

Mereo BioPharma's Policy on Compassionate Use/Expanded Access

The ideal pathway for a patient to access to an investigational drug is through a clinical trial (www.clinicaltrials.gov) sponsored by industry, academic institutions, and or government agencies. Through conduct of a rigorous and well controlled clinical trial, an investigational drug is assessed by the study sponsor and regulatory health agencies (FDA, EMA, HC, etc.) to ensure the development of safe and effective treatment for patients.

However, Mereo BioPharma (Mereo) understands that entry into a clinical trial may not be possible for all patients due to a variety of reasons and as such, expanded access may an option for patients with a life-threatening condition and serious disease condition.

In accordance with guidance set by regulators, requests for expanded access to an investigational drug are reviewed and determined on a case by case basis in a fair manner by Mereo using the following criteria:

- Confirmation that the patient has a serious or life-threatening condition, has exhausted all available treatment options, and does not qualify for a clinical trial.
- A risk/benefit analysis based on available clinical data and other information to ensure the benefit to the patient outweigh the risks.
- Confirmation that Mereo has an adequate supply of the investigational drug.
- Making the investigational drug available will not negatively impact or delay the conduct of clinical trials or regulatory review or approval of the investigational drug for broader patient access.

Patients with interest in gaining expanded access to a Mereo investigational drug should discuss it with their treating physician. All requests must be submitted by the patient's treating physician; Mereo may require more detailed information in order to fully evaluate a request. The requesting physician must also agree to obtaining appropriate regulatory and institutional review board approvals and comply with regulatory obligations, including obtaining patient consent, patient monitoring and safety reporting. Each request will be given careful consideration by Mereo whose decisions are final.

Physicians seeking expanded access for their patients who have no other treatment options should submit their request to Expanded-Access@Mereobiopharma.com. Mereo will review all requests and will its best effort respond within 30 days.