G1 Therapeutics Policy and Protocols for Expanded Access to Investigational Agents

G1 Therapeutics is dedicated to developing medical treatments that address significant unmet needs for people with a diagnosis of cancer. We are currently evaluating our investigational treatments in clinical trials so that we can fully understand how they work, which patients are most likely to benefit and carefully determine safety and efficacy.

People who have exhausted current cancer treatments may seek access to investigational treatments through clinical trials. However, sometimes a person with cancer is not able to participate in a clinical trial, and a physician may request that the investigational treatment be made available to him or her outside of the trial.

If possible, the U.S. Food and Drug Administration (FDA) prefers that investigational treatments be provided as part of a clinical trial, to make certain of the proper use of the investigational treatment and that the person is carefully monitored for possible side effects. Furthermore, making investigational treatments available to people outside of clinical trials may diminish trial participation, which is crucial to the development of new therapies that advance cancer care.

G1 is committed to helping people with a diagnosis of cancer who may benefit by accessing our investigational treatments in a scientifically and ethically responsible manner. The following criteria are used when considering a request:

1. *The investigational treatment must be in active clinical studies in human subjects.*
   This enables us to comply with local regulations on manufacturing, preclinical safety and reporting obligations, and to ensure that trained personnel are responsible for the safe shipment of the investigational treatment.
2. *Participants must first be considered for ongoing clinical trials of the investigational treatment.*
   Clinical trials incorporate regular safety monitoring, and create a venue for investigator training on the therapy's potential risks. Moreover, clinical trials can establish clinical benefit, thus transforming an investigational therapy into an approved drug that can be accessed by a wider population.
3. *The person must have a serious, immediately life-threatening disease or condition.*
4. *The potential benefits to the person must outweigh the potential risks of the investigational treatment.*
5. *The requesting physician must be qualified, agree to directly supervise treatment, be willing to obtain an Investigational New Drug Application (IND) from the FDA and otherwise comply with relevant U.S. federal and state regulations.*
6. *The physician requesting access must provide:*
   - A scientifically justified rationale for the theoretical benefit of the investigational treatment;
   - A statement that approved therapies typically used to treat the disease have been exhausted;
   - A statement that there are no other viable therapy options, including participation in clinical trials.
7. *There must be sufficient clinical data to identify an appropriate dose (amount and frequency of the investigational treatment given), dosage form, and route of administration.*
8. *After meeting the needs of other existing patients enrolled in the ongoing clinical trials with the investigational treatment, G1 Therapeutics must have a sufficient supply of the investigational treatment to reasonably accommodate the likely duration of treatment for the expanded access request.*