

Mereo BioPharma's Policy on Early Access/ Compassionate Use

The ideal pathway for a patient to access an investigational drug is through a formal clinical trial (www.clinicaltrials.gov) sponsored by industry, academic institutions, government agencies, foundations, patient-led organisations, etc., and governed by stringent regulations and ethics controls. Through conduct of rigorous and well-controlled clinical trials, an investigational drug is assessed by the study sponsor and regulatory agencies (FDA, EMA etc.) to ensure the development of a safe and effective treatment for patients.

However, Mereo BioPharma (Mereo) understands that entry into a clinical trial may not be possible for all patients for many different reasons and as such, expanded access may be 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, or the appropriate commercial partner, 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 outweighs the risks;
- Confirmation that Mereo has an adequate supply of the investigational drug; and
- That making the investigational drug available will not negatively impact or delay the conduct of clinical trials and/ or regulatory review and approval of the investigational drug for broader patient access.

Potential for early access is also governed by country-specific laws and regulations and these may affect availability of the investigational therapy in that country or region. For example, whether regulatory authorities where you/your child live allow early access to investigational therapies through a locally appropriate regulation.

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 to complying with regulatory obligations, including obtaining patient consent, and conducting patient monitoring and safety reporting. Each request from a treating physician 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 exercise its best efforts to respond within 30 days.