Viracta Therapeutics (Viracta) is committed to bringing new, innovative therapies to patients by conducting rigorous clinical trials and obtaining marketing approval by the FDA and other regulatory authorities.

At Viracta, we understand that sometimes people may seek access to investigational therapies before they are reviewed and approved by a regulatory authority, such as the U.S. Food and Drug Administration (FDA). This can be done in two ways, through clinical trials and expanded access programs.

Participation in clinical trials is the first and most preferable route, because clinical trials generate data regarding the safe and efficacious use of the investigational therapy. Those data help inform whether the benefits of the investigational therapy outweigh the risks; whether it should be approved by the regulatory authorities leading to wider availability and if approved, when and how it should be used.
Expanded access refers to the use of an investigational therapy outside a clinical trial for a patient with a serious or immediately life-threatening disease or condition when no comparable or satisfactory alternative therapy options are available.

If participation in clinical trials is not an option, several factors, consistent with regulatory agencies' guidelines, should be taken into account when considering expanded access program or single patient expanded access. These include:

- The investigational therapy must be part of an active clinical development program and not yet approved.
- The patient must have a serious and life-threatening disease with no alternative therapeutic options, including participation in ongoing relevant clinical trials.
- The patient must be ineligible for current clinical trials of the investigational therapy.
- There must be sufficient clinical evidence, based on available safety and efficacy information, that the potential benefit to the patient would likely outweigh the potential risks.
- The patient must meet pertinent medical criteria for access to the investigational therapy as established by the Viracta medical professionals working on the drug development program.
- Access to the investigational therapy must not interfere with completion of clinical investigations to support regulatory approval of the investigational therapy, which would make the therapy available to many more patients.
- There must be a sufficient supply of the investigational medicinal product to reasonably accommodate the likely method and duration of treatment.
- The treating physician must be qualified, agree to directly supervise treatment, be willing to provide relevant data to support regulatory submissions, and must otherwise comply with relevant regulations, including those relating to safety reporting.

Currently, Viracta Therapeutics believes that participation in one of our clinical trials is the most appropriate way to access our investigational therapies. In occasional circumstances, it may be possible to extend treatment after participating in one of our clinical trials via single patient expanded access. Please refer to clinicaltrials.gov for a listing of available studies.

If you are a treating physician, who believes your patient meets the criteria detailed above, and would like to submit questions or requests regarding expanded access, please submit your query to ExpandedAccess@Viracta.com. Please note that requests for expanded access must be made by the physician responsible for treating the patient, and each request needs to relate to a single patient, including sufficient supporting detail to enable Viracta to evaluate the expanded access request. We anticipate acknowledging receipt of requests sent to this email within five business days.

In line with the 21st Century Cures Act, Viracta Therapeutics may revise this policy at any time. Viracta's website and policy will be updated with a hyperlink or other reference to the expanded access record on clinicaltrials.gov after such record becomes active.