#### STRO-002-GM1 Phase 1 Clinical Update

AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics: Discovery, Biology, and Clinical Application Boston, MA

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# STRO-002-GM1 Phase 1 Clinical Trial Design

- First patient dosed March 2019
- Key Objectives
  - Part 1: Safety, MTD, RP2D, PK, ADA, preliminary efficacy
  - Part 2: Response rates, duration of response, PFS (RECIST 1.1), safety, PK

#### • Key Inclusion and Exclusion Criteria

- Inclusion : Relapsed or relapsed/refractory disease
- Exclusion: Prior FolRα targeting ADC, low grade ovarian carcinoma, clinically significant pre-existing ocular disorders

## STRO-002-GM1 Phase 1 Clinical Trial Design



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



Current Status - Oct 15, 2019 (1)

- STRO-002 has been well tolerated; most AEs are grade 1 and no DLTs have been observed
  - 80% of AEs reported are grade 1; 15% grade 2 and 5% grade 3
  - No grade 4 or 5 events have been reported
  - No prophylactic corticosteroid eye drops are being utilized
  - No infusion reactions have been observed

#### • Enrollment is ongoing at 6.0 mg/kg dose level; MTD has not been reached

- 13 patients have been treated
- Dose levels 0.5, 1.0, 1.8, 2.9 and 4.3 mg/kg have been cleared

Current Status - Oct 15, 2019 (2)

- Preliminary PK profile reveals an estimated  $t_{1/2}$  for total antibody of 22-76 hours
  - Exposure increased with dose in an apparent linear manner.
- Preliminary evidence of clinical benefit and anti-tumor activity has been observed in this heavily pre-treated patient population:
  - One confirmed PR by RECIST 1.1 (Cycle 5) with a confirmed CA-125 response
  - Two ongoing patients have confirmed stable disease per RECIST 1.1, one up to Cycle 5, one up to Cycle 10
  - Three ongoing patients at 4.3 mg/kg have stable disease per RECIST 1.1 at Cycle 3 (unconfirmed)
- STRO-002 demonstrates potent anti-tumor activity in PDX models of endometrial cancer supporting further clinical development in this indication



## List of STRO-002 Active Study Sites

#### STRO-002-GM1 study:

- Medical College of Wisconsin, Dr. Denise Uyar
- Rocky Mountain Cancer Center, Dr. Sami Diab
- University of Chicago, Dr. John Moroney
- Thomas Jefferson University, Dr. Russell Schilder
- Levine Cancer Institute, Dr. Wendel Naumann
- Miami Cancer Institute, Dr. John Paul Diaz
- Comprehensive Cancer Centers of Nevada, Dr. Fadi Braiteh
- Tennessee Oncology, Sarah Cannon, Dr. Erika Hamilton

#### **Dose Escalation Schema, STRO-002-GM1**



ICF- informed consent form; D- day; DLT- dose limiting toxicity; N= number of patients treated

#### **STRO-002-GM1 Baseline Characteristics**

Characteristic	Total N=13	
Age, median (range), years	61 (52-69)	
Median time from diagnosis in years (range)	6.5 years (1.3 - 17.1)	
ECOG performance status, median (range)	0 (0-1)	
0, N (%)	7 (54)	
1, N (%)	6 (46)	
Race/Ethnicity, N (%)		
Black or African American	2 (15)	
White	11 (85)	
Disease Subtype, N (%)		
Ovarian	10 (77)	
Fallopian tube	2 (15)	
Peritoneal	1 (8)	
Median lines of prior therapy (range)	6 (2-8)	
Prior PARP inhibitor	5 (38)	
Prior Bevacizumab	10 (77)	
Prior checkpoint inhibitor	3 (23)	

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### **STRO-002-GM1: TEAEs in > 15% of Patients**

Treatment Emergent Adverse Events (TEAE)				
TEAE >15%	Number of Subjects N=13 (%)			
Nausea	6 (46)			
Fatigue	5 (39)			
Headache	4 (31)			
Insomnia	4 (31)			
Vomiting	4 (31)			
Abdominal pain	3 (23)			
Dizziness	3 (23)			

The emerging STRO-002 safety profile includes mostly mild adverse events- 95% of all AEs reported are grade 1 or 2

Data as of Oct 15, 2019 TEAE- treatment emergent adverse events

# **Grade 3 Treatment Emergent Adverse Events**

Grade 3 TEAE					
Adverse Event (Grade)	Number of Subjects N=13 (%)				
Small intestine obstruction	2 (15)				
Neutropenia	2 (15)				
Dehydration	1 (8)				
Hypokalemia	1 (8)				
Hyponatremia	1 (8)				
Hematuria	1 (8)				

- Neutropenia events (dose level 4.3 mg/kg and 6.0 mg/kg) were noted to be likely or highly likely related to STRO-002 treatment.
- All other grade 3 events we listed as 'not related' or 'doubtful' regarding relationship to study drug and occurred in patients at time of disease progression.
- As of October 15, 2019, no grade 4 or grade 5 events have been reported.

## **STRO-002 Treatment Duration**

8 patients remain on STRO-002 as of Oct 15, 2019



- Duration of study was calculated from first dose of STRO-002 until disease progression.
- All discontinuations were due to disease progression.
- Partial response (PR) and stable disease (SD) are measured by investigator using RECIST 1.1 criteria.
- Progressive disease (PD) was either by RECIST 1.1 criteria or clinical progression

## **STRO-002 Treatment Duration**

Arranged by Dose level



Weeks from First Dose

# Unconfirmed Target Lesion Response, Cycle 3 Day 1 (C3D1) by RECIST 1.1



# Confirmed Target Lesion Response, Cycle 5 Day 1 (C5D1) by RECIST 1.1



#### **Percent Change in CA-125 from Baseline (N=13)**



Percent change from baseline of CA-125 levels. One patient with confirmed CA-125 response also has a confirmed PR per RECIST 1.1.

#### Percent Change in CA-125 from Baseline ≥ 1.8 mg/kg (N=11)



Weeks from first dose

Percent change from baseline of CA-125 levels. One patient with confirmed CA-125 response also has a confirmed PR per RECIST 1.1.

#### **Preliminary Pharmacokinetic Summary** Total Antibody (TAB), C1D1



#### LLOQ = 25ng/mL

Dose Range:0.5-4.3 mg/kgCmax range: $9.7-118 \mu \text{g/mL}$ AUC<sub>0-tlast</sub> range: $661-7928 \text{ h} \cdot \mu \text{g/mL}$ Half-life range:22-76h

Dose mg/kg	ID	Cmax ng/mL	tmax h	clast ng/mL	tlast h	AUC0- tlast h∙ng/mL
0.5	1037001	9680	1.083	32.8	336	661101
1.0	1127001	27900	1.083	70.8	336	1653731
1.8	1127002	49200	1.083	228.0	168	2499424
1.8	1157001	38200	1.083	71.8	336	1704969
1.8	1177001	60700	2.000	25.1	336	1937031
2.9	1037002	69000	1.083	1400.0	336	3647336
2.9	1137001	64700	2.000	901.0	336	5108849
2.9	1157002	77100	1.083	114.0	336	3190167
4.3	1137002	118000	1.083	8870.0	168	7928009

Log-linear plot of total antibody serum concentrations vs time by dose (mg/kg) group and ID with a table of pharmacokinetic parameters after the first intravenous dose of STRO-002. Preliminary PK profile reveals an estimated half-life for total antibody of 22-76 hours while exposure increased with dose in an apparent linear manner.

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