SUTRO BIOPHARMA

CRITERIA FOR CONSIDERATION OF COMPASSIONATE USE ACCESS TO INVESTIGATIONAL MEDICINES IN CLINICAL TRIALS

In cases where a clinical trial isn't an option, and the patient has exhausted all available treatment options, the Institutional Review Board/Ethics Committee and/or regulators/health authorities are also involved in the process to provide a treating physician with an investigational drug pre-approval. Such individual use of an investigational drug pre-approval is often called "expanded access" or "compassionate use," but may go by other names.
At Sutro Biopharma, investigational drugs may be provided under the following conditions: patients who are diagnosed with a serious or life-threatening disease, who have exhausted approved treatment options, and who are not eligible for 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, or some other global Health Authority, approval of the medicine or otherwise compromise the potential development of the investigational medicine. Following approval by a regulatory authority of a medicine for commercial use, existing compassionate use access programs will be concluded in an orderly manner.
Additionally, patients must not be eligible (i.e., do not qualify) for ongoing (or soon opening) clinical trials of the investigational medicine, and applicable laws and regulations in the country of treatment must permit the patient's use of the investigational or unapproved product.

A Potential Risk-Benefit Assessment for Patients

It's important to remember that investigational drugs have not yet received regulatory approval; therefore, their potential risks and benefits are not yet established. Doctors and patients should consider all possible benefits and risks when seeking compassionate use to an investigational drug.
The treating physician, following consultation with the Sutro clinical team, will need to determine whether the potential benefit to the patient seeking access to the investigational medicine always outweighs the collective potential risks to the patient, 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 some clinical data to identify a 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. In the European Union, expanded access programs are implemented by each member state with its own rules and procedures.
- For additional information, please reach out to: access@sutrobio.com.

For the Physician

- The treating physician attending to the patient receiving an investigational drug under a Compassionate Use Access program must be properly licensed and fully qualified to administer the investigational product.
- The treating physician must agree in writing to comply with:
    - Any applicable jurisdiction-specific legal and regulatory requirements related to providing an investigational drug under Compassionate Use Access; and
    - Any requirements made by Sutro relating to safety reporting, drug supply and use, and protection of intellectual property.

- The treating physician should request access from Sutro by emailing 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.