

**Dr. Wendel Naumann of The Levine Cancer Institute, *Non-Audio* Presentation of STRO-002 Antibody-Drug Conjugate (ADC)**

**American Association for Cancer Research (AACR) Virtual Annual Meeting 2020  
April 27, 2020**

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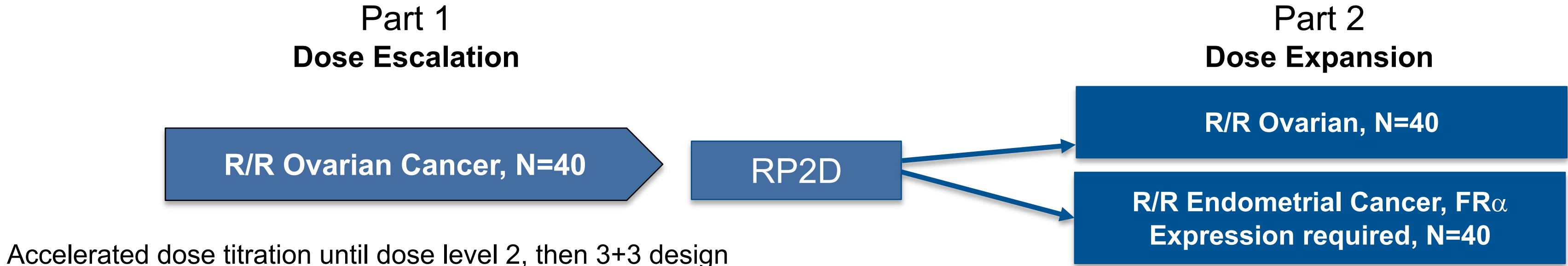
# STRO-002-GM1, a First in Human, Phase 1 study of STRO-002, an anti-Folate Receptor-alpha (FR $\alpha$ ) Antibody Drug Conjugate (ADC), in Patients with Advanced Platinum-Resistant/Refractory Epithelial Ovarian Cancer (OC), including Fallopian Tube or Primary Peritoneal Cancers

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## STRO-002-GM1, Phase 1 Study Design, Enrollment Started March 2019

Key Inclusion : Advanced platinum-resistant/refractory disease; patients are **NOT being selected for FR $\alpha$  expression** (all comers), **No limit on prior number of therapies**  
 Key Exclusion: Prior FR $\alpha$  targeting ADC, low grade ovarian carcinoma, clinically significant pre-existing ocular disorders



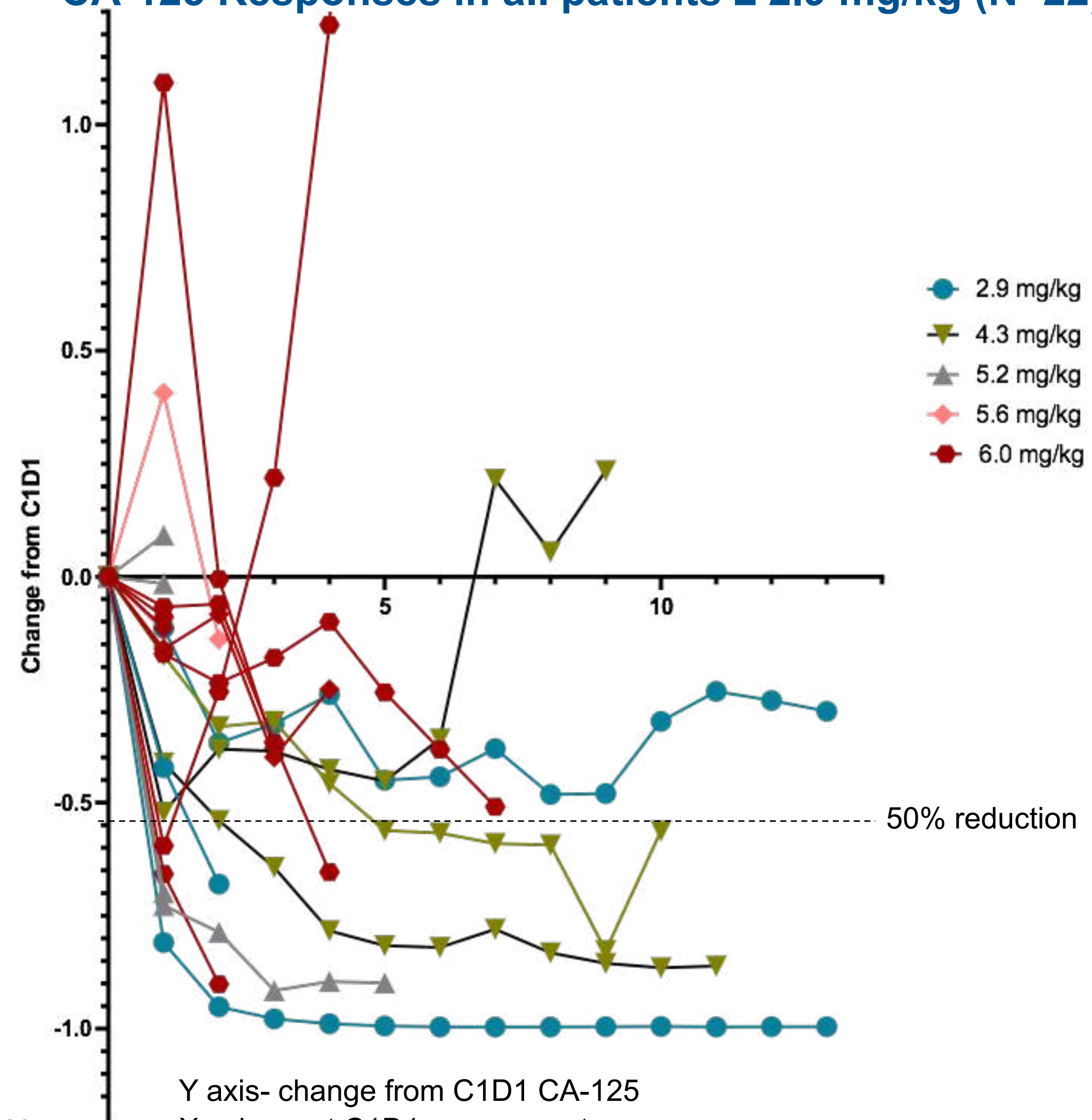
### Key Objectives

- Part 1: Safety, MTD, RP2D, PK, ADA, preliminary efficacy
- Part 2: Response rates, duration of response, PFS (RECIST 1.1), safety, PK

# Patient Demographics and CA-125 Responses

Characteristic	Total N = 27 (%)
Age, median (range), years	60 (47-76)
Median time from diagnosis (range)	3.9 years (0.6- 17.1)
Median lines of prior therapy (range)	5 (2-10)
Prior PARP inhibitor	16 (59)
Prior Bevacizumab	20 (74)
Prior checkpoint inhibitor	7 (26)
Other experiment therapy	8 (30)
> 2 previous platinum regimens	12 (46)
Dose Level of STRO-002	
0.5 mg/kg, 1.0 mg/kg, 1.8 mg/kg	5 (19)
2.9 mg/kg	3 (11)
4.2 mg/kg	3 (11)
5.2 mg/kg	5 (19)
5.6 mg/kg	2 (7)
6.0 mg/kg	8 (30)
6.4 mg/kg	1 (4)

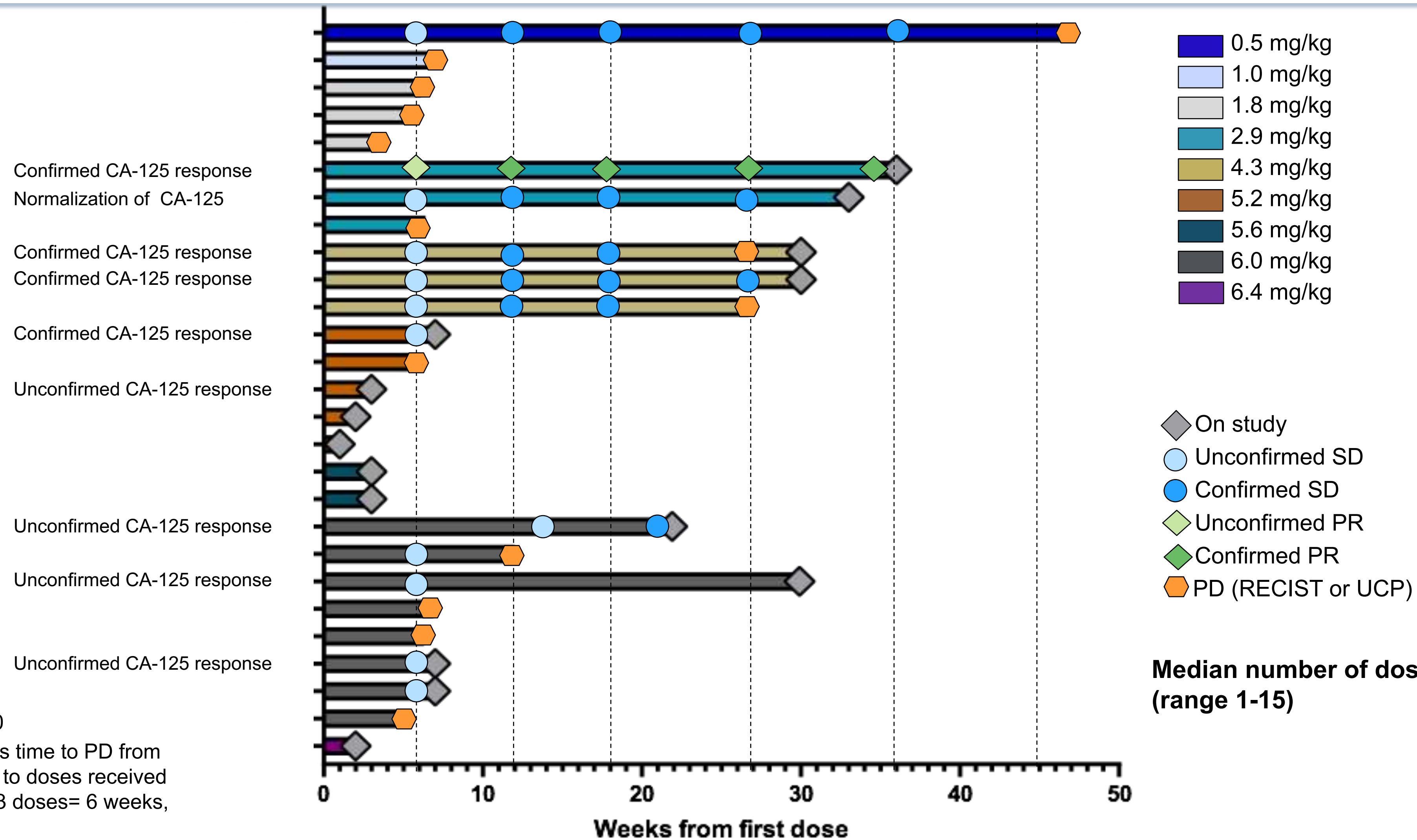
CA-125 Responses in all patients  $\geq 2.9$  mg/kg (N=22)



Data as of 1 Apr 2020

# Treatment Duration and RECIST Assessment

15/27 (56% Still on Study Treatment)



Data as of 1 Apr 2020

Duration calculated as time to PD from 1<sup>st</sup> dose or according to doses received (2 doses = 3 weeks, 3 doses = 6 weeks, etc.)

# Treatment Emergent AEs in $\geq 20\%$ of Patients (N=26) (without causality attribution)

- The emerging STRO-002 safety profile includes mostly mild adverse events - 89% of all AEs reported are grade 1 or 2.
- 2 DLTs have been reported: neuropathy (6.0 mg/kg); bone pain (6.4 mg/kg). Neutropenia reversible within 1 week.

Treatment Emergent Adverse Events (TEAE)					
TEAE >20%	Grade 1	Grade 2	Grade 3	Grade 4*	N= 26 (%)
Fatigue	7 (27)	9 (35)	2 (8)		18 (69)
Nausea	12 (46)	4 (15)			16 (61)
Neutropenia/ Neutrophil count decreased			6 (23)	6 (23)	12 (46)
Constipation	6 (23)	6 (23)			12 (46)
Arthralgia	2 (8)	5 (19)	4 (15)		11 (42)
Abdominal pain	5 (19)	2 (8)	3 (12)		10 (39)
Decreased appetite	7 (27)	3 (12)			10 (39)
Vomiting	6 (23)	3 (12)			9 (35)
AST increased	7 (27)	1 (4)			8 (31)
Diarrhea	5 (19)	1 (4)	1 (4)		7 (27)
Dizziness	5 (19)	2 (8)			7 (27)
Peripheral neuropathy	2 (8)	4 (15)	1 (4)		7 (27)
Headache	5 (19)	1 (4)			6 (24)
Insomnia	4 (15)	2 (8)			6 (24)
Myalgia	3 (12)	2 (8)			6 (24)

\* No other grade 4 events have been reported.

Data as of 1 Apr 2020

# Conclusions

**STRO-002 is the first ADC generated with cell free protein synthesis technology to be tested in patients with solid tumors. Follow-up is early. Enrollment is ongoing.**

## **RECIST Responses**

### Confirmed Responses/Stable Disease

- 1 Partial Response up to 36 weeks, patient still on treatment
- 6 Stable Disease (SD)
  - Up to 18 weeks for 3 pts, up to 27 weeks for 2 pts and up to 45 weeks for 1 patient

### Unconfirmed Responses/Stable Disease

- 4 Stable Disease at 6 weeks in ongoing pts
- 6/27 = 22% not yet evaluable for RECIST

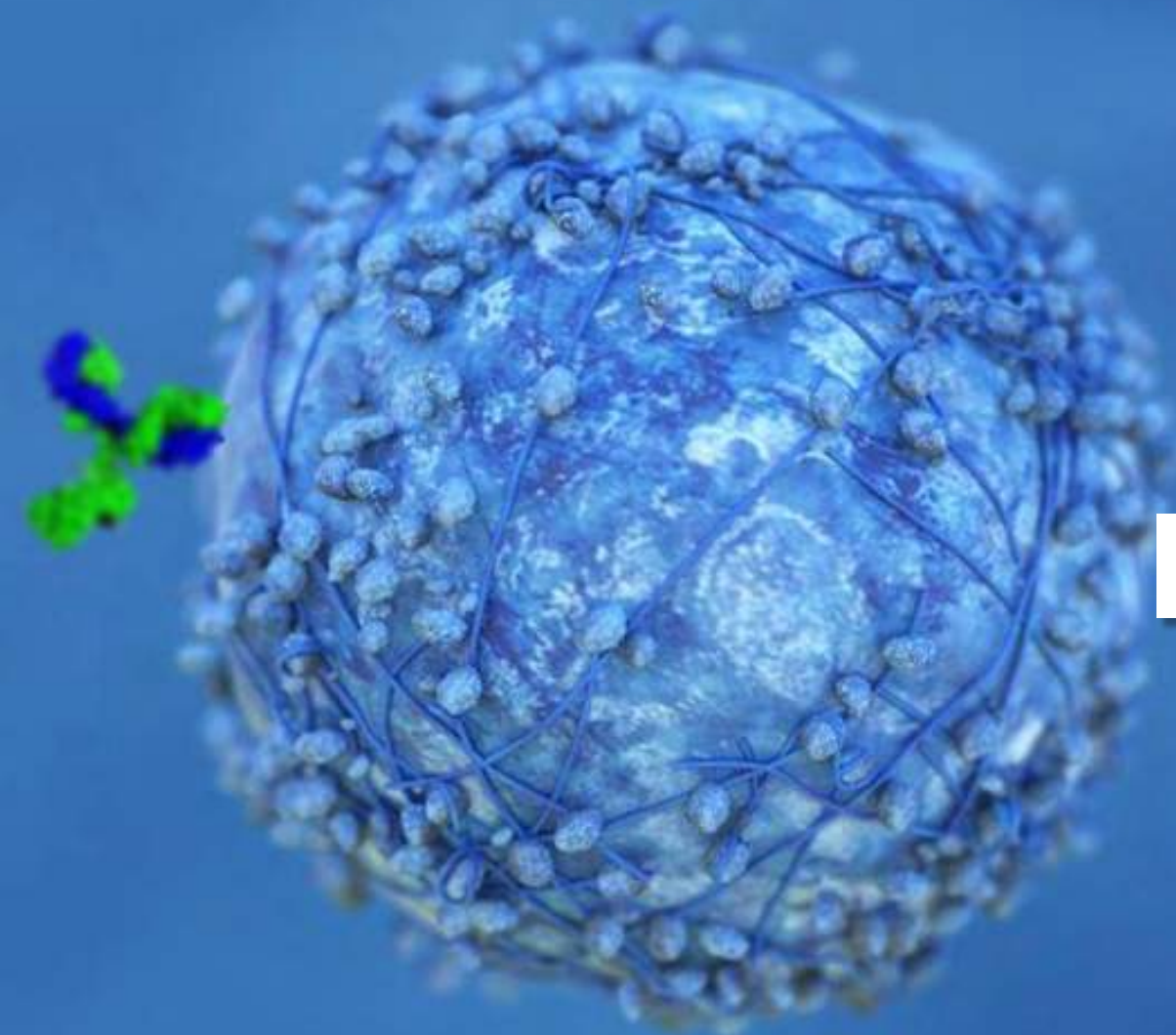
## **CA-125 Responses**

- 4 confirmed CA-125 responses and 1 CA-125 normalization
- 4 unconfirmed CA-125 responses in ongoing pts

## **AE Summary**

- MTD has not been reached
- Arthralgia/exacerbation of peripheral neuropathy and reversible neutropenia suggest that RP2D will be in 5.2 mg/kg – 6.0 mg/kg range.

**The preliminary safety profile and evidence of anti-tumor activity and clinical benefit is encouraging, particularly in this heavily pre-treated, platinum resistant/refractory patient population that has not been enriched for FR $\alpha$  expression.**



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