Expanded Access to Investigational Medicines

Aerovate Therapeutics (Aerovate) is focused on the advancement of novel therapeutics to help people with rare cardiopulmonary diseases gain control over their health, and their lives. At this time, we remain in an early stage of development and therefore, we will only be able to offer our investigational products to patients participating in our clinical studies. We encourage participation in a clinical study as this will enable us to progress development to a stage where we may be able to offer broader access to these investigational products, including for expanded access. For a listing of our currently available clinical studies, please visit *CT.gov for AV-101-002*.

As we continue to develop our clinical pipeline, we encourage you to check back to this website for updates regarding our policy on expanded access to our investigational medicines.

Our decision to offer expanded access to our investigational drugs in the future will depend on the following core considerations:

- Sufficient evidence of the safety and effectiveness of the investigational product is available to support its expanded access use in the particular patient population.
- Sufficient assurance that providing investigational products does not delay
 progression of the clinical development program and the ultimate goal of providing
 patients with access to approved safe, and effective drugs.
- Adequate drug supply is available to support expanded access in addition to any ongoing clinical study supply needs.
- The patient is unable to participate in any open clinical trial based on the trial's inclusion and exclusion criteria, or if participation in the study is not geographically feasible.

If you are a health care provider who is interested in learning more about one of our investigational therapies, or a physician with questions about participation in one of our clinical trials, please submit a request to info@aerovatetx.com. The company will acknowledge requests as soon as possible, usually within 5 business days of receipt. Please note that Aerovate reserves the right to revise this expanded access policy at any time.