agenus

Expanded Access Policy

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1. Clinical Trials

Agenus believes that participating in clinical trials is the best way for patients to access Agenus investigational medicines prior to approval. To participate in a trial, you must meet certain criteria. For those who meet the criteria to join a clinical trial, participation offers the chance to contribute to medical research that may benefit many others. Participation in a clinical trial comes with certain risks; that is why "informed consent" is a required step in the process of enrolling.

For information on Agenus' currently enrolling clinical trials, **click here**.

2. Compassionate or Expanded Access

In some extreme circumstances when participation in an ongoing clinical trial is not possible, patients with life-threatening diseases may seek and regulators may grant special access to investigational medicines outside of a clinical trial setting. These situations are typically referred to as "compassionate use" or "expanded access" cases.

It's important to remember that investigational drugs have not yet received regulatory approval; therefore, their potential risks and benefits are not yet established. Doctors and patients should consider all possible benefits and risks when seeking compassionate access to an unapproved product.

Agenus will review requests for compassionate use of its investigational products under the following criteria:

- The patient's disease is life-threatening.
- Have undergone appropriate standard treatments without success, and comparable or satisfactory alternative treatments to diagnose, monitor or treat the disease or condition are not available, or it is medically contra-indicated to receive those treatments -e.g. an anaphylactic reaction.
- Sufficient preliminary efficacy and safety data exist for the product in order for Agenus to make a benefit-risk analysis consistent with this policy. This would not occur earlier than the end of Phase 1b studies, and depending on the clinical program, potentially even later.
- Sufficient clinical data is available to identify an appropriate dose.
- The patient's treating physician and Agenus' Head of Clinical Development both believe there is the potential for the patient to reasonably expect benefit from the treatment, and there is robust evidence to support the possibility that the patient will benefit.
- Are ineligible for participation in any ongoing clinical study of the investigational drug, including lack of access due to geographic limitations.
- Compassionate access will not adversely impact the clinical development program, in particular, the conduct of a pivotal clinical trial that is required for regulatory approval.

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- The request must be made by the patient's treating physician, who must be a qualified and licensed MD, unsolicited by Agenus or any other individual or organization.

If all these conditions are met, Agenus will consider compassionate use requests from treating physicians taking into account the potential of benefit for the patient while not accepting undue risk to the patient's safety, the strength of the clinical data, the phase of development, and the potential impact on the clinical development program.

All requests will be evaluated in a fair, unbiased manner. Patients with comorbidities that are contraindicated for the requested therapy which may impose safety risks that have not been sufficiently studied will be excluded. Any pre-approval access to investigational product must always comply with the applicable country-specific laws and regulations, including medicine importation requirements, and approvals from applicable regulatory bodies and by an Institutional Review Board or Ethics Committee from the treating hospital must be secured. If approved, the patient (or his or her guardian) must provide informed consent and consent to comply with the safety and monitoring requirements defined by Agenus. The treating physician must also agree to comply with the safety and monitoring requirements. Compassionate use will cease being made available if ongoing clinical trials do not demonstrate a positive risk benefit to patients.

For patients that meet Agenus' criteria, treating physicians can make a request via **compassionateuse@agenusbio.com.** Please submit sufficient supporting detail with your request to enable Agenus to evaluate the patient's circumstances based on the criteria listed in this policy. Receipt of a request will usually be acknowledged within 5 business days.

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