KOL Discussion of STRO-002 Data

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Agenda for Today

Торіс	Speaker
Welcome and Introduction Forward Looking Statements Welcome and KOLs Introduction	Ed Albini, Chief Financial Officer Bill Newell, Chief Executive Officer
STRO-002 GM1 Data Discussion STRO-002 MOA Phase 1 Dose-Escalation Data	Lainie P. Martin, M.D.
STRO-002 Development Overview Phase 1 Dose-Expansion Design Regulatory Path Forward	Arturo Molina, M.D., Chief Medical Officer
Q&A Panel	Lainie P. Martin, M.D. R. Wendel Naumann, M.D. Bill Newell Arturo Molina, M.D. Trevor Hallam, Ph.D., Chief Scientific Officer Ed Albini
Closing Remarks	Bill Newell



Meet the Investigators and Speakers Dr. Lainie P. Martin and Dr. R. Wendel Naumann



Lainie P. Martin, M.D.

Leader, Gynecology/Oncology Program and Associate Professor of Medicine at Hospital of the University of Pennsylvania Sutro Biopharma Clinical Advisory Board

Dr. Martin is a medical oncologist specializing in the treatment of gynecologic cancers. She was recruited to the University of Pennsylvania to serve as the Leader of the Gynecologic Medical Oncology Program. She is an Associate Professor in the department of Hematology/Oncology at the University of Pennsylvania and serves as the Associate Director of the Gynecologic Oncology Clinical Research Unit.

She spent 15 years at the Fox Chase Cancer Center where she led the Gynecologic Research Program and served as the interim Physician Director of the Office of Clinical Research as well as cochair of the Scientific Review Committee. She has served as the Principal or Site Principal Investigator on over 75 trials and has extensive experience in the design and management of Phase I, II and III clinical trials.



R. Wendel Naumann, M.D.

Professor & Director of Gynecologic Oncology Research and Associate Medical Director of Clinical Trials at Levine Cancer Institute, Atrium Health Sutro Biopharma Clinical Advisory Board

Dr. Naumann is currently Professor & Director of Gynecologic Oncology Research and Associate Medical Director of Clinical Trials at the Levine Cancer Institute, Atrium Health. He did his residency in Obstetrics and Gynecology and fellowship in Gynecologic Oncology at the University of Alabama School of Medicine in Birmingham. He has served as a board member on the Executive Council of the Society of Gynecologic Oncology (SGO) and the Chair of Education Committee and was a co-director of the SGO Winter meeting.

Dr. Nauman has an interest in chemotherapy development including targeted therapies and immune therapies and runs the phase I trials in gynecologic oncology at the Levine Cancer Institute. He has served as a member of the GOG/NRG corpus committee and the Developmental Therapeutics committee.





FolRa-Targeting ADC

STRO-002 GM1 Phase 1 Dose Escalation Data Discussion

Lainie P. Martin, M.D.



Potential Best-in-Class ADC for Ovarian and Endometrial Cancers STRO-002 is an optimized ADC using precisely positioned non-natural amino acids

Novel homogeneous antibody drug conjugate (ADC) using **precisely positioned non-natural amino acids**

Targets **FolRa**, which is overexpressed in certain cancers including ovarian cancer

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**

Structure of hemiasterlin linker-warhead following conjugation as follows:







31 Patients Are Evaluable for Response in Dose-Escalation



- (1) 1 patient withdrew consent secondary to AE, 1 patient withdrew consent and went to hospice, 1 patient had grade 5 AE, which was unrelated per investigator
- (2) As of October 30, 2020

SUTRO

STRO-002 GM1, Phase 1 Study Has a Two-Part Design Phase 1 to establish safety and early signs of efficacy to inform registration-directed trial



(1) Illustration on dose-escalation excludes initial dose levels of 0.5-1.8mg/kg as they were not clinically active

Ovarian Patients In Dose-Escalation Study Were Heavily Pre-Treated Median 6 prior lines of therapy, including SOC, bevacizumab, PARPi, CPI, and clinical trials

	Characteristic	All Patients (N=39)		
	Age, median	61 years (range, 48–79)		
	Tumor type, n			
	EOC	31 (80%)		
	Fallopian tube	6 (15%)		
	Primary peritoneal	2 (5%)		
	ECOG PS, n			
	0	22 (56%)		
	1	17 (44%)		
	Time since diagnosis, median	3.9 years (range, 0.6–17.0)		
	Time since diagnosis, median Number of prior lines of therapy, median	3.9 years (range, 0.6–17.0) 6 (range, 2–11)		
	Time since diagnosis, median Number of prior lines of therapy, median Previous therapies, n	3.9 years (range, 0.6–17.0) 6 (range, 2–11)		
	Time since diagnosis, medianNumber of prior lines of therapy, medianPrevious therapies, nPlatinum	3.9 years (range, 0.6–17.0) 6 (range, 2–11) 39 (100%)		
	Time since diagnosis, medianNumber of prior lines of therapy, medianPrevious therapies, nPlatinum≥ 3 prior platinum regimens	3.9 years (range, 0.6–17.0) 6 (range, 2–11) 39 (100%) 18 (46%)		
	Time since diagnosis, medianNumber of prior lines of therapy, medianPrevious therapies, nPlatinum≥ 3 prior platinum regimensTaxanes	3.9 years (range, 0.6–17.0) 6 (range, 2–11) 39 (100%) 18 (46%) 38 (97%)		
	Time since diagnosis, medianNumber of prior lines of therapy, medianPrevious therapies, nPlatinum≥ 3 prior platinum regimensTaxanesBevacizumab	3.9 years (range, 0.6–17.0) 6 (range, 2–11) 39 (100%) 18 (46%) 38 (97%) 32 (82%)		
	Time since diagnosis, medianNumber of prior lines of therapy, medianPrevious therapies, nPlatinum≥ 3 prior platinum regimensTaxanesBevacizumabPARP inhibitors	3.9 years (range, 0.6–17.0) 6 (range, 2–11) 39 (100%) 18 (46%) 38 (97%) 32 (82%) 23 (59%)		
	Time since diagnosis, medianNumber of prior lines of therapy, medianPrevious therapies, nPlatinum≥ 3 prior platinum regimensTaxanesBevacizumabPARP inhibitorsCheckpoint inhibitors	3.9 years (range, 0.6–17.0) 6 (range, 2–11) 39 (100%) 18 (46%) 38 (97%) 32 (82%) 23 (59%) 8 (21%)		

STRO-002 Dose Levels (Q3W, n)	All Patients (N=39)
0.5 mg/kg, 1.0 mg/kg, and 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 ⁽¹⁾	10 (26%)
6.4 mg/kg ⁽¹⁾	1 (3%)

(1) DLTs occurred in 2 patients:

- Grade 2 neuropathy/grade 3 arthralgia at 6.0 mg/kg Q3W
- Grade 3 bone pain at 6.4 mg/kg Q3W

Data as of October 30, 2020



STRO-002 Was Generally Well Tolerated 86% of TEAEs remain Grade 1-2 and no observed ocular toxicity signal

Common TEAEs > 25% By Grade (1)

All Safety Evaluable Patients	Grade 1 N (%)	Grade 2 N (%)	Grade 3 N (%)	Grade 4 N (%)	Overall (N=39) N (%)
Fatigue	8 (20.5)	17 (43.6)	4 (10.3)	0	29 (74.4)
Nausea	15 (38.5)	10 (25.6)	0	0	25 (64.1)
Constipation	12 (30.8)	12 (30.8)	0	0	24 (61.5)
Neutropenia	0	1 (2.6)	9 (23.1)	13 (33.3)	23 (59.0)
Arthralgia	8 (20.5)	7 (17.9)	6 (15.4)	0	21 (53.8)
Decreased appetite	10 (25.6)	10 (25.6)	0	0	20 (51.3)
Neuropathy	3 (7.7)	12 (30.8)	3 (7.7)	0	18 (46.2)
Abdominal pain	7 (17.9)	5 (12.8)	3 (7.7)	0	15 (38.5)
AST increased	10 (25.6)	2 (5.1)	1 (2.6)	0	13 (33.3)
Dizziness	10 (25.6)	3 (7.7)	0	0	13 (33.3)
Vomiting	8 (20.5)	5 (12.8)	0	0	13 (33.3)
Diarrhea	8 (20.5)	3 (7.7)	1 (2.6)	0	12 (30.8)
Headache	7 (17.9)	3 (7.7)	0	0	10 (25.6)
Insomnia	6 (15.4)	4 (10.3)	0	0	10 (25.6)
Pyrexia	8 (20.5)	2 (5.1)	0	0	10 (25.6)

(1) Not included in table are two Grade 5 events, both previously reported and unrelated to study drug by investigator assessment: death not otherwise specified and acute GI bleed

Note: Data as of October 30, 2020

Tumor Reduction Observed in Majority of Patients 10 patients met criteria for response



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(1) Maximum % change from baseline in sum of longest diameter in evaluable patients treated with STRO-002 at ≥ 2.9 mg/kg Q3W, N=31

(2) CR in patient treated at 2.9 mg/kg with resolution of peritoneal disease

Note: Data as of October 30, 2020



Tumor Regression and Control Over Time Deepening of responses over time and others with disease control remaining on study



(1) CR in patient treated at 2.9 mg/kg with resolution of peritoneal disease Note: Data as of October 30, 2020

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Patient With Ongoing PR Remains on Study The patient achieved 74% tumor reduction after 4 cycles and remains on study⁽¹⁾



Confirmed PR after 4 cycles



57-year-old woman with platinum resistant ovarian cancer progressing after 4 prior regimens received STRO-002 at 5.2 mg/kg Q3W and remains on study treatment

(1) Patient remains on study as of October 30, 2020

Clinical Benefit Seen in Heavily Pre-Treated Patient Population Disease control rate of 74% at 12 weeks in RECIST-evaluable population



(1) Duration calculated as date of PD or time from first dose to last dose given (including 4 patients deriving clinical benefit post progression per investigator assessment) Note: Data as of October 30, 2020



Responses Observed Across Heavily Pre-Treated Patients PRs occurred with fixed dose regimen AND post dose adjustments



(1) Duration calculated as date of PD or time from first dose to last dose given Note: Data as of October 30, 2020

FolRa Expression by Immunohistochemistry ⁽¹⁾

In emerging data, responses and anti-tumor activity observed across various FolRa expression levels



FOLR1 PS2+ Score:	Weak/Absent Expression	Moderate Expression	High Expression
PR	1	1	0
PRu	0	0	1
SD	3	1	4
PD	2	0	0

(1) Assessed by Ventana FOLR1 expression assay based on available archival tissue from dose-escalation patients Note: Data as of October 30, 2020



Key Findings in Dose-Escalation Study STRO-002 is a potentially important option for patients with limited treatment alternatives

STRO-002 provided clinical benefit in an all- comers, late line patient population	86% of the AEs were Grade 1-2 and corticosteroid eyedrops were not required	Wide therapeutic index allows for for long-term dosing	Improved outcomes in responses and DCR as data matures	Heterogeneity of tumor regression and response
Patients experienced a median of 6 prior lines of therapy, including SOC, bevacizumab, PARPi, CPI, and clinical trials	Neutropenia generally reversed within a week, without G-CSF. Peripheral neuropathy/arthralgia managed with dose reduction/delay without evidence of compromised efficacy	Encouraging product profile with STRO-002 generally well tolerated and MTD was not reached. Antitumor activity and responses were observed in multiple dose levels	74% of the patients had disease control ≥12 weeks, which is clinically relevant in this population	Some patients had delayed responses, observed after initial and variable period of stable disease. 10 of 31 patients remain on study ⁽¹⁾



STRO-002 GM-1 Next Steps Expansion Cohort and Development Plan

Arturo Molina, M.D., Sutro Biopharma Chief Medical Officer



Ovarian Cancer Dose-Expansion Trial Design Rationale Generate data in less heavily pre-treated population to inform registration study design

Randomization between 4.3 mg/kg and 5.2 mg/kg Q3W

Fresh or archival tumor **tissue required** prior to enrollment to capture FolRα-expression

Redefining patient inclusion/exclusion criteria for **platinum status and prior approved therapies**

Exclusion of patients with ≥ grade 2 peripheral neuropathy Determine optimal efficacious dose that is well-tolerated and maintains dose intensity

Study will begin with **All Comers** and ongoing expression analysis will **inform subsequent enrichment strategy**

Characterize efficacy and safety profile in less heavily pre-treated population to inform registration-directed study



Preliminary Dose-Expansion Ovarian Cancer Data in 2021 Inform regulatory discussions and accelerate registration strategy





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Selected Ventana's Validated FolRa Assay to Further Support STRO-002 Clinical Development Towards Registration









The FOLR1 Assay exhibits:

- A dynamic range of staining
- Crisp membrane staining
- Low cytoplasmic staining
- Low background staining



Path Forward for STRO-002 Clinical Development Next steps for moving towards registration-directed study

STRO-002 has been clinically efficacious at multiple doses, starting at 2.9 mg/kg Q3W	Further dose optimization will be explored during dose- expansion	Anti-tumor activity was observed across a range of FolRa expression in dose-escalation	Expansion cohort in ovarian will enroll less heavily pre-treated patients	EOP1/2 FDA meeting anticipated for 2H 2021
Dose reductions or delays were not associated with loss of anti-tumor activity	Exploring randomized doses of 4.3 & 5.2 mg/kg will inform dose for registration- directed studies	Larger sample size will be needed to determine enrichment strategy	Monotherapy unenriched ovarian cancer cohort is planned to be initiated in 4Q 2020. Endometrial cohort (FoIRα-selected) to follow	Preliminary dose- expansion data expected 2H2021. Potential for accelerated approval pathway with single arm registration- directed study







Q&A Panel

Principal Investigators



Lainie P. Martin, M.D. Medicine at Hospital of the University of Pennsylvania



R. Wendel Naumann, M.D. Levine Cancer Institute, Atrium Health

Sutro Biopharma Team



Bill Newell, Chief Executive Officer



Arturo Molina, M.D. Chief Medical Officer



Trevor Hallam, Ph.D. Chief Scientific Officer



Ed Albini Chief Financial Officer



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





