Access to Investigational Medicines Policy

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agenus

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 also 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. Expanded Access (also known as Compassionate Use)

In some extreme circumstances when participation in an ongoing clinical trial is not possible, patients with serious or life-threatening diseases may seek special access to investigational medicines outside of a clinical trial setting. These are typically referred to as "expanded access" or "compassionate use" cases, and require a careful review through official channels to ensure that **all FDA-established requirements** are met. 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 expanded access to an unapproved product.

Agenus will review requests for expanded access to its investigational products according to the following criteria:

- The patient's disease is serious or life-threatening.
- The patient has 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., due to the risk of anaphylaxis.
- Sufficient preliminary efficacy and safety evidence exists in order to make a well-reasoned 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' Clinical Development team believe there is a reasonable possibility the patient will benefit from the treatment, and there is evidence to support this belief.

- This patient is 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.
- 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 for patient benefit, risks to the patient's safety, the strength of the clinical data, the phase of development, and any potential impact to 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 which have not been sufficiently studied, will be excluded. Any pre-approval access to the investigational product must always comply with the applicable country-specific laws and regulations, including medicine importation requirements and approvals from applicable regulatory bodies. Further, Institutional Review Board or Ethics Committee approval from the treating institution 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 continue to demonstrate a positive risk/benefit profile for patients.

For patients that meet criteria, treating physicians can initiate a request by sending an email to **compassionateuse@agenusbio.com**. Please ***do not*** include any identifying patient information in the initial email. Receipt of a request will usually be acknowledged within 5 business days.