Treovir Criteria for Consideration of Access to Investigational Agents via Compassionate Use/Expanded Access Programs:

Compassionate Use/Expanded Access:

Treovir, LLC ("Treovir") will consider providing individual patients access to an investigational medicine outside of a clinical trial (often called "compassionate use" or "expanded access") only when all of the following criteria are met:

General Criteria:

Medicine Must be in Active Clinical Development:

The investigational medicine must be part of an active clinical development program where Treovir is actively studying the medicine in patients. Once the FDA approves a medicine, neither existing expanded access programs nor compassionate use will be available.

Granting Access Must Not Interfere with Clinical Trials and Potential Approval:

Granting access to an investigational medicine must not interfere with the completion of important clinical trials, including utilization of necessary investigational agent necessary for these 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 to be recruiting) clinical trials of the investigational medicine. Geographic limitations to participation in a clinical trial would not meet this criterion.

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 in receiving the medication, including the outcome of the disease itself.
- Patients or their health care providers must also independently provide, be able to obtain and fund or provide proof of being able to do so, any required diagnostic and pathological testing that are deemed required in order to ensure the safety and appropriateness of the risk-benefit potential prior to considering the request. Treovir does not offer financial assistance for any of this required testing.
- Patients with underlying medical conditions that may pose safety risks, per the chief scientific officer's opinion, that have not been sufficiently characterized or studied, would not be eligible for participation.

Dosing:

- There must be sufficient clinical data to identify an appropriate dose (amount and frequency of the medicine given) for the patient's clinical disease/diagnosis/stage of illness.
- The patient must be able to procure or provide evidence of ability to fund the ancillary items that may be required for delivery of any of Treovir's investigational agents in a safe and effective manner (for example: catheters, infusion tubing and pump).
- The patient must provide evidence that the investigational product can be prepared under the appropriate conditions and administered at an appropriately trained center approved by Treovir.
- Treovir does not provide any ancillary materials or provide financial support for any materials that may be required to safely and effectively deliver their investigational agents as part of compassionate use programs.

Clinical Investigational Material:

Treovir must have adequate supply of the investigational medicine available beyond the amounts necessary for current and planned clinical studies to support FDA approval(s).

Expanded Access/Compassionate Use Program Patient Criteria (including but not limited to):

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, or in the opinion of qualified medical personnel, is not a suitable candidate for these existing therapies
- No other viable therapy options, including participation in ongoing relevant clinical trials

For the Patient's Treating Physician:

- 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 Treovir can provide the investigational medicine. The IRB at the treating center would be the most likely IRB to provide review and approval.
- Requests for Expanded Access should be made by the patient's treating physician. Treating physicians are asked to avoid submission of any personal information (e.g. subject names) covered as protected health information in the initial Request for Expanded Access.
- Treovir will make all reasonable attempts to review and respond to Expanded Access requests within 30 days.
- In the initial Request for Expanded Access, the treating physician should be prepared to provide relevant details, including but not limited to:
  - Phone number for key point of contact (required for consideration).
  - The specific medical condition for which you are inquiring.
  - What diagnostic information exists to support the diagnosis/medical condition.
  - Additional questions will be asked depending on this disease.
  - The general medical status of the patient for whom treatment is being sought. Additional questions may be asked to further clarify eligibility.
  - Where the patient for whom treatment is being sought lives and if they are able to travel to an appropriate/participating center for treatment.

FDA Regulatory Submission:

If approved by the IRB and Treovir for Compassionate Use / Expanded Access, Treovir will file the necessary documentation with the FDA on the patient's behalf.

For additional information:

For Compassionate Use/Expanded Access email info@treovir.com and reference Compassionate Use Inquiry in the subject line.

NO SOLICITATION/VENDOR INQUIRIES, PLEASE