Year in Review: GU Oncology

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COI DISCLOSURES

- Consultant/ Advisory role: Astra Zeneca, Bayer, BMS, Corvus, Exelixis, Genentech, Janssen, Novartis, Pfizer, EMD Serono
- Institutional Research funds: Bayer, BMS, Corvus, Novartis, Pfizer, Merck, Celldex, Astellas, Seattle Genetics, Calithera Therapeutics, Immunomedics

Objectives

Updates in GU Oncology-2019

- Kidney Cancer
- Bladder cancer
- Prostate Cancer

Question 1

- A 56 y/o male was recently referred to you for stage IV RCC (to lung, lymph nodes and adrenal) and has favorable risk per IMDC. What is the best treatment option?

1. Ipilimumab plus nivolumab
2. Sunitinib
3. High dose IL-2
4. Axitinib plus pembrolizumab
5. 2 and 4

Question 2

- A 68 y/o female patient has a history of stage IV bladder cancer. She was found to have progressive disease after 1st line platinum and 2nd line pembrolizumab. Her performance status is ECOG1. What is the next best step?

1. Cisplatin rechallenge
2. RT-PCR testing for FGFR2/3
3. Hospice care
4. Switch to nivolumab

Question 3

- A 71-year-old with newly-diagnosed metastatic prostate cancer patient is referred to you. His prostate biopsy showed GS 4+3=7 adenocarcinoma. He has two bone mets and PSA of 112 and normal counts and CMP and has no other co-morbidities. What is the best first treatment for this patient?

1. ADT alone
2. ADT plus enzalutamide
3. Bilateral orchiectomy only
4. ADT plus docetaxel

NCCN: Advanced Kidney Cancer

PRINCIPLES OF SYSTEMIC THERAPY FOR RELAPSE OR STAGE IV DISEASE

FIRST-LINE THERAPY FOR CLEAR CELL HISTOLOGY			
Risk	**Preferred regimens**	**Other recommended regimens**	**Useful under certain circumstances**
Favorable[a]	• Axitinib + pembrolizumab • Pazopanib • Sunitinib	• Ipilimumab + nivolumab • Cabozantinib (category 2B) • Axitinib + avelumab	• Active surveillance[b] • Axitinib (category 2B) • High-dose IL-2[c]
Poor/ intermediate[a]	• Ipilimumab + nivolumab (category 1) • Axitinib + pembrolizumab (category 1) • Cabozantinib	• Pazopanib • Sunitinib • Axitinib + avelumab	• Axitinib (category 2B) • High-dose IL-2[c] • Temsirolimus[d]

SUBSEQUENT THERAPY FOR CLEAR CELL HISTOLOGY		
Preferred regimens	**Other recommended regimens**	**Useful under certain circumstances**
• Cabozantinib (category 1) • Nivolumab (category 1) • Ipilimumab + nivolumab	• Axitinib (category 1) • Lenvatinib + everolimus (category 1) • Axitinib + pembrolizumab • Everolimus • Pazopanib • Sunitinib • Axitinib + avelumab (category 3)	• Bevacizumab or biosimilar[e] (category 2B) • Sorafenib (category 2B) • High-dose IL-2 for selected patients[c] (category 2B) • Temsirolimus[d] (category 2B)

MUNICH 2018 ESMO congress

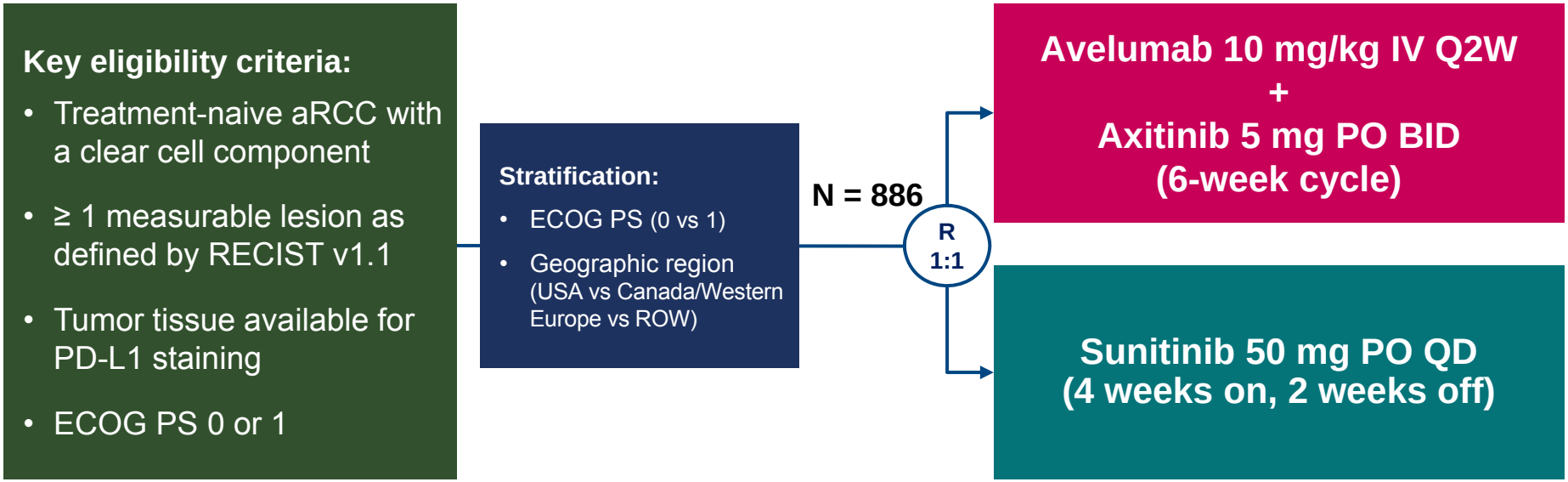
JAVELIN Renal 101: Randomized Phase 3 Trial of Avelumab + Axitinib vs Sunitinib as First-Line Treatment of Advanced Renal Cell Carcinoma

Robert J. Motzer,[1] Konstantin Penkov,[2] John Haanen,[3] Brian Rini,[4] Laurence Albiges,[5] Matthew T. Campbell,[6] Christian Kollmannsberger,[7] Sylvie Negrier,[8] Motohide Uemura,[9] Jae Lyun Lee,[10] Howard Gurney,[11] Raanan Berger,[12] Manuela Schmidinger,[13] James Larkin,[14] Michael B. Atkins,[15] Jing Wang,[16] Paul B. Robbins,[17] Aleksander Chudnovsky,[16] Alessandra di Pietro,[18] and Toni K. Choueiri[19]

[1]Memorial Sloan Kettering Cancer Center, New York, NY, USA; [2]Private Medical Institution Euromedservice, Pushkin, St. Petersburg, Russian Federation; [3]Netherlands Cancer Institute, Amsterdam, Netherlands; [4]Cleveland Clinic Taussig Cancer Institute, Cleveland, OH, USA; [5]Institut Gustave Roussy, Villejuif, France; [6]The University of Texas MD Anderson Cancer Center, Houston, TX, USA; [7]British Columbia Cancer Agency, Vancouver, BC, Canada; [8]Centre Léon Bérard, Lyon, France; [9]Osaka University Hospital, Osaka, Japan; [10]University of Ulsan College of Medicine, Asan Medical Center, Seoul, Korea; [11]Macquarie University, Sydney, NSW, Australia; [12]Chaim Sheba Medical Center and Tel Aviv University Sackler School of Medicine, Tel HaShomer, Israel; [13]Medical University of Vienna; Department of Medicine I, Clinical Division of Oncology and Comprehensive Cancer Center, Vienna, Austria; [14]The Royal Marsden NHS Foundation Trust, London, UK; [15]Georgetown Lombardi Comprehensive Cancer Center Washington, D.C., USA; [16]Pfizer Inc, Cambridge, MA, USA; [17]Pfizer Inc, San Diego, CA, USA; [18]Pfizer SRL, Lombardia, Italy; [19]The Lank Center for Genitourinary Oncology, Dana-Farber Cancer Institute and Brigham and Women's Hospital and Harvard Medical School, Boston, MA, USA

Abstract No. LBA6_PR

JAVELIN Renal 101: study design



BID, twice per day; **ECOG PS**, Eastern Cooperative Oncology Group performance status; **IV**, intravenous; **PO**, orally; **Q2W**, every 2 weeks; **QD**, once per day; **ROW**, rest of the world.

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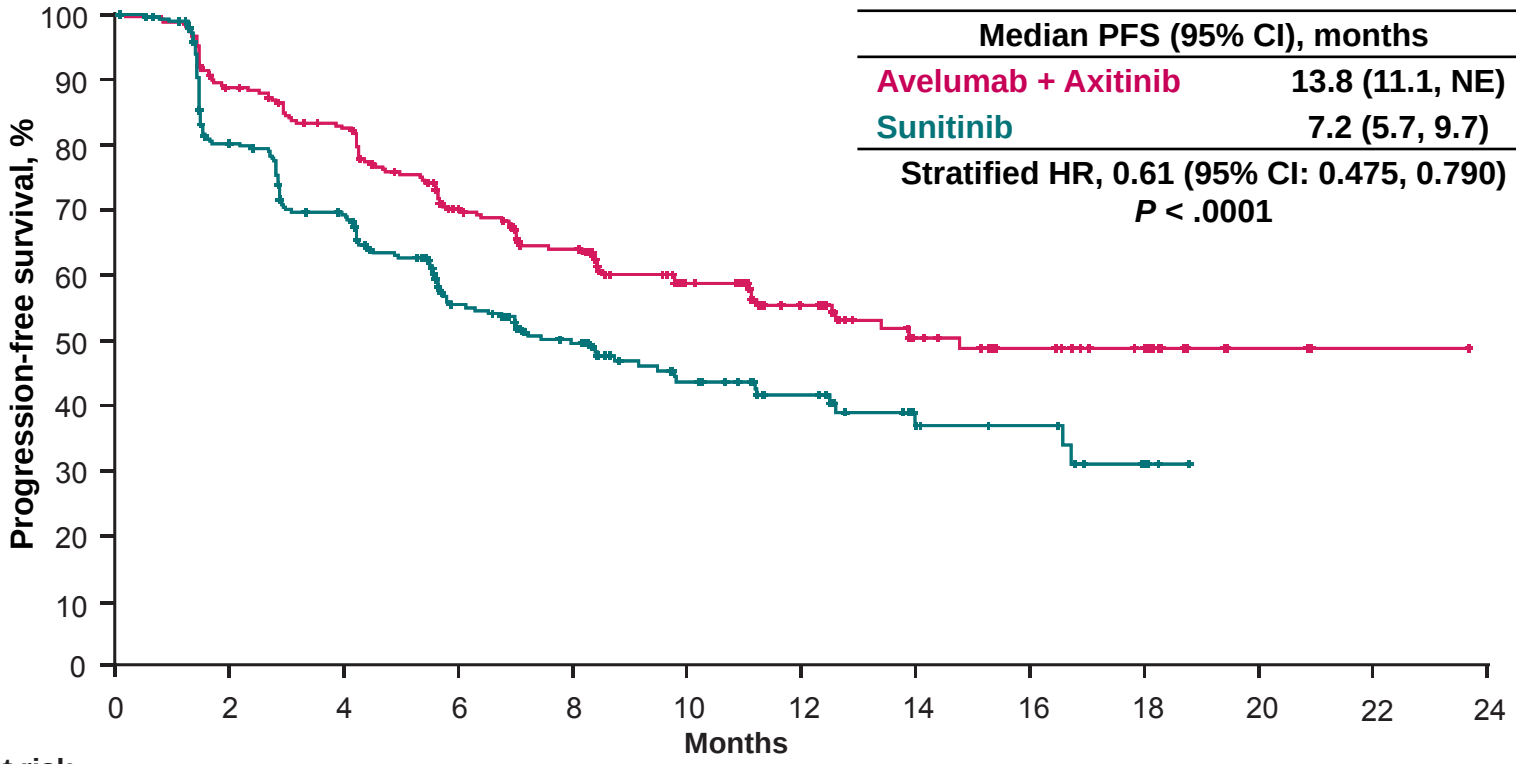
PFS per IRC in the PD-L1+ group

Primary endpoint



Median PFS (95% CI), months	
Avelumab + Axitinib	13.8 (11.1, NE)
Sunitinib	7.2 (5.7, 9.7)

Stratified HR, 0.61 (95% CI: 0.475, 0.790)
***P* < .0001**

Number at risk

Avel + Axit:	270	227	205	154	120	76	53	32	23	13	3	1	0
Sunitinib:	290	210	174	119	85	49	35	16	13	5	0		

Minimum follow-up, 6 months. Median follow-up, 9.9 months (avelumab + axitinib) and 8.4 months (sunitinib).
The PFS analysis crossed the prespecified efficacy boundary based on the alpha-spending function (*P* = .001).

NE, not estimable.

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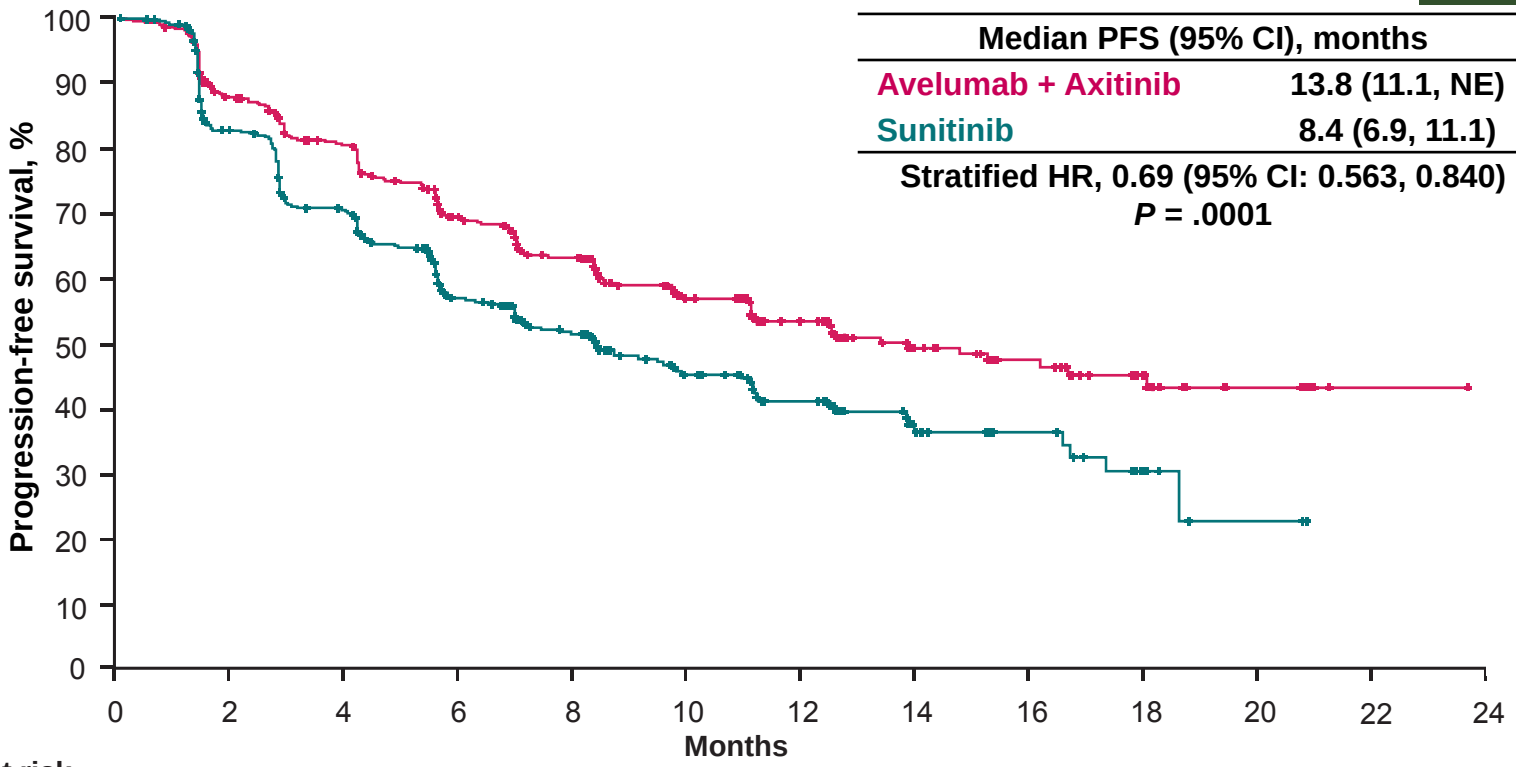
PFS per IRC in the overall population

Key secondary endpoint



Median PFS (95% CI), months	
Avelumab + Axitinib	13.8 (11.1, NE)
Sunitinib	8.4 (6.9, 11.1)

Stratified HR, 0.69 (95% CI: 0.563, 0.840)
***P* = .0001**

Number at risk

Avel + Axit:	442	364	321	250	193	127	94	57	42	24	8	1	0
Sunitinib:	444	329	271	192	144	90	64	29	20	8	2	0	

Minimum follow-up, 6 months. Median follow-up, 10.8 months (avelumab + axitinib) and 8.6 months (sunitinib).
The PFS analysis crossed the prespecified efficacy boundary based on the alpha-spending function (*P* = .001).

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Confirmed objective response

Secondary endpoint

Per IRC	PD-L1+ group (N = 560)		Overall population (N = 886)	
	Avelumab + Axitinib (N = 270)	Sunitinib (N = 290)	Avelumab + Axitinib (N = 442)	Sunitinib (N = 444)
Objective response rate (95% CI), %	**55 (49.0, 61.2)**	**26 (20.6, 30.9)**	**51 (46.6, 56.1)**	**26 (21.7, 30.0)**
Best overall response, %*				
Complete response	4	2	3	2
Partial response	51	23	48	24
Stable disease	27	43	30	46
Progressive disease	11	22	12	19
Not evaluable†	4	7	6	8
Patients with ongoing response, %‡	73	65	70	71
Per investigator assessment				
Objective response rate (95% CI), %	**62 (55.8, 67.7)**	**30 (24.5, 35.3)**	**56 (51.1, 60.6)**	**30 (25.9, 34.7)**
Best overall response, %				
Complete response	4	3	3	2
Partial response	58	27	53	28

Median duration of response was not yet reached in either treatment arm in either population.

* Patients without target lesions at baseline per IRC who achieved non-complete response/non-progressive disease: 3% (avelumab + axitinib) and 2% (sunitinib) in the PD-L1+ group; 2% (avelumab + axitinib) and 2% (sunitinib) in the overall population. † Including patients with no postbaseline assessments. ‡ In patients with confirmed complete or partial response.

Pembrolizumab plus Axitinib vs Sunitinib as First-Line Therapy for Advanced Renal Cell Carcinoma: KEYNOTE-426

Thomas Powles,[1] Elizabeth R. Plimack,[2] Viktor Stus,[3] Rustem Gafanov,[4] Robert Hawkins,[5] Dmitry Nosov,[6] Frédéric Pouliot,[7] Boris Alekseev,[8] Denis Soulières,[9] Bohuslav Melichar,[10] Ihor Vynnychenko,[11] Anna Kryzhanivska,[12] Igor Bondarenko,[13] Sergio J. Azevedo,[14] Delphine Borchiellini,[15] Cezary Szczylik,[16] Maurice Markus,[17] Raymond S. McDermott,[18] Jens Bedke,[19] Sophie Tartas,[20] Yen-Hwa Chang,[21] Satoshi Tamada,[22] Qiong Shou,[23] Rodolfo F. Perini,[24] Mei Chen,[24] Michael B. Atkins,[25] Brian I. Rini[26]

[1]Barts Health and the Royal Free NHS Trusts, Barts Cancer Institute, and Queen Mary University of London, London, UK; [2]Fox Chase Cancer Center, Philadelphia, PA; [3]Dnipropetrovsk Medical Academy of Ministry of Health of Ukraine, Dnipro, Ukraine; [4]Russian Scientific Center of Roentgenoradiology, Moscow, Russia; [5]The Christie NHS Foundation Trust, Manchester, UK; [6]Central Clinical Hospital with Outpatient Clinic, Moscow, Russia; [7]CHU de Québec and Université Laval, Québec City, QC; [8]Hertzen Moscow Cancer Research Institute, Moscow, Russia; [9]Centre Hospitalier de l'Universitaire de Montréal, Montréal, QC; [10]Palacky University Medical School and Teaching Hospital, Olomouc, Czech Republic; [11]Sumy State University, Sumy Regional Oncology Center, Sumy, Ukraine; [12]Ivano-Frankivsk National Medical University, Ivano-Frankivsk, Ukraine; [13]Dnipropetrovsk Medical Academy, Dnipro, Ukraine; [14]Hospital de Clínicas de Porto Alegre, Porto Alegre, Brazil; [15]Centre Antoine Lacassagne, Université Côte d'Azur, Nice, France; [16]Military Institute of Medicine, Warsaw, Poland (currently affiliated with the Department of Oncology, Postgraduate Education Center ECZ, Otwock, Poland); [17]Rocky Mountain Cancer Center, Colorado Springs, CO, USA; [18]Adelaide and Meath Hospital and University College Dublin, Dublin, Ireland; [19]Department of Urology, Eberhard-Karls University Tübingen, Tübingen, Germany; [20]Hôpitaux Universitaires de Lyon, Lyon, France; [21]Taipei Veterans General Hospital, Taipei, Taiwan; [22]Osaka City University Hospital, Osaka, Japan; [23]MSD China, Beijing, China; [24]Merck & Co., Inc., Kenilworth, NJ, USA; [25]Georgetown–Lombardi Comprehensive Cancer Center, Washington, D.C.; [26]Cleveland Clinic Taussig Cancer Institute, Cleveland, OH

PRESENTED AT: **2019 Genitourinary Cancers Symposium | #GU19**

Presented by: Thomas Powles

KEYNOTE-426 Study Design

Key Eligibility Criteria

- Newly diagnosed or recurrent stage IV clear-cell RCC
- No previous systemic treatment for advanced disease
- Karnofsky performance status ≥70
- Measurable disease per RECIST v1.1
- Provision of a tumor sample for biomarker assessment
- Adequate organ function

Stratification Factors

- IMDC risk group (favorable vs intermediate vs poor)
- Geographic region (North America vs Western Europe vs ROW)

R (1:1)

N = 432 → Pembrolizumab 200 mg IV Q3W for up to 35 cycles + Axitinib 5 mg orally twice daily[a]

N = 429 → Sunitinib 50 mg orally once daily for first 4 wks of each 6-wk cycle[b]

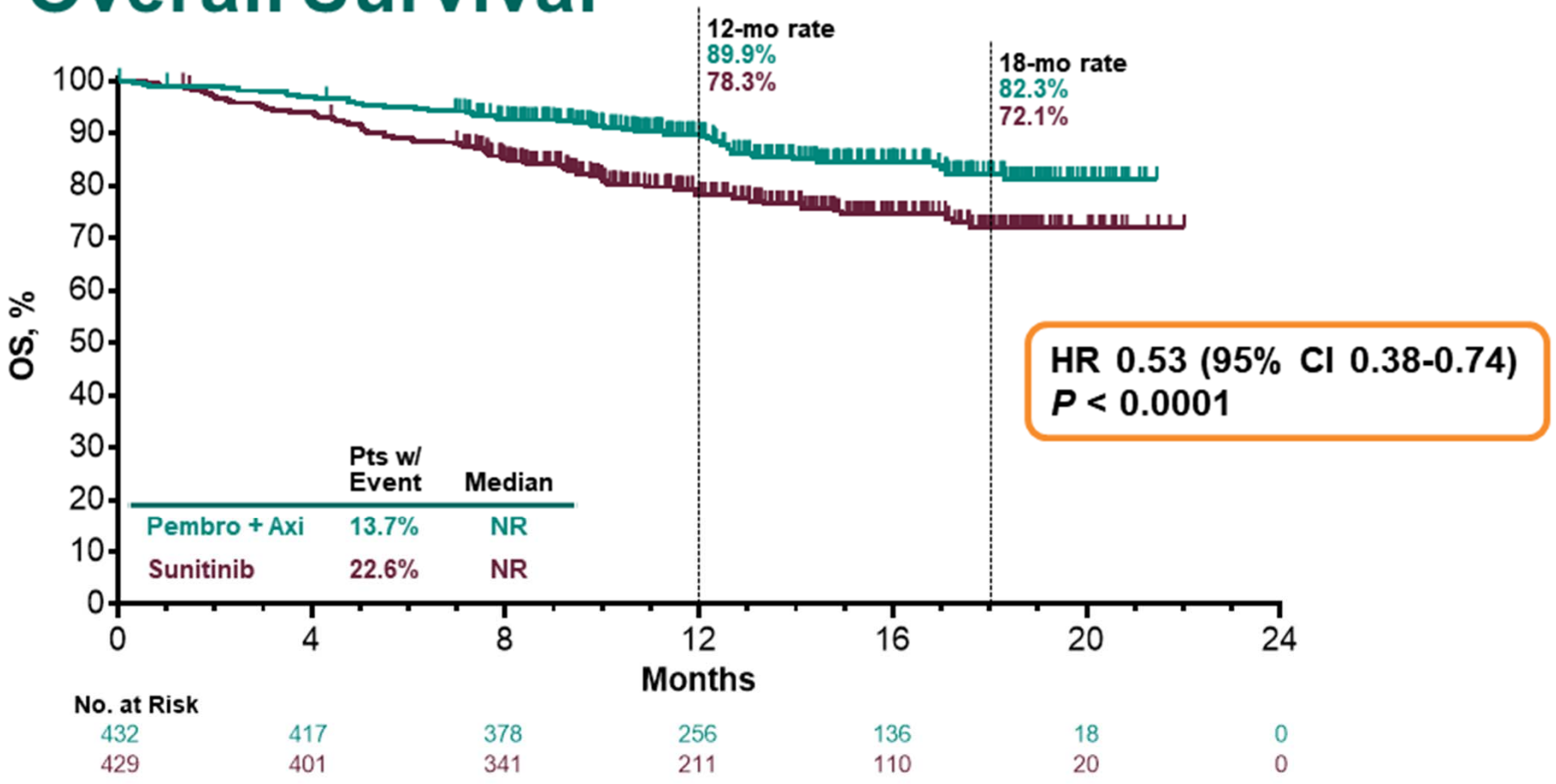
End Points

- **Dual primary:** OS and PFS (RECIST v1.1, BICR) in ITT
- **Key secondary:** ORR (RECIST v1.1, BICR) in ITT
- **Other secondary:** DOR (RECIST v1.1), PROs, safety

[a]Axitinib dose could be increased to 7 mg, then 10 mg, twice daily if safety criteria were met; dose could be reduced to 3 mg, then 2 mg, twice daily to manage toxicity.
[b]Sunitinib dose could be decreased to 37.5 mg, then 25 mg, once daily for the first 4 wks of each 6-wk cycle to manage toxicity.
BICR, blinded independent central radiologic review; DOR, duration of response; PROs, patient-reported outcomes; ROW, rest of world.
KEYNOTE-426 is a randomized, open-label, phase 3 study (ClinicalTrials.gov identifier NCT02853331).

Powles KN426 ASCO-GU 2019

Overall Survival



HR 0.53 (95% CI 0.38-0.74)
P < 0.0001

Data cutoff date: Aug 24, 2018.

NCCN: Advanced Bladder Cancer

PRINCIPLES OF SYSTEMIC THERAPY

Subsequent systemic therapy for locally advanced or metastatic disease (Stage IV) (post-platinum)[c] Participation in clinical trials of new agents is recommended.	
Preferred regimen • Pembrolizumab (category 1)[18]	Other recommended regimens • Albumin-bound paclitaxel[27] • Paclitaxel or docetaxel[25] • Gemcitabine[14] • Pemetrexed[26]
Alternative preferred regimens • Atezolizumab[19] • Nivolumab[20] • Durvalumab[21] • Avelumab[22,23] • Erdafitinib[d,24]	Useful in certain circumstances based on prior medical therapy • Ifosfamide[28] • Methotrexate • Ifosfamide, doxorubicin, and gemcitabine[16] • Gemcitabine and paclitaxel[15] • Gemcitabine and cisplatin[4] • DDMVAC with growth factor support[2]

Subsequent systemic therapy for locally advanced or metastatic disease (Stage IV) (post-checkpoint inhibitor) Participation in clinical trials of new agents is recommended.	
Preferred regimen for cisplatin ineligible, chemotherapy naïve • Gemcitabine/carboplatin	Other recommended regimens • Albumin-bound paclitaxel[27] • Paclitaxel or docetaxel[25] • Gemcitabine[14] • Pemetrexed[26]
Preferred regimens for cisplatin eligible, chemotherapy naïve • Gemcitabine and cisplatin[4] • DDMVAC with growth factor support[2]	Useful in certain circumstances based on prior medical therapy • Ifosfamide[28] • Methotrexate • Ifosfamide, doxorubicin, and gemcitabine[16] • Gemcitabine and paclitaxel[15]

Abstract 4503

First Results From the Primary Analysis Population of the Phase 2 Study of Erdafitinib (JNJ-42756493) in Patients With Metastatic or Surgically Unresectable Urothelial Carcinoma and *FGFR* Alterations

Arlene O. Siefker-Radtke,[1] Andrea Necchi,[2] Se Hoon Park,[3] Jesus Garcia-Donas,[4] Robert A. Huddart,[5] Earle F. Burgess,[6] Mark T. Fleming,[7] Arash Rezazadeh,[8] Begoña Mellado,[9] Sergey Varlamov,[10] Monika Joshi,[11] Ignacio Duran,[12] Scott T. Tagawa,[13] Anne O'Hagan,[14] Anjali N. Avadhani,[14] Bob Zhong,[14] Peter De Porre,[15] and Yohann Loriot[16]
on behalf of the BLC2001 Study Group sponsored by Janssen Research & Development

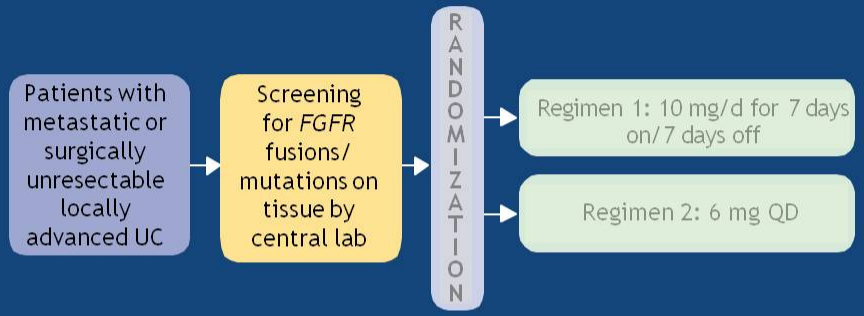
[1]The University of Texas MD Anderson Cancer Center, Houston, Texas, USA; [2]Fondazione IRCCS Istituto Nazionale dei Tumori, Milan, Italy; [3]Samsung Medical Center, Seoul, Korea; [4]Clara Campal Comprehensive Cancer Center, Madrid, Spain; [5]Institute of Cancer Research, Sutton, London, UK; [6]Levine Cancer Institute, Carolinas HealthCare System, Charlotte, North Carolina, USA; [7]Virginia Oncology Associates, US Oncology Research, Norfolk, Virginia, USA; [8]Norton Healthcare, Louisville, Kentucky, USA; [9]Institut d'Investigacions Biomèdiques August Pi i Sunyer (IDIBAPS), Barcelona, Spain; [10]Altai Regional Cancer Center, Barnaul, Russia; [11]Penn State Cancer Institute, Hershey, Pennsylvania, USA; [12]Hospital Universitario Marques de Valdecilla, Santander, Cantabria, Spain; [13]Weill Cornell Medical College, New York, NY, USA; [14]Janssen Research & Development, Spring House, Pennsylvania, USA; [15]Janssen Research & Development, Beerse, Belgium; [16]Institut Gustave Roussy, Villejuif, France

PRESENTED AT: 2018 ASCO ANNUAL MEETING #ASCO18

PRESENTED BY: Arlene O. Siefker-Radtke

Presented By Arlene Siefker-Radtke at 2018 ASCO Annual Meeting

Phase 2 BLC2001 Study Design



Regimen 3[a]:
8 mg QD with PD Uptitration to 9 mg QD
n = 99

Primary end point
ORR
Secondary end points
PFS, DoR, OS, safety, predictive biomarker evaluation, and PK

Patients
• Progression on ≥ 1 line prior systemic chemo or within 12 months of (neo)adjuvant chemo OR • Chemo-naïve: cisplatin ineligible per protocol criteria[b]
• Prior immunotherapy was allowed

Primary hypothesis:
- ORR in Regimen 3 is > 25%
- One-sided α = 0.025
- 85% power

[a]Dose uptitration if ≥ 5.5 mg/dL target serum phosphate not reached by Day 14 and if no TRAEs.
[b]Ineligibility for cisplatin: impaired renal function or peripheral neuropathy.

Abbreviations: DoR, duration of response; PD, pharmacodynamics; PFS, progression-free survival; PK, pharmacokinetics; QD, daily; TRAEs, treatment-related adverse events.

Antitumor Activity

Study has met the primary objective

		[95% CI]
Patients, n	99	
Response per investigator assessment[a,b], n (%)		
ORR	**40 (40.4)**	[30.7-50.1]
Complete response	3 (3.0)	
Partial response	37 (37.4)	
Stable disease	39 (39.4)	
Progressive disease	18 (18.2)	
Median time to response	1.4 months	
Median duration of response	5.6 months	[4.2-7.2]
ORR among patient subgroups, n (%)		
Chemo-naïve vs progressed/relapsed after chemo	5/12 (41.7) vs 35/87 (40.2)	
With vs without visceral metastases	30/78 (38.5) vs 10/21 (47.6)	

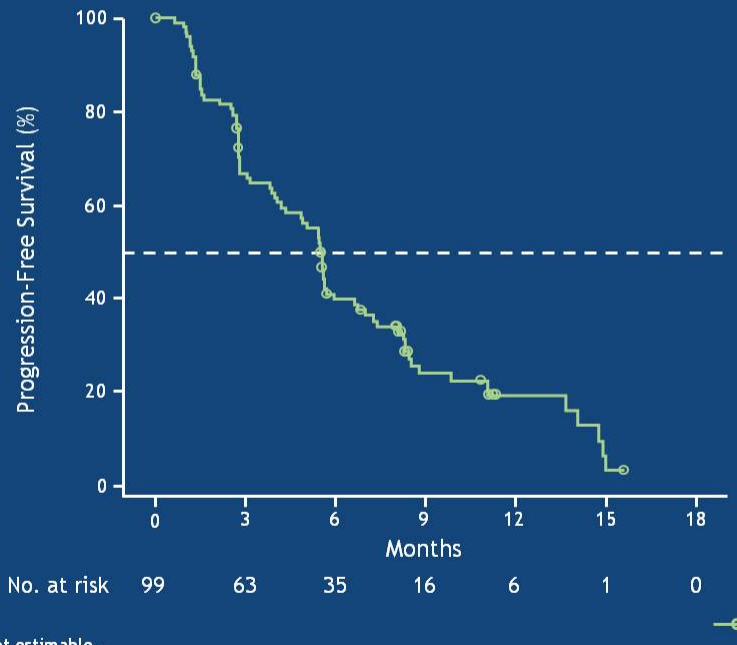
[a]Confirmed with second scan at least 6 weeks following the initial observation of response.
[b]Response in 2 patients was unknown.

21.2% of patients remain on study treatment after 11 months of follow-up

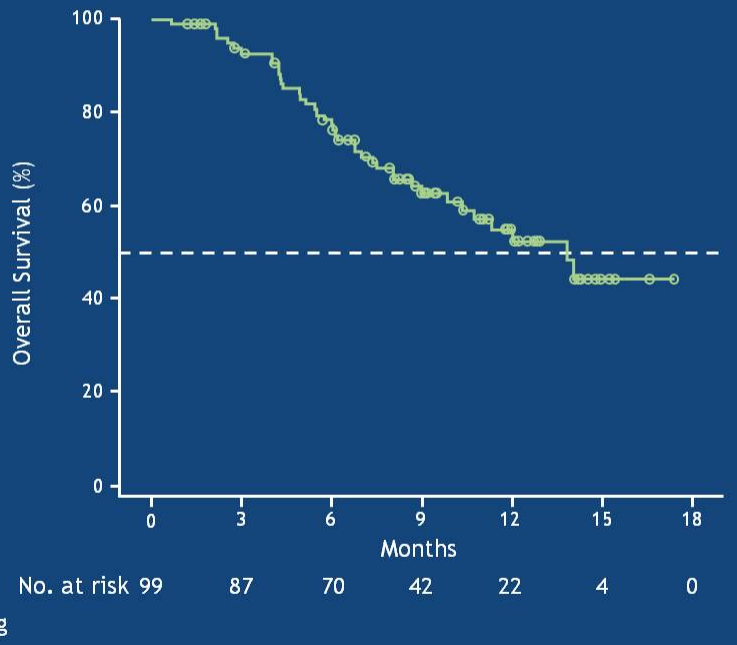
Abbreviations: CI, confidence interval

Progression-Free Survival ~6 Months
Overall Survival > 1 Year

Median PFS = 5.5 months (95% CI, 4.2-6.0)
Progression/death events = 77



Median OS = 13.8 months (95% CI, 9.8-NE)
Survival events = 40



8 mg

Abbreviation: NE, not estimable.

Presented By Arlene Siefker-Radtke at 2018 ASCO Annual Meeting

Randomized double-blind phase II study of maintenance pembrolizumab versus placebo after first-line chemotherapy in patients with metastatic urothelial cancer: HCRN GU14-182

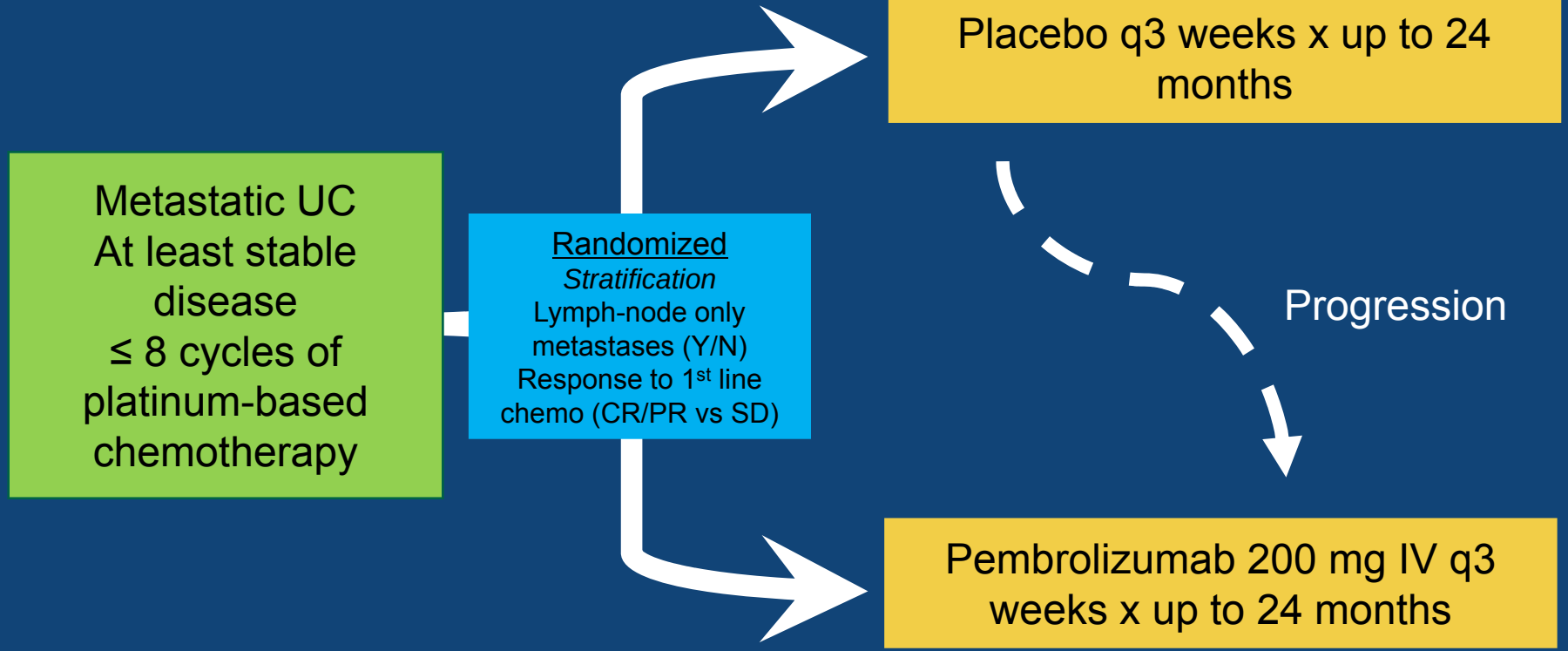
Matthew D. Galsky, Sumanta K. Pal, Amir Mortazavi, Matthew I. Milowsky, Saby George, Sumati Gupta, Mark T. Fleming, Long H. Dang, Daniel M. Geynisman, Radhika Walling, Robert S. Alter, Erwin L. Robin, Jue Wang, Shilpa Gupta, David D. Chism, Joel Picus, George Philips, David I. Quinn, Noah M. Hahn, Menggang Yu

Icahn School of Medicine at Mount Sinai; City of Hope National Medical Center, Duarte, CA; Ohio State University; University of North Carolina at Chapel Hill School of Medicine; Roswell Park Cancer Institute; Huntsman Cancer Institute-University of Utah Health Care; Virginia Oncology Associates; University of Florida; Fox Chase Cancer Center; Community Cancer Center; John Theurer Cancer Center at Hackensack University Medical Center; University of Arizona Cancer Center at Dignity Health St. Joseph's Hospital and Medical Center; Masonic Cancer Center, University of Minnesota; Vanderbilt University Medical Center; Washington University School of Medicine; Georgetown University Hospital; USC Norris Comprehensive Cancer Center; Johns Hopkins University School of Medicine; University of Wisconsin; Hoosier Cancer Research Network

PRESENTED AT: 2019 ASCO ANNUAL MEETING #ASCO19

PRESENTED BY:

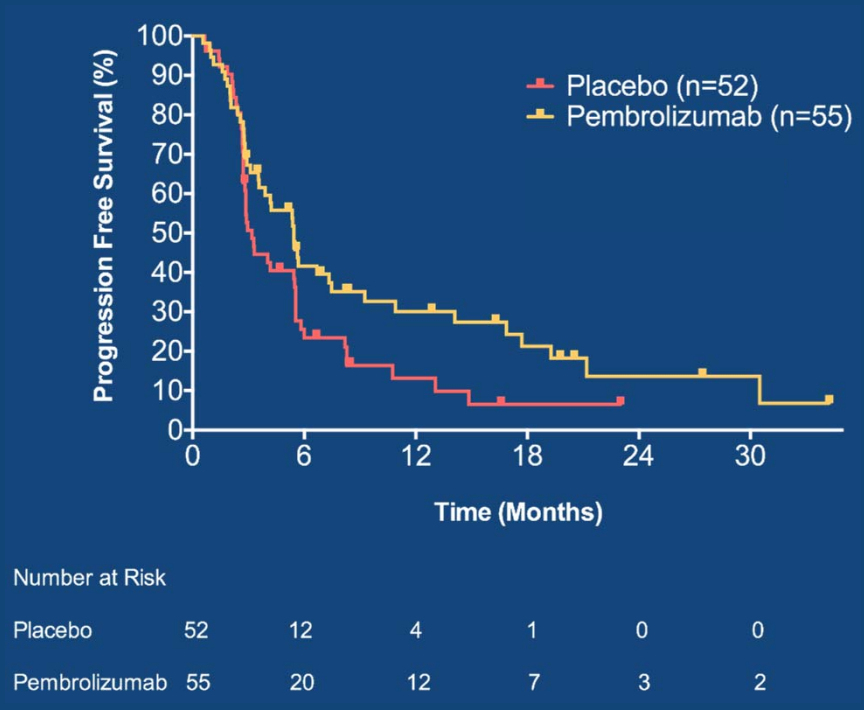
HCRN GU14-182



Objective Response Rate (RECIST 1.1)

Characteristic	Placebo (n=52)	Pembrolizumab (n=55)
Not evaluable (baseline CR)	10	9
Overall response	12%	22%
Partial response	12%	13%
Complete response	0	9%
Stable disease	29%	35%
Progressive disease	54%	33%
Unknown	5%	10%

Progression-free Survival



Number at Risk						
Placebo	52	12	4	1	0	0
Pembrolizumab	55	20	12	7	3	2

Median PFS and 95% CI
Placebo: 3.2 (2.8, 5.5)
Pembrolizumab: 5.4 (3.6, 9.2)

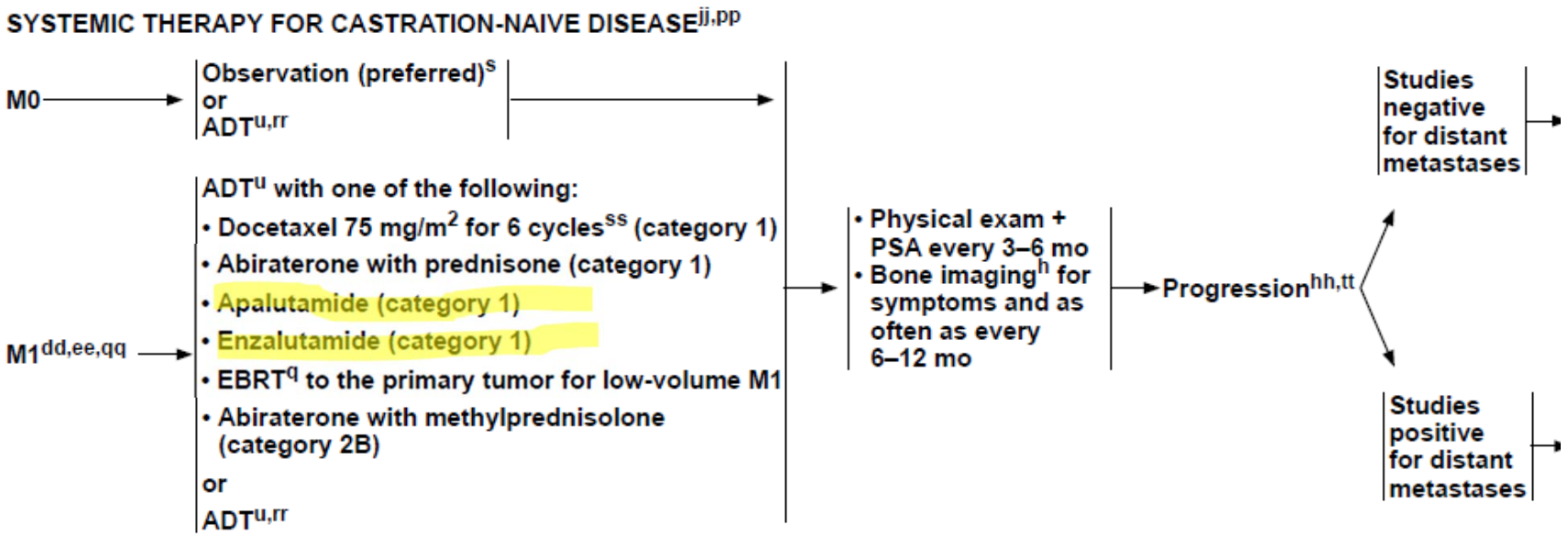
Hazard Ratio: 0.64 (0.41, 0.98)

Log rank $p = 0.038$

Bladder summary

- Switch-maintenance pembrolizumab significantly delays disease progression in patients with Muc
- Erdafitinib approved for FGFR2/3 variants of met TCC

NCCN: Advanced Prostate Cancer-Metastatic Castration Naive



OVERALL SURVIVAL (OS) RESULTS OF A PHASE III RANDOMIZED TRIAL OF STANDARD OF CARE THERAPY WITH OR WITHOUT ENZALUTAMIDE FOR METASTATIC HORMONE SENSITIVE PROSTATE CANCER (mHSPC)

ENZAMET (ANZUP 1304): AN ANZUP-LED INTERNATIONAL CO-OPERATIVE GROUP TRIAL (NHMRC CTC, CCTG, CTI, DFCI)

Christopher Sweeney, Andrew Martin, Robert Zielinski, Alastair Thomson, Thean Hsiang Tan, Shahneen Sandhu, M. Neil Reaume, David Pook, Francis Parnis, Scott North, Gavin Marx, John McCaffrey, Ray McDermott, Nicola Lawrence, Lisa Horvath, Mark Frydenberg, Simon Chowdhury, Kim Chi, Martin Stockler, Ian Davis

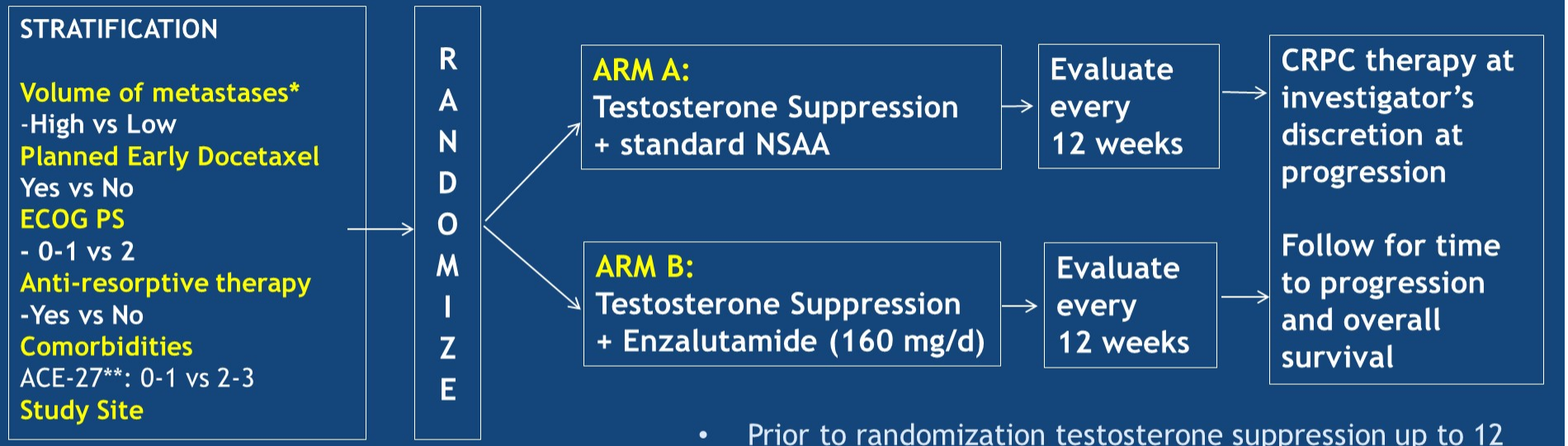
ANZUP® Cancer Trials Group Limited

PRESENTED AT: 2019 ASCO® ANNUAL MEETING #ASCO19

PRESENTED BY: Christopher Sweeney, MBBS

Presented By Christopher Sweeney at 2019 ASCO Annual Meeting

ENZAMET Treatment



- Prior to randomization testosterone suppression up to 12 weeks and 2 cycles of docetaxel was allowed.
- Intermittent ADT and cyproterone were not allowed
- NSAA: bicalutamide; nilutamide; flutamide
- *High volume: visceral metastases and/or 4 or more bone metastases (at least 1 beyond pelvis and vertebral column)
- **Adult Co-morbidity Evaluation-27

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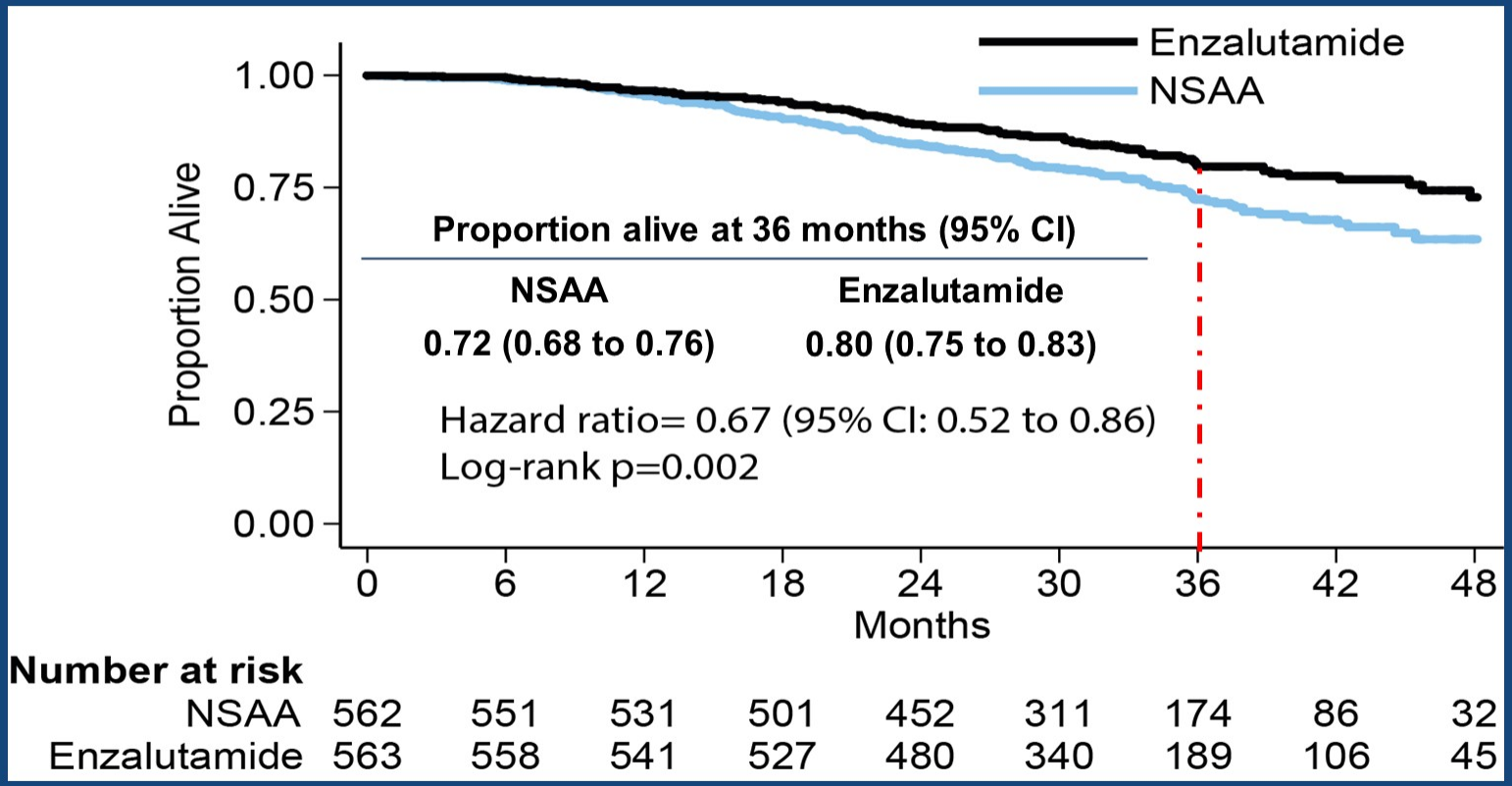
PRESENTED BY: Christopher Sweeney, MBBS

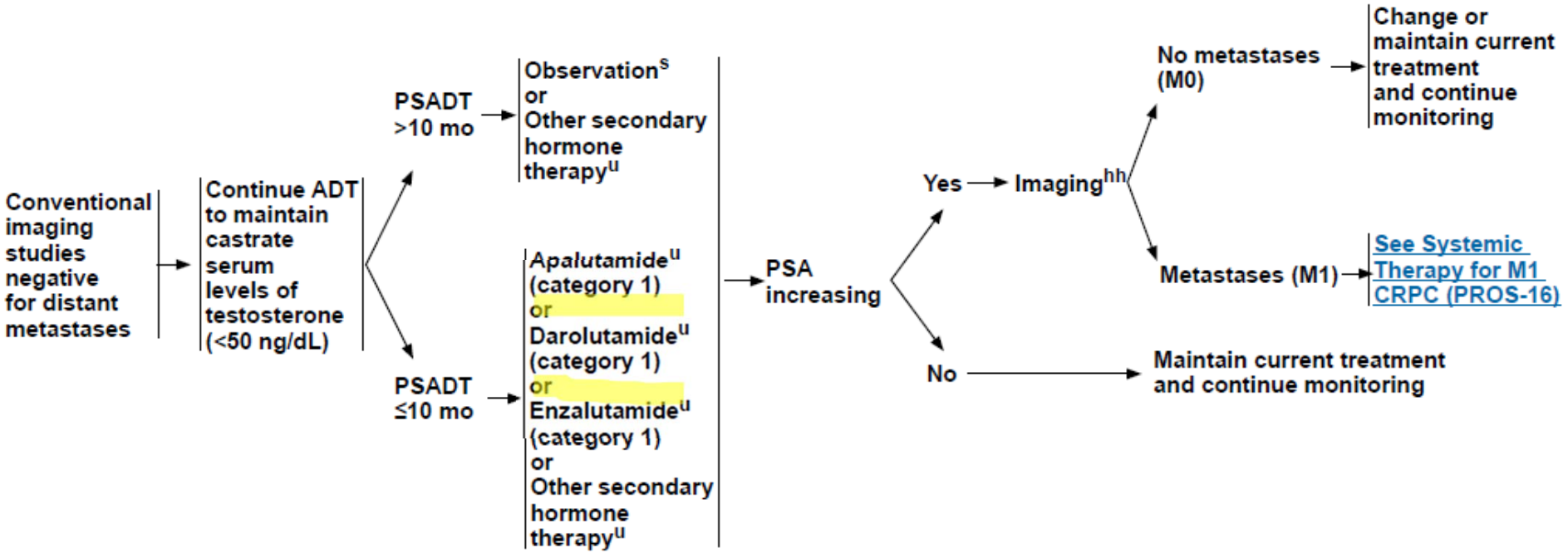
Primary endpoint: Overall survival



Presented By Christopher Sweeney at 2019 ASCO Annual Meeting

NCCN: Advanced Prostate Cancer: M0 CRPC

SYSTEMIC THERAPY FOR M0 CASTRATION–RESISTANT PROSTATE CANCER (CRPC)



Conclusions

Kidney cancer: new first line standards of care

- Axitinib and avelumab
- Axitinib and pembrolizumab

Advanced Bladder cancer:

- Switch maintenance with pembrolizumab offers prolonged PFS.
- Erdafitinib offers PFS benefit to FRFR2/3 positive bladder cancer patients.

CSPC:

- Apalutamide
- Enzalutamide

CRPC (M0):

- Darolutamide
- Enzalutamide

Question 1

- A 56 y/o male was recently referred to you for stage IV RCC (to lung, lymph nodes and adrenal) and has favorable risk per IMDC. What is the best treatment option?

1. Ipilimumab plus nivolumab
2. Sunitinib
3. High dose IL-2
4. Axitinib plus pembrolizumab
5. 2 and 4

Question 2

- A 68 y/o female patient has a history of stage IV bladder cancer. She was found to have progressive disease after 1st line platinum and 2nd line pembrolizumab. Her performance status is ECOG1. What is the next best step?

1. Cisplatin rechallenge
2. RT-PCR testing for FGFR2/3
3. Hospice care
4. Switch to nivolumab

Question 3

- A 71-year-old with newly-diagnosed metastatic prostate cancer patient is referred to you. His prostate biopsy showed GS 4+3=7 adenocarcinoma. He has two bone mets and PSA of 112 and normal counts and CMP and has no other co-morbidities. What is the best first treatment for this patient?

1. ADT alone
2. ADT plus enzalutamide
3. Bilateral orchiectomy only
4. ADT plus docetaxel