Independent Data Monitoring Committee Charter

Study: STRO-002-GM3:

A Phase 2 Open-label Study Evaluating the Efficacy and Safety of Luveltamab Tazevibulin (STRO-002) in Women with Relapsed Platinum-resistant Epithelial Ovarian Cancer (including Fallopian Tube or Primary Peritoneal Cancers) Expressing Folate Receptor alpha (FOLR1)

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CONFIDENTIAL

Sutro Biopharma Approvals

Signatory Name and Title	Signature and Date
William Bleker **Vice President, Safety**	Signature: DocuSigned by: William Bleker 2D8CE9EA67B44A2... **Date:** 11/21/2023
Craig Berman **Vice President, Clinical Development**	Signature: DocuSigned by: Craig Berman 5F6E2B695E6E41A... **Date:** 11/24/2023
Lin Lu **Executive Director, Biostatistics**	Signature: DocuSigned by: Lin Lu 5FBFC1B5752F494... **Date:** 11/24/2023
Anne Borgman **Chief Medical Officer**	Signature: DocuSigned by: Anne Borgman DBDC53AAAA5A49D... **Date:** 11/24/2023

DATA MONITORING COMMITTEE MEMBERSHIP APPROVALS

Signatory Name and Title	Signature and Date
Physician #1 (Chairperson) Michael J. Birrer, MD, PhD	Signature: DocuSigned by: Michael Birrer BA25C3CA9D4A409... **Date:** 11/25/2023
Physician #2 Stefan Glück, MD, PhD, FRCPC	Signature: DocuSigned by: 90FB6CE2BED8421... **Date:** 11/25/2023
Physician #3 Prof Jonathan A Ledermann MD FRCP FMedSci	Signature: DocuSigned by: Prof Jonathan A Ledermann MD FRCP C5BE7428BBDB4F4... **Date:** 11/27/2023
Physician Statistician Scott Emerson, MD, PhD	Signature: DocuSigned by: Scott Emerson, MD, PhD 90F726023FB9431... **Date:** 11/27/2023

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1.0 INTRODUCTION

This charter is for the Independent Data Monitoring Committee (IDMC) for Sutro Biopharma Protocol STRO-002-GM3 entitled - A Phase 2 Open-label Study Evaluating the Efficacy and Safety of Luveltamab Tazevibulin (STRO-002) in Women with Relapsed Platinum-resistant Epithelial Ovarian Cancer (including Fallopian Tube or Primary Peritoneal Cancers) Expressing Folate Receptor alpha (FOLR1).

This charter will define the primary responsibilities of the IDMC, its relationship with other trial components, its membership, and the purpose and timing of its meetings. The charter will also provide the procedures for ensuring confidentiality and proper communication, an outline of the statistical monitoring guidelines to be implemented by the IDMC, an outline of the content of the Open and Closed sessions, and relevant materials that will be generated for the IDMC.

2.0 PRIMARY OBJECTIVES OF THE IDMC

The IDMC is an independent committee responsible acting in an advisory capacity to Sutro Biopharma to monitor the safety of participants enrolled in Study STRO-002-GM3 by reviewing and assessing safety data and the emerging risk/benefit balance at regular intervals and on an ad-hoc basis.

The overall objectives of the IDMC include:

- Protect patient welfare.
- Review safety data to investigate any potential safety risks to the patients participating in the study that would suggest a change in study conduct or the informed consent form.
- Provide recommendations for any change to study conduct required from an emerging safety concern.
- Provide recommendations about stopping or continuing the trial based upon an emerging safety concern.
- May be asked to review safety and efficacy data from for dose optimization and selection of dose for Part 2 and make suggestions for the final dose selection for Part 2, which the Sponsor will take into consideration.
- From time-to-time, the Sponsor may request additional data review activities to support the conduct of the trial.

3.0 IDMC MEMBERSHIP

IDMC membership will be comprised of 3 independent physicians and 1 independent physician statistician as selected by the Sponsor. One of the IDMC members will be selected by the Sponsor to serve as the IDMC chairperson. The physicians with exception of the statistician will have the necessary clinical and data review committee experience in either hematology/oncology or gynecologic oncology to participate in the IDMC. Additional members may be added as per the recommendation of the IDMC chairperson. Ad hoc participation by additional subject matter experts will be per recommendation of the IDMC chairperson or Sponsor with approval by the Sponsor. The replacement of any IDMC members will be at the discretion of the Sponsor. IDMC meetings will be coordinated by an independent IDMC coordinator. An independent unblinded statistician who is separate from the STRO-002-GM3 study statistician and IDMC statistician will provide data outputs to the IDMC coordinator to distribute to the IDMC. The Sponsor will select the IDMC coordinator who will not be engaged otherwise in the study conduct of STRO-002-GM3. IDMC members are to act independently and are not intended to be involved in the study conduct of STRO-002-GM3.

4.0 PRIMARY RESPONSIBILITIES

4.1 IDMC Members

- Enter into a consulting agreement that includes confidentiality obligations and conflict of interest provisions. To continue membership, IDMC members must not have a conflict of interest.
- Review and approve the IDMC charter.
- Review safety data provided for IDMC meetings.
- Participate in IDMC open and closed session meetings.
- Provide recommendations for any change to study conduct or additional safety analyses that are warranted from review of the safety data provided in the IDMC meetings.
- Delete IDMC meeting materials after the completion of the IDMC meetings and IDMC recommendations for the meeting are finalized by the IDMC chairperson.

4.2 IDMC Chairperson

Throughout the trial, the IDMC Chairperson will serve in a leadership role and will be authorized and charged with the following additional responsibilities:

- Is notified by the IDMC Coordinator that IDMC materials are available in the secured portal (e.g., SharePoint) and s/he informs the remaining IDMC members.
- Conduct all IDMC meetings; ensure that all relevant data have been reviewed by the IDMC members; and that any issues have been addressed.
- Notify the IDMC coordinator and Sponsor of any additional safety analyses or the request for input from additional non-IDMC subject matter experts as per IDMC recommendations.
- Ensure that the members of the IDMC are present when IDMC deliberations are made in closed session, IDMC recommendations are discussed and IDMC voting procedures are conducted.
- Provide IDMC approval of the minutes for the Open and Closed Sessions and maintain confidentiality until database lock is complete.
- Communicate, author, sign, and provide the final recommendations of the IDMC to the Sponsor (Chief Medical Officer, VP of Clinical Development, VP of Medical Safety and Pharmacovigilance). The IDMC Chairperson is responsible for the finalization of the minutes from the Closed Sessions. If the IDMC is divided in opinion on any major issue affecting the IDMC's recommendation, the IDMC Chairperson is responsible for assembling and presenting the majority and dissenting opinions for all recommendations to the Chief Medical Officer.
- The IDMC reserves the right to meet with one another, as well as convene a meeting with the management at Sutro, in case of a need for communication.

4.3 IDMC Coordinator

A CRO will provide a IDMC coordinator. The IDMC coordinator will attend the Open and Closed Sessions. The IDMC Coordinator will provide administrative, logistical, and coordinating support for the IDMC meetings.

The IDMC Coordinator will be charged with the following responsibilities:

- Coordinate the preparation and distribution of Data Reports for Open and Closed Sessions to IDMC and Data Reports for Open Session only to meeting attendees from the Sponsor.

- Verify that all data required by the IDMC is provided approximately seven (7) days prior to each IDMC meeting.
- Schedule and coordinate arrangements, in conjunction with the Sponsor as needed, for all scheduled IDMC meetings and any IDMC ad hoc meetings.
- Work with the IT Department at the CRO to arrange for a secure portal (e.g., SharePoint) with controlled and restricted access for IDMC Closed Session and Open Session materials. Access and site will be controlled and maintained by and governed by the CRO's SOPS.
- Ensure materials are placed in the correct portal location and access is granted to the appropriate individuals as dictated by this Charter and relevant SOPs. Closed Session site access will be restricted at all times to the four IDMC members and the unblinded biostatistician from the Independent Statistical Team.
- Revoke access immediately upon notification of changes in IDMC membership status.
- Alert the IDMC, Sponsor and the IT Department in the unlikely event that a violation to the site occurs (e.g., failure of IDMC member or meeting attendee to provide status change notification).
- Attend the Open and Closed Sessions of all IDMC meetings; generate draft minutes for Open and Closed Sessions of all IDMC meetings; distribute minutes for IDMC revision and approval.
- Coordinate additional data requests from the IDMC to the Sponsor.
- Provide Sponsor with a copy of a summary of the meeting in PDF format via e-mail, which includes minutes from the Open Session and/or additional requests.
- Work with the IT Department at the CRO to arrange for a secure file (e.g., SharePoint) with controlled and restricted access, which will be maintained for Open and Closed Sessions of IDMC meetings, all related key IDMC correspondence and minutes. Access and site will be controlled and maintained by and governed by the CRO's SOPS. Provide this file to Clinical Development after database lock is completed.
- Convene/request executive sessions with the Sponsor, if requested by the IDMC.

4.4 Sponsor

The Sponsor, Sutro Biopharma, will have the following responsibilities:

- Select IDMC Chairperson and members.
- Prepare and ratify the IDMC Charter.
- Ensure relevant clinical or other data is provided to the IDMC including updates to Investigators Brochure, Study Protocol, and Informed Consent Forms.
- Attend Open Sessions of IDMC meetings (to include representatives from Clinical Development, Clinical Operations, Medical Safety & Pharmacovigilance, and Biostatistics)
- Provide the study update and convey safety summaries during the Open Sessions of the IDMC Meetings.
- Notify the IDMC chairperson of any expedited SAEs with fatal and/or life-threatening outcomes within 5 days of Sponsor's first knowledge of the event and all other expedited SAE reports within 15 days of Sponsor's first knowledge of the event.
- Notify the IDMC chairperson of any change to study conduct including but not limited to protocol amendments, sponsor decision for study hold or termination.
- Notify the IDMC chairperson in a timely manner of any regulatory authority notifications of requirements to a change in study conduct or need for relevant further safety analyses.
- Advise appropriate individuals of IDMC recommendations, and notify regulatory authorities, other agencies, Institutional Review Boards/Independent Ethics Committees and investigators when required or necessary.

4.5 Independent Statistical Team

In order to protect study data integrity, an independent statistical team, not involved in study design, decisions on trial conduct, trial modifications, or decisions on modifications to the Statistical Analysis Plan (SAP), will provide the IDMC Data Reports. The Project Biostatisticians will not receive the treatment assignment list for patients in the database until final database lock in order to protect the integrity of data and the robustness of results, and to minimize bias arising during the conduct and analysis of STRO-002-GM3.

The responsibilities of the unblinded biostatistician from the Independent Statistical Team are as follows:

- Work closely with the Project Biostatisticians to develop and finalize the IDMC analysis plan and tables.

- Provide IDMC Data Reports as outlined in the list of Tables and Listings included in the **Appendix** for the Open and Closed Sessions to the IDMC Coordinator for distribution to IDMC members.
- Provide ad-hoc analyses as requested by the IDMC members to IDMC Coordinator for distribution to IDMC members.
- Provide consultation regarding the information presented in the IDMC Data Reports.
- Attend the Closed Session of the IDMC Meetings as a nonvoting member.
- Maintain an archive of electronic copies of data outputs and SAS programs used to generate the IDMC Data Reports.

5.0 IDMC MEMBERS

IDMC Member (Role)	Contact Information
Physician #1 (Chairperson)	Michael J. Birrer, MD, PhD Vice Chancellor UAMS Director, Winthrop P. Rockefeller Cancer Institute Director, Cancer Service Line Professor of Biochemistry & Molecular Biology Director's Endowed Chair for the Winthrop P. Rockefeller Cancer Institute 4301 W. Markham St Little Rock, AR 72205-7199 Mjbirrer@uams.edu 501-526-2272
Physician #2	Stefan Glück, MD, PhD, FRCPC Professor Emeritus of Medicine Oncology Hematology Immunology Biotech 6061 La Gorce Drive Miami Beach FL 33140 stefanglu@gmail.com 1-786-942-8335
Physician #3	Prof Jonathan A Ledermann MD FRCP FMedSci Professor of Medical Oncology Clinical Director UCL Cancer Institute Paul O'Gorman Building, 72 Huntley Street, London WC1E 6DD j.ledermann@ucl.ac.uk PA Dita Richards Tel: +44 (0)20 3108 4261
Physician Statistician	Scott Emerson, MD, PhD Professor Emeritus, Biostatistics University of Washington 7055 54th Avenue NE Seattle WA 98115 scott@emersonstatistics.com C: 206-459-5213

6.0 CONFLICTS OF INTEREST

The IDMC membership has been restricted to individuals free of apparent significant conflicts of interest. The source of these conflicts may be financial, scientific, or regulatory in nature. The IDMC members should not own stock in Sutro Biopharma. The IDMC members will disclose to

the Sponsor and fellow members any consulting agreements or financial interests they have with Sutro Biopharma, with the contract research organization (CRO) for the trial, or with other sponsors having products that are competitive with those being evaluated in this trial. The Sponsor will be responsible for deciding whether these consulting agreements or financial interests materially impact the members' objectivity.

The IDMC members will be responsible for advising fellow members of any changes in these consulting agreements and financial interests that occur during the course of the trial. Any IDMC member who develops significant conflicts of interest during the course of the trial should resign from the IDMC and be replaced at the discretion of the Sponsor.

IDMC membership is to continue for the duration of the clinical trial. If any members leave the IDMC during the course of the trial, the sponsor will promptly appoint their replacements, as necessary.

7.0 TIMING AND PURPOSE OF THE IDMC MEETINGS

7.1 Organizational Meeting

The initial meeting of the IDMC will be a general Organizational Meeting, which will discuss the role and functioning of the IDMC, the format and content of the Open Data Outputs and Closed Data Outputs used to present trial results at future IDMC meetings as outlined in the IDMC charter.

7.2 Scheduled and AD-Hoc Meetings

IDMC meetings will be initiated after 20 subjects have been randomized and dosed with 1 cycle of therapy. Thereafter, IDMC meetings will typically occur on a quarterly basis. The frequency of the regularly scheduled meetings may be increased per the recommendation of the IDMC chairperson and Sponsor approval. The timing of meetings will be scheduled to review Sponsor recommendations of optimized dose selection from Part 1 of the study and to review safety data at the time and to support formal interim and final efficacy analyses. Ad hoc meetings may be scheduled as required per recommendation of the IDMC chairperson and Sponsor request.

7.3 Safety Reviews

The IDMC will perform a safety review at each IDMC meeting. Safety information, including treatment emergent adverse events (TEAEs), serous TEAEs, deaths, etc. (see Tables and Listings outlined in **Appendix**). IDMC safety reviews will include expedited serious adverse events (SAEs) with fatal and/or life-threatening outcomes within 7 days of Sponsor's first knowledge of the event and all other expedited SAEs within 15 days of Sponsor's first knowledge of the event.

Non-expedited SAEs will be summarized from the clinical database and reviewed according to the IDMC review schedules as indicated in this charter.

If the IDMC recommends putting the study on hold for safety issues, an additional safety review by the IDMC will be scheduled prior to re-initiating the study. Guidelines for the IDMC additional safety review will be issued prior to re-initiating the study.

8.0 PROCEDURES TO ENSURE CONFIDENTIALITY AND PROPER COMMUNICATION

To enhance the integrity and credibility of the trial, procedures will be implemented to ensure the IDMC has sole access to evolving information from the clinical trial regarding comparative results of safety data, aggregated by treatment arm. An exception will be made to permit access to the unblinded statistician from the Independent Statistical Team who will be responsible for serving as a liaison between the database and the IDMC. The study's Medical Monitor and Pharmacovigilance will be provided access on an ongoing basis to patient-specific information on SAEs to satisfy the standard requirement for prompt reporting to the regulatory authorities.

At the same time, procedures will be implemented to ensure proper communication is achieved between the IDMC and the Sponsor. To provide a forum for exchange of information among various parties who share responsibility for the successful conduct of the trial, a format for Open Sessions and Closed Sessions will be implemented. The intent of this format is to enable the IDMC to preserve the confidentiality of the safety data while at the same time providing opportunities for interaction between the IDMC and others who have valuable insights into trial-related issues.

Until the study is officially terminated, and database is closed, communication of information will be restricted. Information regarding results of safety outputs and IDMC deliberations will not be discussed outside the membership of the IDMC (with the caveat that the unblinded Independent Biostatistician will also participate in the Closed Sessions of the IDMC).

9.0 ORGANIZATION OF THE IDMC MEETINGS

9.1 Open Sessions

In order to allow the IDMC to have adequate access to information provided by the Sponsor or by regulatory authorities, a joint session (called an Open Session) between the Sponsor, the IDMC Coordinator, and all IDMC members will be held. On rare occasions, e.g., an unscheduled urgent meeting, a majority of IDMC members will be acceptable. This session gives the IDMC an opportunity to query issues that have arisen during their review. The Sponsor Medical Monitor will provide an overview of the study status. With this format, important

interactions are facilitated through which problems affecting trial integrity can be identified and resolved. These individuals will either be present at the IDMC meeting or attend by a telephone link.

9.2 Closed Sessions

Closed Sessions involving only IDMC members, IDMC Coordinator, and the unblinded biostatistician from the Independent Statistical Team will be held to allow discussion of confidential data from the clinical trial. In order to ensure that the IDMC will be fully informed in its primary mission of safeguarding the interest of participating patients, the IDMC will be able to access the treatment assignment of individual patients in its assessment of safety data.

At each IDMC Closed Session meeting, the IDMC will develop a consensus list of recommendations, including a recommendation concerning continuation of the trial. At the conclusion of the Closed Session, the IDMC will agree on a brief summary report of recommendations. Recommendations will be approved by a majority vote of the IDMC voting members.

Following each Closed Session, a joint session between the Sponsor, the IDMC Coordinator, and IDMC members will be held to review the IDMC recommendations.

9.3 Summary of the IDMC Meeting

Two sets of meeting minutes will be prepared: Open Minutes and Closed Minutes drafted by the IDMC Coordinator. Meeting minutes will be drafted within 7 days of each meeting. The minutes will communicate IDMC recommendations. Minutes will be reviewed, approved, and signed by the full IDMC within 7 days. Approval may be provided by email to the IDMC coordinator.

The Open Minutes will describe the proceedings in the Open Session of the IDMC meeting and will summarize all recommendations by the IDMC. Since these minutes will be circulated to the Sponsor and may be distributed to IRB/IECs and Competent Authorities, it is necessary that these minutes do not summarize comparative results for the safety data.

The Closed Minutes will describe the proceedings from the Closed Sessions of the IDMC meeting, including the listing of recommendations by the IDMC. The Closed Minutes will capture discussion items in an anonymous fashion.

The IDMC coordinator will archive all formal correspondence, minutes, and materials, including Data Reports for both Open and Closed Sessions per responsibility defined in Section **4.3**. These will be maintained in a password protected system or in a locked cabinet (for paper files). In addition, the unblinded biostatistician from the Independent Statistical Team will maintain an

archive of all data outputs used to conduct the analyses in electronic files and data report for Closed Sessions with access rights controlled on an individual file per responsibility defined in Section **4.5** above. At the conclusion of the study, a complete set of the minutes and archived data outputs will be sent to the Sponsor's Regulatory Department and will be archived in the Sponsor's study file. The Sponsor will provide a complete collection of IDMC summaries to regulatory authorities as part of the Clinical Study Report.

9.4 IDMC Recommendations

At each meeting of the IDMC during the conduct of the trial, the IDMC will make a recommendation as to the conduct of the study, e.g., updating the Investigator Brochure, Protocol, and or Informed Consent Form. The IDMC may make the following recommendations:

- Continue the study without any changes to the study conduct.
- Changes to the study conduct which may include but not limited to study eligibility, safety monitoring, management of adverse events, study drug dosing, study enrollment including study hold or termination.
- Requirement for additional safety data and analyses
- Requirement for review of safety data by non-Sponsor subject matter experts
- Change to the frequency of regularly scheduled meetings and the need for ad-hoc meetings.

10.0 IDMC DATA

For each IDMC meeting, the unblinded biostatistician from the Independent Statistical Team will prepare the Open Data Outputs and Closed Data Outputs including ad hoc data requests and provide these to the IDMC Coordinator for distribution to the IDMC.

Open Data Outputs, available to all who attend the IDMC meeting, will be presented in pooled data.

Closed Data Outputs, available only to those attending Closed Sessions of the IDMC meeting, will include dosing data and analyses by treatment arm and dose, as applicable.

The IDMC members will receive Data Reports approximately seven (7) days prior to the meeting. The reports should provide information that is accurate, with the last visit date occurring 8 weeks prior to the date of the IDMC meeting.

The following items will be provided to the IDMC as part of the IDMC Data Reports. Additional data may be provided as requested by the IDMC Chairperson.

- Study status including study accrual by month, country, and by institution.
- Notification of any changes of conduct to the study,
- Notification of any relevant regulatory authority communications for the study affecting study conduct
- MedWatch reports for all expedited SAEs.
- Study protocol, informed consent(s) templates, and STRO-002 investigator brochure.
- IDMC Tables and Listings for the IDMC safety reviews found in the **Appendix**.

11.0 REFERENCES

Not applicable

12.0 APPENDIX

Table 1: IDMC Tables and Listings

IDMC No.	Title	Analysis Population
Table 1.1	Subject Disposition (including treatment cessation reason and cause of death)	ITT
Table 1.2	Demographics and Baseline Disease Characteristics including key laboratory values	ITT
Table 1.3	Cancer History	ITT
Table 1.4	Prior Cancer Therapy	ITT
Table 2.0	Exposure	Safety
Table 3.1	All Grade Treatment Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety
Table 3.2	Grade 3 and higher Treatment Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and CTCAE Grade	Safety
Table 3.3	Treatment Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term	Safety
Table 3.4	Deaths with 30 Days of the Last Dose	Safety
Table 3.5	Treatment Emergent Adverse Events leading to Study Drug Delay by System Organ Class and Preferred Term	Safety
Table 3.6	Treatment Emergent Adverse Events leading to Study Drug Reduction by System Organ Class and Preferred Term	Safety
Table 3.7	Treatment Emergent Adverse Events leading to Drug Discontinuation by System Organ Class and Preferred Term	Safety
Table 3.8	Maximal Post-baseline Shift Table by NCI-CTCAE Grade on Key Clinical Lab Tests	Safety

Table 1: IDMC Tables and Listings (Cont'd)

IDMC No.	Title	Analysis Population
Listing 1	Patient Disposition	All patients enrolled
Listing 2	Demographics, Baseline Characteristic, and Cancer History	All patients enrolled
Listing 3	Prior Cancer therapy	All patients enrolled
Listing 4	Study Drug Administration (Contains treatment assignment and produce for Closed Session Only)	All patients enrolled
Listing 6.1	Adverse Events	All patients enrolled
Listing 6.2	Serious Adverse Events[1]	All patients enrolled
Listing 6.3	Adverse Events Leading to Study Drug Discontinuation	All patients enrolled
Listing 6.4	Adverse Events Leading to Death	All patients enrolled
Listing 7.1	Clinically Significant Laboratory Data - Serum Chemistry (NCI CTCAE Grade 3 or Higher)	All patients enrolled
Listing 7.2	Clinically Significant Laboratory Data Hematology and INR (NCI CTCAE Grade 3 or Higher)	All patients enrolled
Listing 8	Deaths	All patients enrolled
Listing 9	Potential DILI per Hy's Law Criteria	All patients enrolled
Listing 10	Post-baseline Values for QTcF Prolongation	All patients enrolled

Note: Listings will be based on all patients randomized in the study. Treatment assignment will not be included in the data listing except for Study Drug Administration which will be included for Closed Sessions only.

[1]A CIOMS II Line Listing of SAEs will also be pulled from the Safety Database.