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

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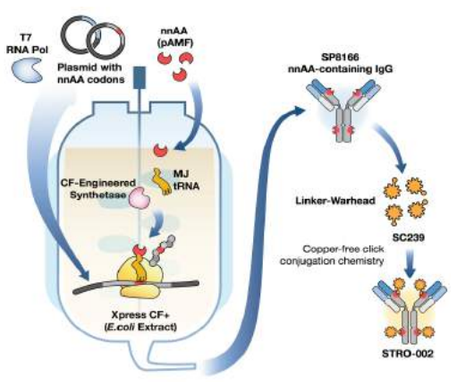
BACKGROUND

- Folate receptor alpha (FRα) is a cell-surface glycoprotein that is overexpressed in OC and endometrial adenocarcinoma.
- Sutro's cell-free synthesis platform enables rapid production and high-throughput selection for optimization of ADC candidates.
- STRO-002 is a novel FolRα-targeting ADC containing an anti-FolRα human IgG1 antibody (SP8166) conjugated to a cleavable dibenzocyclooctyne (DBCO)- 3-aminophenyl-hemiasterlin drug-linker, using site-directed conjugation technology to produce a well-defined ADC with the predominant species having a drug-antibody ratio (DAR) of 4.

Generation of the FolRα-targeting lead antibody and a novel, specific and homogeneous ADC, STRO-002



STRO-002-GM1 OBJECTIVES

- **Primary Objectives (Endpoints)**
  - Dose expansion: Anti-tumor activity of STRO-002 (overall response rate)
- **Secondary Objectives (Endpoints)**
  - Dose escalation: Characterize pharmacokinetics (PK) and immunogenicity (anti-drug antibodies (ADA))
  - Dose expansion: Toxicity, time to event endpoints (duration of response, progression-free survival), additional safety, PK
- **Exploratory Objectives**
  - Dose escalation: Preliminary efficacy, PK correlation with efficacy, biomarkers
  - Dose expansion: Further PK correlation with efficacy, biomarkers

DEMOGRAPHICS AND DISEASE CHARACTERISTICS

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)
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)

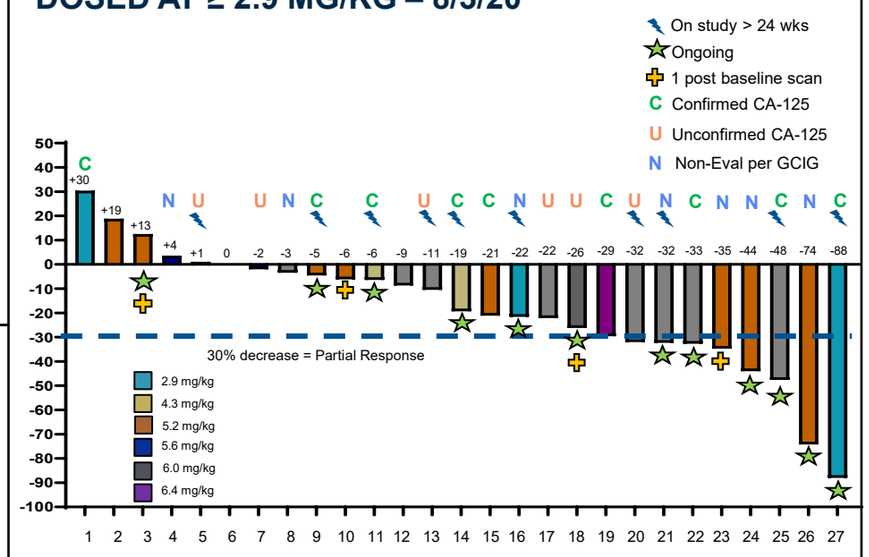
TREATMENT EMERGENT AEs IN > 25% OF PATIENTS

Emerging STRO-002 safety profile includes mostly mild adverse events - 88% of all AEs reported are grade 1 or 2

Treatment Emergent Adverse Events (TEAE) -7/31/20					
TEAE >25%	Grade 1	Grade 2	Grade 3	Grade 4	N= 39(%)
Fatigue	8 (21)	14 (36)	4 (10)	0	26 (67)
Nausea	16 (41)	7 (18)	0	0	23 (59)
Neutropenia/ Neutrophil count decreased	0	3 (8)	7 (18)	10 (26)	20 (51)
Constipation	11 (28)	8 (21)	0	0	19 (49)
Arthralgia	6 (15)	6 (15)	5 (13)	0	17 (44)
Decreased Appetite	10 (26)	7 (18)	0	0	17 (44)
Abdominal pain	5 (13)	4 (10)	3 (8)	0	12 (31)
AST increased	10 (26)	1 (3)	1 (3)	0	12 (31)
Diarrhea	8 (21)	2 (5)	1 (3)	0	11 (29)
Peripheral neuropathy	2 (5)	7 (18)	1 (3)	0	10 (26)
Vomiting	6 (15)	4 (10)	0	0	10 (26)

- 2 DLTs have been reported: neuropathy (6.0 mg/kg); bone pain (6.4 mg/kg)
- Only 1 grade 3 febrile neutropenia reported
- Grade 5 event of death on Day 12 of Cycle 1 with no cause in 1 pt, not related per investigator
- Low rate of keratitis (n = 2) with long-term dosing (1 grade 3 in a patient inadvertently dosed at 7.0 mg/kg and another patient at 5.2 mg/kg); only 1 pt required therapeutic corticosteroid eyedrops

ENCOURAGING RECIST RESPONSE AND STABLE DISEASE IN HEAVILY PRE-TREATED PATIENT DOSED AT ≥ 2.9 MG/KG – 8/3/20



3 pts off study before post baseline scan
4 pts ongoing, not yet at first post baseline scan

POTENT EFFICACY PROFILE IS EMERGING AS STRO-002-GM1 STUDY CONTINUES TO MATURE

Analyses based on 34 patients treated at ≥ 2.9 mg/kg
- 30 evaluable for RECIST response

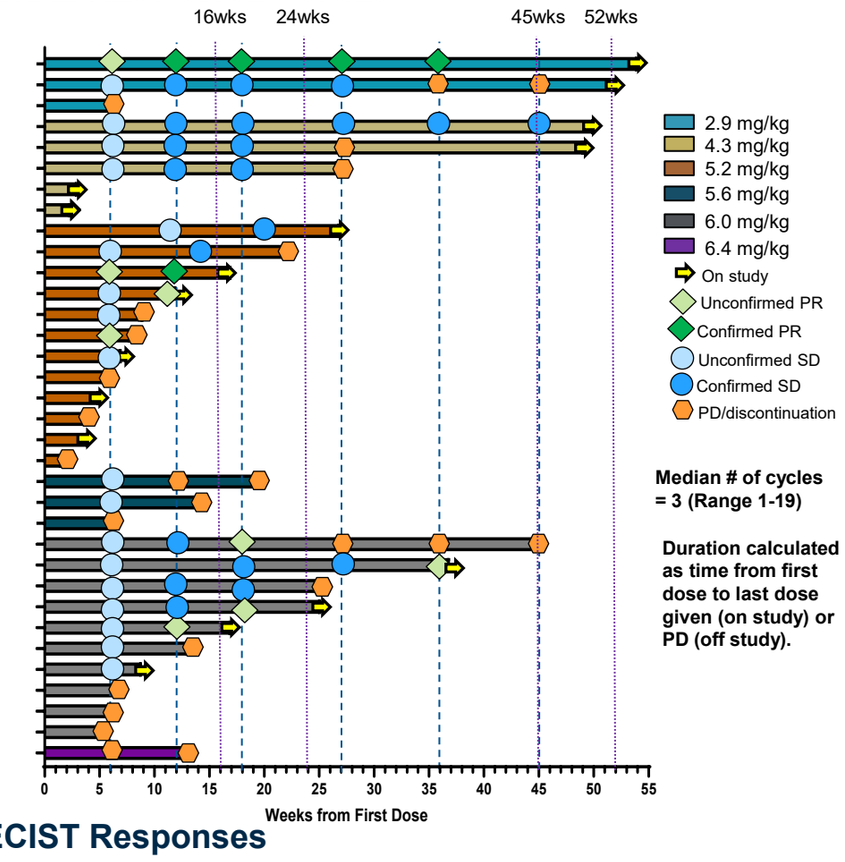
Continued increase in response rate and disease control rate
- 8 Partial Responses (PRs)
  - 2 confirmed, 6 unconfirmed
  - **7 PRs at > 12 weeks = 23% (7/30) ORR**
- 13 stable disease (SD)
  - 7 confirmed at >12 weeks = 23% (7/30)
  - 6 unconfirmed, 2 remain on study
- **47% (14/30) disease control rate (DCR)**

Duration on study encouraging
- 14 pts > 16 weeks, 10 pts > 24 weeks, 5 pts > 45 weeks, 2 pts > 52 weeks

Continued increase in CA-125 responses per GCIG criteria
- 42% (10/24) have confirmed CA-125 responses
- 7 unconfirmed (2 ongoing and pending confirmation)

CA-125 responses continue to track well with disease control

70% (21/30) EVALUABLE PATIENTS HAVE INITIAL POST-BASELINE SCANS THAT SHOW STABLE DISEASE OR PARTIAL RESPONSE – 8/3/20



Median # of cycles = 3 (Range 1-19)

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

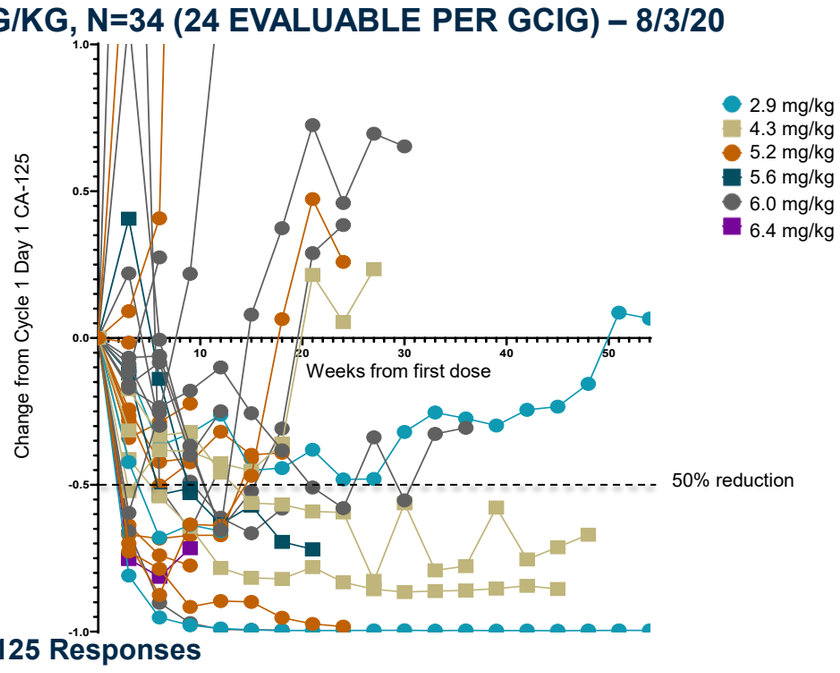
RECIST Responses

- 34 pts, with N= 30 pts evaluable (4 not yet at 1st scan post baseline)
- 8 PRs: 2 confirmed, 6 unconfirmed (4 continue); **7 PRs at > 12 weeks**
- 13 SD: 7 confirmed (12 weeks), 6 unconfirmed (2 continue)
- Disease Control Rates (PR + con SD) = 14/30 (47%)

Duration of Treatment

- 29% (10/34) of pts treated at ≥ 2.9 mg/kg remained on study > 24 weeks
- 41% on study > 16 weeks, 15% on study >45 weeks , 6% on study > 1 yr
- 47% patients remain on study treatment

CA-125 RESPONSE IN PATIENTS TREATED AT ≥ 2.9 MG/KG, N=34 (24 EVALUABLE PER GCIG) – 8/3/20



CA-125 Responses

16/24 (67%) evaluable patients have ≥ 50% reduction in CA-125
- 10/24 (42%) have confirmed CA-125 responses per GCIG
- 2/24 (8%) ongoing patients (confirmation pending/possible)
- 5/24 (21%) pts discontinued without confirmation
- 9 pts not evaluable (C1D1 CA-125 ≤ 2x upper limit ref. range)
- 1 ongoing pt with no post C1D1 assessment yet

SUMMARY/CONCLUSION

Promising Emerging Efficacy and Safety Profile in this Heavily Pretreated Unselected Patient Population
- Evidence of anti-tumor activity observed starting at 2.9 mg/kg
- Overall response rate of 23% and disease control rate 47%
- Partial responses observed after initial period of stable disease
- High rate of CA-125 reductions of ≥ 50% are associated with disease control
- Improved efficacy outcomes expected as trial matures

STRO-002 is generally well tolerated - 88% of all AEs are Grade 1 or 2.
- Most common Grade 3-4 AE is neutropenia, which is reversible within 1 week
- Neuropathy/arthralgia observed at higher doses
- Prophylactic corticosteroid eye drops not required

Further dose optimization will be explored during dose expansion in a less heavily pre-treated patient population
- Anticipate RP2D will be in 4.3 – 5.2 mg/kg range

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