Expanded Access Policy

Viridian does not currently provide access to our investigational products outside of enrollment in clinical trials

Viridian Therapeutics Inc. (Viridian) is a biotechnology company engineering and developing potential best-in-class medicines for people living with serious and rare diseases. Clinical trials to evaluate the safety and effectiveness of our potential new medicines are an essential and required step before we can seek review and potential approval by the Food and Drug Administration (FDA) or other regulatory agencies.

In certain circumstances, people living with a serious or immediately life-threatening disease or condition may gain access to an investigational medicine outside of clinical trials when no comparable or satisfactory alternative therapy options are available. This potential pathway is known as "Expanded Access" and sometimes also called "Pre-approval Access" or "Compassionate Use."

Our goal is to provide access to our investigational medicines at the appropriate time and in a safe manner. We believe enrollment in our ongoing clinical trials is the most effective way of achieving this goal. Therefore, at this time we are unable to provide investigational medicines via expanded access programs and we do not currently accept or grant any requests for expanded access to any of our investigational medicines outside of our clinical programs.

To learn more about Viridian's ongoing clinical programs, please visit clinicaltrials.gov. If you have questions about participating in our clinical trials, please discuss this with your health care provider. If you have questions about this policy or about Viridian, please contact the Viridian Patient Advocacy team at patientadvocacy@viridiantherapeutics.com. Viridian will make every effort to respond to questions within five (5) business days of receipt.

We reserve the right to revise this policy at any time in accordance with the 21st Century Cures Act.

Potential Expanded Access Criteria

As stated above, Viridian does not currently provide Expanded Access to its investigational products. In the event that Viridian may, in the future, consider a request for Expanded Access, each request would be evaluated in accordance with this Policy and would be required to meet the following criteria:

- The patient has a serious disease or condition, has exhausted all reasonable, available treatment options and is not eligible to participate in any appropriate clinical trial.
- The patient must meet any other pertinent medical criteria for access to the investigational product as established by the Viridian medical professionals working on the drug development program.

- The investigational product must be in active clinical development and being studied in a similar disease state to that for which the Expanded Access is requested.
- There must be adequate supply of the investigational product to accommodate the needs of the Expanded Access program without interfering with ongoing and/or planned clinical trials.
- Expanded Access will not delay, interfere with or compromise ongoing clinical trials or the potential approval of the product.
- There is sufficient evidence that the potential benefits to the patient would likely outweigh the potential risks to the patient.
- There is adequate clinical data to support the appropriate dose (amount and frequency) for the investigational product's use in the disease or condition.
- The Expanded Access request must be made by a physician who is qualified and licensed in the United States and who is knowledgeable in the treatment of the disease or condition.
- The patient is a resident of the United States.
- All applicable laws and regulations must be followed.