Criteria for Consideration of Compassionate Use Access to Investigational Medicines in Clinical Trials

Sutro Biopharma will consider providing individual patients compassionate use access to an investigational medicine outside of a clinical trial only when all of the criteria below are met.

General Criteria

Investigational Medicine Must be in Active Clinical Development

The investigational medicine must be part of an active clinical development program (Sutro must be currently studying the medicine in patients).

Granting Access Must Not Interfere with Clinical Trials and Potential Approval

Granting access to an investigational medicine must not interfere with the completion of clinical trials that could support FDA approval of the medicine or otherwise compromise the potential development of the investigational medicine.

Additionally, patients must not be eligible (i.e. do not qualify) for ongoing (or soon opening) clinical trials of the investigational medicine.

A Potential Risk-Benefit Assessment for Patients

The potential benefit to the patient seeking access to the investigational medicine must always be considered to outweigh the collective potential risks to the patient of offering the medicine, including the outcome of the disease itself.

Additionally, patients with underlying medical conditions that may pose safety risks that have not been sufficiently characterized or studied would not be eligible to participate.

Dosing

As applicable, there is sufficient clinical data to identify an appropriate dose (amount and frequency of the medicine given).

Compassionate Use Access

For the patient

The patient has:

- A serious, life-threatening illness.
- Exhausted all available therapies typically used to treat the disease and is no longer responsive to, or able to tolerate, these treatments.
- No other viable therapy options, including participation in ongoing relevant clinical trials.
- The request to Sutro for access to the investigational medicine comes from the patient's qualified physician.

For the investigational medicine

- Sutro must have adequate supply of the investigational medicine, taking into account current and projected demand for the investigational medicine in Sutro's clinical studies.
- In the United States, the FDA and the Institutional Review Board (IRB) (ethics committee that approves and monitors clinical trials involving humans) at the patient's treating hospital or clinic must review and approve the use of the medicine, in the patient, before Sutro can provide it.
- For additional information, please reach out to: access@sutrobio.com.

For the physician

- The treating physician should request access from Sutro by e-mailing access@sutrobio.com; Sutro will evaluate the request according to the criteria set forth above. We respond to all requests as soon as possible, and in most cases we will seek to respond within five business days from receipt.