



STRO
002



FolR α – Targeting ADC Phase 1

Potential Best-in-Class ADC for
Ovarian and Endometrial Cancers

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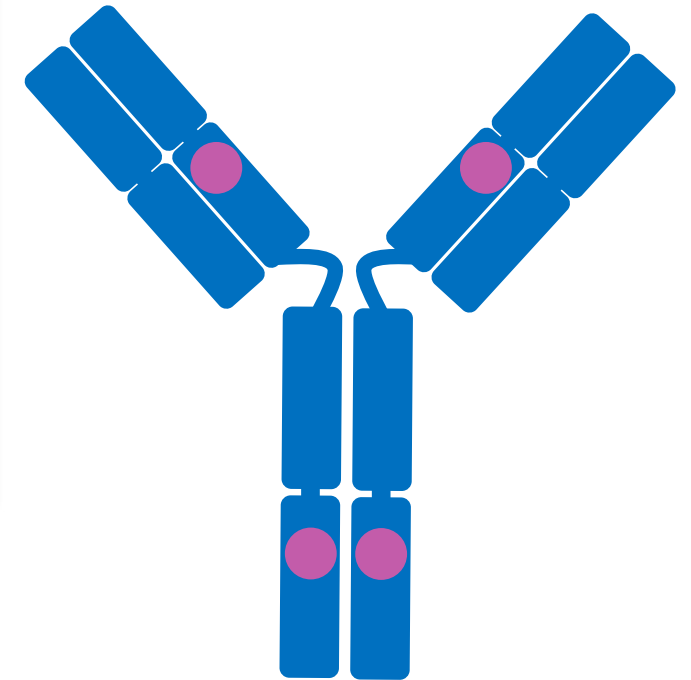
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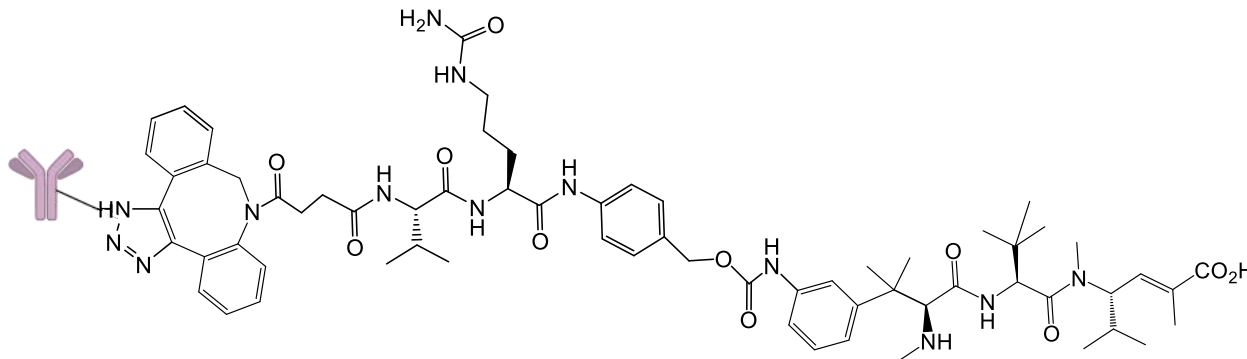
STRO-002 Structure and Design

Optimized molecule provides potential for best-in-class

- STRO-002 is a novel homogeneous antibody drug conjugate using precisely positioned non-natural amino acids
- STRO-002 has a drug-antibody ratio of 4:1, with a proprietary cleavable hemiasterlin linker-warhead that is stable in circulation
- Internalization of the ADC releases hemiasterlin in the tumor cell, resulting in immunogenic cell death of cancer cells



STRO-002

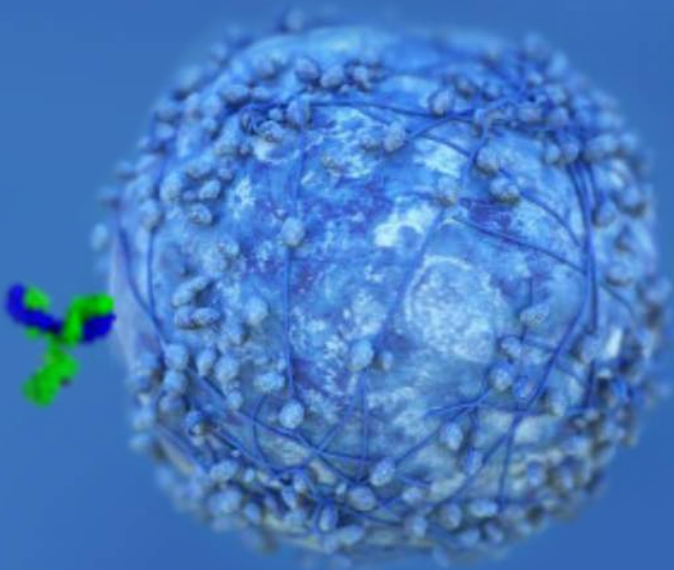


Structure of hemiasterlin linker-warhead following conjugation





Phase 1 Dose-Escalation Data
Presented by
Dr. Wendel Naumann



International Gynecologic Cancer Society Annual Meeting (Sept 10–13, 2020)

Phase 1 Dose-Escalation Study of STRO-002, an anti-Folate Receptor alpha (FR α) Antibody Drug Conjugate (ADC), in Patients with Advanced Platinum-Resistant / Refractory Epithelial Ovarian Cancer (OC)

R. Wendel Naumann¹, Fadi S. Braiteh², John P. Diaz³, Erika Hamilton⁴, Sami Diab⁵, Russell J. Schilder⁶, John W. Moroney⁷, Lainie P. Martin⁸, Denise Uyar⁹, David M. O'Malley¹⁰, Richard Penson¹¹, Clifford DiLea¹², Michael Palumbo¹³, Venita DeAlmeida¹³, Craig J. Berman¹³, Shannon Matheny¹³, Arturo Molina¹³

¹Levine Cancer Institute, Carolinas Medical Center, Charlotte, NC; ²Comprehensive Cancer Centers of Nevada, Las Vegas, NV; ³Miami Cancer Institute at Baptist Health, Miami, FL; ⁴Sarah Cannon Research Institute, Tennessee Oncology PLLC, Nashville, TN; ⁵Rocky Mountain Cancer Center, Aurora, CO; ⁶Sidney Kimmel Cancer Center, Thomas Jefferson University, Philadelphia, PA; ⁷University of Chicago, Chicago, IL; ⁸University of Pennsylvania, Abramson Cancer Center, Philadelphia, PA; ⁹Medical College of Wisconsin, Milwaukee, WI; ¹⁰Ohio State University, Wexner Medical Center, Columbus, OH; ¹¹ Massachusetts General Hospital, Boston, MA; ¹²Aclairo Pharmaceutical Development Group, Vienna, VA; ¹³Sutro Biopharma, Inc., South San Francisco, CA



Phase 1 Clinical Trial Design

Fast Track FDA Registration Pathway Possible Based on Recent Precedents

Part 1 – Dose Escalation

(1 Cohort: Ovarian)

STRO-002



2.9mg/kg
Dose Level*

4.3mg/kg
Dose Level

5.2mg/kg
Dose Level

5.6mg/kg
Dose Level

6.0mg/kg
Dose Level

6.4mg/kg
Dose Level

Recommended Dose for
Expansion Cohorts

Part 2 – Dose Expansion

(2 Cohorts)



Ovarian
Up to n=40



Endometrial
Up to n=40

Key Objectives

Part 1: Safety, MTD, RP2D, PK, ADA, preliminary efficacy

Part 2: Response rates, duration of response, PFS, safety, PK

First Patient Dosed March 2019

All-comers study: Unenriched population (not selected on basis of FRα expression levels)

STRO-002 is given by IV infusion on Day 1 of 21-day cycles

* Excludes initial dose levels of 0.5-1.8mg/kg



Heavily Pretreated Ovarian Cancer Patients: Demographics/Dose Levels

Data as of August 31, 2020

Characteristic	Total N = 39 (%)
Age, median (range), years	61 (48-79)
Tumor type	
EOC	30 (77)
Fallopian tube	7 (18)
Primary peritoneal	2 (5)
ECOG PS	
0	23 (59)
1	16 (41)
Median time from diagnosis (range)	3.9 years (0.6–17.1)
Median lines of prior therapy (range)	5 (2–10)
Platinum	39 (100)
≥ 3 prior platinum regimens	14 (36)
Taxanes	38 (97)
Bevacizumab	31 (79)
PARP inhibitors	23 (59)
Checkpoint inhibitors	8 (21)
Experimental therapy	13 (34)

Characteristic	Total N = 39 (%)
Dose Level of STRO-002	
0.5 mg/kg, 1.0 mg/kg, 1.8 mg/kg	5 (13)
2.9 mg/kg	3 (8)
4.3 mg/kg	5 (13)
5.2 mg/kg	12 (31)
5.6 mg/kg	3 (8)
6.0 mg/kg	10 (26)
6.4 mg/kg	1 (3)



Generally Well Tolerated Without Ocular DLTs or SAEs

Treatment Emergent AEs in $\geq 25\%$ of Patients (without causality attribution)

The emerging STRO-002 safety profile includes **mostly mild adverse events - 87% of all AEs reported are grade 1 or 2**

Treatment Emergent Adverse Events (TEAE)					
TEAE >20%	Grade 1	Grade 2	Grade 3	Grade 4*	N= 39 (%)
Fatigue	7 (18)	16 (41)	4 (10)		27 (69)
Nausea	15 (38)	9 (23)			24 (62)
Neutropenia/ Neutrophil count decreased		2 (5)	10 (26)	12 (31)	24 (62)
Constipation	12 (31)	9 (23)			21 (54)
Decreased appetite	11 (28)	9 (23)			20 (51)
Arthralgia	6 (15)	7 (18)	5 (13)		18 (46)
Abdominal pain	6 (15)	4 (10)	3 (8)		13 (33)
AST increased	10 (28)	2 (3)	1 (3)		13 (33)
Diarrhea	8 (21)	3 (8)	1 (3)		12 (31)
Dizziness	9 (23)	3 (8)			12 (31)
Peripheral neuropathy	2 (5)	7 (18)	2 (5)		11 (28)
Vomiting	7 (18)	4 (10)			11 (28)
Headache	7 (18)	3 (8)			10 (26)

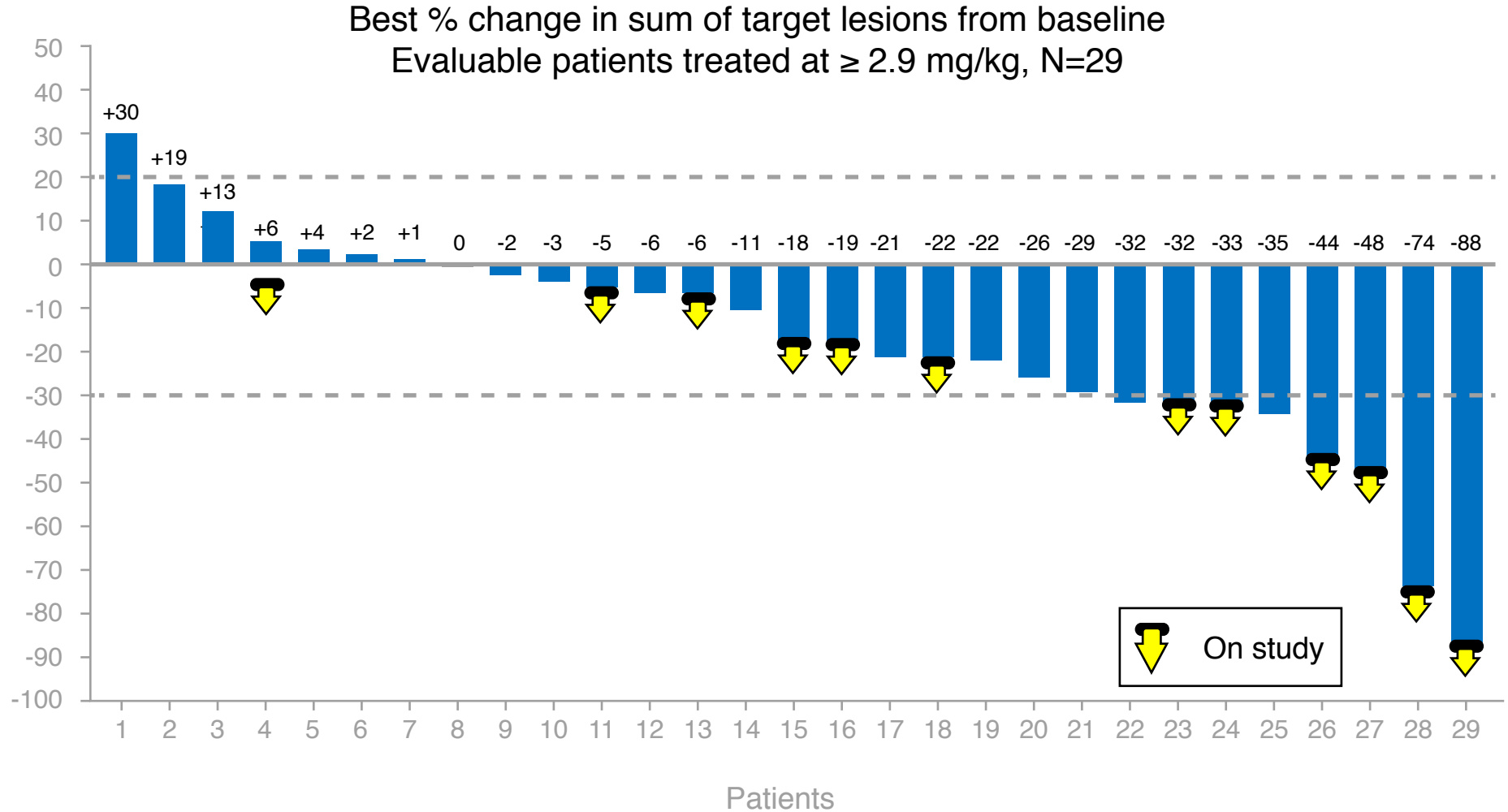
2 DLTs have been reported: neuropathy (6.0 mg/kg); bone pain (6.4 mg/kg)

*Only other Grade 4 events reported include WBC decrease (N=1), febrile neutropenia (N=1), and GI hemorrhage (N=1)

2 Grade 5 events have been observed, both reported as unrelated to study drug: Death NOS (not otherwise specified); Patient above with Grade 4 GI hemorrhage and progressive disease developed Grade 5 Acute GI bleed

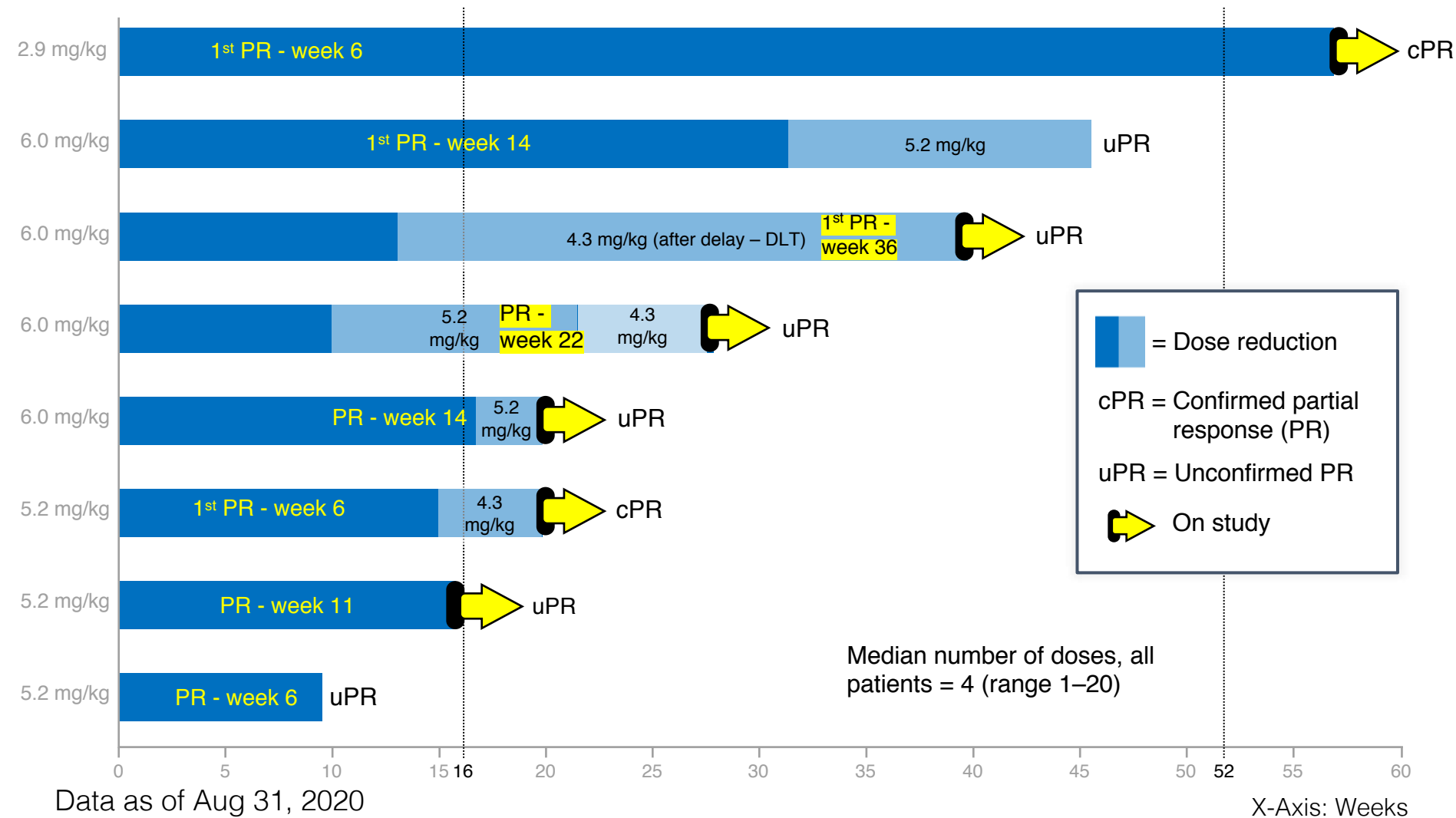
Data as of August 31, 2020

Robust Anti-Tumor Activity in Heavily Pre-Treated, Unselected Patients



4 pts off study before post baseline scan
1 pt ongoing, not yet at first post baseline scan
Data as of August 31, 2020

Partial Response Achieved in 24% of Unenriched, Heavily Pre-Treated Ovarian Cancer Patients



Data as of Aug 31, 2020

Duration calculated as time from first dose to last dose given (on study) or date of PD (off study).



Partial Response with 74% Tumor Reduction

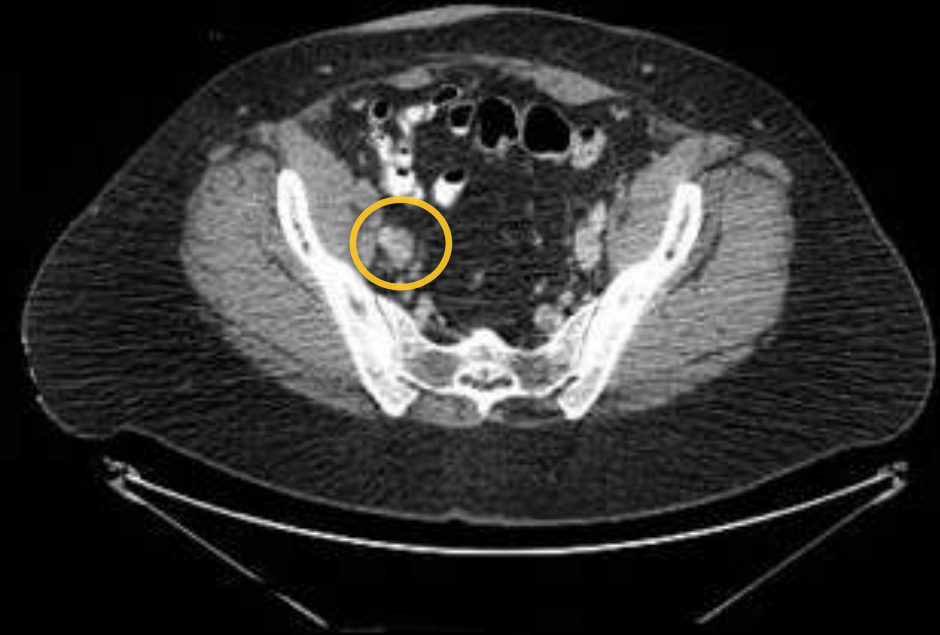
Patient Continues on Treatment

Baseline



3/16/20

Confirmed PR after 4 cycles

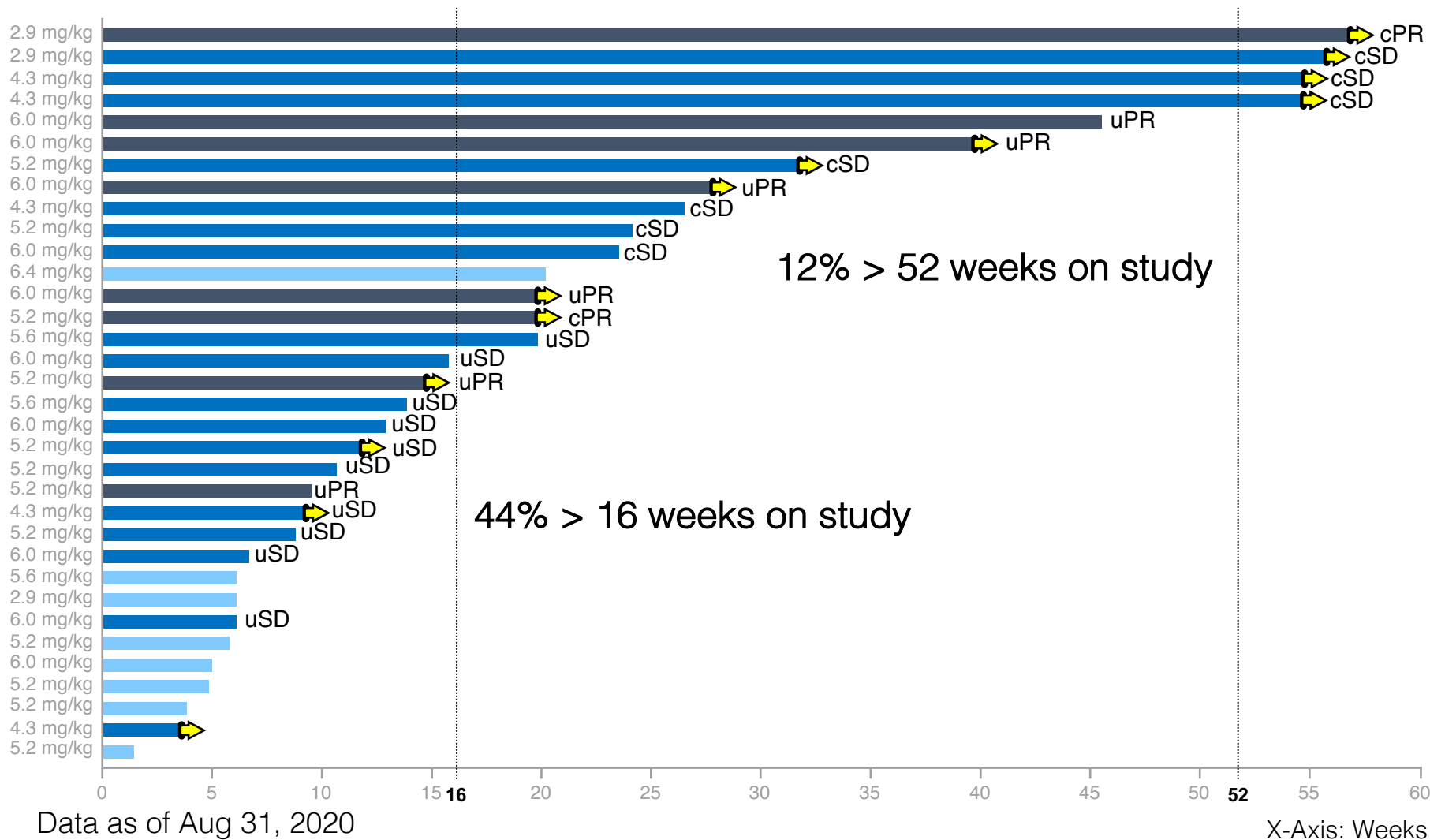


06/29/20

57-year-old woman with platinum resistant ovarian cancer progressing after 4 prior regimens received STRO-002 at 5.2 mg/kg and remains on study treatment



Long Duration on Study and Disease Control Observed in Unenriched, Heavily Pre-Treated Ovarian Cancer Patients



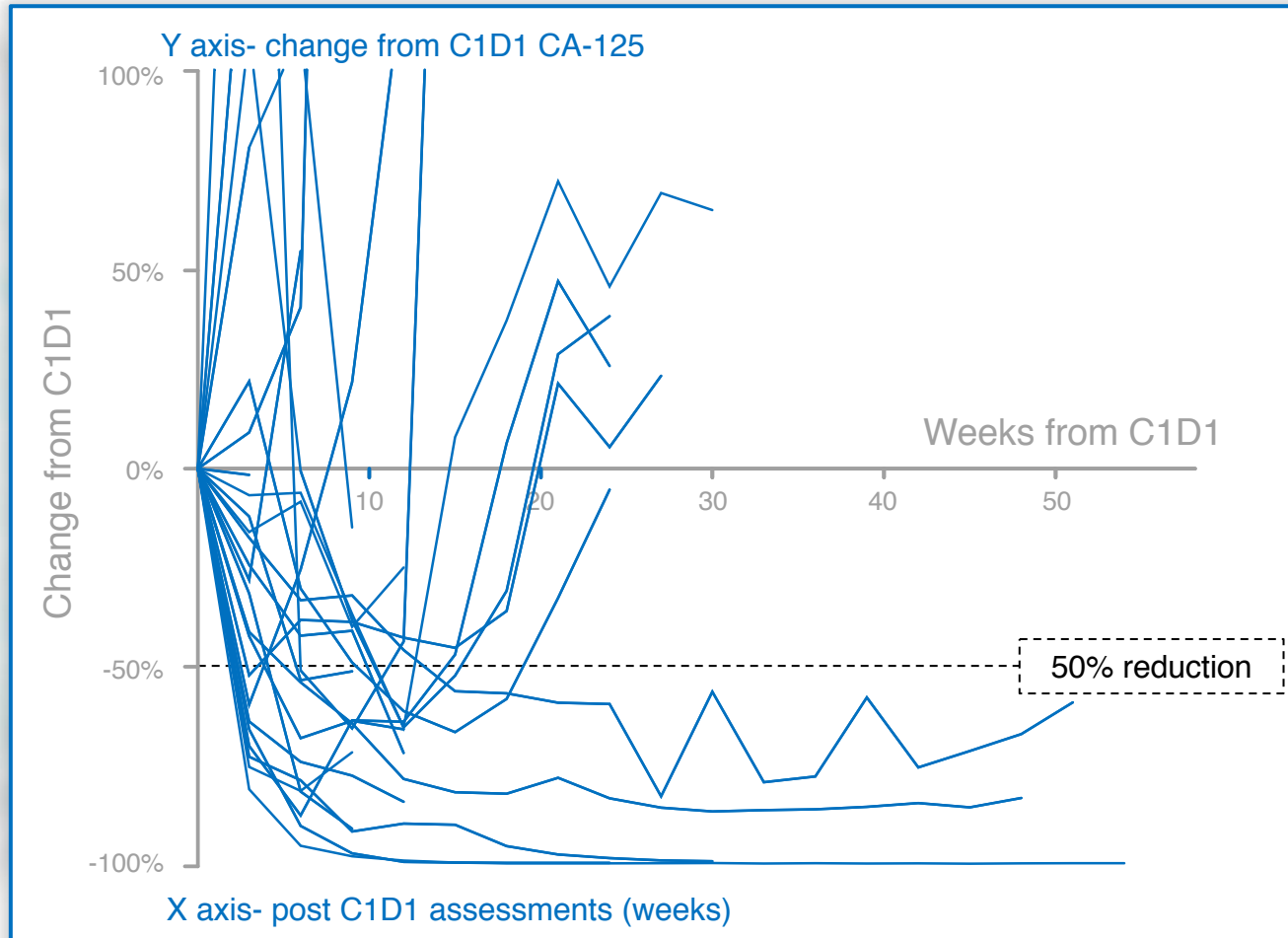
ORR: 24% (8/33)

DCR at ≥ 12 weeks:
60% (20/33)

cPR = Confirmed partial response (PR)
 uPR = Unconfirmed PR
 cSD = Confirmed stable disease (SD)
 uSD = Unconfirmed SD
 On study

Median number of doses, all patients = 4 (range 1-20)

High Rates of CA-125 Responses are Associated with Anti-Tumor Activity



72% (18/25) of patients with elevated CA-125 levels at baseline had $\geq 50\%$ reduction in CA-125 in at least 1 post-treatment timepoint

- 10/25 (40%) have confirmed CA-125 reductions $\geq 50\%$ that is maintained and confirmed 28 days later
- 9 pts not evaluable for CA-125 response per GCIIG criteria*

CA-125 decreases $\geq 50\%$ from baseline are associated with tumor control with RECIST responses and stable disease

*Gynecologic Cancer InterGroup (GCIIG) criteria requires an elevated baseline CA-125 level of at least twice the upper limit of normal

Promising Efficacy in a Heavily Pre-treated, Resistant/Refractory Unenriched Patient Population

Improved efficacy outcomes (increased ORR and DCR) observed as data matures with longer follow-up

- Overall response rate is 24% (8/33)
- High DCR of 60% at ≥ 12 weeks and 47% at ≥ 16 weeks
- Population not enriched for high FR α expression
- 38% (13/34) of patients still on study with potential to further improve efficacy outcomes

Heterogeneity of tumor regression and response, with some delayed partial responses observed after initial and variable period of stable disease

High rate of CA-125 responses ($\geq 50\%$) are associated with anti-tumor activity

STRO-002 is Generally Well Tolerated

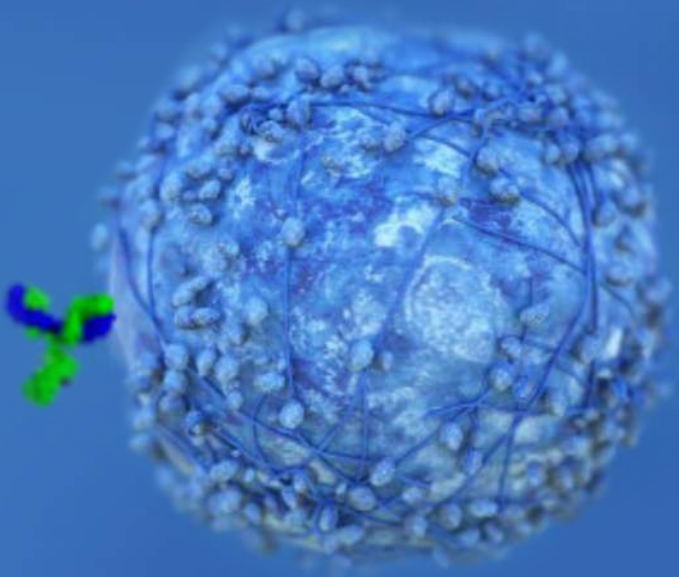
Safety Profile Is Encouraging

- 87% of AEs were Grade 1–2
- No need for prophylactic corticosteroid eyedrops
- Neutropenia readily reverses within 1 week, without the need for G-CSF
- Peripheral neuropathy/arthralgia can be managed with dose reduction/delay without evidence of compromised efficacy

Acknowledgements

Our gratitude to the women who chose to participate in this study and their families

Thank you to the STRO-002-GM1 investigators and study staff for their diligence in caring for these patients



Summary and Next Steps

Arturo Molina, MD, MS

Improved Efficacy Outcomes (Increased ORR and DCR) Observed as Data Matures with Longer Follow-Up

STRO-002 Clinical Data Readout

		April 20 th , 2020 Interim Analysis	August 31 st , 2020 Interim Analysis
N ≥ 2.9 mg/kg*		25 (20 evaluable)	34 (33 evaluable)
Median Age		61 (47–76)	61 (48–79)
Median Prior Lines		5 (2–10)	5 (2–10)
RECIST	Responses	1 PR	8 PRs
	ORR	5% (1/20) of evaluable pts	24% (8/33) of evaluable pts
	DCR @ ≥12 Wks	40% (8/20) of evaluable pts	60% (20/33) of evaluable pts
Dur. on Study	Pts on Study @ 16 Wks	32% (8/25)	44% (15/34)
	Pts on Study @ 52 Wks	n/a	12% (4/34)
CA-125	Reduction in level of ≥50%	57% (12/21)	72% (18/25)

***38% (13/34) of patients still on study** with potential to further improve efficacy outcomes

Summary and Next Steps in Clinical Development

- STRO-002 is clinically efficacious at multiple doses, starting at 2.9 mg/kg
 - Dose reductions or delays were not associated with loss of anti-tumor activity
- Further dose optimization will be explored during dose expansion
 - Anticipate RP2D will be in 4.3 – 5.2 mg/kg range
- Expansion cohort will seek to enroll less heavily pre-treated patients
 - Monotherapy unenriched expansion cohort in ovarian cancer planned for 4Q20
- Two FR α IHC assays are being compared for accuracy and consistency
- EOP1/2 FDA meeting planned for next year



STRO
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FolR α – Targeting ADC Phase 1

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