

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): June 15, 2019

SUTRO BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38662

(Commission File Number)

47-0926186
(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 144-12 under the Exchange Act (17 CFR 240.144-12)
- 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.

Sutro Biopharma, Inc. presented the presentation attached hereto as Exhibit 99.1 at the 2019 European Hematology Association Congress on June 15, 2019.

The information furnished with this report, including Exhibit 99.1, 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 | Sutro 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: June 17, 2019

By: _____
/s/ Edward Albini
Edward Albini
Chief Financial Officer

Preliminary Results of a Phase 1 Dose Escalation Study of the First-in-Class Anti-CD74 Antibody Drug Conjugate (ADC), STRO-001, in Patients with Advanced B-Cell Malignancies

June 15, 2019
European Hematology Association Meeting

Arturo Molina, MD, MS
Chief Medical Officer



Summary and Conclusions (1)

- STRO-001 is the first ADC generated with novel cell-free protein synthesis technology and site-specific conjugation to be tested in the clinic.
- STRO-001 has been generally well tolerated.
 - Most AEs are grade 1 or 2.
- MTD has not been reached. Enrollment is ongoing at:
 - 0.65 mg/kg in multiple myeloma (MM) cohort.
 - 0.91 mg/kg in non-Hodgkin lymphoma (NHL) cohort.
- Mild infusion reactions have been observed, requiring standard of care pre-medications.

Data as of May 14, 2019

14 June 2019

SUTRO
BIOPHARMA

Summary and Conclusions (2)

- No ocular toxicity signals have been observed.
- Two thromboembolic DLTs have been observed in 2 patients with very bulky disease (>15 cm) and other pre-existing factors for thrombosis.
- Preliminary PK profile in 3 patients reveals an estimated half-life for total antibody of 37-47 hours.
- Anti-drug antibodies (ADA) have not been detected.
- Preliminary anti-tumor activity (1 CR and 1 PR) has been observed in two patients with DLBCL.

Data as of May 14, 2019

14 June 2019

SUTRO
BIOPHARMA

STRO-001: Overcoming Therapeutic Window Limitations of 1st Generation ADC's

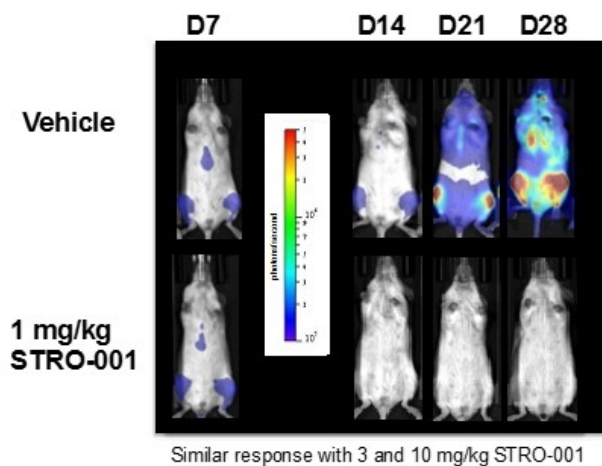
| Property | Description |
|-------------|---|
| Stability | <ul style="list-style-type: none">Warhead is covalently conjugated to two specific sites on the antibody (DAR = 2) using a stable non-cleavable linker |
| Potency | <ul style="list-style-type: none">Optimized positioning of linker / maytansinoid derivative warhead for effective targeting of CD74-positive tumor cells |
| Selectivity | <ul style="list-style-type: none">Hydrophilic nature of potent intracellular catabolites translates to low permeability to surrounding cells once cancer cell is killed – reduces potential for toxicity to surrounding normal tissue |
| Safety | <ul style="list-style-type: none">Homogenous design results in a single species product creating more precise dosing and potential for improved therapeutic index |

Designed to optimize multiple properties to widen therapeutic index

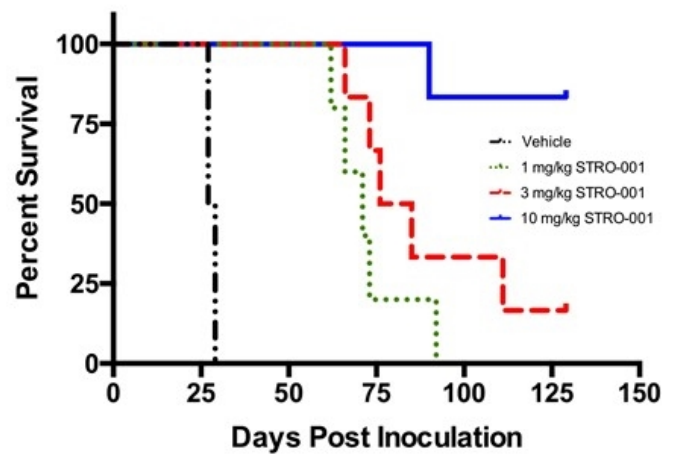
STRO-001 in Multiple Myeloma

Potent preclinical anti-tumor activity

Bioluminescent Imaging of Tumor Cells



Survival in MM1S-luc Xenograft Model



STRO-001 Results in Significant Reduction of Tumor Burden in Single Doses of 1, 3 and 10 mg/kg

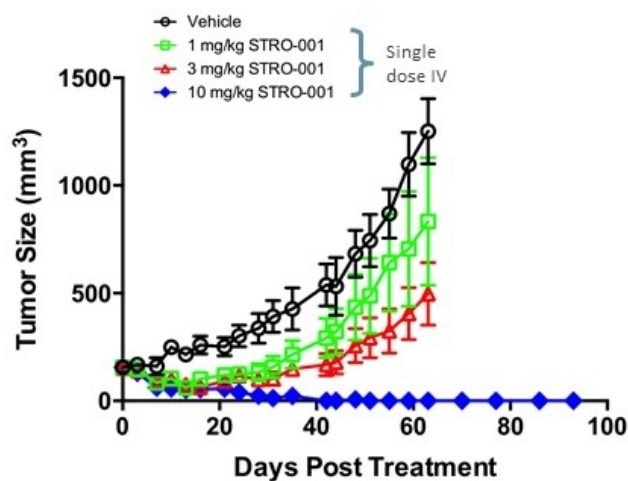
STRO-001 Results in Meaningful Survival Benefits

Source: Sutro Biopharma report, Evaluation of STRO-001 Efficacy Against Established Disseminated MM1S-luc Human Multiple Myeloma In Female NSG Mice, Report TR-PHRM-0071-V1.0, dated July 20, 2017.

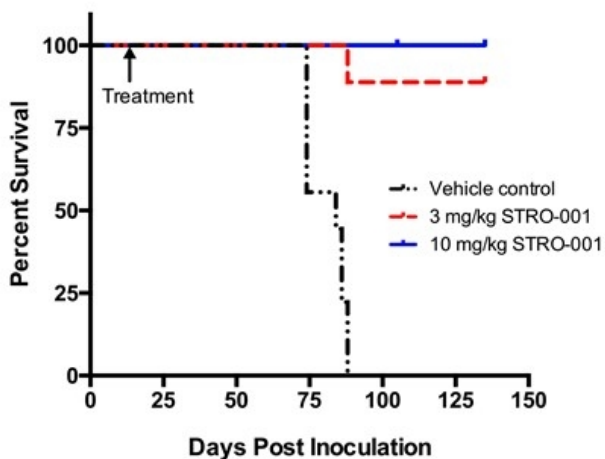
STRO-001 in DLBCL and Mantle Cell

Promising preclinical efficacy and anti-tumor activity

Tumor Growth in Murine Xenograft DLBCL Model



Survival in Murine Xenograft Mantle Cell Model



10 mg/kg of STRO-001 Induced Complete Tumor Regression in All 7 Mice and Resulted in No Tumor Re-Growth 90 Days Post Treatment

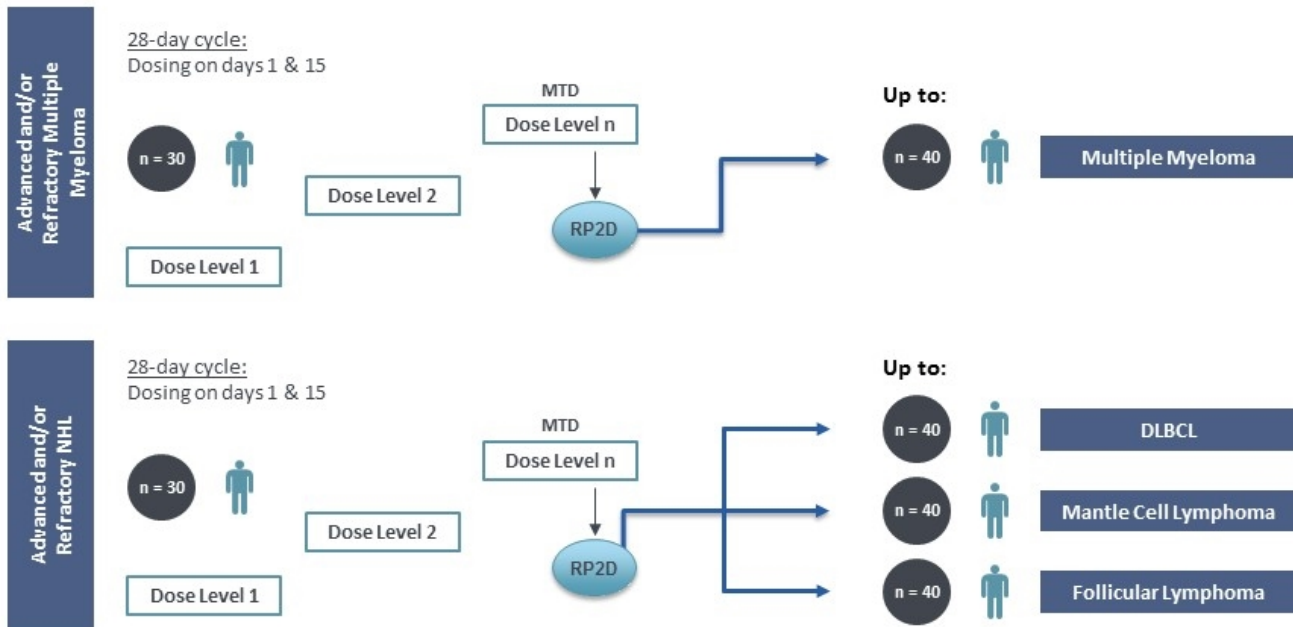
10 mg/kg of STRO-001 Resulted in 100% Survival on Day 135

Source: Sutro Biopharma report, Efficacy of STRO-001 in Tumors in SCID Mice, TR-PHRM-0072-V1.0, dated July 11, 2017; Sutro Biopharma report, Evaluation of STRO-001 Efficacy in Disseminated Mino Model in SCID Mice, Report TR-PHRM-0011-V1.0, dated July 13, 2017.

STRO-001-BCM1 Phase 1 Clinical Trial Design

Part 1 — Dose Escalation (2 Cohorts)

Part 2 — Dose Expansion (4 Cohorts)



Clinical data will drive expansion

STRO-001-BCM1 Study – Patient Demographics

| Characteristic | Cohort A (MM) N =10 | Cohort B (NHL) N=11 | Total N=21 |
|---|------------------------|------------------------|----------------|
| Age, median (range), years | 64.5 (42-80) | 64 (21-82) | 64 (21-82) |
| Median time from diagnosis in years (range) | 6.4 (1.3-13.6) | 3.2 (1.0-29.8) | 4.0 (1.0-29.8) |
| ECOG performance status, median (range) | 1 (0-2) | 1 (0-2) | 1 (0-2) |
| 0, N (%) | 4 (40) | 3 (27) | 7 (33) |
| 1, N (%) | 5 (50) | 7 (64) | 12 (57) |
| 2, N (%) | 1 (10) | 1 (9) | 2 (10) |
| Race/Ethnicity, N (%) | | | |
| Black or African American | 1 (10) | 0 | 1 (5) |
| Hispanic/Latino | 1 (10) | 2 (18) | 3 (14) |
| White | 8 (80) | 9 (82) | 17 (81) |

Data as of May 14, 2019

14 June 2019

SUTRO
BIOPHARMA

STRO-001-BCM1 Study – Patient Demographics

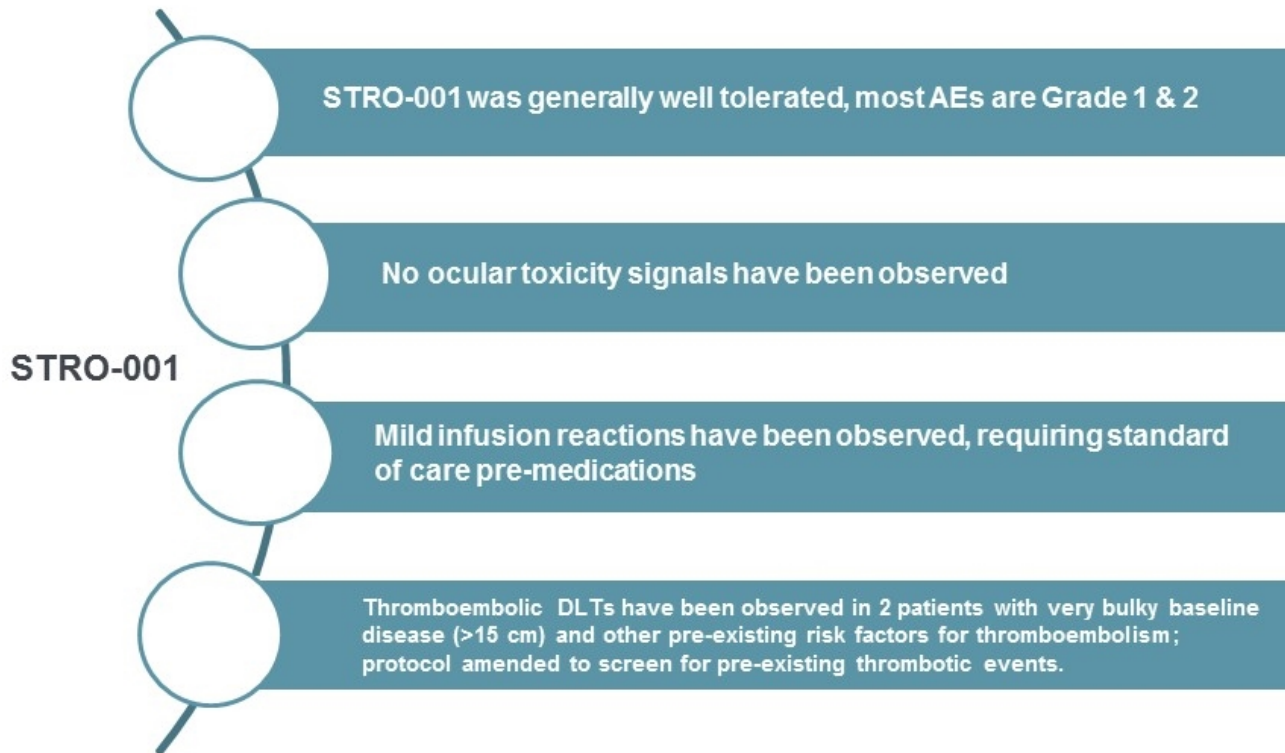
| Characteristic | Cohort A (MM) N =10 | Cohort B (NHL) N=11 | Total N=21 |
|---|------------------------|------------------------|---------------|
| Disease Subtype, N (%) | | | |
| Multiple myeloma | 10 (100) | N/A | 10 (48) |
| Follicular lymphoma | N/A | 3 (27) | 3 (14) |
| Marginal zone lymphoma | | 1 (9) | 1 (5) |
| Mantle cell lymphoma | | 1 (9) | 1 (5) |
| DLBCL | | 4 (36) | 4 (19) |
| Burkitt's lymphoma | | 1 (9) | 1 (5) |
| DLBCL/FL | | 1 (9) | 1 (5) |
| Median lines of prior therapy (range) | 6 (3-11) | 4 (2-12) | 6 (2-12) |
| Prior autologous stem cell transplant, N (%) | 6 (60) | 2 (18) | 8 (38) |
| Prior related donor allogeneic stem cell transplant, N (%) | 1 (10) | 0 | 1 (5) |
| Prior unrelated donor allogeneic stem cell transplant, N(%) | 0 | 1 (9) | 1 (5) |
| Prior CAR-T therapy, N (%) | 1 (10) | 1 (9) | 2 (10) |

Data as of May 14, 2019

14 June 2019

SUTRO
BIOPHARMA

STRO-001 Initial Safety Data Profile



Treatment Emergent AEs in $\geq 15\%$ of Patients

| Treatment Emergent Adverse Events (TEAE) | |
|--|--------------------------------|
| TEAE $\geq 15\%$ | Number of Subjects N=21 (%) |
| Fatigue | 6 (29) |
| Chills | 6 (29) |
| Nausea | 5 (24) |
| Fever | 5 (24) |
| Cough | 4 (19) |
| Infusion related reaction | 4 (19) |

Data as of May 14, 2019

The emerging STRO-001 safety profile includes mostly mild adverse events- 91% of all AEs are grade 1 or 2. Observance of infusion reactions prompted a premedication requirement in a protocol amendment.

Grade ≥ 3 Treatment Emergent AEs

| Grade ≥ 3 TEAE | |
|-----------------------------|--------------------------------|
| Adverse Event (Grade) | Number of Subjects N=21 (%) |
| Thromboembolic event (3,5) | 2 (10) |
| Fall (3) | 1 (5) |
| Hyponatremia (3) | 1 (5) |
| Lung infection (3) | 1 (5) |
| Pleural effusion (3) | 1 (5) |
| Pneumothorax (3) | 1 (5) |
| Urinary tract infection (3) | 1 (5) |

Data as of May 14, 2019

All grade ≥ 3 events were assessed as not related to study drug with the exceptions of the thromboembolic events and hyponatremia, which have been assessed by the investigator as 'possibly' related to STRO-001 treatment. The thromboembolic events were in patients with very bulky disease (>15 cm) and other pre-existing factors for thrombosis.

14 June 2019

SUTRO
BIOPHARMA

Dose Limiting Toxicities in Two High-Risk Patients

Dose Limiting Toxicities Summary

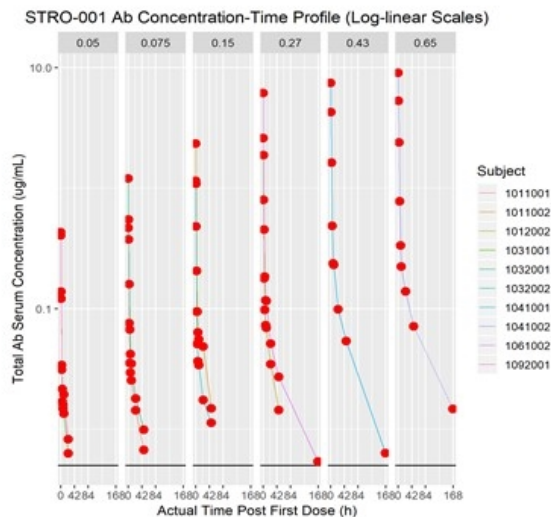
| | |
|------------------------------|--|
| Cohort A (MM) 0.65 mg/kg | Grade 5 thromboembolic event- Patient passed away suddenly 8 days after first dose of study treatment. An autopsy revealed patient had extensive bilateral pulmonary embolism as cause of death. There were multiple risk factors for thromboembolism such as bulky plasmacytomas in the abdomen (9 x 6 x 2.5 cm), pelvis (ovary 17 x 14 x 3.9 cm) and two focal areas of marked narrowing of small and large intestine by plasmacytoma, prolonged car ride to and from clinic, partial small bowel obstruction and possible dehydration. Code status was "DNR" Initial investigator assessment was "not related to study drug" |
| Cohort B (NHL) 0.91 mg/kg | Grade 3 thromboembolic event- Nine days after the second dose of STRO-001, the patient reported feeling short of breath. A CT showed left upper lobe pulmonary emboli, acute venous thrombosis involving bilateral external iliac veins, and common femoral veins. The CT scan also showed progressive extensive persistent adenopathy in the chest (lymph nodes measuring 3.5 x 1.3 cm, 2.4 x 1.2 cm, 2.8 x 1.8 cm, 4.4 x 3.2 cm, 2.4 x 2.1 cm), abdomen (soft tissue mass 7.9 x 4.5 x 10.0 cm, lymph node- 15.3 x 8.6 cm, 13.0 x 7.9 cm), and pelvis (6.6x 2.5 cm, 6.7x 6.2 cm, 6.4 x 4.3 cm, 3.0 x 1.7 cm), with encasement of the inferior vena cava and abdominal aorta. After the second event, attribution was changed to "possibly related" by the Safety Evaluation Team. |

The 2 DLTs observed in STRO-001-BCM1 study are described above.

Subsequently, the protocol was amended to screen for pre-existing thromboembolism/thrombotic events.

Initial Pharmacokinetic Profile Suggests Dose Proportionality

- Log-linear plot of total antibody serum concentrations vs time by dose (mg/kg) group
- Pharmacokinetic parameters after the first intravenous dose of STRO-001.
- Preliminary PK profile in 3 patients reveals estimated half-life for total antibody of 37-47 hours.
- No ADA detected in the 32 samples from 10 patients



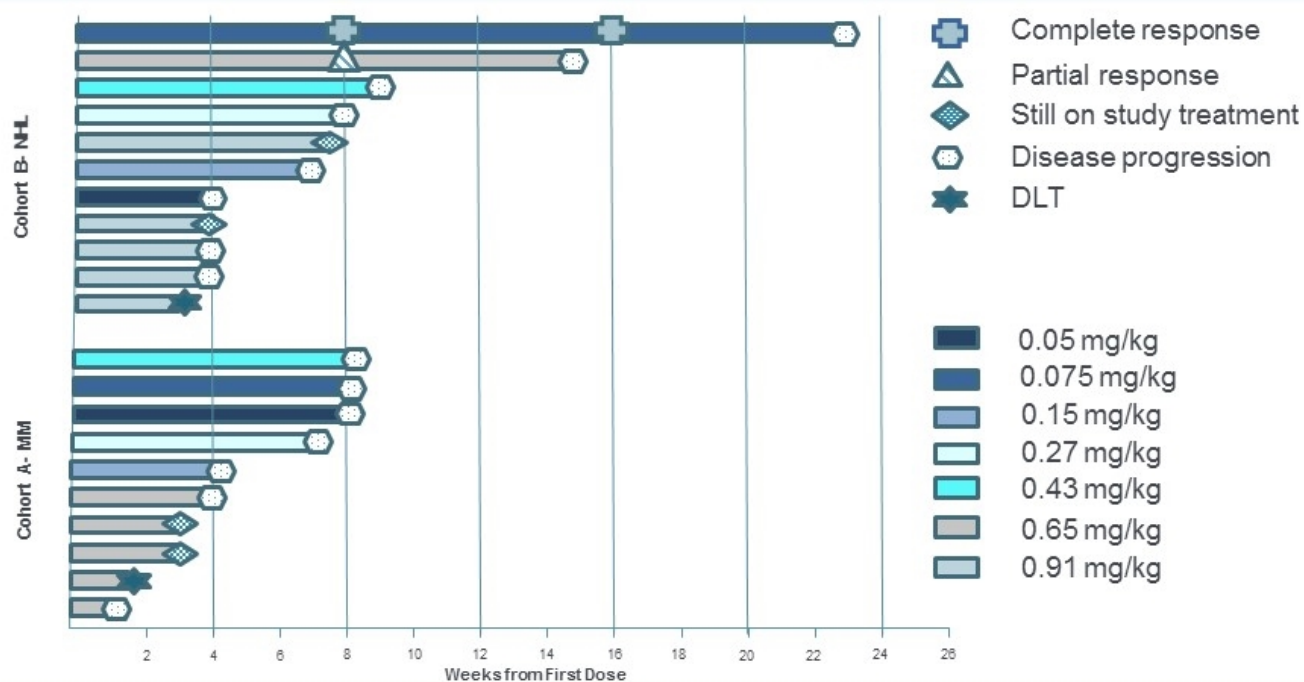
| Dose (mg/kg) | Cmax ug/mL | tmax h | t1/2 h | AUC0-t1/2 h ug/mL |
|--------------|------------|--------|--------|-------------------|
| 0.05 | 0.432 | 1.083 | 24 | 0.93 |
| 0.05 | 0.406 | 1.083 | 24 | 0.92 |
| 0.075 | 0.469 | 1.083 | 48 | 1.85 |
| 0.075 | 1.200 | 1.083 | 48 | 3.28 |
| 0.15 | 2.350 | 1.083 | 48 | 6.21 |
| 0.15 | 1.150 | 1.083 | 48 | 2.96 |
| 0.27 | 2.600 | 1.083 | 48 | 5.85 |
| 0.27 | 6.170 | 1.083 | 168 | 14.60 |
| 0.43 | 7.490 | 1.083 | 168 | 26.44 |
| 0.65 | 9.080 | 1.083 | 168 | 34.29 |

No Detectable Anti-Drug Antibodies (ADA) to STRO-001

- 32 available samples were sent for ADA testing. None of the samples had detectable ADA to STRO-001
- Samples are taken at screening, each cycle starting with Cycle 2 and at End of Treatment

| DOSE LEVEL | COHORT A (MM) | COHORT B (NHL) | ADA PRESENT? |
|-------------|---------------|----------------|--------------|
| 0.05 MG/KG | 4 SAMPLES | 2 SAMPLES | NO |
| 0.075 MG/KG | 4 SAMPLES | 7 SAMPLES | NO |
| 0.15 MG/KG | 3 SAMPLES | 3 SAMPLES | NO |
| 0.27 MG/KG | 2 SAMPLES | 3 SAMPLES | NO |
| 0.43 MG/KG | 3 SAMPLES | - | NO |
| 0.65 MG/KG | 1 SAMPLES | - | NO |

STRO-001: Phase 1 Study Duration of Study Treatment



Preliminary anti-tumor activity (1 CR and 1 PR) has been observed in two patients with DLBCL. Duration of study was calculated from first dose of STRO-001 until disease progression or patient experienced a DLT as of May 14, 2019

Complete Response to STRO-001 in a Patient with DCBCL

Patient is an 82-year-old man diagnosed with Stage III diffuse large B-cell lymphoma (DLBCL), non-GC type in 2015

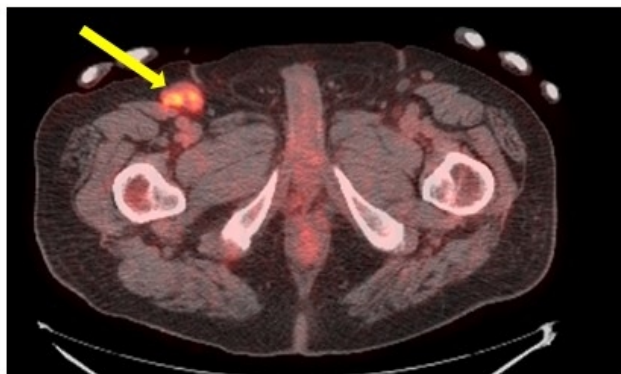
Treatment prior to study entry:

- CHOP-R,
- Rituximab/lenalidomide
- Bendamustine/rituximab
- Obinituzumab/gemcitabine/oxaliplatin

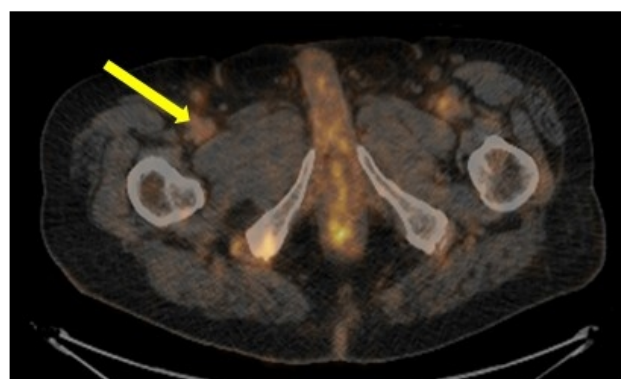
Patient received 12 doses of STRO-001, and had a complete response (CR) at Cycle 3 and Cycle 5 scans

Patient had progressive disease at Cycle 7

Complete Response in a Patient with DLBCL



Baseline Scan: Right inguinal lymph node, 34.2 x 15.6 mm, SUV 5.52
Spleen 94 mm
Overall Deauville : 4



Cycle 3 Day 1 Scan: Right inguinal lymph node, 25.3 x 12.7 mm, SUV 2.65
Spleen 72 mm
Overall Deauville : 2
Complete response

Partial Response to STRO-001 in a Patient with DCBCL

64 year old man diagnosed with double-hit DLBCL in August 2017

Treatment prior to study entry:

- CHOP-R x 1 and da-EPOCH x 6 between Aug 2017–Nov 2017
- Rituximab, ifosfamide, carboplatin, etoposide (RICE) with IT prophylaxis from Dec 2017 – Jan 2018 for refractory disease
- Rituximab and XRT in Feb 2018
- Rituximab, gemcitabine + oxaloplatin in March -April 2018 with XRT
- Yescarta (CAR-T) in May 2018 with partial response.
- Rituximab and lenalidomide in Nov 2018 for progressive disease

Patient received 8 doses of STRO-001, and had a partial response (PR) at Cycle 3

Patient had progressive disease at Cycle 5

Summary and Conclusions (1)

- STRO-001 is the first ADC generated with novel cell-free protein synthesis technology and site-specific conjugation to be tested in the clinic.
- STRO-001 has been generally well tolerated.
 - Most AEs are grade 1 or 2.
- MTD has not been reached. Enrollment is ongoing at:
 - 0.65 mg/kg in multiple myeloma (MM) cohort
 - 0.91 mg/kg in non-Hodgkin lymphoma (NHL) cohort.
- Mild infusion reactions have been observed, requiring standard of care pre-medications.

Data as of May 14, 2019

14 June 2019

SUTRO
BIOPHARMA

Summary and Conclusions (2)

- No ocular toxicity signals have been observed.
- Two thromboembolic DLTs have been observed in 2 patients with very bulky disease (>15 cm) and other pre-existing factors for thrombosis.
- Preliminary PK profile in 3 patients reveals an estimated half-life for total antibody of 37-47 hours.
- Anti-drug antibodies (ADA) have not been detected.
- Preliminary anti-tumor activity (1 CR and 1 PR) has been observed in two patients with DLBCL.

Data as of May 14, 2019

14 June 2019

SUTRO
BIOPHARMA

Preliminary Results of a Phase 1 Dose Escalation Study of the First-in-Class Anti-CD74 Antibody Drug Conjugate (ADC), STRO-001, in Patients with Advanced B-Cell Malignancies

June 15, 2019
European Hematology Association Meeting

Arturo Molina, MD, MS
Chief Medical Officer

SUTRO
BIOPHARMA
