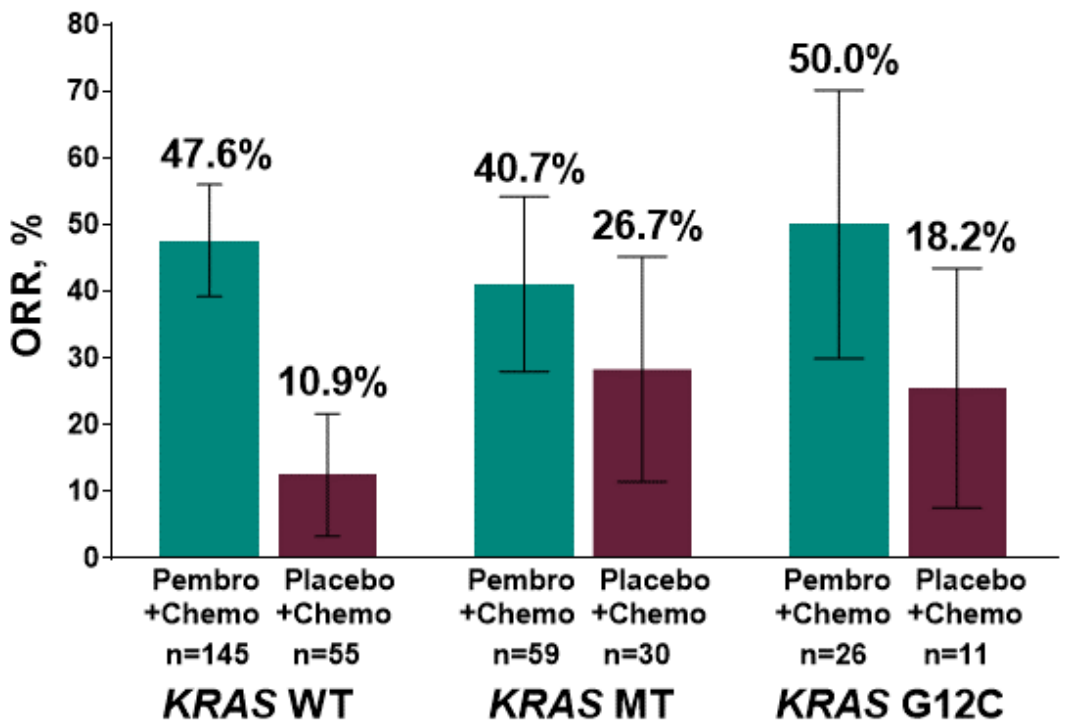
- Whole-exome sequencing (WES) of tumor tissue and matched normal DNA (blood) were performed[2]
- Prevalence of *KRAS* mutations (including G12C) and associations of *KRAS* mutations with tTMB and PD-L1 as well as with clinical efficacy were explored
- Due to limited size of the subgroups, data are summarized descriptively

1. Gandhi L et al. *N Engl J Med* 2018;378_2078-92 2. Cristescu R et al. *Science* 2018;362:pii:eaar3593.

Results

Gadgeel KN189 ESMO-IO 2019

Association of *KRAS* Mutation with ORR

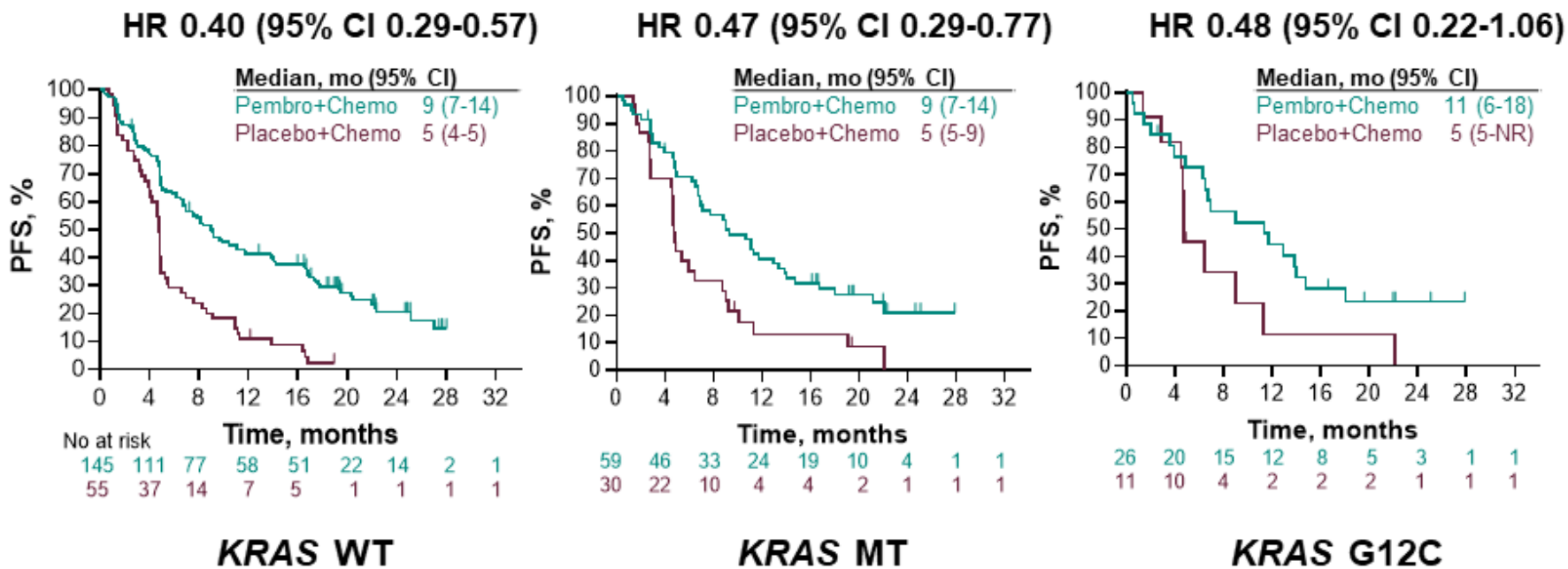


Data cutoff date: Sep 21, 2018.

Results

Gadgeel KN189 ESMO-IO 2019

Association of *KRAS* Mutations with PFS



Total ITT Population (N=616): HR 0.48 (95% CI, 0.40-0.58)[1]

1. Gadgeel SM et al. *J Clin Oncol* 2019;39(suppl):abstr 9013.

Data cutoff date: Sep 21, 2018.

Breast cancer

Society for Immunotherapy of Cancer

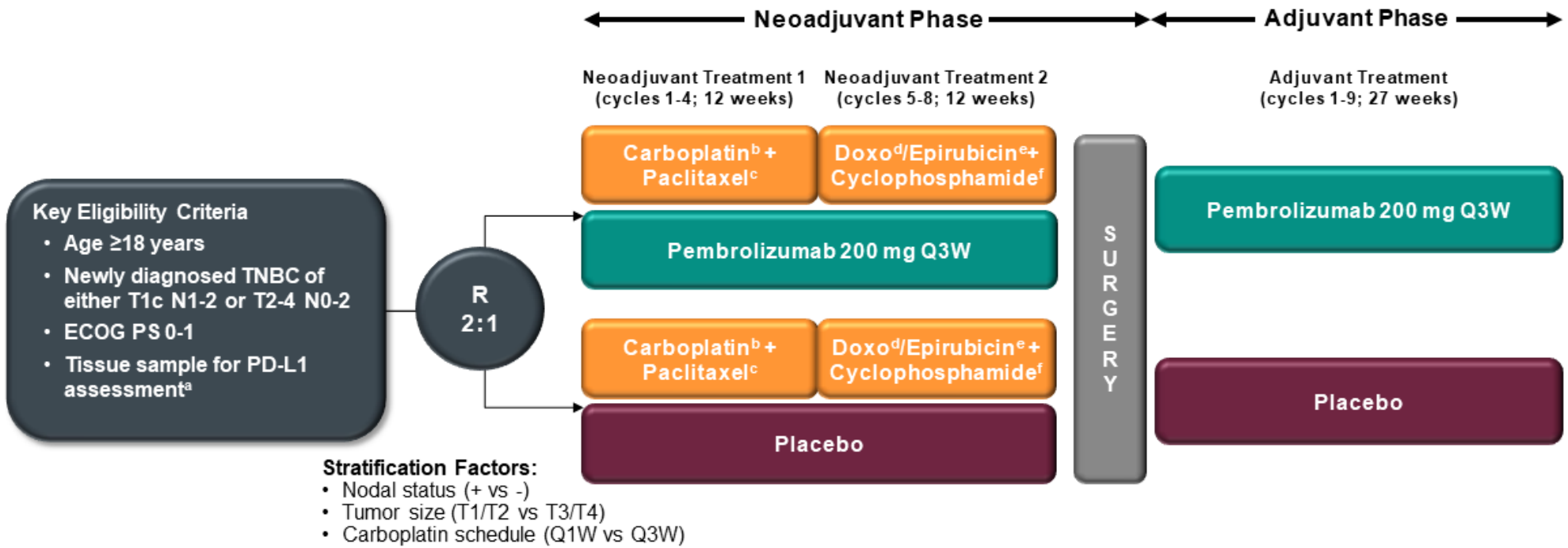
KEYNOTE-522: Phase 3 study of pembrolizumab (pembro) + chemotherapy (chemo) vs placebo (pbo) + chemo as neoadjuvant treatment, followed by pembro vs pbo as adjuvant treatment for early triple-negative breast cancer (TNBC)

Peter Schmid[1], Yeon Hee Park[2], Marta Ferreira[3], Marie-Ange Mouret-Reynier[4], Seock-Ah Im[5], Jin-Hee Ahn[6], Maria Gion[7], Rina Hui[8], Sally Baron-Hay[9], Jean-Francois Boileau[10], Mei-Ching Liu[11], Nadia Harbeck[12], Masato Takahashi[13], Theodoros Foukakis[14], Peter A Fasching[15], Fatima Cardoso[16], Jay Andersen[17], Michael Untch[18], Margarita Tokar[19], Florence Dalenc[20], Michael Danso[21], Debra Patt[22], Sherko Kümmel[23], Carsten Denkert[24], Lajos Pusztai[25], Jonas Bergh[14], Heather McArthur[26], Liyi Jia[25], Gursel Aktan[25], Vassiliki Karantza[27], Rebecca Dent[28], Javier Cortes[29] and Joyce O'Shaughnessy[30]

[1]Barts Cancer Institute, Queen Mary University of London, London, United Kingdom[2]Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Korea, Republic of[3]Instituto Português de Oncologia do Porto Francisco Gentil (IPO-Porto), Porto, Portugal[4]Centre Jean-Perrin, Clermont-Ferrand, France[5]Seoul National University, Seoul, Korea, Republic of[6]Asan Medical Center, University of Ulsan College of Medicine, Seoul, Korea, Republic of[7]Ramon y Cajal University Hospital, Madrid, Spain[8]Westmead Breast Cancer Institute, Westmead Hospital and the University of Sydney, Sydney, NSW, Australia[9]Royal North Shore Hospital, Sydney, NSW, Australia[10]McGill University, Jewish General Hospital Segal Cancer Centre, Montréal, QC, Canada[11]Koo Foundation Sun Yat-Sen Cancer Center, Taipei, Taiwan, China[12]Breast Center, University of Munich (LMU), Munich, Germany[13]Hokkaido Cancer Center, Sapporo, Japan[14]Department of Oncology-Pathology, Karolinska Institutet and Breast Cancer Centre, Cancer theme, Karolinska University Hospital, Solna, Sweden[15]University Hospital Erlangen, Comprehensive Cancer Center Erlangen-EMN, Erlangen, Germany[16]Breast Unit, Champalimaud Clinical Center/Champalimaud Foundation, Lisbon, Portugal[17]Compass Oncology, US Oncology, Portland, OR;[18]Breast Cancer Center, Helios Klinikum Berlin Buch, Berlin, Germany[19]Soroka University Medical Center, Ben-Gurion University of the Negev, Beer-Sheva, Israel[20]Institut Claudius-Regaud, IUCT-oncopôle, Toulouse, France[21]Virgina Oncology Associates, Norfolk, VA;[22]Texas Oncology, Austin, TX;[23]Kliniken Essen-Mitte, Essen, Germany[24]Institute of Pathology, Charité–Universitätsmedizin Berlin, Berlin, Germany[25]Merck and Co., Rahway, NJ;[26]Cedars-Sinai Medical Center, Los Angeles, CA;[27]Merck & Co., Inc., Kenilworth, NJ;[28]University of Toronto, Toronto, ON, Canada[29]IOB Institute of Oncology, Quiron Group; Vall d'Hebron Institute of Oncology (VHIO), Madrid & Barcelona, Spain[30]Texas Oncology, Dallas, TX

San Antonio Breast Cancer Symposium®, December 10-14, 2019

KEYNOTE-522 Study Design (NCT03036488)



Stratification Factors:
- Nodal status (+ vs -)
- Tumor size (T1/T2 vs T3/T4)
- Carboplatin schedule (Q1W vs Q3W)

Neoadjuvant phase: starts from the first neoadjuvant treatment and ends after definitive surgery (post treatment included)

Adjuvant phase: starts from the first adjuvant treatment and includes radiation therapy as indicated (post treatment included)

[a]Must consist of at least 2 separate tumor cores from the primary tumor.
[b]Carboplatin dose was AUC 5 Q3W or AUC 1.5 Q1W.
[c]Paclitaxel dose was 80 mg/m^2 Q1W.
[d]Doxorubicin dose was 60 mg/m^2 Q3W.
[e]Epirubicin dose was 90 mg/m^2 Q3W.
[f]Cyclophosphamide dose was 600 mg/m^2 Q3W.

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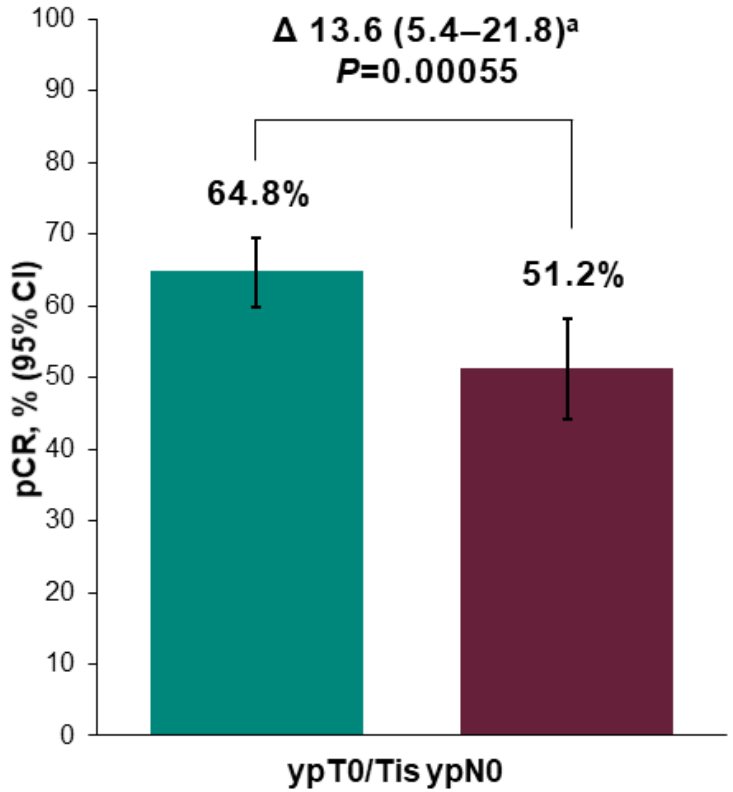
Definitive pCR Analysis



- Definitive pCR analysis to test primary hypothesis of pCR based on prespecified first 602 patients (pre-calculated P value boundary for significance of 0.003)
- Consistent benefit seen with pCR defined as ypT0 ypN0 and ypT0/Tis

Placebo + Chemo

Pembro + Chemo

[a]Estimated treatment difference based on Miettinen & Nurminen method stratified by randomization stratification factors. Data cutoff date: September 24, 2018.

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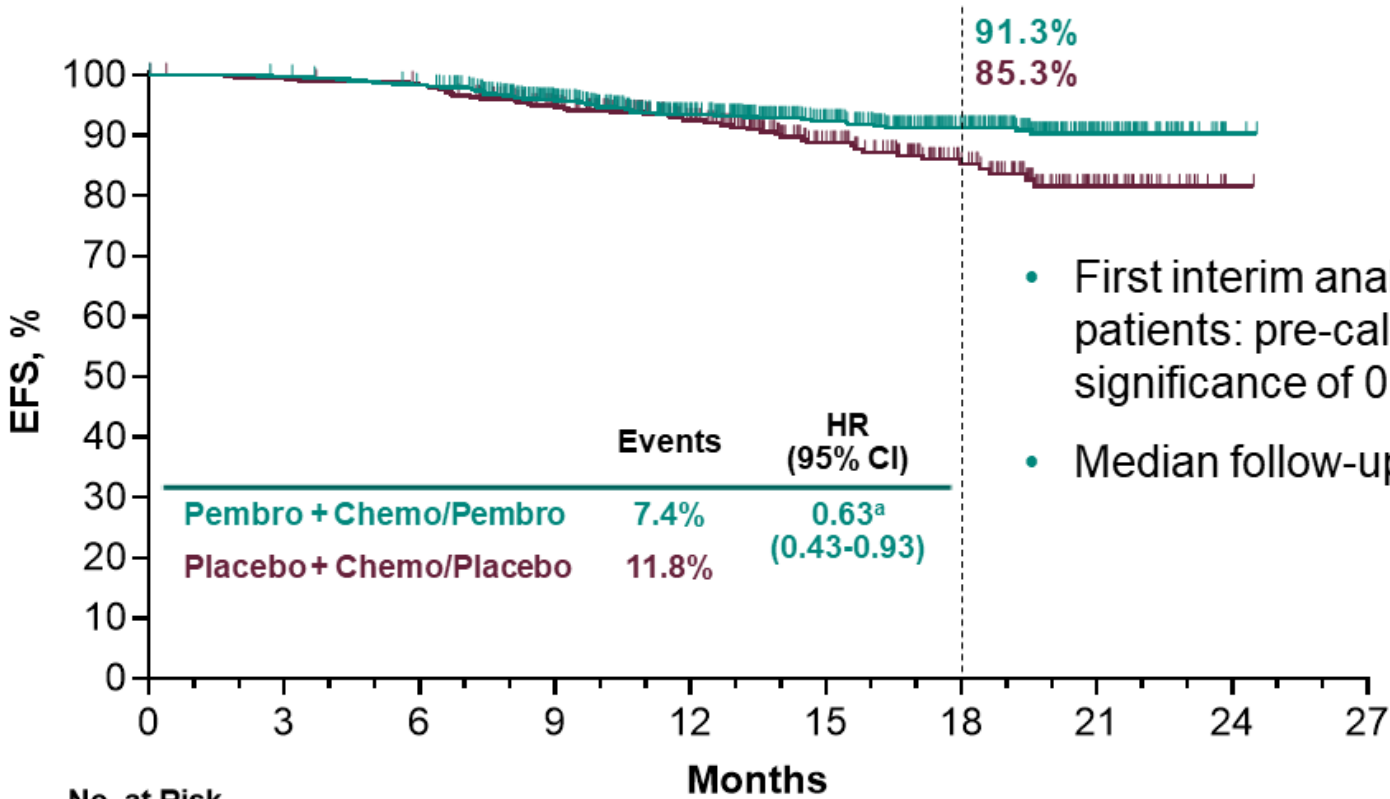
First Pre-planned Interim Analysis for EFS



- First interim analysis of EFS based on 1174 patients: pre-calculated P value boundary for significance of 0.000051 (HR <0.4)
- Median follow-up, 15.5 months

[a]Pre-specified P value boundary of 0.000051 not reached at this analysis (the first interim analysis of EFS). Hazard ratio (CI) analyzed based on a Cox regression model with treatment as a covariate stratified by the randomization stratification factors. Data cutoff April 24, 2019.

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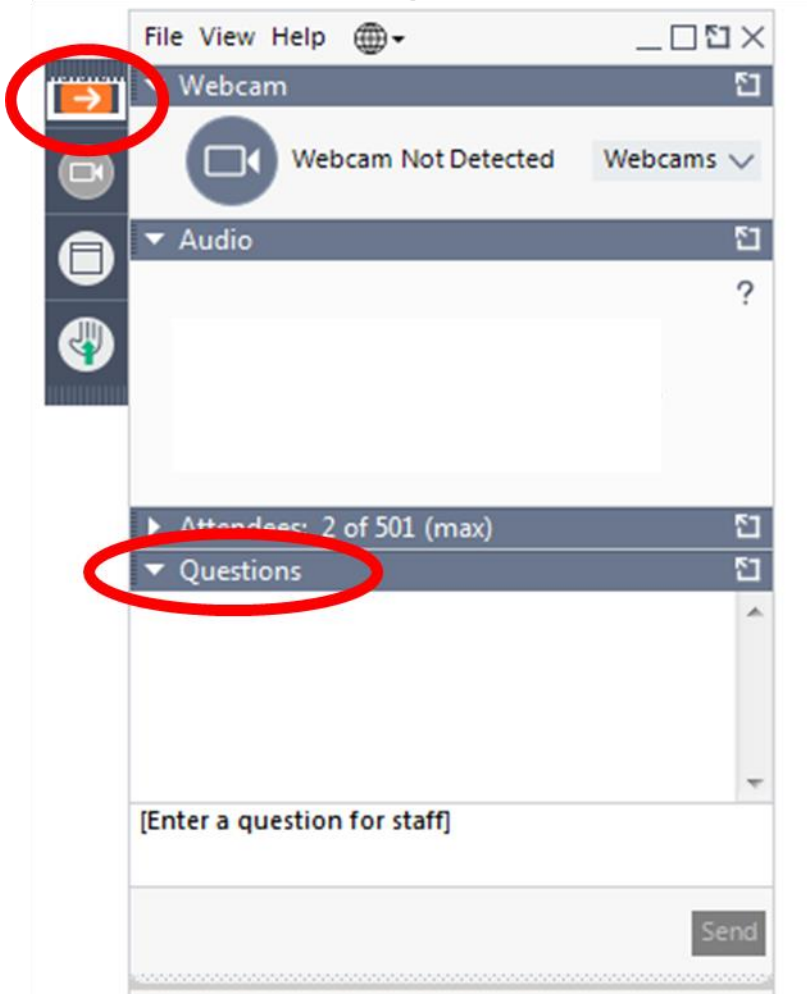
Conclusions and future directions

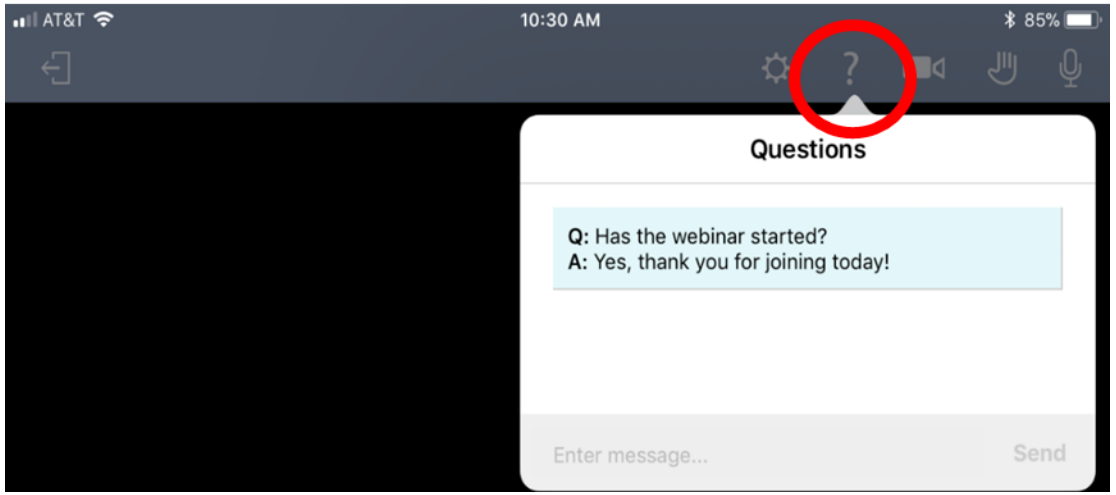
- Immune checkpoint inhibitors are expanding into more indications and disease states
- Very few agents are used as monotherapy – combinations becoming the norm
- Still searching for optimal biomarkers

How to Submit Questions

Computer



Mobile Phone



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Thank you for attending the webinar!

Jointly provided by Postgraduate Institute for Medicine and the Society for Immunotherapy of Cancer

This webinar is supported, in part, by independent medical education grant funding from Amgen, AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb, Celgene Corporation, Exelixis, Inc., Genentech, Incyte Corporation and Merck & Co., Inc.

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Acknowledgements

Thank you to all of the ESMO presenters for sharing their slides!

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