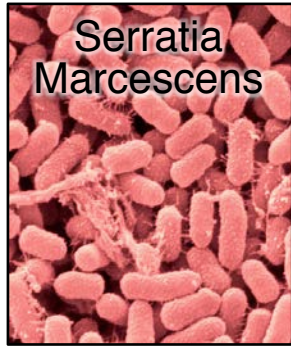
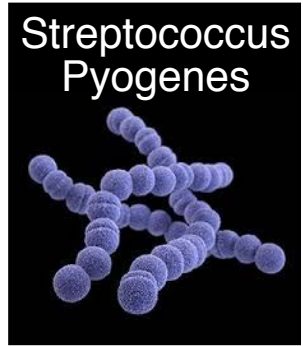


**2020**  
**Year in Review**  
**Endometrial and Cervical Cancers**

Richard T Penson MD MRCP  
Clinical Director Medical Gynecologic Oncology  
Massachusetts General Hospital

# History of Immunotherapy



Coley's Toxin  
1891

Abs  
1956

1960

1970

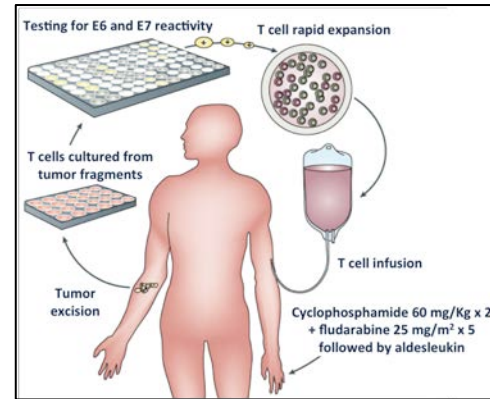
1980

1990

2000

2010

2020



Ipilimumab  
3/25/11

Pembrolizumab  
9/4/14  
Nivolumab  
12/22/14

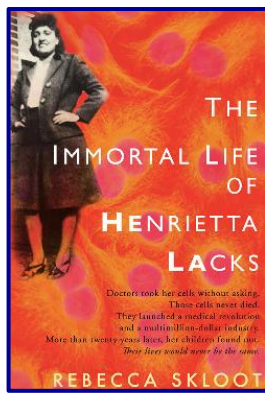
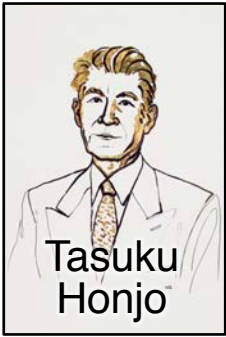
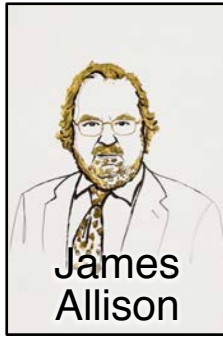
Pembrolizumab  
MSI-H/dMMR  
5/23/17

Pembrolizumab  
Cervical Cancer  
6/12/18

Pembrolizumab  
Lenvatinib  
(Acc.)  
9/19/19

Bacille Calmette-Guérin  
(BCG) 1976

IL2  
1991



Morgan DA, et al. *Science*. 1976;193:1007-1008; Morales A, et al. *J Urol*. 1976;116:180-182; Decker WK, et al. *Cytokine Growth Factor Rev*. 2009;20:271-281; Yuraszek T, et al. *Clin Pharmacol Ther*. 2017;101:634-645; Hinrichs CS, et al. *J Clin Oncol*. 2014;32(5s):LBA3008.

# Promise of Molecular Biomarkers: TCGA Subgroups

Subgroup	Incidence TCGA	Incidence GOG210	Cancer Mortality
Copy # Low	40%	49%	5%
<i>TP53</i> mut	30%	8%	19%
MSI+ / MMR-deficient	25%	39%	8%
POLE	5%	4%	3%

Cosgrove CM, et al. Gynecol Oncol. 2018;148:174-180

Levine DA. Nature. 2013;497:67-73

MacKay HJ, et al. Oncotarget 2017;8:84579-84594

# **Efficacy of Pembrolizumab in Patients With Noncolorectal High Microsatellite Instability/Mismatch Repair–Deficient Cancer: Results From the Phase II KEYNOTE-158 Study**

Aurelien Marabelle, MD, PhD<sup>1</sup>; Dung T. Le, MD<sup>2</sup>; Paolo A. Ascierto, MD<sup>3</sup>; Anna Maria Di Giacomo, MD<sup>4</sup>; Ana De Jesus-Acosta, MD<sup>2</sup>; Jean-Pierre Delord, MD, PhD<sup>5</sup>; Ravit Geva, MD, MSc<sup>6</sup>; Maya Gottfried, MD<sup>7</sup>; Nicolas Penel, MD, PhD<sup>8</sup>; Aaron R. Hansen, MBBS<sup>9</sup>; Sarina A. Piha-Paul, MD<sup>10</sup>; Toshihiko Doi, MD, PhD<sup>11</sup>; Bo Gao, MBBS, PhD<sup>12</sup>; Hyun Cheol Chung, MD, PhD<sup>13</sup>; Jose Lopez-Martin, MD, PhD<sup>14</sup>; Yung-Jue Bang, MD, PhD<sup>15</sup>; Ronnie Shapira Frommer, MD<sup>16</sup>; Manisha Shah, MD<sup>17</sup>; Razi Ghori, PhD<sup>18</sup>; Andrew K. Joe, MD<sup>18</sup>; Scott K. Pruitt, MD, PhD<sup>18</sup>; and Luis A. Diaz Jr, MD<sup>19</sup>

J Clin Oncol 2020;38(1):1-10

# Tumor Type Specific Antitumor Activity

**TABLE 3.** Antitumor Activity for Tumor Types With Greatest Enrollment

Tumor Type	No.	CR, No.	PR, No.	ORR, % (95% CI)	Median PFS, Months (95% CI)	Median OS, Months (95% CI)	Median DOR, Months (range)
Endometrial	49	8	20	57.1 (42.2 to 71.2)	25.7 (4.9 to NR)	NR (27.2 to NR)	NR (2.9 to 27.0+)
Gastric	24	4	7	45.8 (25.6 to 67.2)	11.0 (2.1 to NR)	NR (7.2 to NR)	NR (6.3 to 28.4+)
Cholangiocarcinoma	22	2	7	40.9 (20.7 to 63.6)	4.2 (2.1 to NR)	24.3 (6.5 to NR)	NR (4.1+ to 24.9+)
Pancreatic	22	1	3	18.2 (5.2 to 40.3)	2.1 (1.9 to 3.4)	4.0 (2.1 to 9.8)	13.4 (8.1 to 16.0+)
Small intestine	19	3	5	42.1 (20.3 to 66.5)	9.2 (2.3 to NR)	NR (10.6 to NR)	NR (4.3+ to 31.3+)
Ovarian	15	3	2	33.3 (11.8 to 61.6)	2.3 (1.9 to 6.2)	NR (3.8 to NR)	NR (4.2 to 20.7+)
Brain	13	0	0	0.0 (0.0 to 24.7)	1.1 (0.7 to 2.1)	5.6 (1.5 to 16.2)	–

KEYNOTE-100

9%

Matulonis UA, et al. Ann Oncol. 2019;30(7):1080-1087

# Toxicities

**TABLE 4.** Incidence of Adverse Events

Adverse Event	Patients (N = 233)	
	Any Grade, No. (%)	Grade 3-4*, No. (%)
Treatment-related adverse events		
Any	151 (64.8)	34 (14.6)
Occurring in $\geq$ 5% of patients		
Fatigue	34 (14.6)	2 (0.9)
Pruritus	30 (12.9)	0
Diarrhea	28 (12.0)	0
Asthenia	25 (10.7)	1 (0.4)
Hypothyroidism	19 (8.2)	0
Arthralgia	18 (7.7)	0
Nausea	15 (6.4)	0
Rash	12 (5.2)	0

# Summary

## **Impact on Patient Care and Treatment Algorithms**

- FDA approved tissue agnostic May 23<sup>rd</sup>, 2017
- Exciting new standard of care
- Earlier use of IO more common
- Goal: control not cure Rx beyond 2yrs standard

## **Implications for Future Research**

- IO vs. chemotherapy UNK
- CRISPRing in MMR deficiency potential strategy

# Lenvatinib Plus Pembrolizumab in Patients With Advanced Endometrial Cancer

Vicky Makker, MD<sup>1</sup>; Matthew H. Taylor, MD<sup>2</sup>; Carol Aghajanian, MD<sup>1</sup>; Ana Oaknin, MD, PhD<sup>3</sup>; James Mier, MD<sup>4</sup>; Allen L. Cohn, MD<sup>5</sup>; Margarita Romeo, MD, PhD<sup>6</sup>; Raquel Bratos, MD<sup>7</sup>; Marcia S. Brose, MD, PhD<sup>8</sup>; Christopher DiSimone, MD<sup>9</sup>; Mark Messing, MD<sup>10</sup>; Daniel E. Stepan, MD<sup>11</sup>; Corina E. Dutcus, MD<sup>12</sup>; Jane Wu, PhD<sup>12</sup>; Emmett V. Schmidt, MD, PhD<sup>13</sup>; Robert Orłowski, MD<sup>13</sup>; Pallavi Sachdev, PhD<sup>12</sup>; Robert Shumaker, PhD<sup>11</sup>; and Antonio Casado Herraes, MD, PhD<sup>14</sup>

J Clin Oncol 2020;38(26):2981-2992

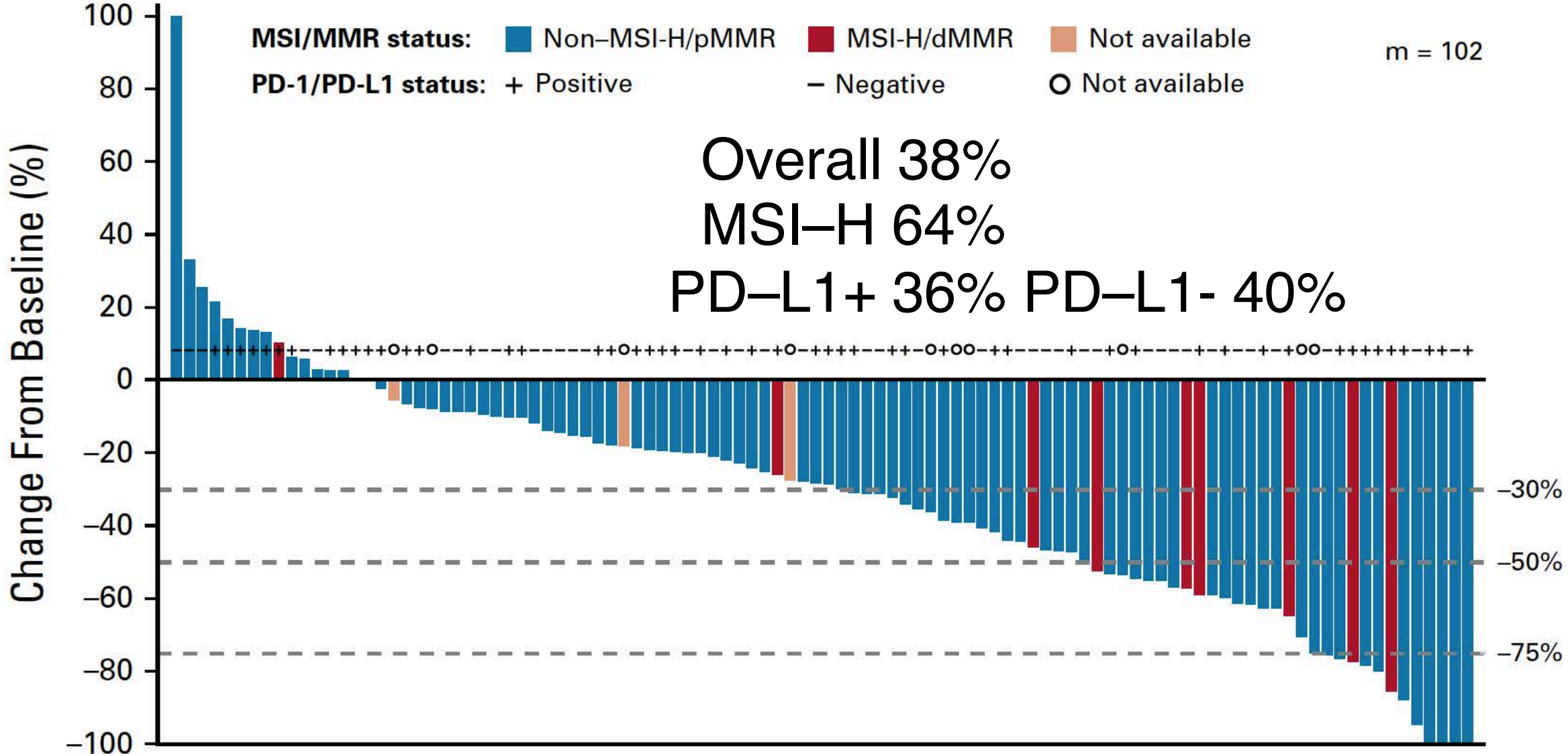
Lenvatinib 20 mg PO QD pembrolizumab 200 mg IV Q21

Primary end point: ORRWk24

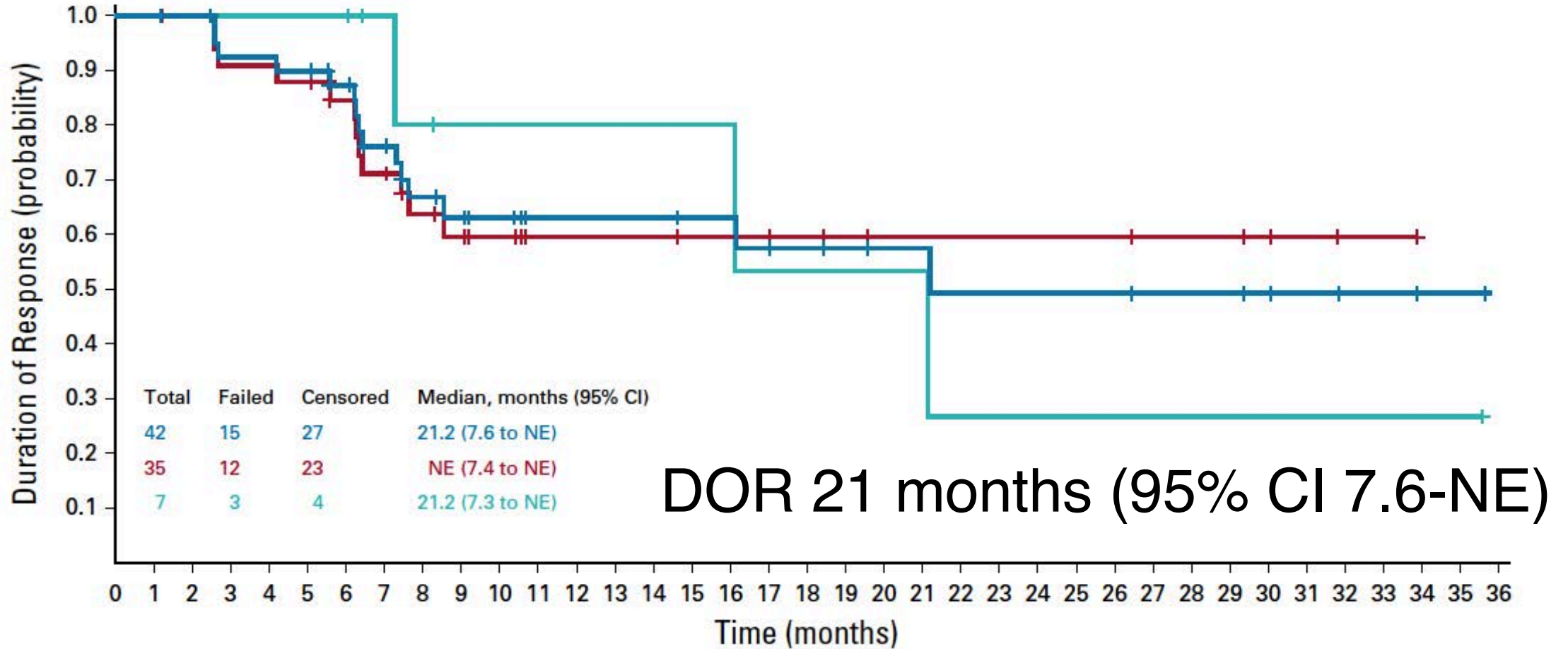
n=108



# Objective Response Rate (ORRWk24)



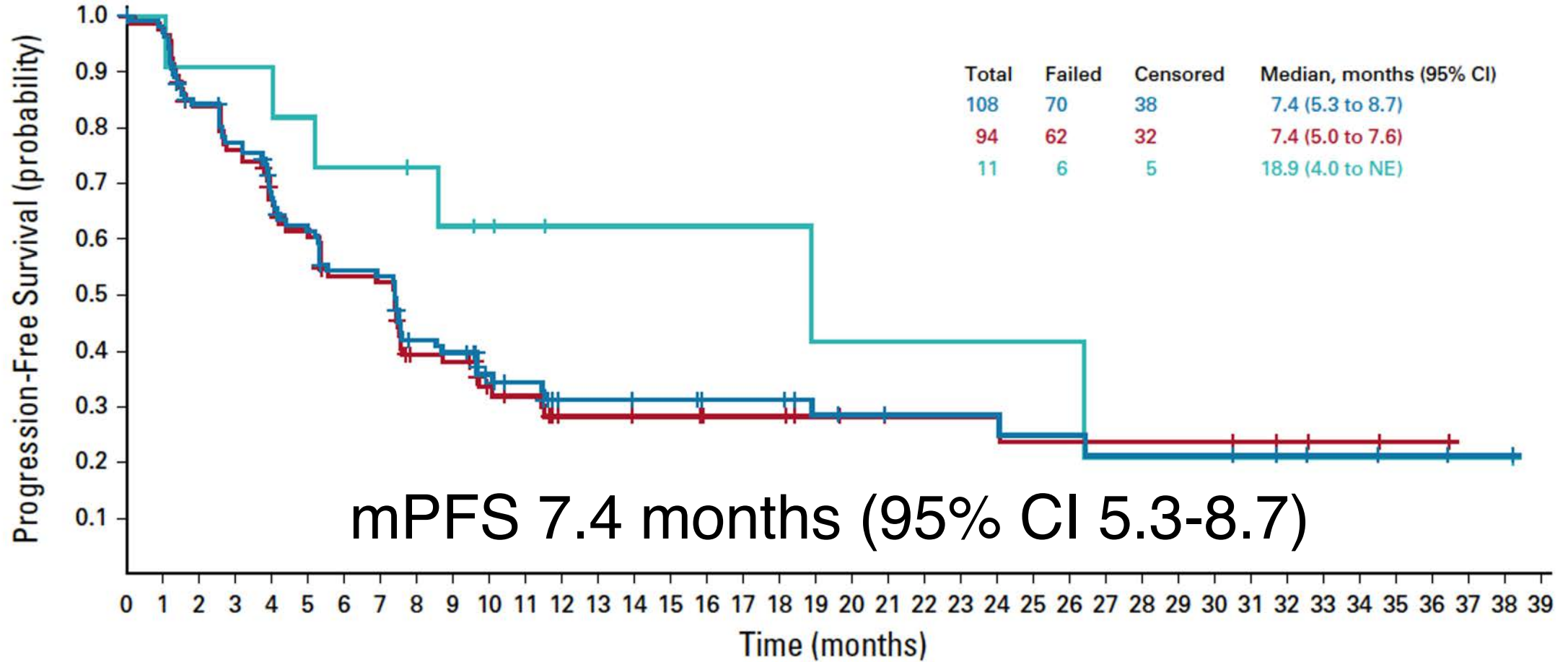
# Duration of Response



No. at risk:

	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36
Total in EC 2L+	42	42	41	37	37	36	32	26	21	17	15	12	12	12	12	11	11	9	9	8	7	7	6	6	6	6	6	5	5	5	4	3	2	2	1	1	0
MSS/pMMR	35	35	34	30	30	29	25	21	17	14	12	9	9	9	8	8	7	7	6	5	5	5	5	5	5	5	4	4	4	3	2	1	1	0	0	0	
MSI-H/dMMR	7	7	7	7	7	7	7	5	4	3	3	3	3	3	3	3	3	2	2	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	0	

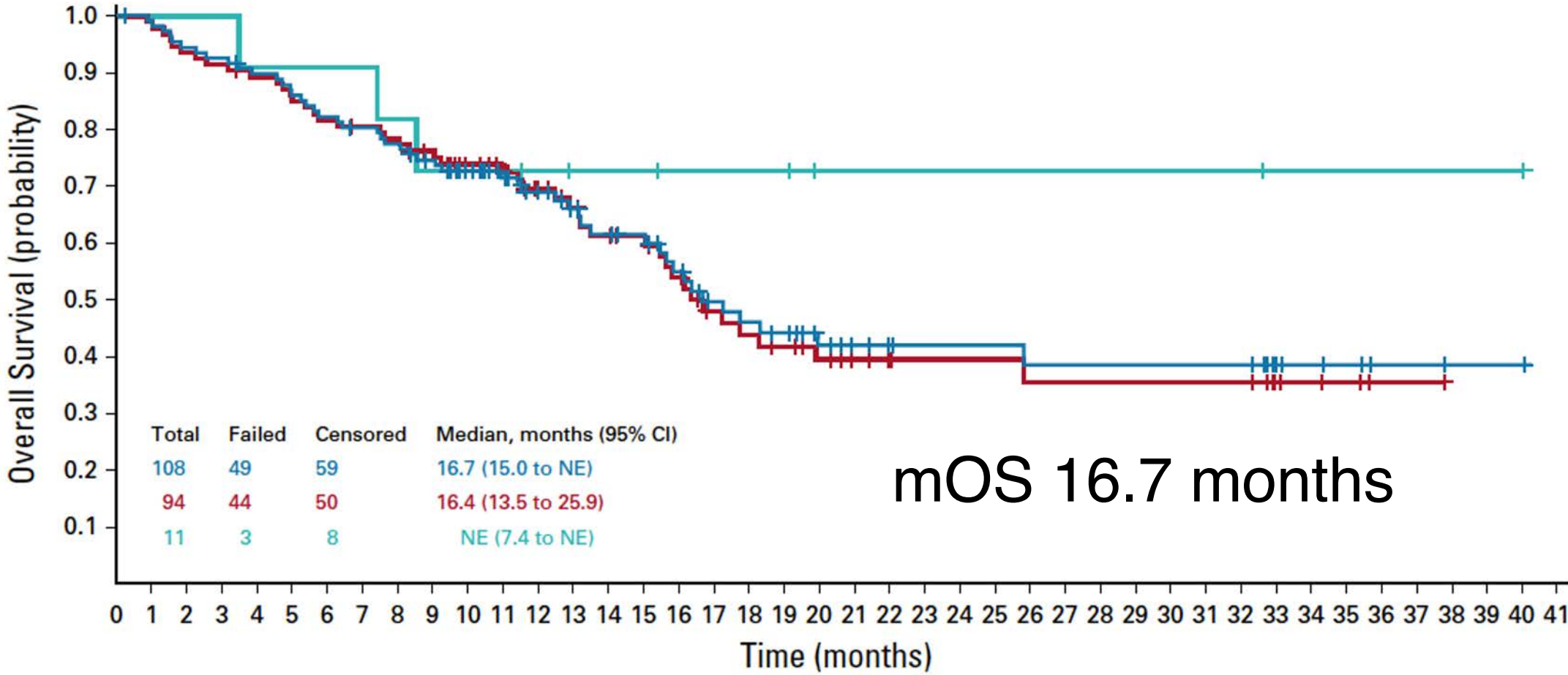
# Progression Free Survival



No. at risk:

	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39
<b>Total in EC 2L+</b>	108	105	88	80	69	61	53	52	37	35	25	22	16	16	15	15	13	13	13	10	9	8	8	8	8	7	7	6	6	6	6	5	4	3	3	2	2	1	1	0
<b>MSS/pMMR</b>	94	91	76	69	59	52	45	44	30	29	20	18	13	13	12	10	10	10	10	8	7	6	6	6	6	5	5	5	5	5	5	4	3	2	2	1	1	0	0	0
<b>MSI-H/dMMR</b>	11	11	10	10	10	9	8	8	7	6	5	4	3	3	3	3	3	3	3	2	2	2	2	2	2	2	2	2	1	1	1	1	1	1	1	1	1	1	1	0

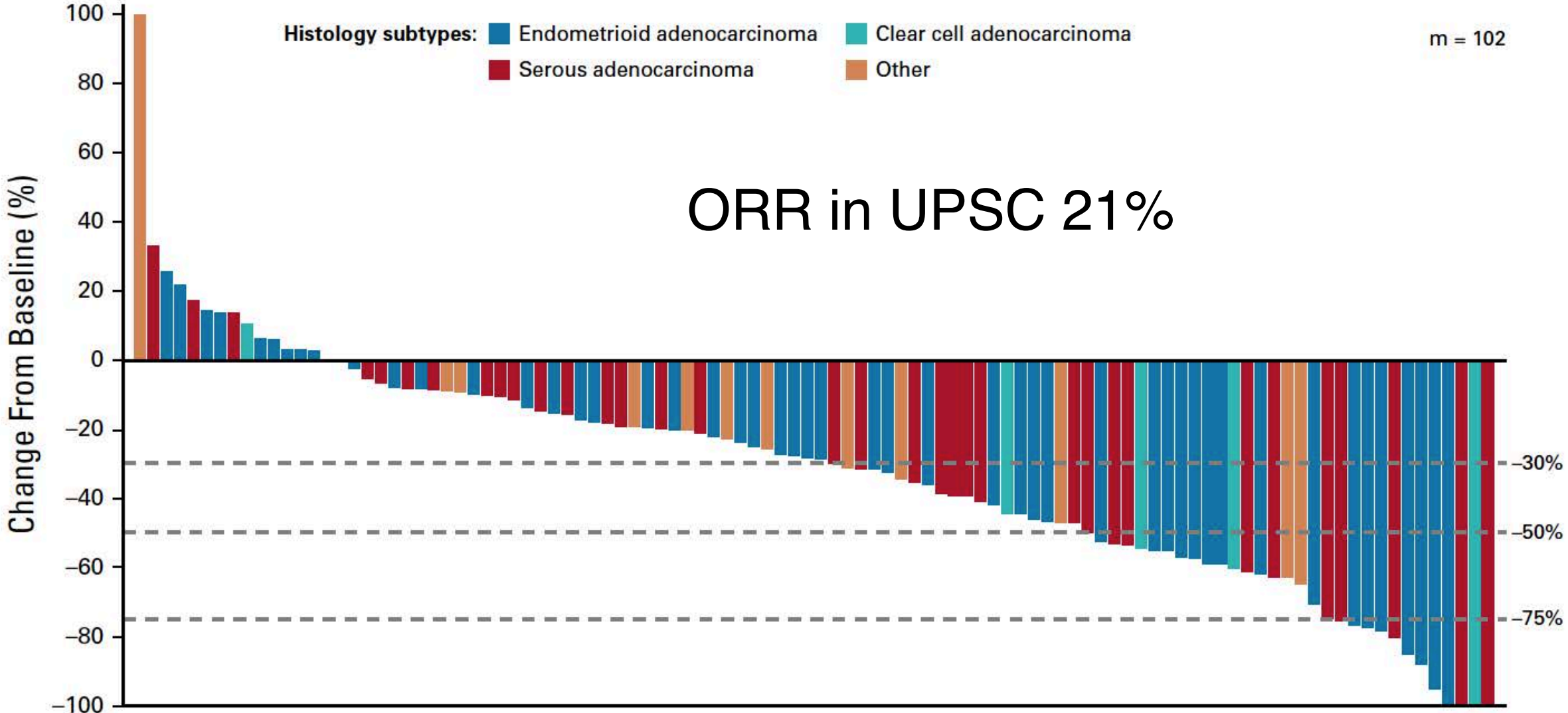
# Overall Survival



No. at risk:

Total in EC 2L+	108	106	101	99	95	91	87	84	81	76	66	59	51	45	41	39	33	27	25	23	18	15	13	12	12	12	11	11	11	11	11	11	11	11	11	6	5	4	2	2	1	1	1	0	
MSS/pMMR	94	92	87	85	82	78	75	73	71	67	57	52	45	40	36	34	29	23	21	19	16	13	11	10	10	10	9	9	9	9	9	9	9	9	9	9	5	4	3	1	1	0	0	0	0
MSI-H/dMMR	11	11	11	11	10	10	10	10	9	8	8	7	6	5	5	5	4	4	4	4	4	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	1	1	1	1	1	1	1	0

# ORR by Histologic Subtype



# Toxicity Promising antitumor activity with manageable toxicity

**TABLE 3.** Treatment-Related Adverse Events ( $\geq 20\%$  any grade or any grade 3 or grade 4 events)

Preferred Term or Basket	Previously Treated EC <sup>a</sup> (n = 108)		All EC (N = 124)	
	Any Grade	Grade 3/4	Any Grade	Grade 3/4
Patients with any treatment-related TEAEs	105 (97.2)	75 (69.4)	120 (96.8)	83 (66.9)
Hypertension <sup>b</sup>	66 (61.1)	35 (32.4)	74 (59.7)	39 (31.5)
Diarrhea	57 (52.8)	7 (6.5)	65 (52.4)	8 (6.5)
Fatigue	56 (51.9)	9 (8.3)	59 (47.6)	9 (7.3)
Decreased appetite	51 (47.2)	0	59 (47.6)	0
Hypothyroidism <sup>c</sup>	48 (44.4)	1 (0.9)	54 (43.5)	1 (0.8)
Nausea	43 (39.8)	3 (2.8)	48 (38.7)	3 (2.4)
Stomatitis	36 (33.3)	0	39 (31.5)	0
Pain and arthralgia <sup>d</sup>	34 (31.5)	2 (1.9)	37 (29.8)	2 (1.6)
Dysphonia	30 (27.8)	0	34 (27.4)	0
PPE and severe skin reactions <sup>e</sup>	29 (26.9)	5 (4.6)	32 (25.8)	6 (4.8)
Vomiting	29 (26.9)	0	31 (25.0)	0
Weight decreased	28 (25.9)	2 (1.9)	30 (24.2)	2 (1.6)
Proteinuria <sup>f</sup>	24 (22.2)	4 (3.7)	30 (24.2)	4 (3.2)
Headache	22 (20.4)	0	25 (20.2)	0
Myalgia	19 (17.6)	1 (0.9)	20 (16.1)	1 (0.8)
Hepatotoxicity and hepatitis <sup>g</sup>	16 (14.8)	3 (2.8)	21 (16.9)	4 (3.2)

# Summary

## **Impact on Patient Care and Treatment Algorithms**

- Established option and FDA approved for MSS EC
- Has rapidly become a new standard of care
- Given toxicity and QOL impact, tailoring dose is key

## **Implications for Future Research**

- Phase III confirmatory trial awaited
- Microenvironment manipulation with IOs
- Relative merit of antiangiogenic > comb IO > PARPi UNK
- Benefit of bevacizumab vs. TKI unknown

JAMA Oncology | **Original Investigation**

# Clinical Activity and Safety of the Anti-Programmed Death 1 Monoclonal Antibody Dostarlimab for Patients With Recurrent or Advanced Mismatch Repair-Deficient Endometrial Cancer

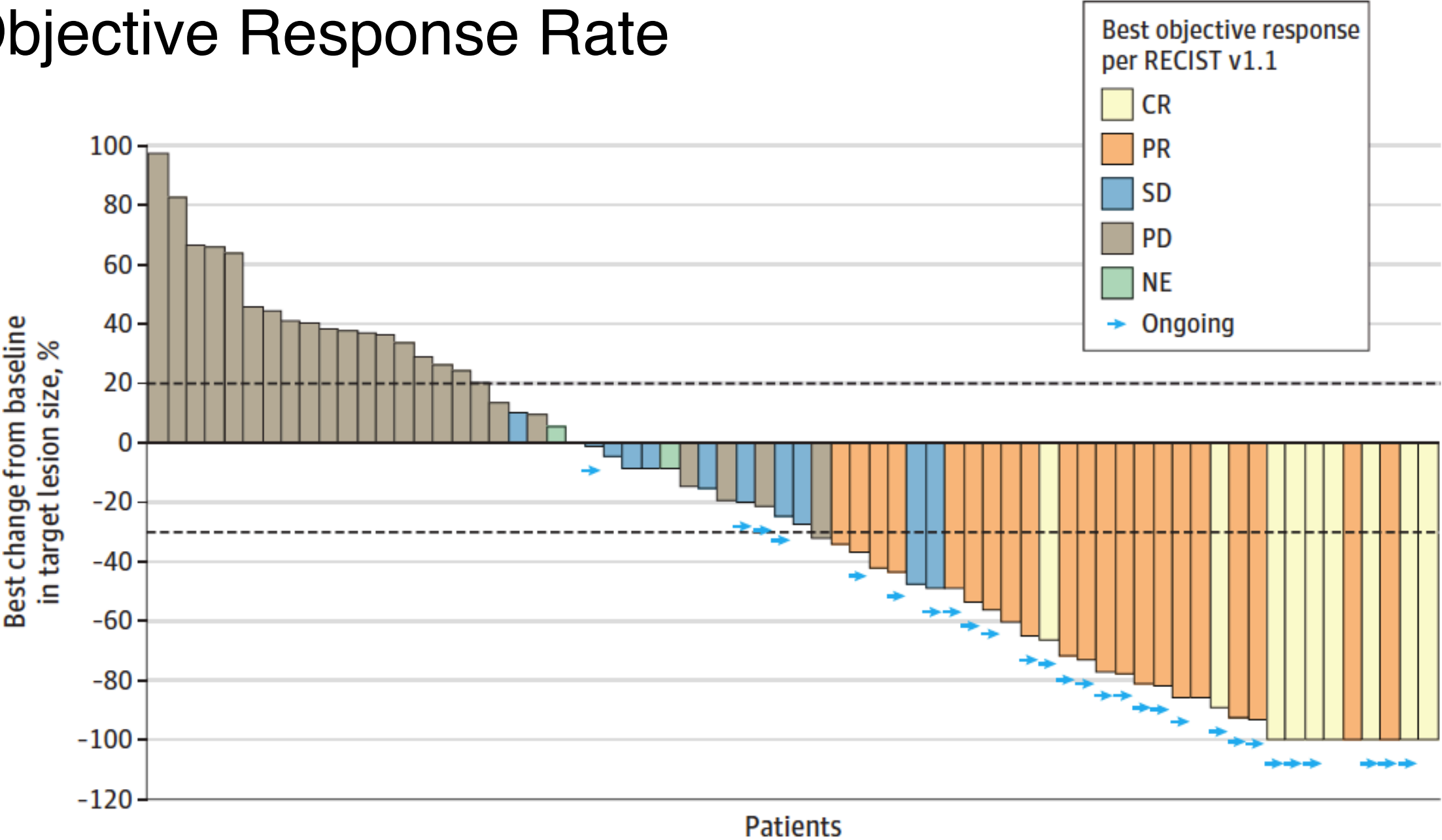
## A Nonrandomized Phase 1 Clinical Trial

Ana Oaknin, MD, PhD; Anna V. Tinker, MD; Lucy Gilbert, MD; Vanessa Samouëlian, MD; Cara Mathews, MD; Jubilee Brown, MD; Maria-Pilar Barretina-Ginesta, MD; Victor Moreno, MD; Adriano Gravina, MD; Cyril Abdeddaim, MD; Susana Banerjee, MD; Wei Guo, PhD; Hadi Danaee, ScD; Ellie Im, MD; Renaud Sabatier, MD

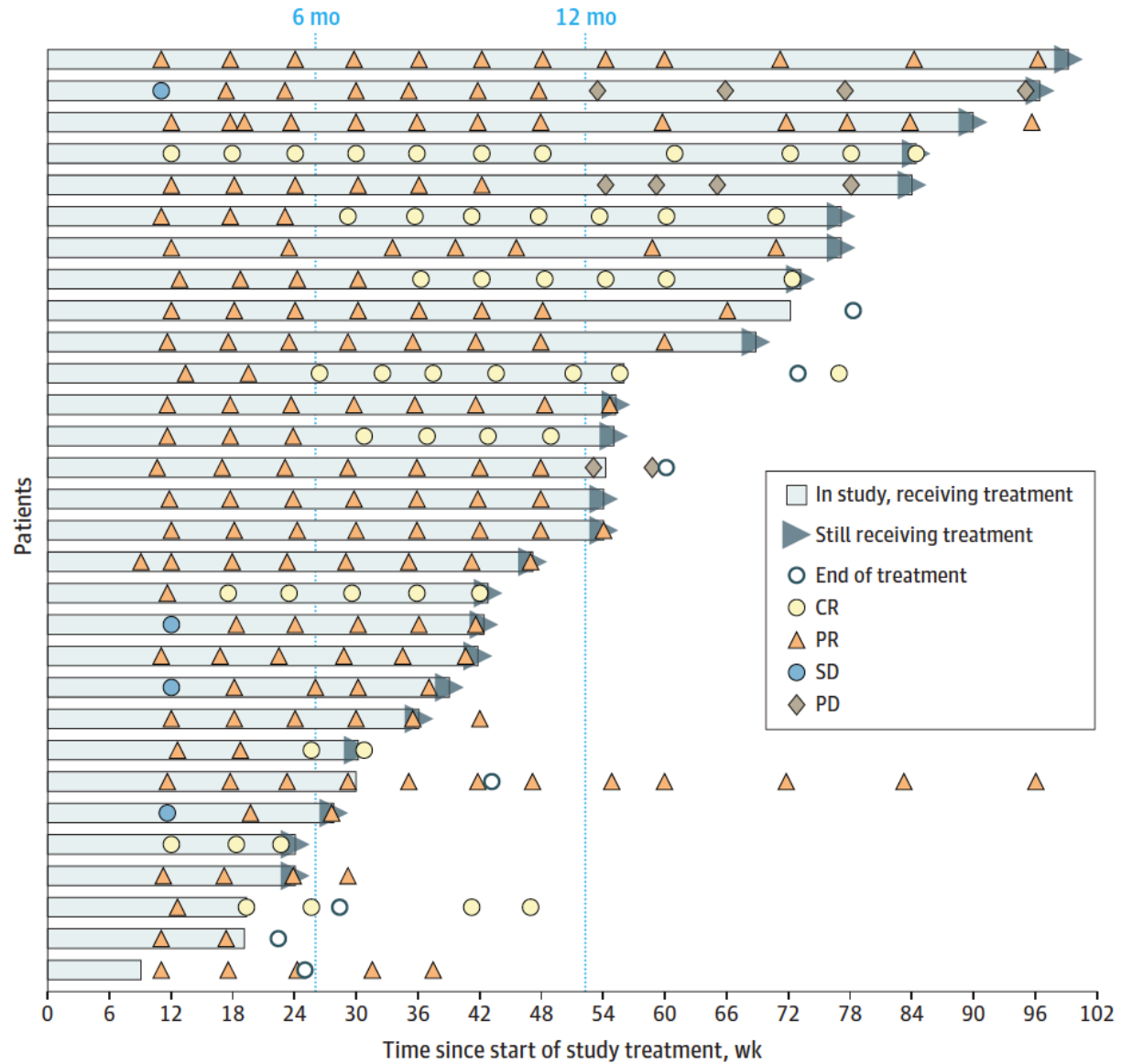
JAMA Oncol 2020;6(11):1-7



# Objective Response Rate



# Duration of Response



# Summary

cORR 42%

cCR 13%

Gr 3 An (3%) & colitis (2%)

Clinically meaningful & durable antitumor activity

Acceptable safety profile

## Impact on Patient Care and Treatment Algorithms

- Dostarlimab potent, high affinity PD-1 receptor blockade
- Typical and manageable PD-1 blockade toxicities

## Implications for Future Research

- Speculation about accelerated approval based on Phase II experience has not yet materialized



NCT03981796

**GOG** Pembrolizumab  
NCT03914612

**AtTEnd** Avelumab  
NCT03603184

Recurrent  
or primary adv.  
Stage III or IV  
endometrial cancer

**Stratification:**  
MSI status  
Prior pelvic RT  
Disease status

R

Dostarlimab 500 mg  
Carboplatin AUC 5  
Paclitaxel 175 mg/m<sup>2</sup>  
Q3W for 6 cycles

Randomized 1:1 n=470

Placebo  
Carboplatin AUC 5  
Paclitaxel 175 mg/m<sup>2</sup>  
Q3W for 6 cycles

Dostarlimab 1000 mg  
Q6W for up to 6 years

**Primary End Point: PFS**

Placebo  
Q6W for up to 3 years



Courtesy of Richard T Penson, MD, MRCP



Mirza MR, et al. ENGOT-EN6/NSGO-RUBY  
A Phase III, randomized, double-blind, multicenter study of dostarlimab + carbo-paclitaxel versus placebo + carbo-paclitaxel in recurrent or primary advanced EC. ASCO 2020;Abs TPS6107.

## Summary

### **Impact on Patient Care and Treatment Algorithms**

- Rapidly accruing registration trial

### **Implications for Future Research**

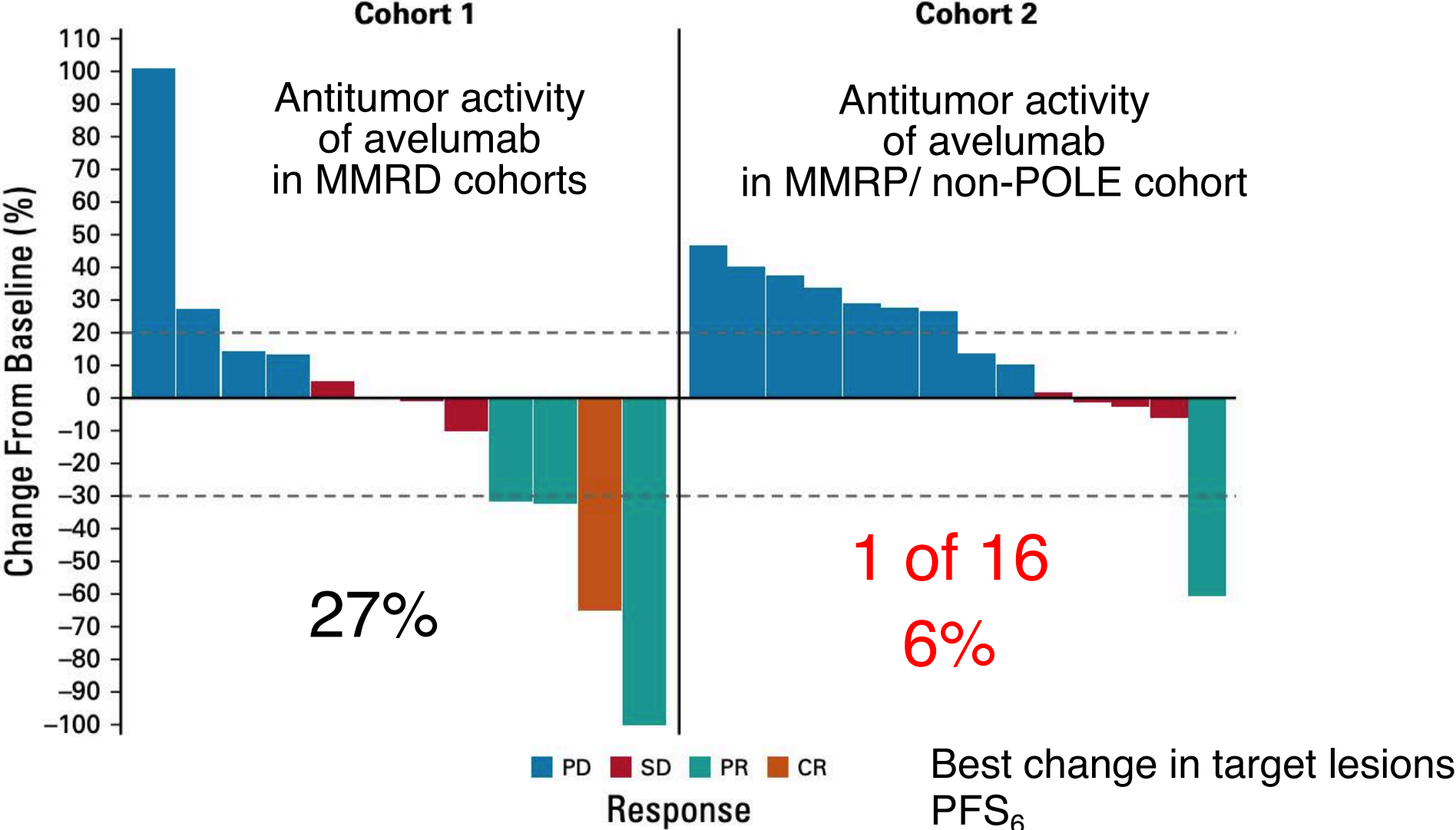
- Will add niraparib in an upcoming amendment to investigate PARP IO benefit

# Phase II Study of Avelumab in Patients With Mismatch Repair Deficient and Mismatch Repair Proficient Recurrent/Persistent Endometrial Cancer

Panagiotis A. Konstantinopoulos, MD, PhD<sup>1</sup>; Weixiu Luo, MS<sup>1</sup>; Joyce F. Liu, MD<sup>1</sup>; Doga C. Gulhan, PhD<sup>2</sup>; Carolyn Krasner, MD<sup>1</sup>; Jeffrey J. Ishizuka, MD, DPhil<sup>1</sup>; Allison A. Gockley, MD<sup>3</sup>; Mary Buss, MD, MPH<sup>4</sup>; Whitfield B. Growdon, MD<sup>5</sup>; Heather Crowe<sup>5</sup>; Susana Campos, MD, MPH<sup>1</sup>; Neal I. Lindeman, MD<sup>3</sup>; Sarah Hill, MD, PhD<sup>3</sup>; Elizabeth Stover, MD, PhD<sup>1</sup>; Susan Schumer, MD<sup>1</sup>; Alexi A. Wright, MD, MPH<sup>1</sup>; Jennifer Curtis, MS<sup>1</sup>; Roxanne Quinn<sup>1</sup>; Christin Whalen, RN<sup>1</sup>; Kathryn P. Gray, PhD<sup>1</sup>; Richard T. Penson, MD<sup>5</sup>; Stephen A. Cannistra, MD<sup>4</sup>; Gini F. Fleming, MD<sup>6</sup>; and Ursula A. Matulonis, MD<sup>1</sup>

J Clin Oncol 2019;37(30):2786-94

# Objective Response Rate

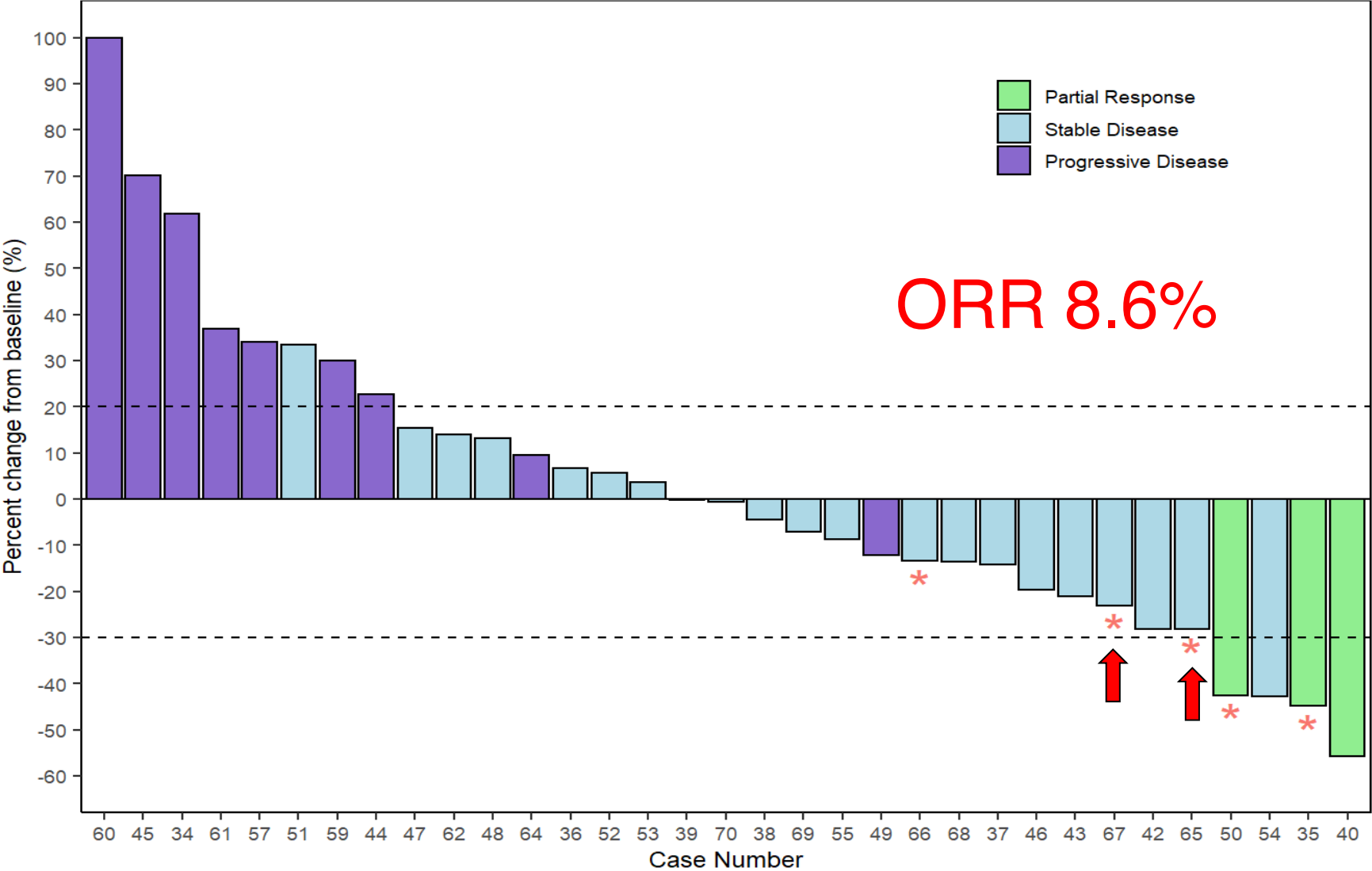


Konstantinopoulos PA, et al.  
Phase II study of PARP inhibitor talazoparib  
and PD-L1 inhibitor avelumab in patients with  
microsatellite stable recurrent / persistent  
endometrial cancer  
Annals Oncol 2020;31(4):S1165 LBA35





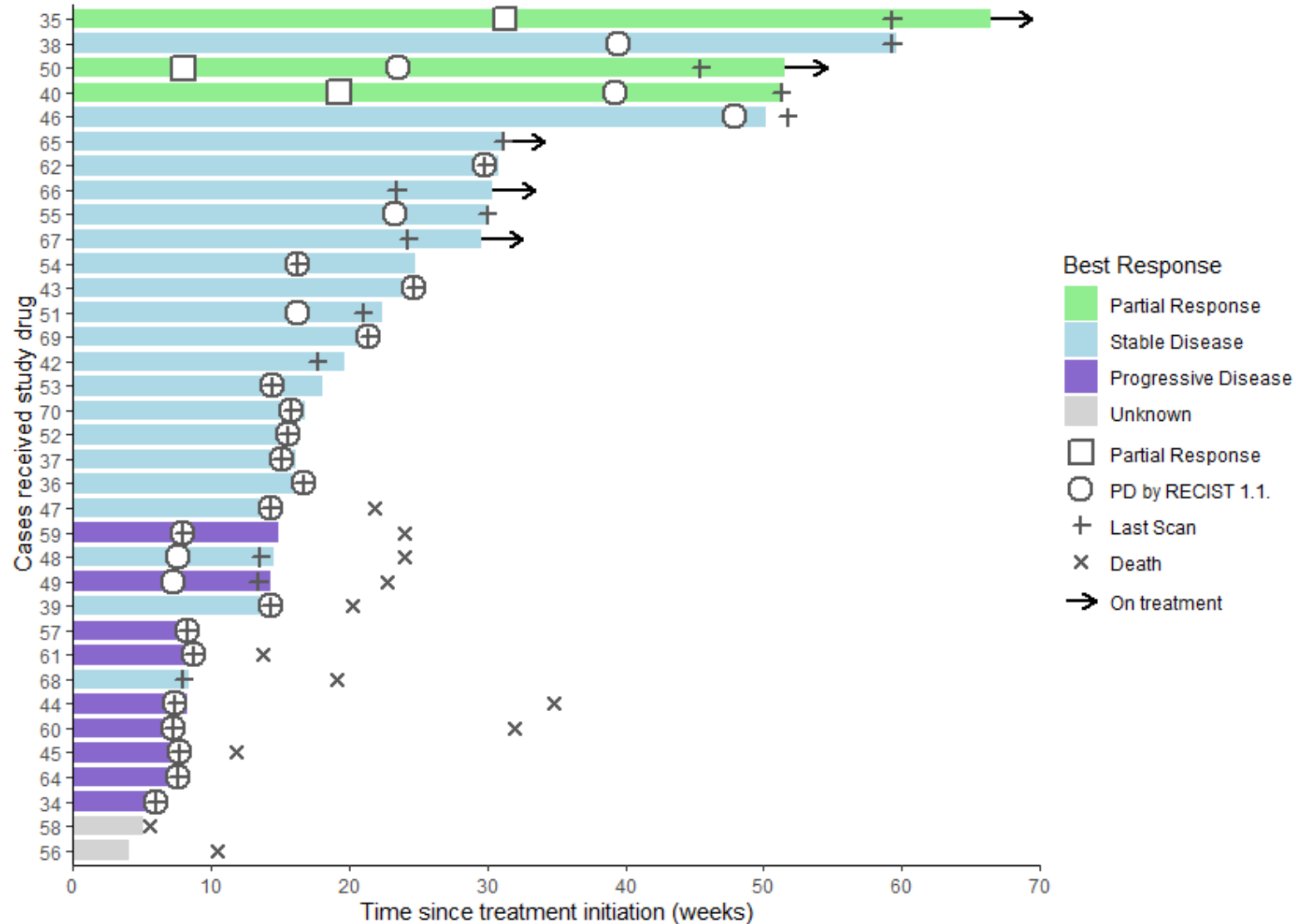
# Objective Response Rate



5 patients still on treatment (\*)

2 patients still on Rx (red arrows) with near PR (23%, 28% reduction)

# Duration of Response



**8 patients  
exhibited PFS<sub>6</sub>  
responses**

3 Endometrioid,  
3 Serous,  
1 Clear Cell  
1 Carcinosarcoma

# Objective Response Rate

## G3+ TREATMENT RELATED TOXICITY

Category	Adverse Events	Grade 3		Grade 4	
		N	%	N	%
Blood and lymphatic system disorders	Anemia	16	45.7	-	-
Investigations	Platelet count decreased	7	20	3	8.6
Investigations	Neutrophil count decreased	4	11.4	-	-
General disorders and admin site conditions	Fatigue	3	8.6	-	-
Blood and lymphatic system disorders	Blood and lymphatic system disorders - Other, specify	1	2.9	-	-
General disorders and admin site conditions	Infusion related reaction	1	2.9	-	-
Renal and urinary disorders	Acute kidney injury	1	2.9	-	-
Renal and urinary disorders	Hematuria	1	2.9	-	-

# Summary

## **Impact on Patient Care and Treatment Algorithms**

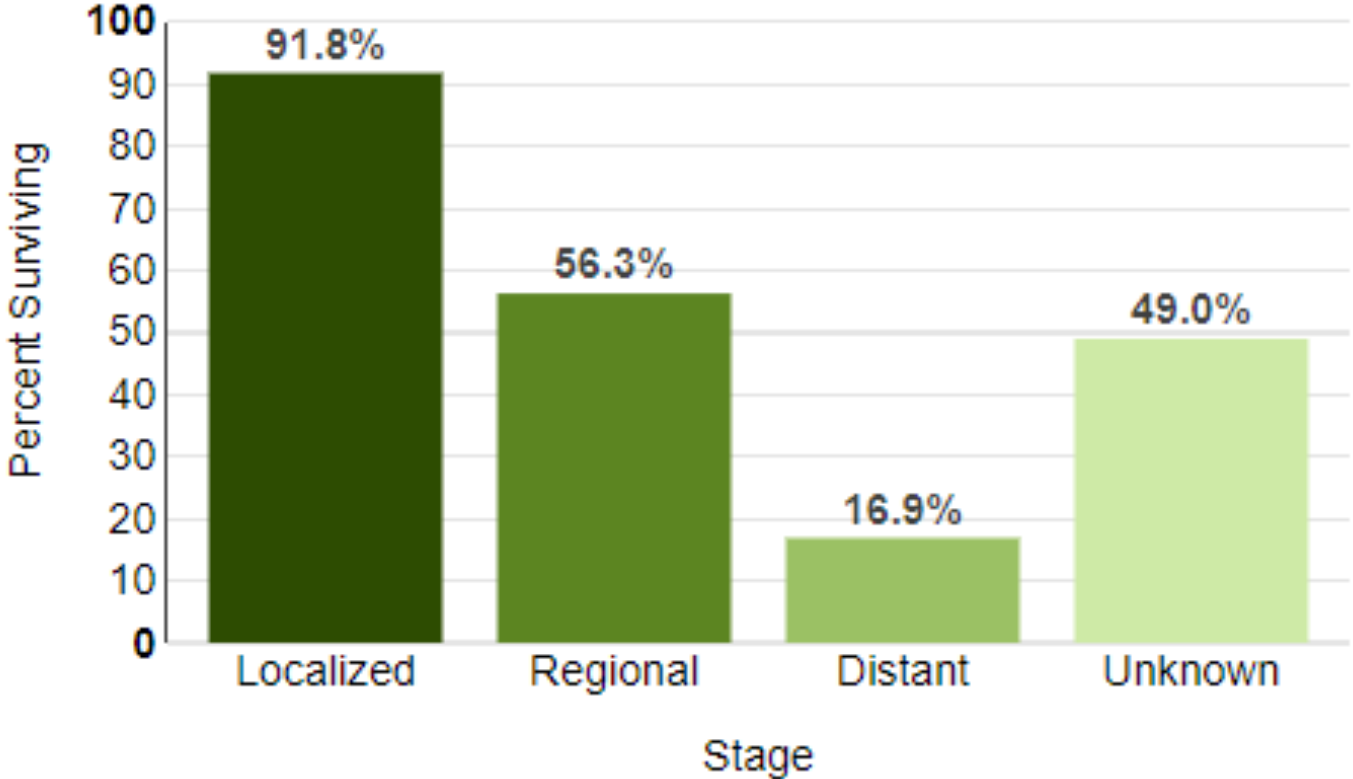
- Notable demonstration of the differences in response to IO between MSI-H and MSS EC
- Augmentation of efficacy and toxicity

## **Implications for Future Research**

- Relative benefit of PD-1 vs. PD-L1 unknown but in X-trial comparisons PD-L1 seems less effective

# Cervical Cancer: Challenges at a Glance

Survival by Stage



Courtesy: Amir Jazaeri MD - MD Anderson Cancer Center

Courtesy of Richard T Penson, MD, MRCP

# **Efficacy and Safety of Pembrolizumab in Previously Treated Advanced Cervical Cancer: Results From the Phase II KEYNOTE-158 Study**

Hyun Cheol Chung, MD, PhD<sup>1</sup>; Willeke Ros, MSc<sup>2</sup>; Jean-Pierre Delord, MD, PhD<sup>3</sup>; Ruth Perets, MD, PhD<sup>4</sup>; Antoine Italiano, MD, PhD<sup>5</sup>; Ronnie Shapira-Frommer, MD<sup>6</sup>; Lyudmila Manzuk, MD<sup>7</sup>; Sarina A. Piha-Paul, MD<sup>8</sup>; Lei Xu, PhD<sup>9</sup>; Susan Zeigenfuss, RN<sup>9</sup>; Scott K. Pruitt, MD, PhD<sup>9</sup>; and Alexandra Leary, MD, PhD<sup>10</sup>

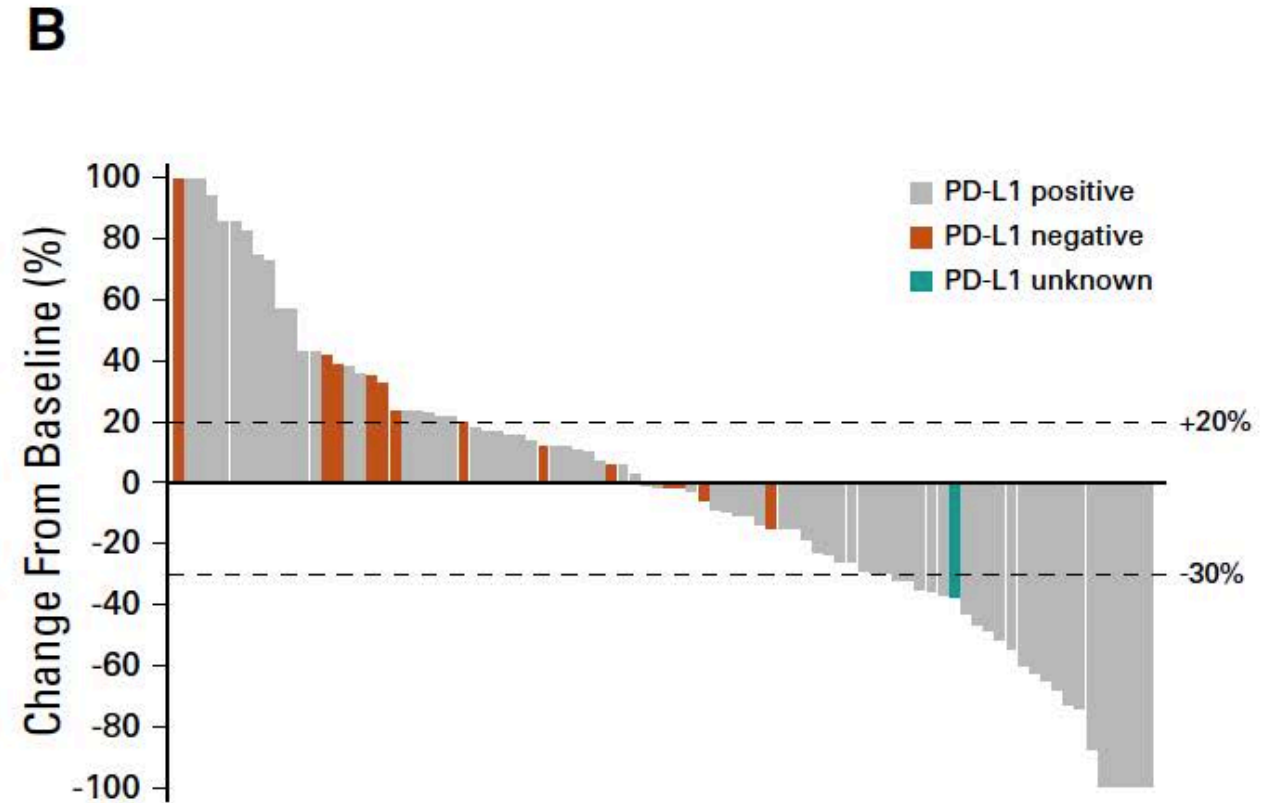
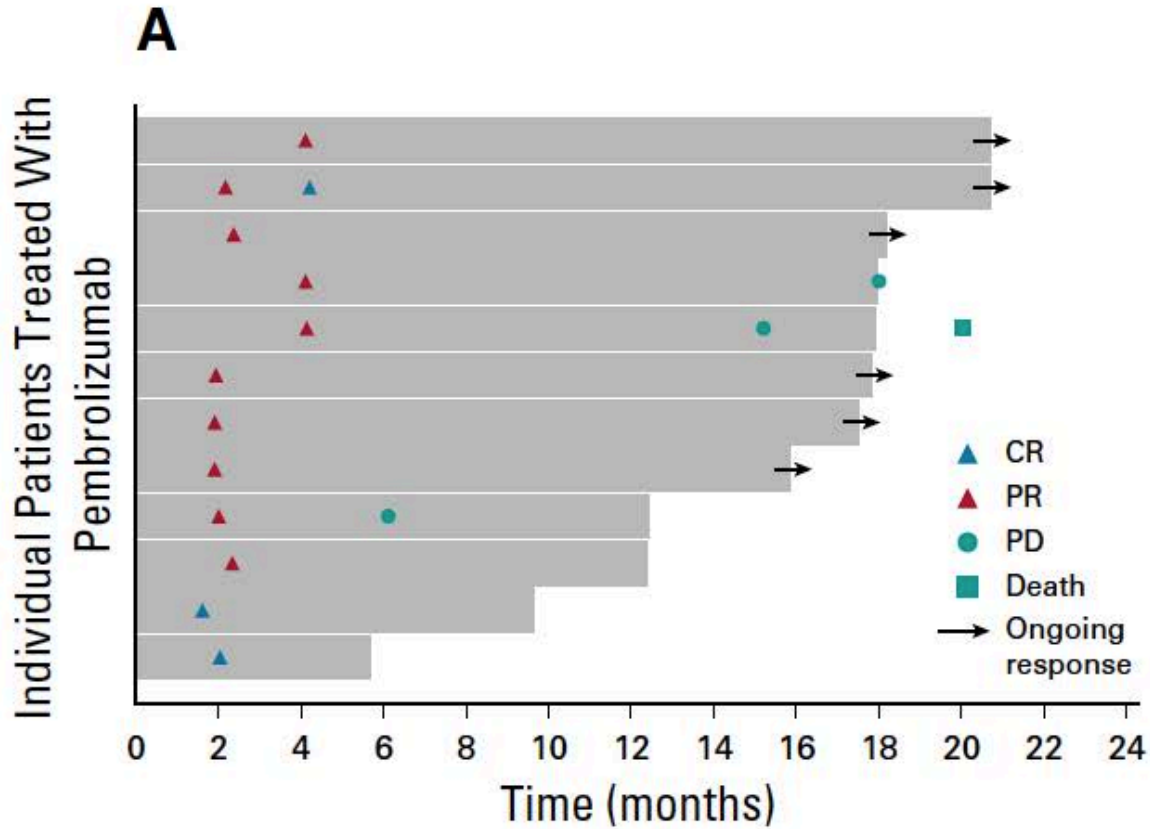
J Clin Oncol 2019;37(17):1470-8

# Objective Response Rate

12%

Antitumor Activity	Total Population (N = 98)*	Total (n = 82)	Previously Treated (n = 77)†	PD-L1–Negative Population (n = 15)
ORR	12 (12.2)	12 (14.6)	11 (14.3)	0 (0.0)
95% CI	6.5 to 20.4	7.8 to 24.2	7.4 to 24.1	0.0 to 21.8
DCR	30 (30.6)	27 (32.9)	24 (31.2)	3 (20.0)
95% CI	21.7 to 40.7	22.9 to 44.2	21.2 to 42.7	4.3 to 48.1
Best overall response				
CR	3 (3.1)	3 (3.7)	2 (2.6)	0 (0.0)
PR	9 (9.2)	9 (11.0)	9 (11.7)	0 (0.0)
SD	18 (18.4)	15 (18.3)	13 (16.9)	3 (20.0)
Progressive disease	55 (56.1)	44 (53.7)	42 (54.5)	10 (66.7)
Not able to be evaluated‡	5 (5.1)	4 (4.9)	4 (5.2)	1 (6.7)
Not able to be assessed§	8 (8.2)	7 (8.5)	7 (9.1)	1 (6.7)
Time to response, months				
Median	2.1	2.1	2.2	—
Range	1.6-4.1	1.6-4.1	1.6-4.1	—
Duration of response, months  ¶				
Median	NR	NR	NR	—
Range	≥ 3.7 to ≥ 18.6	≥ 3.7 to ≥ 18.6	4.1 to ≥ 18.6	—
Estimated rate of response duration, months  ¶				
≥ 6	10 (90.9)	10 (90.9)	10 (90.9)	—
≥ 9	9 (90.9)	9 (90.9)	9 (90.9)	—
≥ 12	7 (79.5)	7 (79.5)	7 (79.5)	—

# Duration of Response





# Summary

## **Impact on Patient Care and Treatment Algorithms**

- FDA approved for PD-L1 +ve cervical cancer
- Exciting new standard of care

## **Implications for Future Research**

- Benefits limited to PD-L1 +ve cervical cancer
- Potential benefit to checkpoint blockage and cellular therapy

## **Tisotumab Vedotin in Previously Treated Recurrent or Metastatic Cervical Cancer AC**

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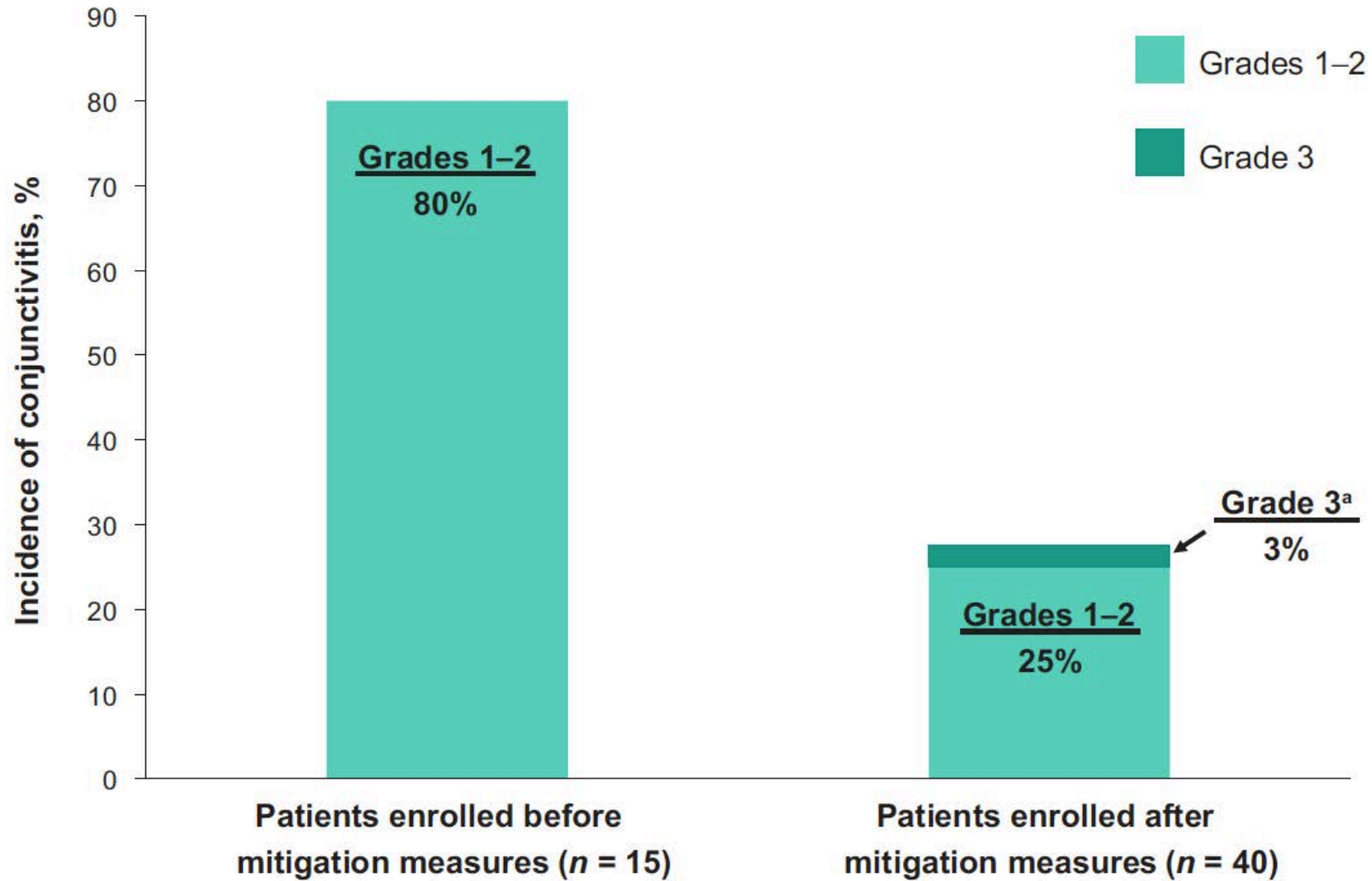
**Clin Cancer Res 2020;26:1220–8**

# Toxicity

**Table 2.** Treatment-emergent AEs.

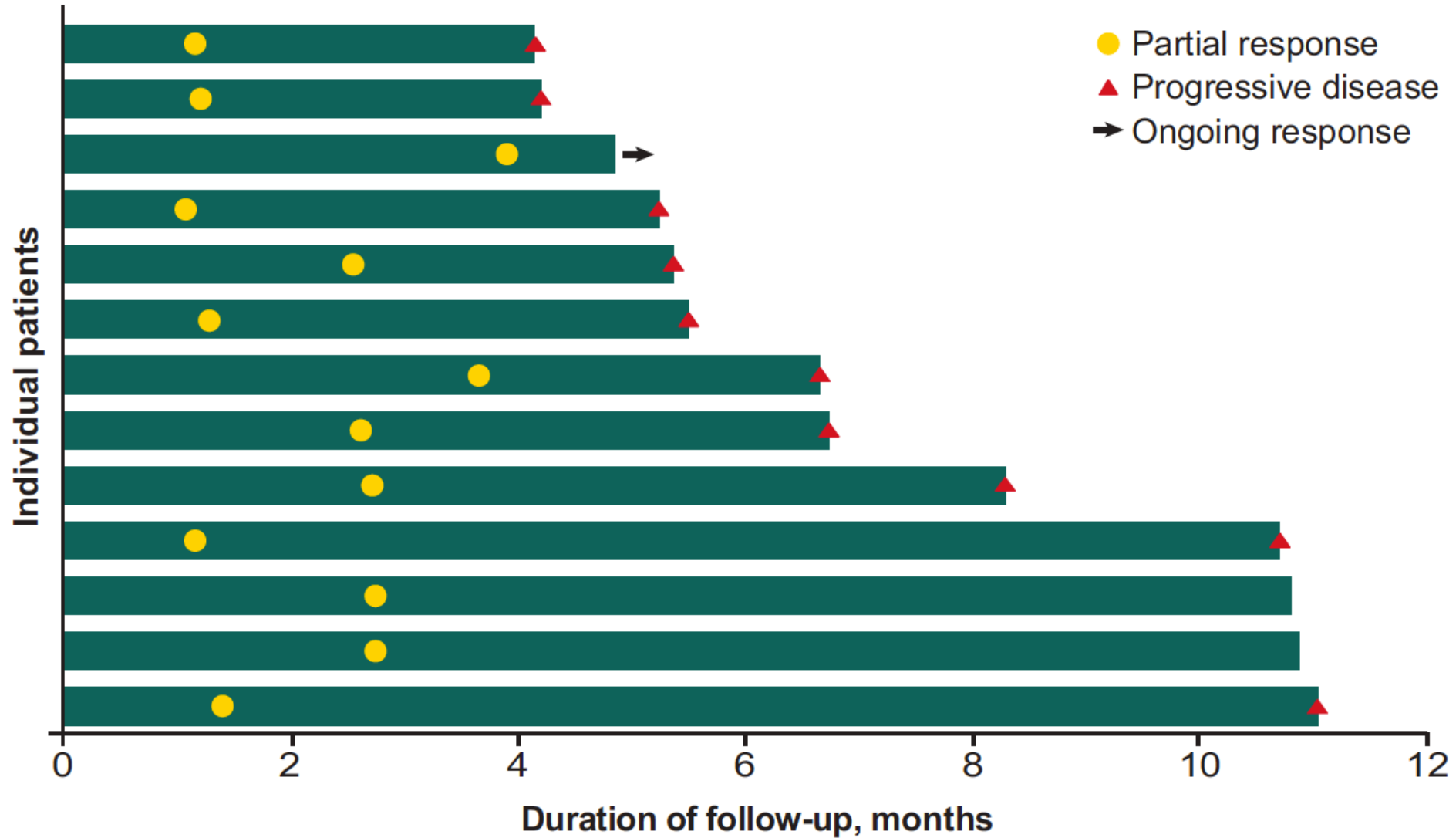
Incidence, <i>n</i> (%)	Cervical cancer cohort	
	<i>N</i> = 55	
	All grade	Grade $\geq 3$
Patients with $\geq 1$ AE	55 (100)	31 (56)
AEs with $\geq 20\%$ incidence		
Epistaxis	28 (51)	0
Fatigue	28 (51)	5 (9)
Nausea	27 (49)	3 (5)
Conjunctivitis	23 (42)	1 (2)
Alopecia	22 (40)	0
Decreased appetite	21 (38)	0
Constipation	20 (36)	1 (2)
Peripheral neuropathy	20 (36)	2 (4)
Vomiting	19 (35)	4 (7)
Diarrhea	16 (29)	1 (2)
Abdominal pain	15 (27)	3 (5)
Anemia	13 (24)	6 (11)
Dry eye	13 (24)	0
Hypokalemia	11 (20)	3 (5)
Pruritus	11 (20)	0
Pyrexia	11 (20)	1 (2)
Urinary tract infection	11 (20)	1 (2)

# Toxicity





# Duration of Response



# Summary

## **Impact on Patient Care and Treatment Algorithms**

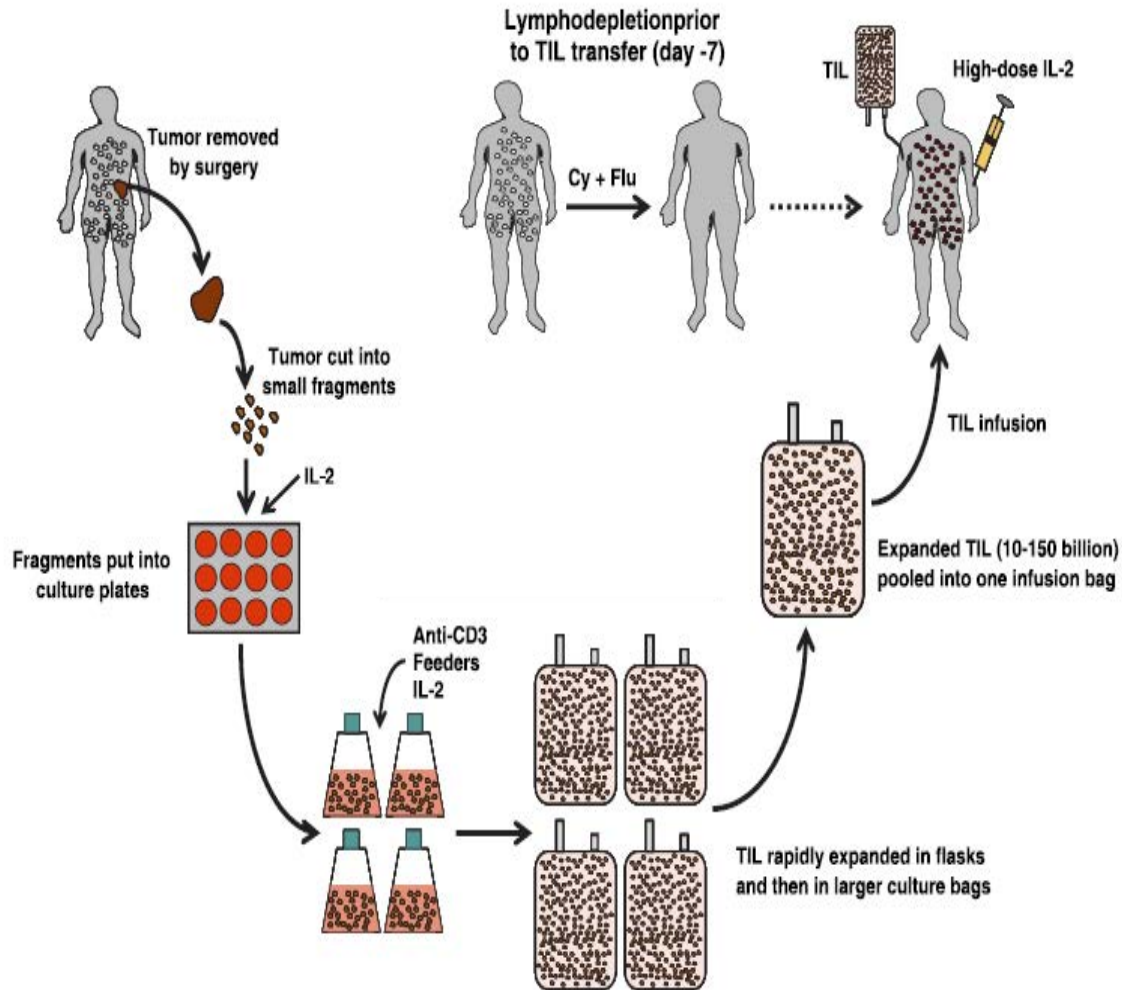
- Exciting new ADC with demonstrated clinical benefit

## **Implications for Future Research**

- Accelerated FDA approval and breakthrough designation have sped up the path from bench to bedside
- Many ADCs in development

# Emerging Therapies

## Adoptive Cell Therapy - TIL



LN-145 Jazaeri A, et al. ASCO 2019 Abs 2538  
Phase 2 multicenter study to evaluate the efficacy and safety of autologous Tumor Infiltrating Lymphocytes (LN-145) in patients with recurrent, metastatic or persistent cervical carcinoma

CR = 11% (3 of 27)

PR = 33% (9 of 27)

Huh WK, et al. ASCO 2016 Abs 5516  
Axalimogene Filolisbac (ADXS11-001)  
Listeria monocytogenes Based Vaccine  
Lm-listeriolysin-O fuses to HPV E7  
Phase 2 GOG/NRG0265 study