CONFERENCE CALL: ENFORTUMAB VEDOTIN

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

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SIX GROWTH DRIVERS IN LATE-STAGE DEVELOPMENT

		Indication	Stage
ONCOLOGY	**enzalutamide**	M1 hormone-sensitive prostate cancer	Filed (US, EU, JP)
		M0 hormone-sensitive prostate cancer	P3
		M1 castration-resistant prostate cancer	Filed (China)
	gilteritinib	Relapsed or refractory AML	Approved (US, JP) Filed (EU)
		Newly diagnosed AML, intensive chemo eligible	P3
		Newly diagnosed AML, intensive chemo ineligible	P3
		AML, post- HSCT maintenance	P3
		AML, post-chemo maintenance	P3
	enfortumab vedotin	mUC, platinum and PD-1/L1 inhibitor pretreated	Filed (US) P3 (EU, JP)
		mUC, PD-1/L1 inhibitor pretreated	P2
		mUC, 1st line	P1
	zolbetuximab	Gastric and gastroesophageal junction carcinoma	P3
		Pancreatic adenocarcinoma	P2
URO/NEPH	**roxadustat**	Japan, anemia associated with chronic kidney disease	Approved, on dialysis P3, not on dialysis
		EU, anemia associated with chronic kidney disease	P3
		Chemotherapy-induced anemia	P2
OTHERS	**fezolinetant**	Menopause-related vasomotor symptoms	P3

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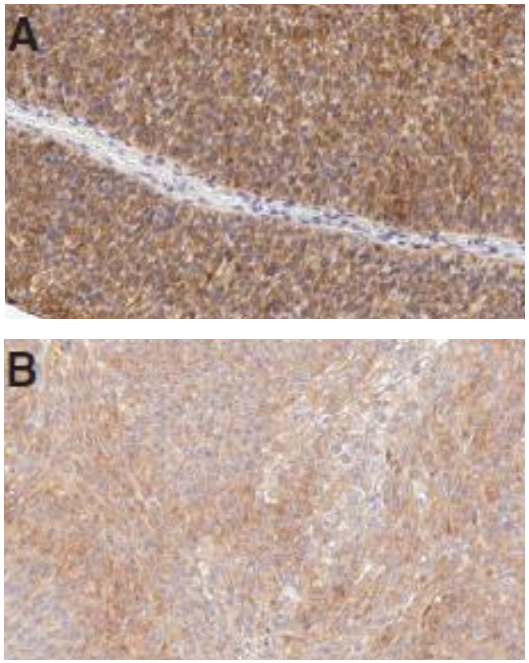
M0: Non-metastatic, M1: Metastatic, AML: Acute myeloid leukemia, HSCT: Hematopoietic stem cell transplant, mUC: Metastatic urothelial cancer

ENFORTUMAB VEDOTIN SUMMARY

- First and only antibody drug conjugate (ADC) that targets Nectin-4, which is highly expressed in urothelial cancers
- Developing in collaboration with Seattle Genetics as a potential treatment for patients with locally advanced or metastatic urothelial cancer
- Data continues to demonstrate favorable benefit-risk profile across studies
  - Granted Breakthrough Therapy Designation by U.S. Food and Drug Administration (FDA) based on Phase 1 study data (March 2018)
  - Biologics License Application (BLA) filed with FDA based on Phase 2 study cohort 1 data (July 2019)
  - Accepted for priority review by US FDA with March 2020 PDUFA date
- Exploring across spectrum of patient populations, including earlier lines of therapy as well as earlier stages of urothelial cancer

ENFORTUMAB VEDOTIN IS THE FIRST AND ONLY ADC TARGETING NECTIN-4

- The Nectin family of cell adhesion molecules play a role in the formation of cell-cell adherens junctions.[1,2]
- Nectin-4 (PVRL4), a transmembrane polypeptide belonging to the Nectin family, is expressed in many solid tumors.[3]
- A total of 83% of bladder cancers on tissue microarray were positive for Nectin-4 expression.[3]



Transitional bladder carcinoma with strong expression of Nectin-4

Transitional bladder carcinoma with moderate expression of Nectin-4

Figures modified from Challita-Eid et al. Cancer Res. 2016;76(10):3003-3013

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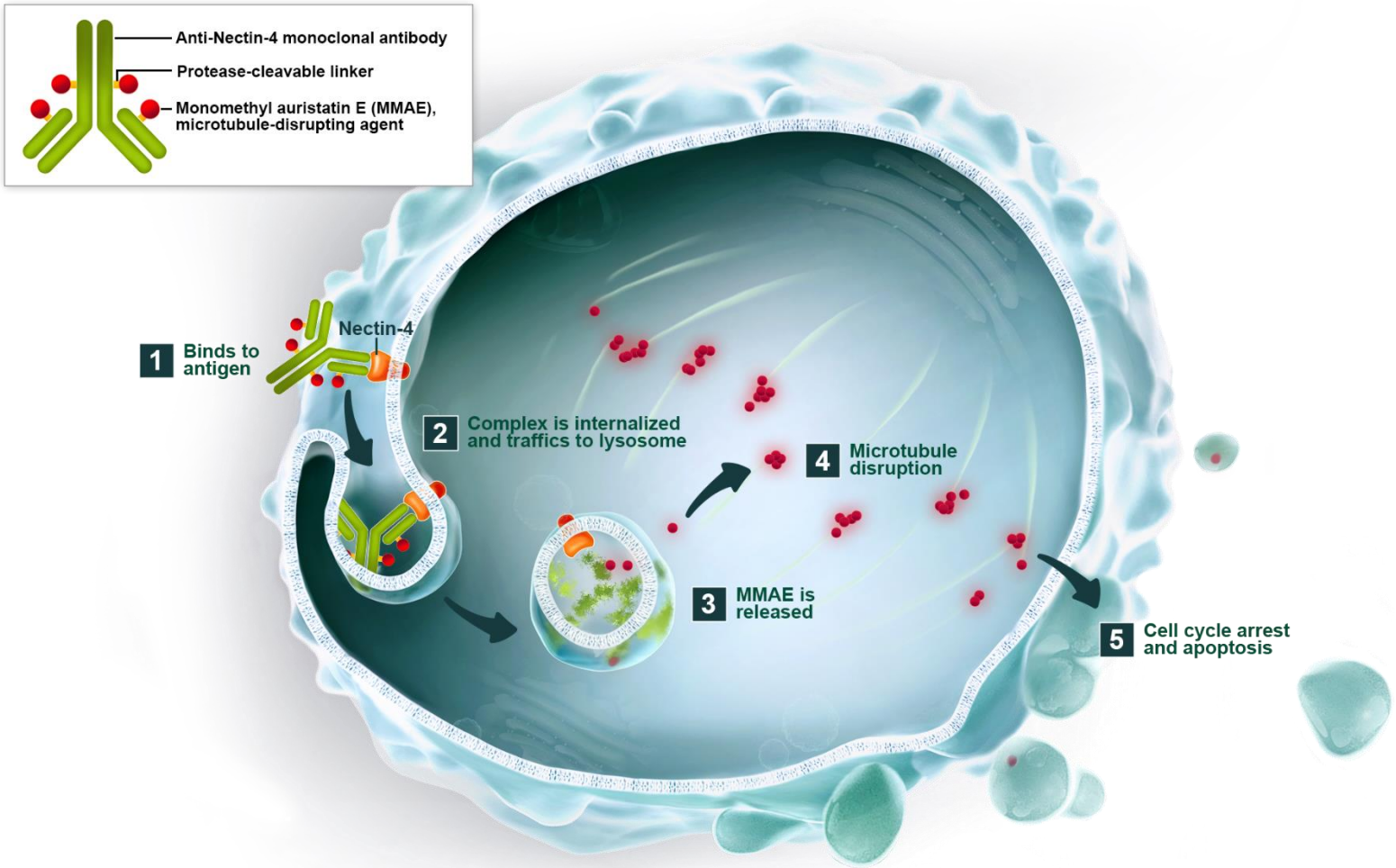
1. Samanta D, Almo SC. Cell Mol Life Sci. 2015;72:645–58; 2. Rikitake Y, Mandai K, Takai Y. J Cell Sci. 2012;125:3713–22; 3. Challita-Eid et al. Cancer Res. 2016;76:3003-13
ADC: Antibody-drug conjugate

ENFORTUMAB VEDOTIN: HOW IT WORKS



Enfortumab vedotin (ASG-22ME) is an investigational agent, and its safety and efficacy have not been established.

Enfortumab vedotin is being developed in collaboration with Astellas Pharma Inc.

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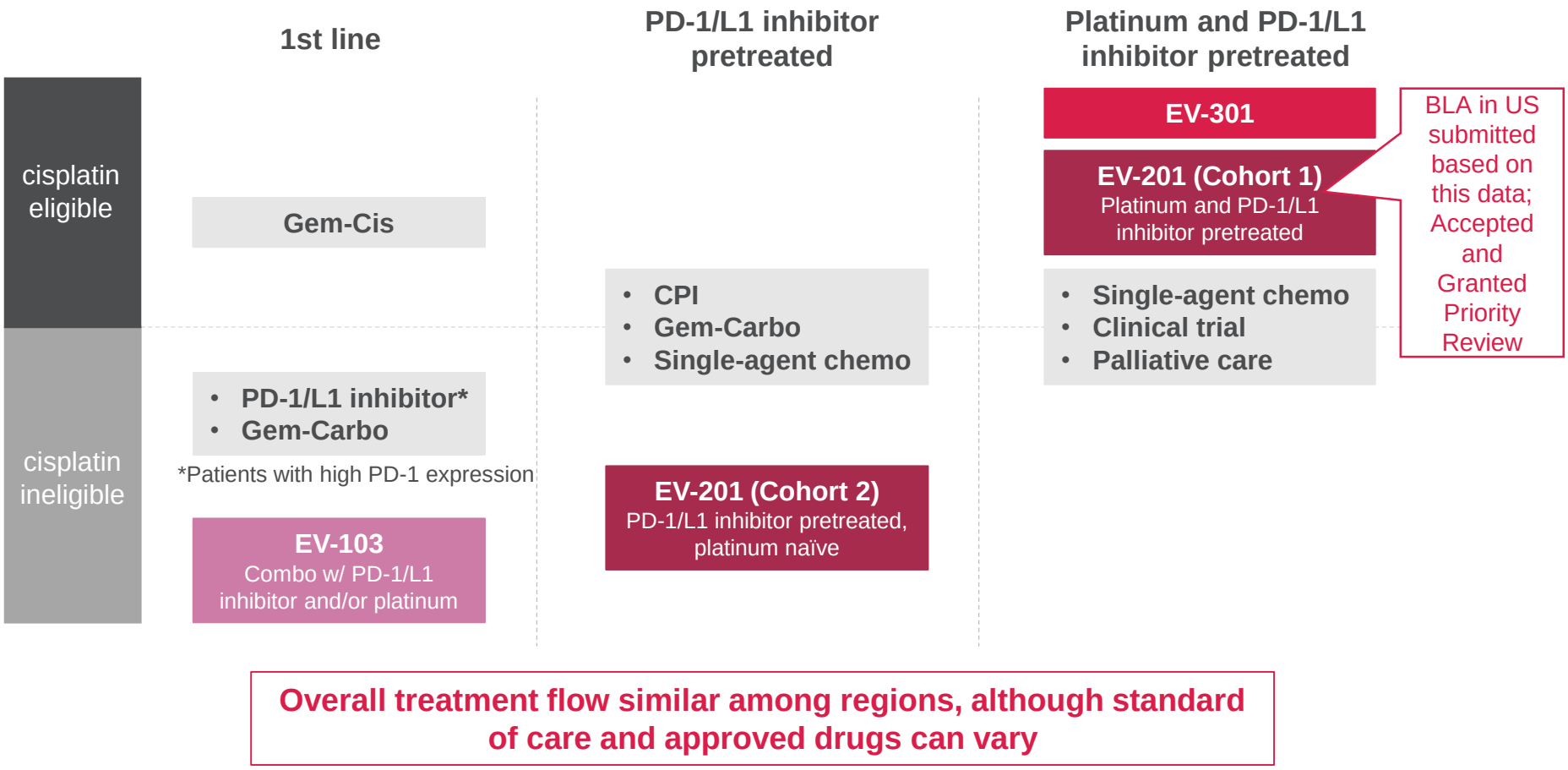
ADC: Antibody-drug conjugate

ENFORTUMAB VEDOTIN PROGRAM IS EXPLORING THE FULL mUC TREATMENT LANDSCAPE



Overall treatment flow similar among regions, although standard of care and approved drugs can vary

mUC: Metastatic urothelial cancer, Gem-Cis: Gemcitabine and cisplatin, Gem-Carbo: Gemcitabine and carboplatin, CPI: Checkpoint inhibitor, BLA: Biologics licensing application

ENFORTUMAB VEDOTIN IN PD-1/L1 INHIBITOR PRE-TREATED POPULATION: EV-201 COHORT 1 DATA USED FOR U.S. BLA SUBMISSION

ORR was 44% in platinum and PD-1/L1 inhibitor pretreated patients

ORR per RECIST v1.1 assessed by BICR	Patients (N=125) n (%)
Confirmed objective response rate	55 (44)
95% confidence interval[1]	(35.1, 53.2)
Best overall response per RECIST v1.1, n (%)	
Complete response	15 (12)
Partial response	40 (32)
Stable disease	35 (28)
Progressive disease	23 (18)
Not evaluable[2]	12 (10)

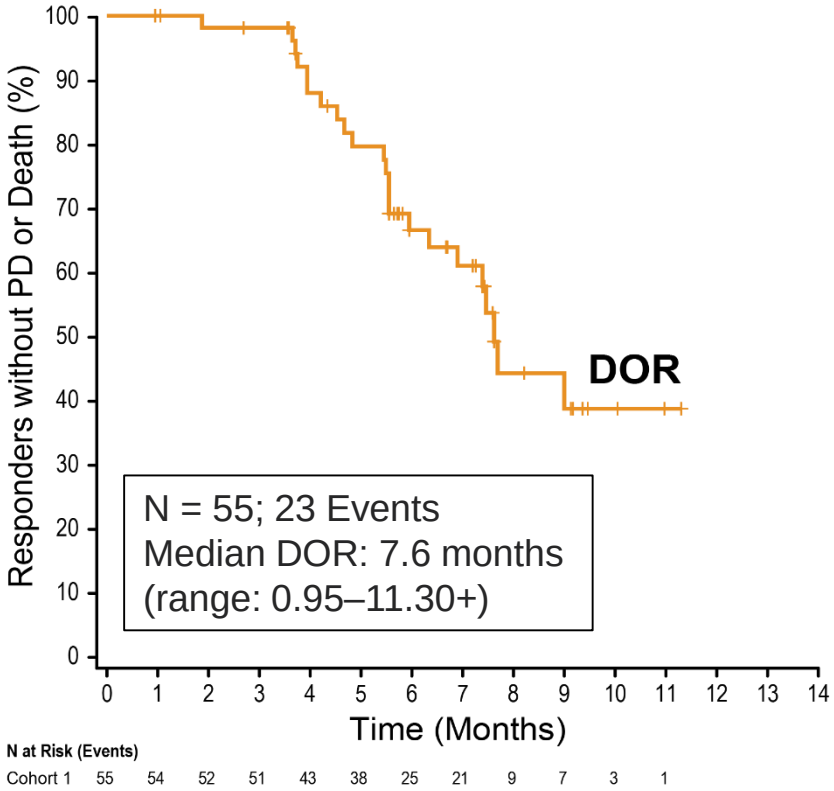
1. Computed using the Clopper-Pearson method
2. Includes 10 patients who discontinued study prior to post-baseline response assessment, 1 patient who had uninterpretable post-baseline assessment, and 1 patient whose post-baseline assessment did not meet the minimum interval requirement for stable disease

Petrylak DP, et al., ASCO2019

BLA: Biologics licensing application, ORR: Objective response rate, RECIST: Response evaluation criteria in solid tumors, BICR: Blinded independent central review

ENFORTUMAB VEDOTIN IN PD-1/L1 INHIBITOR PRE-TREATED POPULATION:
EV-201 COHORT 1 DATA USED FOR U.S. BLA SUBMISSION

DOR was 7.6 months in this heavily pre-treated patient population



EV-201: Cohort 1 Safety data

- **The most common TEAEs occurring in more than 40% of patients**
  - Fatigue, alopecia, rash, decreased appetite, taste distortion and peripheral neuropathy
- **Treatment-related adverse events of interests**
  Events categorized based on queries for related MedDRA terms

Peripheral neuropathy: 50% any grade, 3% ≥Grade 3
- 76% had resolution or events ongoing at Grade 1 at last follow-up

Rash: 48% any grade, 12% ≥Grade 3
- 93% resolution or improvement at last follow-up

Hyperglycemia: 11% any grade, 6% ≥Grade 3
- 1 Grade 4 event, resolved, no need for ongoing medication
- 71% resolution or improvement at last follow-up

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Petrylak DP, et al., ASCO2019
BLA: Biologics licensing application, DOR: Duration of response, TEAE: Treatment-emergent adverse event, MedDRA: Medical Dictionary for Regulatory Activities

EV-103: INITIAL RESULTS OF ENFORTUMAB VEDOTIN PLUS PEMBROLIZUMAB FOR LOCALLY ADVANCED OR METASTATIC UROTHELIAL CARCINOMA

As presented at ESMO 2019

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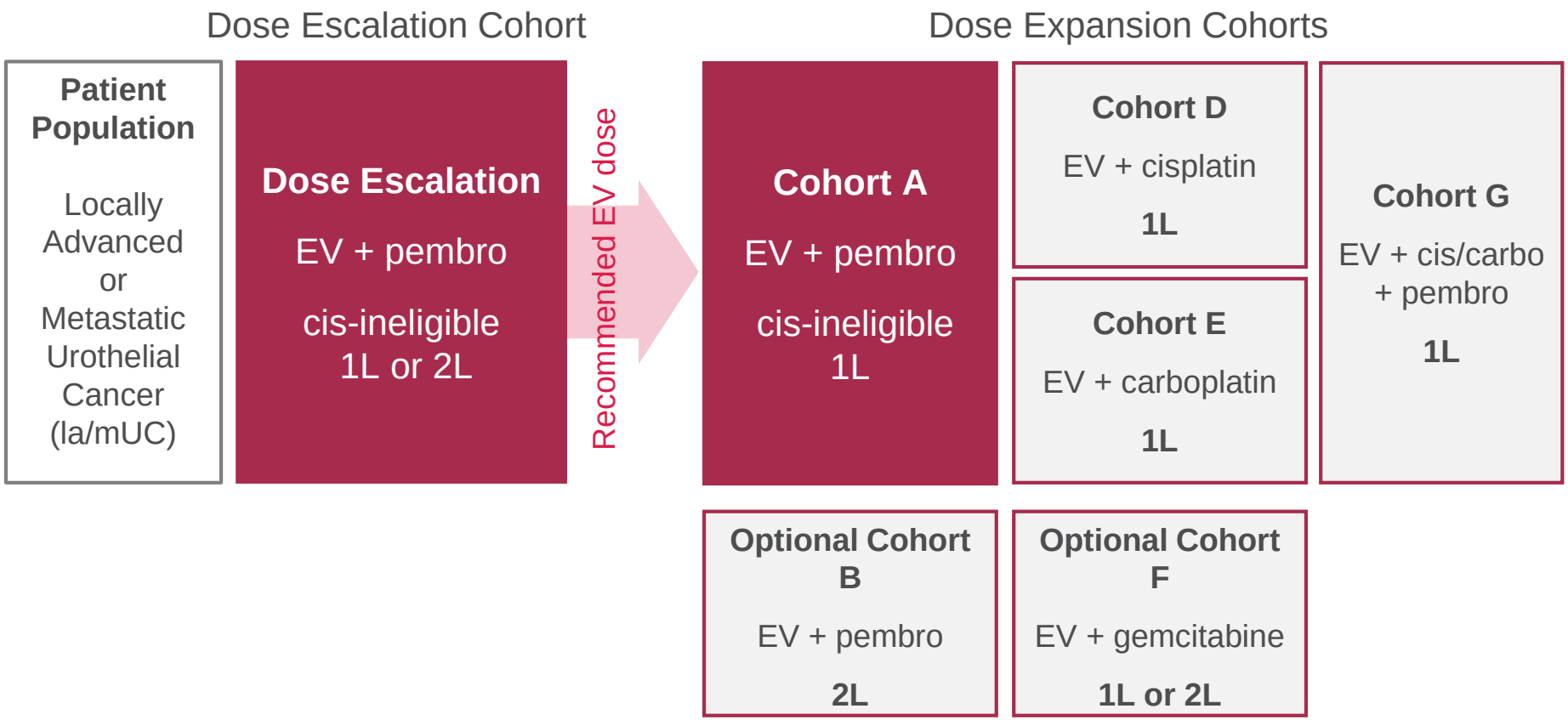
Christopher J. Hoimes, Jonathan E. Rosenberg, Sandy Srinivas, Daniel P. Petrylak, Matthew I. Milowsky, Jaime R. Merchan, Mehmet A. Bilen, Shilpa Gupta, Anne-Sophie Carret, Nancy Yuan, Amal Melhem-Bertrandt, Thomas W. Flaig

STUDY DESIGN: EV-103 (NCT03288545)

An ongoing multi-cohort, open-label, multicenter, Phase 1 study



EV: enfortumab vedotin, pembro: pembrolizumab

ENFORTUMAB VEDOTIN + PEMBROLIZUMAB COHORTS

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

Patient Population	Dose Escalation[1]	Dose Expansion Cohort A
Locally Advanced or Metastatic Urothelial Cancer (la/mUC)	EV 1.25 mg/kg + pembro cis-ineligible 1L (n=5)	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

KEY DEMOGRAPHICS AND DISEASE CHARACTERISTICS

EV 1.25 mg/kg + pembrolizumab in 1L setting 18 June 2019 data cut-off	**Patients (N=45)** n (%)
Male sex, n (%)	36 (80)
Age, yrs, Median (min, max)	69 (51, 90)
ECOG performance status, n (%)	
0	16 (36)
1	23 (51)
2	6 (13)
Primary tumor location, n (%) [1]	
Lower tract	31 (69)
Upper tract	13 (29)
Metastasis sites, n (%)	
Lymph nodes only	4 (9)
Visceral disease	41 (91)
Liver	15 (33)
PD-L1 status by combined positive score,[2] **n (%)**	
<10	19 (42)
≥10	13 (29)
Not evaluable/Not available	13 (29)

1. One patient has primary disease site of origin ‘other’
2. PD-L1 tested using the using the 22C3 PharmDx assay from Agilent/Dako

SUMMARY OF DISPOSITION

EV 1.25 mg/kg + pembrolizumab in 1L setting 18 June 2019 data cut-off	**Patients (N=45)** n (%)
Patients on treatment	24 (53)
Patients off treatment	21 (47)
Reason for treatment discontinuation	
Progressive disease	12 (27)
Adverse event	5 (11)
Patient decision	4 (9)
Patients off study	7 (16)
Reason for study discontinuation	
Patient withdrawal of consent	2 (4)
Death	5 (11)
Median follow-up (min, max)	**7.7 months (0.7+, 15.5)**

DURATION OF TREATMENT

EV 1.25 mg/kg + pembrolizumab in 1L setting

18 June 2019 data cut-off

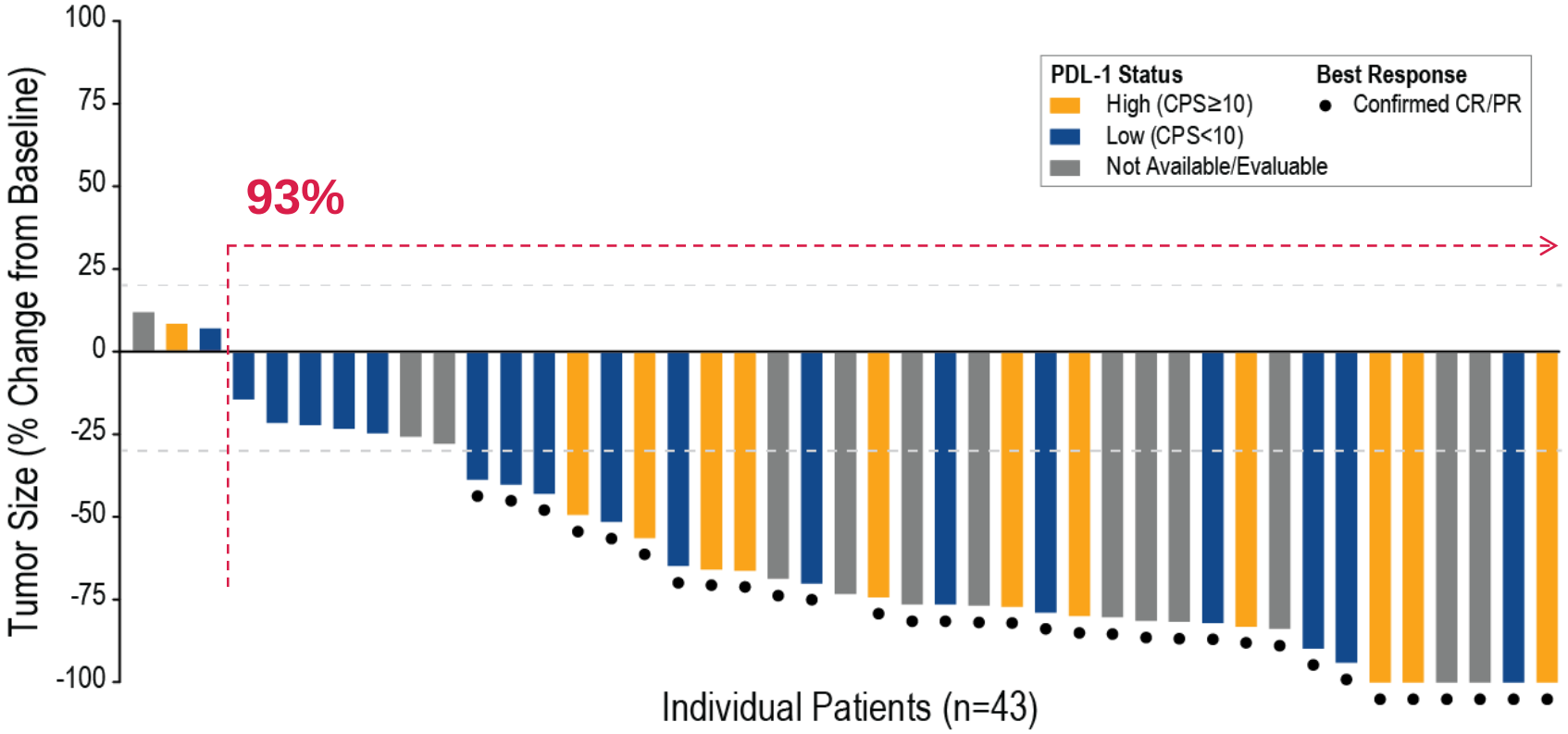
	Patients (N=45)
Duration of treatment (months)	
Median	6.0
Min, Max	1, 13+
Number of treatment cycles per patient	
Median	7.0
Min, Max	1, 17+
Patients on treatment n (%)	24 (53)
Patients off treatment n (%)	21 (47)

OBJECTIVE RESPONSE RATE

ORR per RECIST v1.1 by investigator 18 Jun 2019 data cut-off	**Patients (N=45)** n (%)
Confirmed Objective Response Rate (ORR) 95% confidence interval	**32 (71)** (55.7, 83.6)
Best Overall Response per RECIST v1.1	
Complete response	6 (13)
Partial response	26 (58)
Stable disease	10 (22)
Progressive disease	1 (2)
Not evaluable[1]	2 (4)

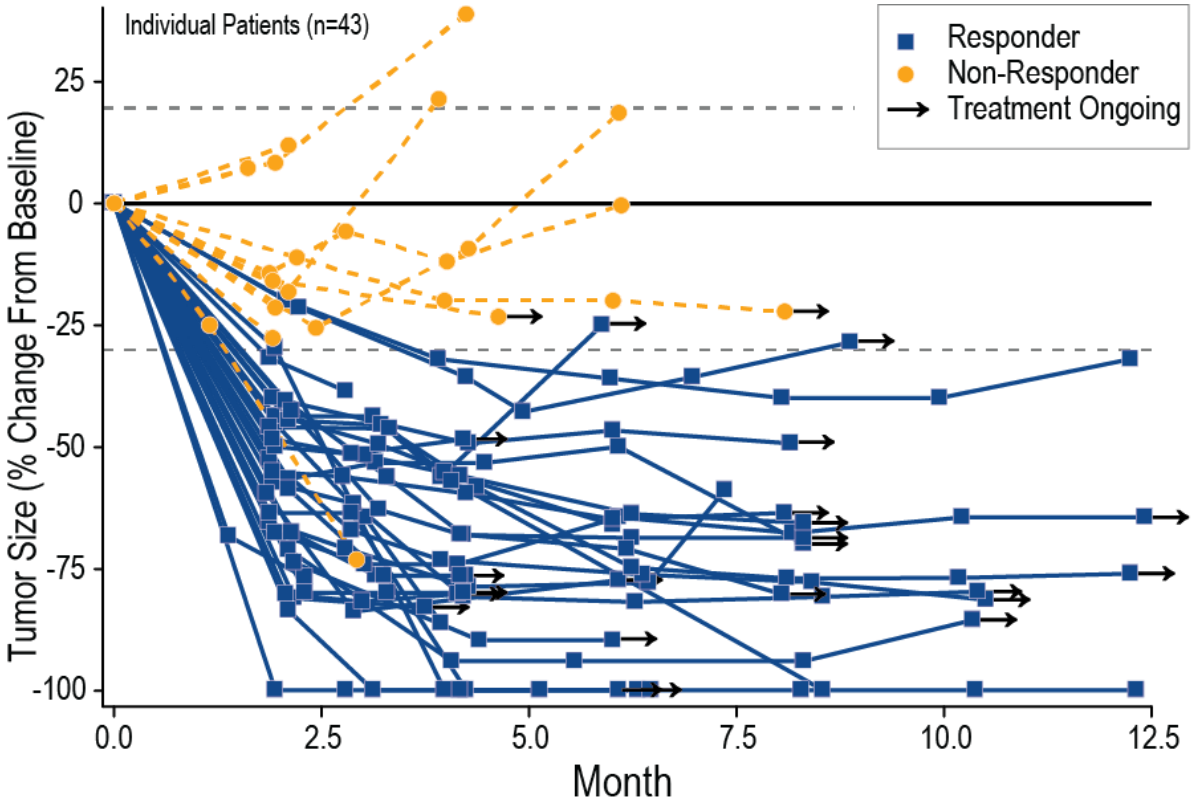
1. Two patients did not have post-baseline response assessments before end-of-treatment: 1 withdrew consent and 1 died before any post-baseline response assessment

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



PD-L1 tested using the 22C3 PharmDx assay from Agilent/Dako

PERCENT CHANGE FROM BASELINE IN SUM OF DIAMETERS OF TARGET LESIONS PER INVESTIGATOR



- 91% of responses observed at first assessment (Week 9±1 week)
- Median time to response: 2.0 months (range: 1.4 to 4.2)
- Duration of response range: 1 to 10.5 months and ongoing
- 22 of 32 responders remain on treatment

TREATMENT-RELATED ADVERSE EVENTS (TRAE)

TRAEs by preferred term Any grade in ≥20% of patients and ≥Grade 3 in ≥10% of patients	**Patients (N=45)** n (%) Any Grade	≥Grade 3
Overall	43 (96)	23 (51)
Fatigue	22 (49)	4 (9)
Alopecia	21 (47)	N/A
Peripheral sensory neuropathy	21 (47)	2 (4)
Diarrhea	18 (40)	2 (4)
Decreased appetite	15 (33)	0
Dysgeusia	14 (31)	N/A
Nausea	13 (29)	0
Pruritus	12 (27)	1 (2)
Rash maculo-papular	12 (27)	3 (7)
Weight decreased	10 (22)	0
Anemia	9 (20)	2 (4)
Lipase increased	7 (16)	6 (13)

7 patients had treatment-related serious AEs (16%)

4 treatment-related discontinuations of EV + pembro due to AEs (9%)

- Peripheral sensory neuropathy most common: 2 patients

1 treatment-related death as reported by investigator (2%)

- Multiple organ dysfunction syndrome
- Confounded by concomitant acute onset of atrial fibrillation, corticosteroids, and amiodarone

N/A: Non-applicable

TREATMENT-RELATED ADVERSE EVENTS OF CLINICAL INTEREST (AECI)

Rates of peripheral neuropathy, rash, and hyperglycemia similar to EV monotherapy in post-platinum, post-PD-1/L1 mUC patients (EV-201, Cohort 1)[1]

AECI: categorized by related MedDRA terms	Patients (N=45) n (%)		Time to first onset (months) median (min, max)
	Any Grade	≥Grade 3[a]	Any Grade
Peripheral neuropathy	22 (49)	2 (4)	2.2 (1, 6)
Rash	21 (47)	5 (11)	0.4 (0, 7)
Hyperglycemia (non-fasting)	5 (11)	3 (7)	0.5 (0, 3)

a. No grade 5 events

AECI: determined by investigator	Patients (N=45) n (%)	
	Any Grade	≥Grade 3[a]
Immune-mediated AE requiring systemic steroids	9 (20)	5 (11)[b]

a. No grade 5 events.
b. Events occurred in 1 patient each. Grade 3: pneumonitis, dermatitis bullous, lipase increased, tubulointerstitial nephritis; Grade 4: myasthenia gravis

1. Rosenberg et al. J Clin Oncol. Epub July 2019

EV-103 SUMMARY AND CONCLUSIONS

- High unmet need for effective and tolerable therapies in 1L cisplatin-ineligible la/mUC patients
- Enfortumab vedotin + pembrolizumab demonstrates encouraging activity in 1L cisplatin-ineligible la/mUC patients in EV-103
  - High ORR (71%)
  - Rapid responses (91% at first assessment) that appear durable
  - Activity regardless of PD-L1 expression
  - Safety appears manageable and tolerable; AECI similar to monotherapy
- Enfortumab vedotin + pembrolizumab has the potential to become a platinum-free option for cisplatin-ineligible la/mUC patients in the 1L setting

NEXT STEPS

What we look forward to next with enfortumab vedotin

- Continue progressing EV clinical development program
- Continue engagement with regulatory authorities globally
- Plan a Phase 3 study combining EV and pembrolizumab

THANK YOU

QUESTIONS