Precigen Expanded Access Policy

Precigen is dedicated to developing next generation gene and cell therapies focused in immuno-oncology, autoimmune disorders, and infectious diseases, providing hope to patients with unmet medical needs and their families. Consistent with Precigen's mission to bring innovative therapies to patients with serious or life-threatening diseases, we are focused on enrolling and conducting the clinical trials necessary to gain regulatory approvals to make our therapies available broadly to patients as quickly as possible.

We are also committed to a rigorous clinical development process to evaluate the safety and efficacy of investigational therapies through clinical trials. If clinical trials establish an investigational therapy is safe and effective, marketing approvals will be sought from regulatory Health Authorities with the goal of making these treatments broadly available to the patient communities.

At the same time, we understand that there are patients who will not be eligible for our clinical trials and may not have options for potentially effective alternative therapies. In these circumstances, Precigen will consider providing a requesting licensed physician with pre-approval access to a specific Precigen investigational therapy for the treatment of an individual patient outside of a clinical trial when certain conditions are met. These conditions include, but are not limited to, the following:

- The condition or disease being studied is serious, irreversibly disabling or immediately life-threatening and there are no comparable or satisfactory alternative treatments for the patient;
- The patient is willing to travel to a Precigen-approved facility with necessary expertise to administer an investigational therapy and get the appropriate follow-up and monitoring post-therapy;
- There is sufficient clinical data on the investigational therapy to determine an appropriate dose and schedule for the patient's specific condition;
- A benefit-risk analysis, based on both the available clinical data as well as the requesting physician's assessment of the individual patient's condition and medical history, supports making the investigational therapy available;
- Making the investigational therapy available will not negatively impact or delay the conduct of clinical trials, regulatory review, or approval of the investigational therapy for broader patient access; and
- Adequate supply of the investigational therapy is available.

We continually evaluate the safety and efficacy profile of each of our investigational therapies based on evolving clinical data. Each disease, patient, and investigational therapy under development is unique, and as such, requests will be considered on a case-by-case basis. Completed requests for expanded access will be evaluated in a fair, equitable manner; however, Precigen cannot guarantee that the investigational therapy will be available to a specific patient. Any expanded access will also be subject to local laws or regulations, and the patient must provide informed consent. Approval of requests for expanded access must be obtained from the applicable regulatory Health Authority and Institutional Review Board or Ethics Committee.

Further information on available Precigen clinical trials can be found at our website, www.precigen.com, or at the U.S. Government's website for clinical trials, www.clinicaltrials.gov.

Requests for information on expanded access to investigational therapies must be made by a licensed physician and may be submitted to expandedaccess@precigen.com. Precigen may require more detailed information in order to fully evaluate a request (e.g., de-identified patient current condition and medical history). It is anticipated that acknowledgement of any expanded access questions or requests will be made by Precigen within five (5) business days of receipt.

This policy shall not serve as a guarantee of access to any specific investigational therapy by any individual patient. Precigen reviews its policies from time to time to ensure conformity with applicable laws and regulations including the 21st Century Cures Act. Precigen reserves the right to revise this policy at any time.