Expanded Access & Compassionate Use

Patients facing serious illnesses who have exhausted all available treatment options often want to know if and how they can receive early access to investigational drugs that haven't yet been approved by government regulatory agencies. The information below explains options that may be available to patients in these circumstances.

1. Clinical Trials

For new medicines and vaccines to be legally approved for use, companies like Aiolos Bio are required to evaluate their safety and effectiveness in clinical trials and submit trial results to regulatory agencies. 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 patient "informed consent" is a required step in the process of enrolling.

Find a trial on clinicaltrials.gov (all sponsors, including Aiolos Bio.)

2. Expanded Access or Compassionate Use

In cases where a clinical trial isn't an option, and the patient has exhausted all available treatment options, regulators/health authorities may grant permission for us to provide a treating physician with an investigational drug pre-approval. Such individual use of an investigational drug pre-approval is often called "expanded access" or "compassionate use" but may go by other names. Aiolos Bio refers to these requests as expanded access.

For expanded access requests please email info@aiolosbio.com.

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 investigational drug.

Please feel free to contact us with any questions.