Veralox Therapeutics is committed to the development and careful evaluation of novel therapeutics with the goal to help patients. Currently our therapies are investigational, which means that they have not been approved as safe and effective by the United States Food and Drug Administration (FDA) or other Health Authorities. We believe it is important to provide our investigational therapies to patients who are participating in the setting of one of our clinical trials. Use outside of a clinical trial can potentially compromise the broader development program that is being conducted to carefully evaluate the safety and efficacy of the therapy in support of product registration. However, we recognize that access through a clinical trial is not always possible for every patient and there may be circumstances, particularly later in development, where investigational therapies may be made available to Physicians via Expanded Access. At this time, we are not yet providing Expanded Access.

Once our clinical trials have progressed to Phase 3 and we are able to provide Expanded Access, to be eligible for access to one of our investigational therapies via an Expanded Access mechanism, a physician must certify that the patient for whom the request is being submitted meets the following criteria*:

- The patient has received all available standard treatments without success
- The patient is not eligible to participate in any ongoing clinical study of a suitable investigational therapy
- The investigational therapy requested is part of an active ongoing clinical development program as described on our website
- Provision of the investigational therapy will not interfere with the ongoing development program, and the potential benefits to the patient outweigh the potential risks

* Note that meeting these criteria does not guarantee access to any investigational product.

Physicians seeking access outside of a current clinical trial may submit a request providing the information listed above to contact@veralox.com. Receipt of a request will be confirmed electronically within 48 hours. Following receipt of the request, we may require additional information as needed to complete our assessment. Once all of the necessary information is provided for review by our medical experts, a decision for expanded access will be communicated to the Physician within 10-15 business days.

Physicians can obtain more information about FDA's current Expanded Access policies and requirements for enrolling in Expanded Access programs here: https://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm.

A listing of our clinical trials can be found on https://clinicaltrials.gov.