UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 29, 2019

SUTRO BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38662**	**47-0926186**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

310 Utah Avenue, Suite 150,
South San Francisco, California, 94080
(Address of principal executive offices) (Zip Code)

(650) 392-8412
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	STRO	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On October 29, 2019, Sutro Biopharma, Inc. issued a press release announcing initial safety data in ovarian cancer patients from its ongoing Phase I study of STRO-002, a folate receptor alpha (FolRα)-targeting antibody-drug conjugate (ADC) and potent anti-tumor activity in preclinical endometrial cancer patient-derived xenograft (PDX) models, which will be presented at the AACR-NCI-EORTC Molecular Targets and Cancer Therapeutics Conference held in Boston, from October 26-30, 2019 A copy of the press release and presentation are attached as Exhibits 99.1 and 99.2, respectively, to this Current Report on Form 8-K.

The information furnished with this report, including Exhibits 99.1 and 99.2, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Exchange Act or the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

Exhibit Number	**Description**
99.1	Press Release issued by Sutro Biopharma, Inc. on October 29, 2019
99.2	Presentation

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Sutro Biopharma, Inc.

Date: October 29, 2019

By: /s/ Edward Albini

Edward Albini
Chief Financial Officer

Exhibit 99.1

Sutro Biopharma Presents Encouraging Preliminary Clinical Data in Ongoing Phase I Study for STRO-002 Antibody-Drug Conjugate in Patients with Advanced Ovarian Cancer

- *Data is being presented as a poster today at AACR-NCI-EORTC Molecular Targets and Cancer Therapeutics Conference in Boston*
- *STRO-002 was well tolerated in patients with advanced relapsed and refractory ovarian cancer and demonstrated preliminary evidence of anti-tumor activity*
- *Potent anti-tumor activity was seen in preclinical endometrial cancer models*

SOUTH SAN FRANCISCO, Calif., Oct. 29, 2019 – Sutro Biopharma, Inc. (NASDAQ: STRO), a clinical-stage drug discovery, development and manufacturing company focused on the application of precise protein engineering and rational design to create next-generation oncology therapeutics, today announced initial safety data in ovarian cancer patients from its ongoing Phase I study of STRO-002, a folate receptor alpha (FolRα)-targeting antibody-drug conjugate (ADC) and potent anti-tumor activity in preclinical endometrial cancer patient-derived xenograft (PDX) models.

To date, 13 patients have been treated in the Phase I study of STRO-002 and the maximum tolerated dose (MTD) has not been reached. Dose escalation continues with two patients currently being treated at the 6 mg/kg dose level and having completed the dose limiting toxicity (DLT) observation period. There have been no DLTs and no infusion reactions to date in these heavily pre-treated patients. Preliminary evidence of anti-tumor activity was observed in a patient who achieved a confirmed partial response by RECIST 1.1 criteria. This patient also achieved and confirmed a CA-125 response for at least 28 days. Stable disease by RECIST 1.1 has been confirmed in two ongoing patients at cycles 5 and 10 of study treatment. Three ongoing patients at the 4.3 mg/kg dose level have unconfirmed stable disease per RECIST 1.1 at cycle 3. Patients are not receiving prophylactic corticosteroid eye drops. Ninety-five percent (95%) of adverse events were grade 1 or grade 2. The preliminary pharmacokinetic (PK) profile reveals an estimated half-life for the total antibody of 22-76 hours with increasing exposure in an apparent dose dependent manner.

Anti-tumor activity of STRO-002 was assessed in preclinical PDX models of endometrial cancer that expressed varying levels of FolRαHigh FolRα-expressing models showed the highest tumor growth inhibition. Some models with low and medium FolRα expression also exhibited good tumor growth inhibition.

"The emerging safety profile of STRO-002 is very promising," saidArturo Molina, M.D., Chief Medical Officer at Sutro Biopharma "Antibody-drug conjugates offer the ability to preferentially kill tumor cells while avoiding healthy cells. Early signs of clinical benefit are encouraging, and we believe STRO-002 has potential in this heavily pre-treated population of patients with advanced, relapsed and refractory ovarian cancer."

Bill Newell, Sutro's Chief Executive Officer added, "STRO-002 is our second proprietary ADC in clinical trials, and one of our four ADC clinical product candidates from our platform in the past three years, including those of our collaborators. Our goal is to continue to develop targeted therapies for cancer patients. The STRO-002 data add to the growing body of evidence that our ADC development platform and pipeline of products has the potential to help patients with life-threatening cancers."

The ongoing Phase I, open-label, multicenter, dose escalation study with dose expansion of STRO-002 is designed to identify the MTD, the recommended Phase II dose and to evaluate the safety, tolerability, and preliminary anti-tumor

activity of STRO-002 in adults with advanced epithelial ovarian cancer, including fallopian or primary peritoneal cancer, and endometrial cancer. This trial is registered with clinicaltrials.gov identifier NCT03748186.

Additional multimedia content from Sutro regarding STRO-001 and STRO-002 can be foundhere and here.

The poster will be accessible through the Clinical/Scientific Presentation and Publication Highlights page of the News section of the company's website at www.sutrobio.com.

About Sutro Biopharma

Sutro Biopharma, Inc., located in South San Francisco, is a clinical-stage drug discovery, development and manufacturing company. Using precise protein engineering and rational design, Sutro is advancing next-generation oncology therapeutics.

Sutro's proprietary and integrated cell-free protein synthesis and site-specific conjugation platform, XpressCF+™, led to the discovery of STRO-001 and STRO-002, Sutro's first two internally-developed ADCs. STRO-001 is a CD74 ADC currently being investigated in a Phase I clinical trial of patients with advanced B-cell malignancies, including multiple myeloma and non-Hodgkin lymphoma. STRO-001 was granted Orphan Drug Designation by the FDA for multiple myeloma in October 2018. STRO-002 is a folate receptor alpha (FolRα) ADC, currently being investigated in a Phase I clinical trial of patients with ovarian and endometrial cancers. This is the second product candidate to be evaluated in clinical trials resulting from Sutro's XpressCF+™ technology platform. A third program, BCMA-targeting ADC, which is part of Sutro's collaboration with Celgene, recently received FDA clearance for its IND. Sutro's proprietary technology was responsible for the discovery and manufacturing of the BCMA ADC, for which Celgene has worldwide development and commercialization rights. Sutro is entitled to development and regulatory milestone payments and tiered royalties from Celgene for this BCMA ADC.

Sutro is dedicated to transforming the lives of cancer patients by creating medicines with improved therapeutic profiles for areas of unmet need.

To date, Sutro has designed cytokine-based immuno-oncology therapies, ADCs, vaccines and bispecific antibodies primarily directed at clinically-validated targets for which the current standard of care is suboptimal.

Sutro's platform allows it to accelerate discovery and development of potential first-in-class and best-in-class molecules through rapid and systematic evaluation of protein structure-activity relationships to create optimized homogeneous product candidates.

In addition to developing its own oncology pipeline, Sutro is collaborating with select pharmaceutical and biotech companies to discover and develop novel, next-generation therapeutics. As the pace of clinical development accelerates, Sutro and its partners are developing therapeutics designed to more efficiently kill tumors without harming healthy cells.

Follow Sutro on Twitter, @Sutrobio, and atwww.sutrobio.com to learn more about our passion for changing the future of oncology.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, anticipated preclinical and clinical development activities, potential benefits of the company's product candidates and platform and potential market opportunities

for the company’s product candidates. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Although the company believes that the expectations reflected in such forward-looking statements are reasonable, the company cannot guarantee future events, results, actions, levels of activity, performance or achievements, and the timing and results of biotechnology development and potential regulatory approval is inherently uncertain. Forward-looking statements are subject to risks and uncertainties that may cause the company's actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties related to the company's ability to advance its product candidates, the receipt and timing of potential regulatory designations, approvals and commercialization of product candidates, the Company’s ability to maintain and recognize the benefits of certain designations received by product candidates, the timing and results of preclinical and clinical trials, the company's ability to fund development activities and achieve development goals, the company's ability to protect intellectual property, and the Company’s commercial collaborations with third parties and other risks and uncertainties described under the heading "Risk Factors" in documents the company files from time to time with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release, and the company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

# # #

Investor Contacts

John Graziano
Solebury Trout
+1 646-378-2942
jgraziano@soleburytrout.com

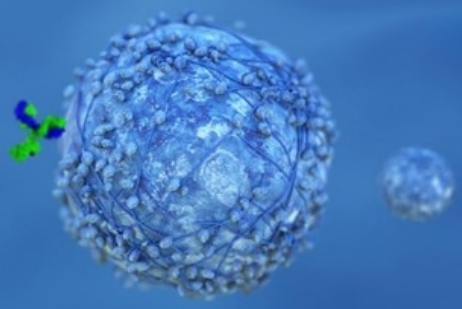
Xuan Yang
Solebury Trout
+1 646-378-2975
xyang@soleburytrout.com

Media Contacts

David Schull
Russo Partners
(212) 845-4271
david.schull@russopartnersllc.com

Scott Stachowiak
Russo Partners
(646) 942-5630
scott.stachowiak@russopartnersllc.com

Exhibit 99.2



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

Arturo Molina, MD, MS
Chief Medical Officer
Oct 29th 2019

SUTRO BIOPHARMA

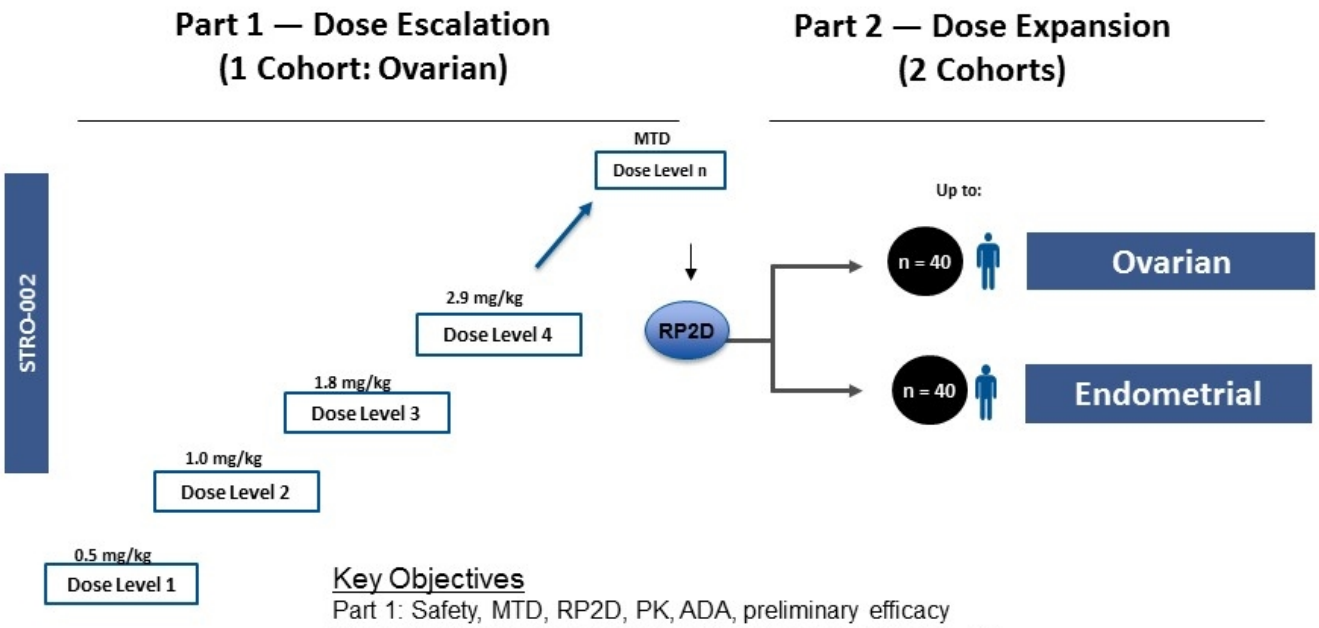
STRO-002-GM1 Phase 1 Clinical Trial Design

- **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



Key Objectives

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

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

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

STRO-002-GM1 Study Overview

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

STRO-002-GM1 Study Overview

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)

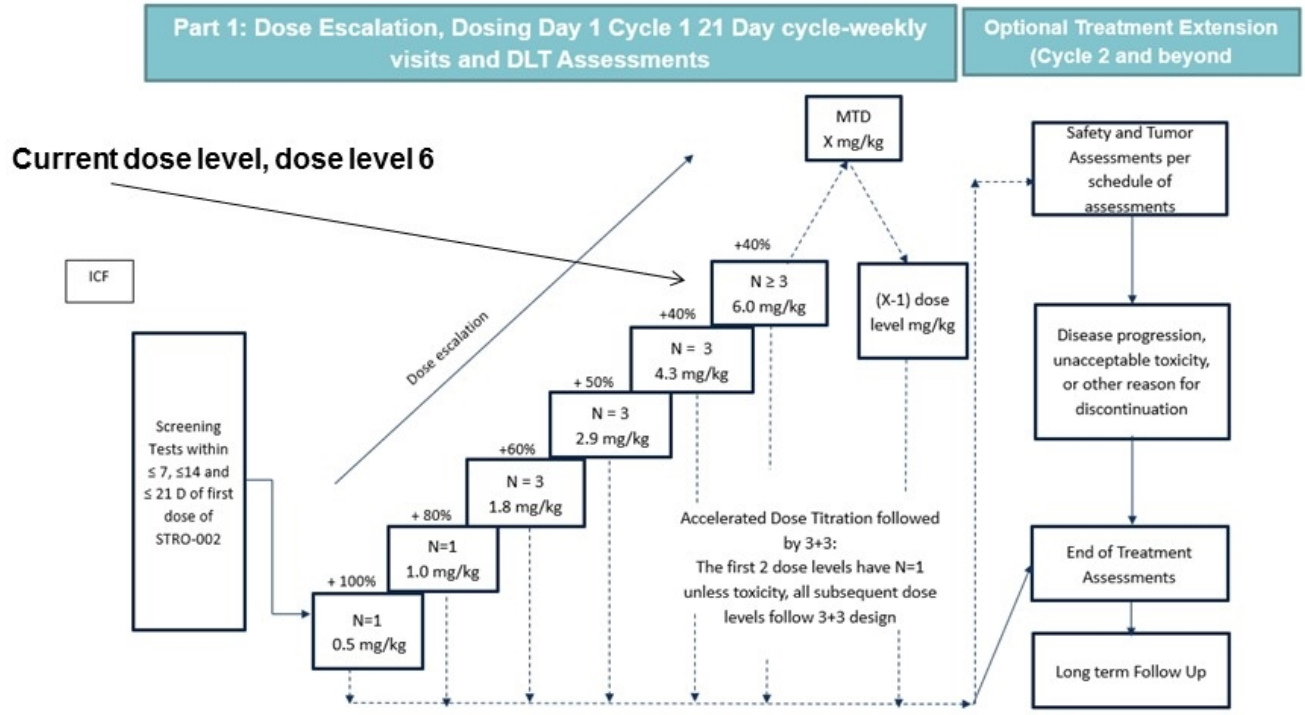
- **STRO-002 demonstrates potent anti-tumor activity in PDX models of endometrial cancer supporting further clinical development in this indication**

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)

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

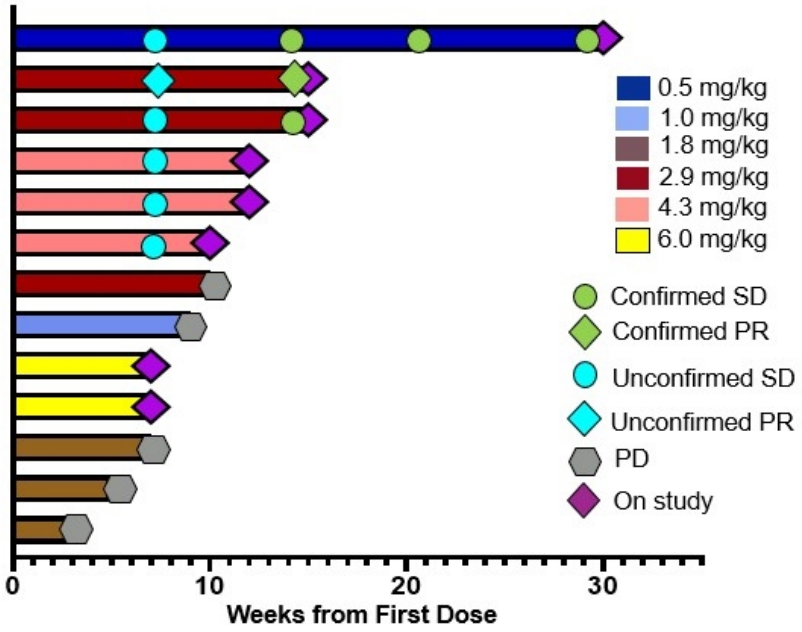
Grade 3 Treatment Emergent Adverse Events

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

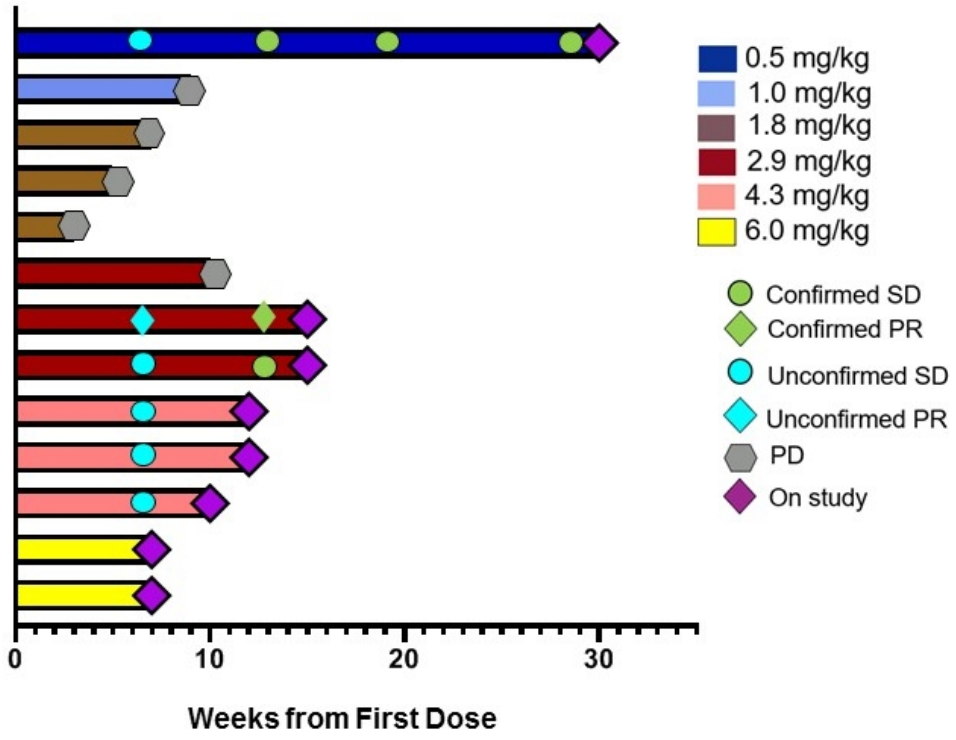
8 patients remain on STRO-002 as of Oct 15, 2019



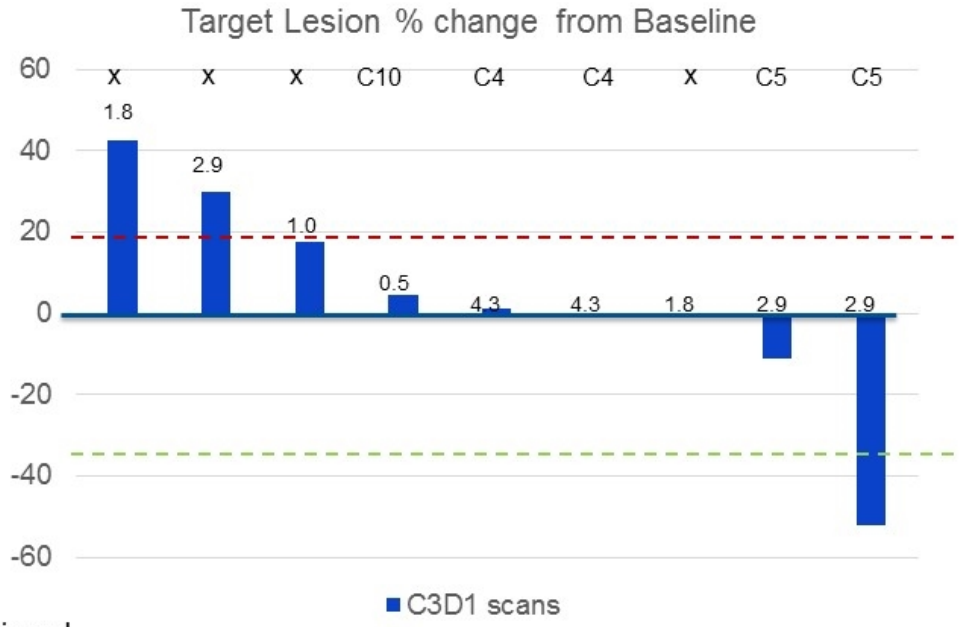
- Duration of study was calculated from first dose of STRO-002 until disease progression.
- All discontinuations were due to disease progression.
- Partial response (PR) and stable disease (SD) are measured by investigator using RECIST 1.1 criteria.
- Progressive disease (PD) was either by RECIST 1.1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

STRO-002 Treatment Duration

Arranged by Dose level



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

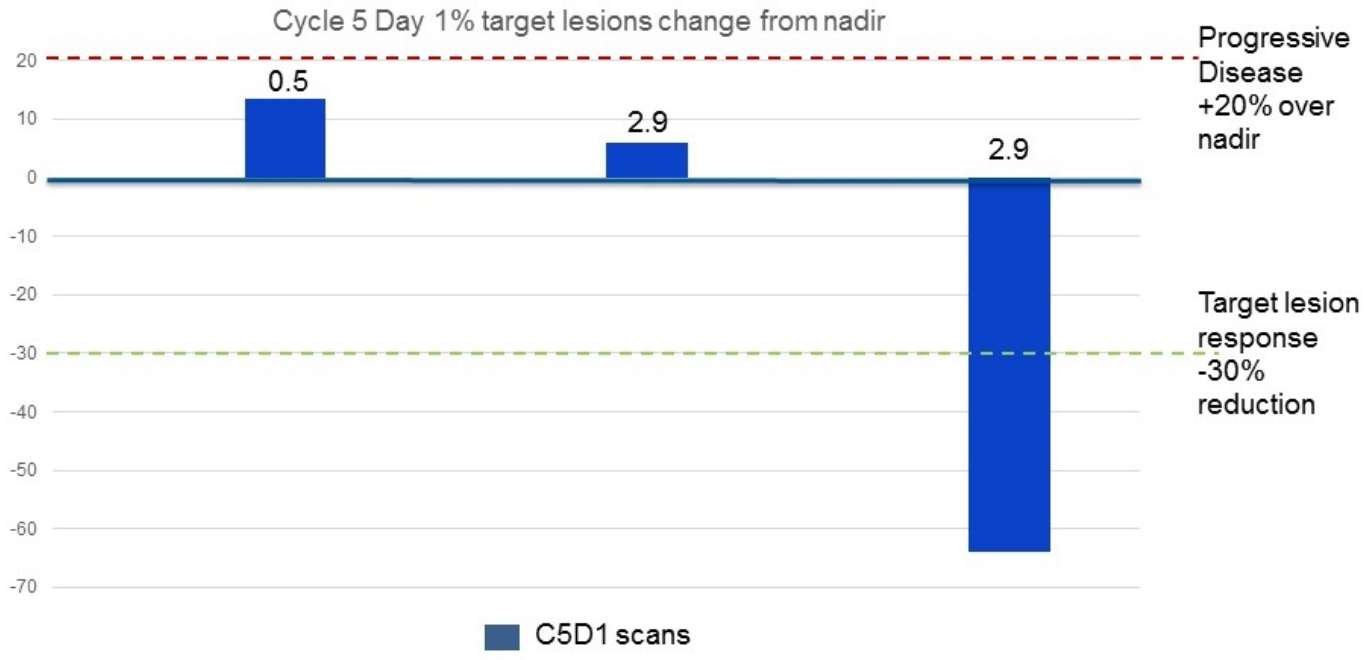


Progressive Disease +20% over Baseline

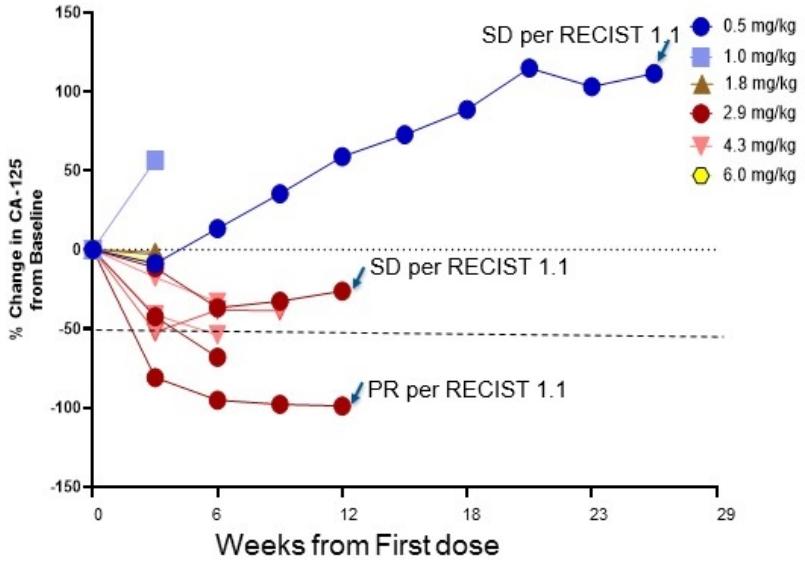
Target lesion response -30% reduction

X Pt discontinued treatment

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

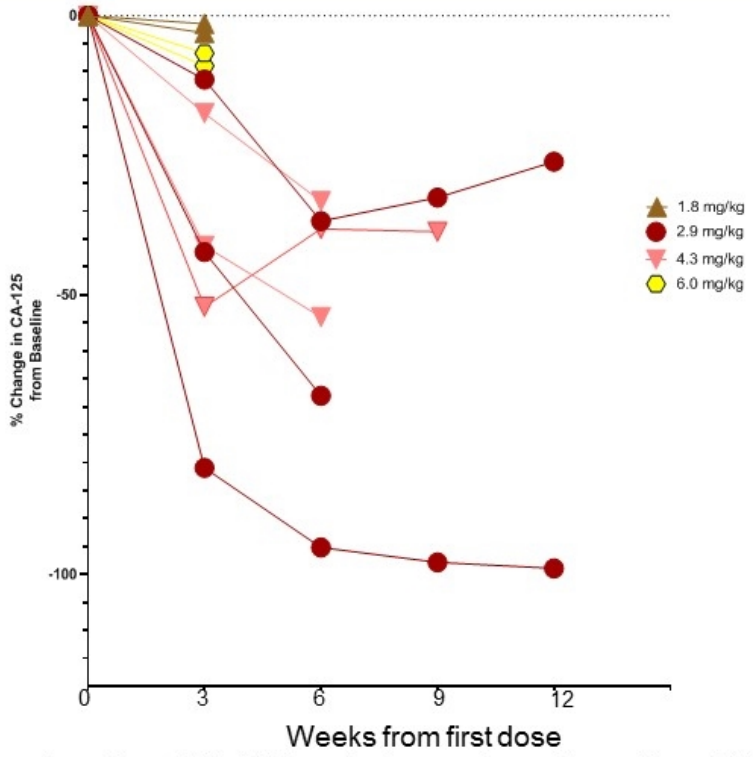


Percent Change in CA-125 from Baseline (N=13)



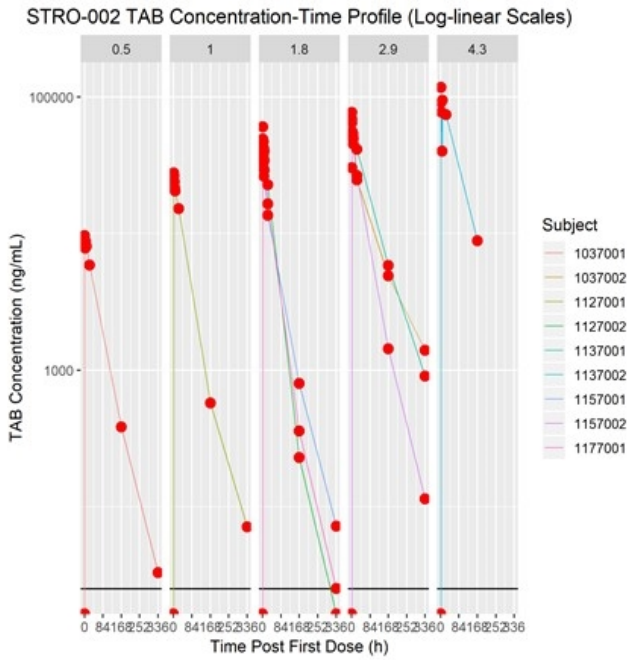
Percent change from baseline of CA-125 levels. One patient with confirmed CA-125 response also has a confirmed PR per RECIST 1.1.

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



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/kg

Cmax range: 9.7-118 µg/mL

$AUC_{0\text{-tlast}}$ range: 661-7928 h·µg/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.

STRO-002-GM1 Study Overview

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 and dose levels 0.5, 1.0, 1.8, 2.9 and 4.3 mg/kg have been cleared

STRO-002-GM1 Study Overview

Current Status Oct 15, 2019 (2)

- **Preliminary PK profile reveals an estimated half-life for total antibody of 22-76 hours**
  - Exposure increased with dose in an apparent linear manner
- **Preliminary evidence of 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**

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

Arturo Molina, MD, MS
Chief Medical Officer
Oct 29th 2019

SUTRO BIOPHARMA